

SECURITIES AND EXCHANGE COMMISSION

FORM 10-K

Annual report pursuant to section 13 and 15(d)

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ANTARES PHARMA, INC.

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**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, 2021

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

For transition period from _____ to _____

Commission file number 001-32302



ANTARES PHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

41-1350192

(I.R.S. Employer Identification No.)

100 Princeton South, Suite 300, Ewing, NJ

(Address of principal executive offices)

08628

(Zip Code)

Registrant's telephone number, including area code: **(609) 359-3020**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.01 per share	ATRS	NASDAQ

Securities registered pursuant to section 12(g) of the Act: None

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

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

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>	Non-accelerated filer	<input type="checkbox"/>
Smaller reporting company	<input type="checkbox"/>	Emerging growth company	<input type="checkbox"/>		

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. Yes ☒ No ☐

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

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant as of June 30, 2021, was \$739.4 million based on the closing price of \$4.36 per share on June 30, 2021 as reported by the NASDAQ Capital Market.

As of February 28, 2022, there were 170,106,346 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive Proxy Statement to be filed within 120 days after the end of the period covered by this report for the registrant’s 2022 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

ANTARES PHARMA, INC.
Annual Report on Form 10-K
For the Year Ended December 31, 2021

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Note Regarding Forward-Looking Statements

This annual report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and the Private Securities Litigation Reform Act of 1995 that are subject to risks and uncertainties. Undue reliance should not be placed on those statements because they are subject to numerous uncertainties and factors relating to our operations and business environment, all of which are difficult to predict and many of which are beyond our control. These statements can be identified by the fact that they do not relate strictly to historical or current facts. Such statements may include words such as “anticipate,” “will,” “estimate,” “expect,” “project,” “intend,” “should,” “plan,” “believe,” “hope,” “may,” “continue,” or other words and terms of similar meaning in connection with any discussion of, among other things, future operating or financial performance, strategic initiatives and business strategies, regulatory or competitive environments, our intellectual property, our commercial operations and product development. In particular, these forward-looking statements include, among others, statements about:

- our expectations about the ongoing COVID-19 pandemic (the “Pandemic”) and any potential disruption or impact to our operations, financial position or cash flows;
- our expectations regarding the continued commercialization of XYOSTED® (testosterone enanthate) injection and the continued growth in prescriptions and revenues related thereto;
- our expectations regarding the commercialization of NOCDURNA® (desmopressin acetate) in the U.S. under a licensing agreement with Ferring International Center S.A. and its affiliates, (“Ferring”) and future sales and revenue from the same;
- our expectations regarding future FDA approval of TLANDO® in the U.S. under a licensing agreement with Lipocine Inc. (“Lipocine”), the manufacturing and commercialization of TLANDO® and future sales and revenue from the same;
- our expectations regarding whether we will exercise the option for LPCN 1111 (“TLANDO XR”) and, if exercised, the future timing and success of the clinical development program for TLANDO XR and future FDA approval, market acceptance and revenue from the same;
- our expectations regarding future sales of OTREXUP® (methotrexate) injection to Otter Pharmaceuticals, LLC (a wholly-owned subsidiary of Assertio Holdings, Inc., together with Assertio Holdings, Inc., as guarantor, individually and collectively referred to as “Otter”) under a newly entered into supply agreement, as well as the ability of Otter to pay remaining installment payments of the purchase price;
- our expectations regarding the ability of our partner, Teva Pharmaceutical Industries, Ltd. (“Teva”), to continue to commercialize Epinephrine Injection USP, the generic equivalent version of EpiPen® (“generic epinephrine injection”), and any future revenue related thereto;
- our expectations regarding the ability of the Covis Group S.a.r.l. (“CG”), who acquired AMAG Pharmaceuticals, Inc. (“AMAG”) (collectively CG and AMAG are herein after referred to as “Covis”) in November 2020, to continue to commercialize Makena® (hydroxyprogesterone caproate injection) and our continued future sales to Covis and royalty revenue from the same, in light of the U.S. Food and Drug Administration’s (“FDA”) proposal to withdraw approval of Makena® (hydroxyprogesterone caproate injection) and the timing and outcome of any hearings and future regulatory actions by the FDA;
- our expectations regarding continued sales of Sumatriptan Injection USP to our partner, Teva, and Teva’s ability to distribute and sell Sumatriptan Injection USP;
- our expectations regarding continued product development with Teva of the teriparatide disposable pen injector, Teva’s ability to obtain FDA approval and AB-rating for the products and if approved Teva’s ability to successfully commercialize the teriparatide disposable pen injector product outside the U.S.;

- our expectations about the development of a rescue pen for an undisclosed drug with our partner Pfizer Inc. (“Pfizer”) and potential future regulatory approval and future revenue from the same;
- our expectations about our development activities with Idorsia Pharmaceuticals Ltd (“Idorsia”) and the timing and results of the Phase 3 clinical trial of the drug device combination product for selatogrel, a new chemical entity being developed for the treatment of a suspected acute myocardial infarction (“AMI”) in adult patients with a history of AMI, and the potential future FDA and global regulatory approval of the same;
- our expectations about the development of ATRS-1902 for adrenal crisis rescue, including the timing and results of clinical trials and our anticipated 505(b)(2) NDA filing with the FDA;

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- our expectations about our other internal and external research and development projects, including but not limited to ATRS-1901 and ATRS-1903, the timing and results of clinical trials, and our anticipated continued reliance on third parties in conducting studies, trials and other research and development activities;
- our expectations about the timing and outcome of pending or potential claims and litigation, including without limitation, the pending securities class action and derivative actions;
- our anticipated continued reliance on contract manufacturers to manufacture, assemble and package our products;
- our anticipated continued reliance on third parties to provide certain services for our products including logistics, warehousing, distribution, invoicing, contract administration and chargeback processing;
- our sales and marketing plans;
- our expectation about our future revenues, our cash flows and our ability to support our operations and maintain profitability;
- our estimates and expectations regarding the sufficiency of our cash resources, anticipated capital requirements and our ability to obtain additional financing, if needed;
- the potential impact of new accounting pronouncements and tax legislation; and
- other statements regarding matters that are not historical facts or statements of current condition.

These forward-looking statements are based on assumptions that we have made considering our industry experience as well as our perceptions of historical trends, current conditions, expected future developments and other factors we believe are appropriate under the circumstances. As you read and consider this annual report, you should understand that these statements are not guarantees of performance results. Forward-looking statements involve known and unknown risks, uncertainties and assumptions, and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. While we believe that we have a reasonable basis for each forward-looking statement contained in this annual report, we caution you that these statements are based on a combination of facts and factors currently known by us and projections of the future about which we cannot be certain. Many factors may affect our ability to achieve our objectives, including:

- potential business interruptions and/or any financial or operational impact as a result of the Pandemic;
- delays in product introduction or unsuccessful marketing and commercialization efforts by us or our partners;
- interruptions in supply or an inability to adequately manage third party contract manufacturers to meet customer supply requirements;
- our inability to obtain or maintain adequate third-party payer coverage of marketed products;
- the timing and results of our or our partners' research projects or clinical trials of product candidates in development;
- actions by the FDA or other regulatory agencies with respect to our products or product candidates of our partners;
- our inability to generate or sustain continued growth in product sales and royalties;
- the lack of market acceptance of our and our partners' products and future revenues from these products;
- a decrease in business from our major customers and partners;
- our inability to compete successfully against new and existing competitors or to leverage our research and development capabilities or our marketing capabilities;

- our inability to establish and maintain our commercial capabilities, our inability to effectively market our services or obtain and maintain arrangements with our customers, partners and manufacturers;
- our inability to attract and retain key personnel;
- changes or delays in the regulatory review and approval process;
- our inability to effectively protect our intellectual property;
- costs associated with future litigation and the outcome of such litigation; and
- adverse economic and political conditions.

The performance of our business and our securities may be adversely affected by these factors and by other factors common to other businesses or to the general economy. Forward-looking statements speak only as of the date on which such statements are made. Actual results could differ materially from those currently anticipated as a result of a number of risk factors, including, but not limited to, the risks and uncertainties discussed in Item 1A of Part II of this Annual Report on Form 10-K. New risks and uncertainties emerge from time to time, and it is impossible for us to predict these events or how they may affect us. Forward-looking statements are qualified by some or all of these risk factors. Therefore, you should consider these forward-looking statements with caution and form your own critical and independent conclusions about the likely effect of these risk factors on our future performance. We undertake no obligation to update or revise any forward-looking statements included in this annual report to reflect events or circumstances after the date on which such statement is made, except as required by law. In light of these risks and significant uncertainties, you should not regard the forward-looking statements in this annual report as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, if at all. You should carefully review the disclosures and the risk factors described in this Annual Report on Form 10-K and in other documents we file from time to time with the Securities and Exchange Commission (“SEC”), including our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K.

PART I

ITEM 1. BUSINESS

Company Overview

Antares Pharma, Inc. (“Antares,” “we,” “our,” “us” or the “Company”) is a specialty pharmaceutical company focused primarily on the development and commercialization of pharmaceutical products and technologies that address patient needs in targeted therapeutic areas. We develop, manufacture and commercialize, for ourselves or with partners, novel therapeutic products using our advanced drug delivery systems that are designed to provide commercial or functional advantages such as improved safety and efficacy, convenience, improved tolerability, and enhanced patient comfort and adherence. We also seek product opportunities that complement and leverage our commercial platform. We have a portfolio of proprietary and partnered commercial products and ongoing product development programs in various stages of development. We have formed partnership arrangements with several different industry leading pharmaceutical companies.

Our FDA-approved products include XYOSTED® (testosterone enanthate) injection; OTREXUP® (methotrexate) injection, which was sold to Otter in December 2021; NOCDURNA® (desmopressin acetate), which is licensed from Ferring; and Sumatriptan Injection USP, which is distributed by Teva. We are also the exclusive supplier of devices to Teva for their Epinephrine Injection USP, the generic equivalent of EpiPen® and EpiPen® Jr.; the devices for Teva’s generic teriparatide; OTREXUP® (methotrexate) injection to Otter beginning in December 2021; and of the Makena® subcutaneous auto injectors to Covis.

2021 Highlights and Areas of Focus

We achieved several significant operating and financial milestones in 2021:

- **Record Revenue and Financial Results** – We generated record revenue of \$184.0 million for the year ended December 31, 2021 as compared to \$149.6 million for the year ended December 31, 2020, representing year-over-year growth of 23.0%. We generated record pre-tax income of \$62.3 million resulting in net income and basic earnings per share of \$46.3 million and \$0.27, respectively, for the year ended December 31, 2021 as compared to net income and basic earnings per share of \$56.2 million and \$0.34, respectively, for the year ended December 31, 2020. Earnings per share on a fully diluted basis was \$0.26 for the year ended December 31, 2021 compared to \$0.33 for the year ended December 31, 2020.
- **Significant Growth of XYOSTED®** – Our proprietary product XYOSTED® (testosterone enanthate) injection, indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone, continued to grow significantly in 2021, generating annual net revenue of \$62.2 million for the year ended December 31, 2021 compared to \$46.5 million for the year ended December 31, 2020. We attribute this 33.7% increase to successful marketing strategies, achieving and maintaining targeted reimbursement coverage, and our ability to continue to leverage our virtual capabilities to support the growth in 2021 despite the challenges presented by the Pandemic. XYOSTED® is the only FDA approved subcutaneous testosterone enanthate product for once-weekly, at-home self-administration of testosterone replacement therapy.
- **Expanded Product Portfolio with In-License of TLANDO®** – We entered into an exclusive license agreement with Lipocine for the product TLANDO® (testosterone undecanoate) in the U.S., a twice-daily oral formulation of testosterone for testosterone replacement therapy indicated for conditions associated with a deficiency or absence of endogenous testosterone, or hypogonadism in adult males. TLANDO® was granted tentative approval from the FDA in December 2020 and will be eligible for final FDA approval and marketing in the U.S. upon expiration of the exclusivity period previously granted to Clarus Therapeutics, Inc. (“Clarus”) for JATENZO® on March 27, 2022. On February 3, 2022, we announced

the FDA's acceptance of our NDA resubmission for TLANDO[®] with a target action date set for March 28, 2022. We continue to prepare for the launch of TLANDO[®] in 2022 pending final FDA approval after the expiration of JATENZO[®]'s exclusivity period.

- ***Aligned Proprietary Portfolio with Divestiture of OTREXUP[®]*** – We divested and sold our proprietary product line OTREXUP[®] (methotrexate) injection for the treatment of rheumatoid arthritis to Otter in December 2021 for a total purchase price of \$44.0 million (the “Asset Purchase Agreement”), subject to finalization of changes in closing inventory to be transferred. This divestiture allows us to further align our commercial detailing strategy to focus on the urology and endocrinology fields to enhance our growth strategy for XYOSTED[®], NOCDURNA[®] and the anticipated launch of TLANDO[®] in 2022. With the asset sale, we will continue to manufacture and supply OTREXUP[®] to Otter as a partnered product.

- ***Significant Progress on Our Adrenal Crisis Rescue Pen (ATRS-1902)*** – We further advanced our ATRS-1902 development program with positive results from a Phase 1 clinical study for adrenal crisis and were granted Fast Track designation by the FDA. The results support the advancement of our ATRS-1902 development program to a pivotal clinical study for the treatment of acute adrenal insufficiency (“adrenal crisis”) in adults and adolescents, using our Vai™ novel proprietary rescue pen platform to deliver a liquid stable formulation of hydrocortisone. We anticipate starting this pivotal clinical study in the second quarter of 2022 and expect to submit a 505(b)(2) NDA with the FDA by the end of 2022 pending the success of the pivotal clinical study.
- ***Continued Navigation of the Global Pandemic*** – We have taken several measures to manage and minimize the impact of the Pandemic on our business. We have implemented safety measures and protocols to protect the health and safety of our employees and comply with governmental and public health guidelines while ensuring the sustainability of our business operations and continuity of product supply. We continue to monitor the situation, including the COVID-19 variants, and potential effects on our business, suppliers, partners and workforce. We have implemented a hybrid work environment with the ability to shift remote as necessary to limit the number of individuals in our facilities to those necessary for essential functions such as research, development, manufacturing and supply. While our field-based team has resumed in-person interaction with fewer restrictions, we believe we are also well-positioned with our virtual capabilities to continue to engage healthcare professionals and patients through the Pandemic and beyond.

In addition to these significant achievements and areas of focus in 2021, we continued to devote resources and advance our internal research and development programs to further expand our product pipeline. We also made significant progress on partnered development projects, made investments in capital improvements and infrastructure, and maintained a disciplined approach to growth and operating expenditures to support our continued and future growth.

Product Portfolio Overview

The following table provides an overview of our proprietary and partnered commercial products and product opportunities:

<u>Approved Products</u>	<u>Drug</u>	<u>Partner</u>	<u>Disease/Condition</u>	<u>Territory</u>
XYOSTED® (testosterone enanthate) injection	Testosterone	None	Testosterone Replacement Therapy (“TRT”)	U.S.
OTREXUP® (methotrexate) injection ¹	Methotrexate	None ¹	Rheumatoid Arthritis; pJIA, Psoriasis	U.S.
NOC DURNA® (desmopressin acetate)	Desmopressin	None ²	Nocturnal Polyuria	U.S.
Epinephrine Injection USP (generic equivalent to EpiPen® and EpiPen® Jr.)	Epinephrine	Teva	Anaphylaxis	U.S.
Sumatriptan Injection USP (generic version of Imitrex® STATdose Pen®)	Sumatriptan succinate	Teva	Migraines	U.S.
Makena® Subcutaneous Auto Injector	Hydroxy-progesterone caproate	Covis	Reduced Risk of Pre-term Birth	U.S.
Teriparatide Injection (generic version of Forsteo®)	Teriparatide	Teva	Osteoporosis	Outside U.S.
<u>Select Products in Development</u>	<u>Drug</u>	<u>Partner</u>	<u>Indication</u>	<u>Territory</u>
TLANDO® (testosterone undecanoate) ³	Testosterone	None ³	Testosterone Replacement Therapy (“TRT”)	U.S.
Disposable Pen Injector ⁴	Exenatide	Teva	Diabetes	U.S.
Disposable Pen Injector	Teriparatide	Teva	Osteoporosis	U.S.
QuickShot® Auto Injector	Undisclosed	Pfizer	Undisclosed Rescue Pen	U.S.
QuickShot® Auto Injector	Selatogrel	Idorsia	Acute Myocardial Infarction	Worldwide
Drug/Device Product	ATRS-1901	None	Urologic Oncology	U.S.
Drug/Device Product	ATRS-1902	None	Endocrinology	U.S.
Drug/Device Product	ATRS-1903	None	Immunology	U.S.

¹ Certain worldwide assets used in the operation of the OTREXUP® product were sold to Otter in December 2021. We will continue to manufacture and supply OTREXUP® to Otter as a partnered product under a separate supply agreement.

² Distributed and sold by us under an exclusive license agreement with Ferring.

³ TLANDO® was granted tentative approval from the FDA in December 2020 and will be eligible for final FDA approval and marketing in the U.S. upon expiration of the exclusivity period previously granted to Clarus for JATENZO® on March 27, 2022. TLANDO® is expected to be distributed and sold by us under an exclusive license agreement with Lipocine pending final approval from the FDA. We announced the FDA’s acceptance of our application for final approval on February 3, 2022 with a target action date set for March 28, 2022.

⁴ On February 25, 2022, Teva notified us that it was terminating the exenatide program and related agreement due to a lack of commercial viability. The termination is effective August 23, 2022.

For a detailed discussion of our proprietary and partnered approved and marketed products, and other products currently in development, see “**Our Products**” and “**Research and Development**” sections below included in Item 1 of Part I of this Annual Report on Form 10-K.

Corporate Information

Antares was incorporated under Delaware law in 2005 with principal executive offices located in Ewing, New Jersey. We have two wholly owned subsidiaries in Switzerland (Antares Pharma AG and Antares Pharma IPL AG) and operate under a single reportable operating segment, which encompasses all of our pharmaceutical products and technologies. Segment and geographic financial information are included in Note 2 and Note 14 to the Consolidated Financial Statements in Item 8 of Part II of this Annual Report on Form 10-K.

Our Strategy and Market Opportunity

Our strategy is to grow the business through targeted investments in internal and partnered product development and other corporate opportunities, as well as leverage our commercial infrastructure, primarily focused in certain therapeutic areas. We have built a robust commercial organization to market and sell our proprietary products and have significant experience in developing drug/device combination products and navigating the regulatory approval process.

Historically, our focus has been primarily the market for self-administered injectable drugs. We identify development and commercialization opportunities, both internally and through partnered or business development opportunities that apply patented drug delivery technologies to new or existing approved drug formulations. Through these opportunities, we seek to enhance the drug delivery methods and provide commercial and/or functional advantages, such as improved safety and efficacy, reduced side effects, convenience and enhanced patient comfort and adherence. In addition to self-administered injectable drugs, we explore opportunities beyond injectable drugs that may complement our strategy and leverage our capabilities. We pursue these opportunities both on our own or with partners. We believe this strategy offers a distinct value to patients, healthcare providers, pharmaceutical partners and our shareholders.

Injection is a common drug delivery pathway, and the delivery of pharmaceutical therapies through injection systems often improves the systemic bioavailability of those treatments by overcoming absorption barriers common with oral and, in some cases, transdermal delivery. Improved bioavailability is beneficial when evaluating the role of route of administration on pharmaceutical efficacy. We believe that our advanced injection technology platforms provide drug delivery solutions that can result in improved safety and efficacy, reduced side effects, and enhanced patient comfort and adherence. Many pharmaceutical companies focus on the development of important chronic care products and emergency rescue therapies that can be administered only by injection. We believe our advanced injection technologies uniquely address these market needs and are well suited for both the branded and generic marketplace.

We and our partners have historically sought, and are in the process of seeking, FDA approval for certain product candidates primarily using the 505(b)(2) NDA (New Drug Application) or ANDA (Abbreviated New Drug Application) approval pathways, as well as more recently the 505(b)(1) NDA pathway with certain partners, which are further described in the **“Government Regulation”** section below included in Item 1 of Part I of this Annual Report on Form 10-K. Our technology platforms allow for device customization, which can provide multiple opportunities in both the 505(b)(2) NDA and generic market spaces, as well as the 505(b)(1) NDA pathway.

According to a *Market Research Engine* report, it is estimated that the global injectable drug delivery market will grow to \$1.3 billion by 2024, representing a compounded annual growth rate of 12.9% in the forecast period. This expected growth is attributable to several factors, including label expansion for approved products, increasing the patient pool for such products, a pipeline of injectable medications at various stages of clinical development, and the increasing incidence of certain diseases that will necessitate the utilization of injectable medications.

See also **“Our Products”** and **“Research and Development”** below, included in Item 1 of Part I of this Annual Report on Form 10-K for additional discussion of market size and opportunities relative to the current therapeutic areas associated with our existing portfolio of products and products in development.

Our Competitive Strengths

We believe our key competitive strengths are our commercial capabilities and infrastructure, proprietary injection technologies, and our ability to form significant strategic alliances with industry-leading pharmaceutical partners to develop and commercialize products. We also believe our management team has unique knowledge of, and experience in the drug/device combination product space along with navigating the related regulatory approval process, which creates opportunities for us and potential pharmaceutical partners. Our business model for developing and commercializing proprietary and partnered products has been validated, we believe, by the successive FDA approvals of our NDAs for XYOSTED[®] and OTREXUP[®] and our ANDA for Sumatriptan Injection USP, as well as the FDA approval of Teva's AB-rated generic version of the EpiPen[®].

Intellectual Property, Patents, Trade Secrets and Proprietary Information

We strive to protect and enhance the proprietary technologies that we believe are important to our business and rely on know-how and continuing technological innovation to develop, strengthen and maintain our competitive position. When appropriate, we seek protection for our products and proprietary information by means of U.S. and international patents and trademarks. We currently hold a portfolio of patents with expirations ranging from 2021 to 2038, and numerous patent applications pending in the U.S. and other countries. These patents consist primarily of design, formulation and method-of-use patents.

In addition to our patents and patent applications, our proprietary know-how and inventions play an important role in protecting our products and technologies, and provide protection beyond patents and regulatory exclusivity. We strive to preserve the confidentiality of our proprietary know-how and inventions by maintaining physical security of our sites and electronic security of our information technology systems. We also require all employees, contractors and third-party consultants with access to proprietary information to execute confidentiality agreements prohibiting the disclosure of confidential information to anyone outside the Company. These agreements also require disclosure and assignment to us of discoveries and inventions made by such individuals while devoted to Company-sponsored activities. Partners with which we have entered into development agreements have the right to certain technology developed in connection with such agreements.

Human Capital

We believe that our success is largely dependent upon our ability to attract and retain qualified employees. We currently have 201 full-time employees and 2 part-time employees, of which 40 employees are based in our New Jersey corporate facility, 65 employees in our Minnesota operations and 98 employees based in the field. Our workforce includes 108 employees directly involved in or supporting our commercial sales organization, 27 in research and development, 37 in manufacturing and quality and 31 in corporate and administrative functions. We are not party to any collective bargaining arrangements. Although we believe that the size of our current workforce is appropriate to achieve our objectives, we may hire additional employees with specialized expertise as we continue to grow our business. We believe that we have been successful to date in attracting skilled and experienced scientific and business professionals.

We continue to focus on building a high performing organization with an engaging work culture and have established initiatives to support this strategic priority. We perform periodic employee engagement surveys, set and monitor retention goals, and intend to invest in training and leadership development to cultivate our emerging leaders. Additionally, we are committed to diversity and inclusion as a core focus of our human capital strategy. We embrace differences, diversity and varying perspectives amongst our employee base, and are proud to be an equal opportunity employer. We do not discriminate based on race, religious creed, color, national origin, ancestry, physical disability, mental disability, medical condition, genetic information, marital status, sex, gender, gender identity, gender expression, age, military or veteran status, sexual orientation or any other protected characteristic established by federal, state or local laws. A diverse workforce, as well as an inclusive culture and work environment, are fundamentally important and strategic to us, beginning with our Board of Directors and extending to all levels of the organization. As of December 31, 2021, our total employee base was 56% diverse on the basis of gender and race. We also have implemented company-wide diversity and inclusion training.

We strongly believe that the success of Antares depends, in part, on open and regular communication with employees to help foster a high performing and engaged workforce. To help ensure that employees fully understand the Company's long-term strategy and annual goals, along with how their work contributes to the Company's success, we use a variety of channels to facilitate open and direct communication, including: (i) quarterly CEO Town Hall meetings; (ii) regular ongoing update communications; and (iii) employee engagement surveys.

We believe our success depends upon our ability to attract and retain highly qualified employees. Talent management and leadership development is critical to our ability to execute on our long-term growth strategy. We strive to provide pay, benefits, and services that

are competitive to market and create incentives to attract and retain employees. Our compensation package includes market-competitive pay, discretionary broad-based stock grants and bonuses, health care and retirement benefits, paid time off and family leave. We also continue to advance transparency in our pay and representation data by complying with all applicable statutory filing requirements. To help support the development and advancement of our high performing employees, we offer training and development programs encouraging advancement from within and continue to fill our team with strong and experienced management talent. We leverage both formal and informal programs to identify, foster, and retain top talent throughout the organization.

Our compensation philosophy is to pay for performance, support the Company's business strategies, and offer competitive compensation arrangements to attract and retain key individuals and therefore, have established a Compensation Committee of the Board of Directors. Consistent with this philosophy, the Compensation Committee considers the impact of our corporate performance in determining compensation for named executive officers, as well as each named executive officer's individual performance, macroeconomic conditions, and data from peer group companies.

Our Technology and Product Platforms

Pressure assisted auto injection is a form of parenteral drug delivery that continues to gain acceptance and demand among the medical and patient community. Encompassing a wide variety of sizes and designs, our technology operates by using pressure to force the drug, in solution or suspension, through the skin and deposits the drug into the subcutaneous or intramuscular tissue. We have designed disposable, pressure assisted auto injector devices to address acute and chronic medical needs, such as rheumatoid arthritis and psoriasis, allergic reactions, migraine headaches, testosterone deficiency and maternal health. Our current platforms include the VIBEX® and the VIBEX® QuickShot® disposable pressure assisted auto injection systems, the Vai™ auto injector and disposable pen injection systems.

VIBEX® Auto Injectors

Our proprietary VIBEX® disposable auto injector systems combine a spring-based power source with a shielded needle, which delivers the needed drug solution subcutaneously or intramuscularly. To minimize the anxiety and perceived pain associated with injection-based technologies, the VIBEX® system features a triggering collar that shields the needle from view. The patented retracting collar springs back and locks in place as a protective needle guard after the injection, making the device safe for general disposal. We believe the key competitive advantages of the VIBEX® system include: reliable subcutaneous or intramuscular injection, designed to work with conventional pre-filled syringes, rapid injection with ability to deliver viscous solutions, ease of use in emergencies, and reduced pain.

The primary goal of the VIBEX® disposable pressure assisted auto injector is to provide a fast, safe, and time-efficient method of self-injection. This device is designed around conventional single dose pre-filled syringes, which is a primary drug container, offering ease of transition for potential pharmaceutical partners. Our proprietary product OTREXUP® (product line, excluding the NDA, sold to Otter in December 2021) uses the VIBEX® auto injector system for delivery of methotrexate. We also have two license agreements with Teva for our VIBEX® system, one for Teva's generic epinephrine auto injector and the other for our Sumatriptan Injection USP.

VIBEX® QuickShot® Auto Injectors

An advancement of our proprietary line of VIBEX® auto injectors is the VIBEX® QuickShot® auto injector system, which offers a dose capacity of 1 mL or greater in a compact design. VIBEX® QuickShot® is designed to enhance performance on the attributes we believe most critical to patient acceptance, which are speed, comfort and discretion. VIBEX® QuickShot® achieves these advancements by incorporating a novel triggering mechanism and space-saving spring configuration. The unique design also accommodates fast injection of highly viscous drug products that less-powerful conventional auto injectors are typically unable to deliver. Many self-injectable drugs that are currently marketed or in clinical development are of higher viscosity and are formulated to be administered in a 1 mL dose volume. Our proprietary product XYOSTED®, and the Makena® subcutaneous auto injector that we developed with our partner Covis, were developed using the VIBEX® QuickShot® auto injector platform. We also have a development agreement with Pfizer to develop a rescue pen utilizing our VIBEX® QuickShot® auto injector system with an undisclosed Pfizer drug. In addition, we have a development agreement with Idorsia for a drug device combination product using a variation of our VIBEX® QuickShot® auto injector device with a new chemical entity selatogrel which is being developed for the treatment of acute myocardial infarction.

Vai™ Auto Injector

We developed the versatile Vai™ auto injector platform to meet evolving market needs. The Vai™ auto injector builds off the capabilities of our VIBEX® and QuickShot® platforms adding automatic needle insertion, subcutaneous or intramuscular injections of up to 1 inch and delivered volumes of up to 2 mL. The Vai™ auto injector can accommodate 1 mL standard, 1 mL long, and 2.25 mL syringes. The auto-insert technology is intended to improve compliance for drug products requiring deep intramuscular injections. This innovative device is easily convertible to different fill volumes and needle lengths and was designed specifically to meet the reliability requirements for emergency use applications while maintaining the simple and intuitive two-step process of administration of the QuickShot® device.

Pen Injector System

Our multi-dose, disposable pen injector technology complements our portfolio of single-use pressure assisted auto injector devices. The disposable pen injector devices are designed to deliver drugs by injection through needles from multi-dose cartridges. Our disposable pen injectors are designed for chronic conditions such as diabetes, which require daily injection of a product. Depending on dosage, our pens can deliver up to thirty days of drug. We have licensed our pen injector device technology to Teva for two products in late-stage development: (i) a multi-dose pen with teriparatide for the treatment of osteoporosis (a generic form of Forteo[®]); and (ii) a multi-dose pen with exenatide for the treatment of diabetes (a generic version of BYETTA[®]). On February 25, 2022, Teva notified us that it was terminating the exenatide program and related agreement due to a lack of commercial viability. The termination is effective August 23, 2022.

Our Products

The following is a discussion of our approved and marketed commercial products, including proprietary and partnered products. For a discussion of other product candidates currently with tentative approval or in development, see the “**Products with Tentative Approval**” and “**Research and Development**” sections below included in Item 1 of Part I of this Annual Report on Form 10-K.

XYOSTED[®] (testosterone enanthate) Injection

We market and sell in the U.S. our proprietary product XYOSTED[®] (testosterone enanthate) injection for subcutaneous administration of testosterone replacement therapy (“TRT”) in adult males for conditions associated with a deficiency or absence of endogenous testosterone. XYOSTED[®] is the only FDA approved subcutaneous testosterone enanthate product for once-weekly, at-home self-administration and is approved and marketed in three dosage strengths, 50 mg, 75 mg and 100 mg. XYOSTED[®] provides an easy and virtually pain-free administration, low risk of transference and the ability to achieve and maintain steady levels of testosterone.

In the U.S., there are several different formulations for TRT including intramuscular injection, transdermal patches and gels, oral formulations and nasal gels. According to IQVIA National Sales Perspectives[®] (“NSP”) reporting of nationally projected sales activities, the overall U.S. TRT market was approximately \$1.4 billion in 2021 based on wholesale acquisition costs (“WAC”). Total prescriptions in the U.S. TRT market grew by 5.1% to 8.0 million prescriptions in 2021 as compared to 2020, entirely driven by an increase in prescriptions of injectables, which increased by 5.4%. The injectable TRT market grew from \$484.4 million in 2020 to \$545.0 million in 2021, an increase of 12.5% based on WAC. As of December 2021, XYOSTED[®] commanded approximately 65% and 52% of the branded TRT market among Urologists and Endocrinologists, respectively.

Competition in the U.S. testosterone replacement market includes transdermal solutions such as AbbVie’s Androgel[®] 1% and 1.62%, Perrigo’s generic Androgel[®] Topical Gel, 1.62%, Eli Lilly’s Axiron[®], Endo’s Testim[®] and Fortesta[®] (and the authorized generic) and Allergan plc’s (“Allergan”) Androderm[®]. Other forms of TRT include injectables such as Endo’s Aveed[®], Pfizer’s Depo[®]-Testosterone, and several generic oil testosterone products sold by Actavis, Sandoz, Viatris Inc., Teva and others, as well as Testopel[®] pellets by Endo and JATENZO[®], an oral formulation, by Clarus. In addition, Marius Pharmaceuticals has submitted an NDA with the FDA for Kyzatrex, an oral formulation of testosterone, that is pending FDA approval.

OTREXUP[®] (methotrexate) Injection

Prior to December 2021, we marketed and sold in the U.S. our proprietary product OTREXUP[®] (methotrexate) injection. OTREXUP[®] is a subcutaneous methotrexate injection for once weekly self-administration with an easy-to-use, single dose, disposable auto injector, indicated for adults with severe active rheumatoid arthritis (“RA”), children with active polyarticular juvenile idiopathic arthritis and adults with severe recalcitrant psoriasis.

In December 2021, we sold certain assets used in the operation of the OTREXUP[®] product to Otter under an Asset Purchase Agreement for a total purchase price of \$44.0 million (the “Asset Purchase Agreement”), subject to finalization of changes in closing inventory to be transferred. Pursuant to a separate supply agreement, Otter is responsible for supplying the pre-filled syringe of methotrexate and we will continue to manufacture and oversee the assembly and packaging of the final product which is sold to Otter as a partnered product. Further, we entered into a license agreement with Otter in which we granted Otter a worldwide, exclusive, fully paid-up license to certain patents relating to OTREXUP[®] that may also relate to our other products for Otter to commercialize and otherwise exploit OTREXUP[®] in the field as defined in the license agreement.

The primary competitor in the RA market is Medexus Pharma which markets and sells Rasuvo[®], a once-weekly, subcutaneous, single-dose auto-injector of methotrexate indicated for the treatment of rheumatoid arthritis, psoriasis and juvenile idiopathic arthritis (JIA), which is a direct competitor to OTREXUP[®]. Cumberland Pharmaceuticals, Inc. also recently received FDA approval and launched RediTrex[®], a methotrexate injection in the U.S. Competition in the methotrexate market also includes tablets and parenteral dosage forms that are distributed in the U.S. by several generic manufacturers, including Teva, Pfizer, Viatris Inc. (“Viatris”), Hospira and Accord Healthcare. Beyond disease modifying anti-rheumatic drugs (“DMARDs”), other commonly used pharmaceutical treatments for rheumatoid arthritis include analgesics, non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids and biologic response modifiers. In addition to methotrexate, the other DMARDs include azathioprine (Imuran[®]), cyclosporine (Neoral[®]), hydroxychloroquine (Plaquenil[®]), auranofin (Ridaura[®]), leflunomide (Arava[®]) and sulfasalazine (Azulfidine[®]). The biologic response modifiers include etanercept (Enbrel[®]), adalimumab (Humira[®]), golimumab (Simponi[®]), tocilizumab (Actemra[®]), certolizumab (Cimzia[®]), infliximab (Remicade[®]), abatacept (Orencia[®]), and rituximab (Rituxan[®]).

NOCDURNA[®] (desmopressin acetate) Sublingual Tablets

We market and sell NOCDURNA[®] (desmopressin acetate) in the U.S., which is the first and only sublingual tablet indicated for the treatment of nocturia due to nocturnal polyuria (“NP”) in adults who awaken at least two times per night to urinate. NOCDURNA[®] is a sublingual tablet, marketed in two dosage strengths, that dissolves quickly under the tongue without water and has been shown in clinical studies to reduce nighttime urination by nearly half (in patients who average three nighttime bathroom visits.) We license NOCDURNA[®] from Ferring. We began detailing NOCDURNA[®] with a soft launch in the fourth quarter of 2020 and reintroduced the product through a re-launch strategy to increase awareness and demand in the first quarter of 2021.

It is estimated that more than 50 million people in the U.S. are affected by nocturia, or frequent waking at night to urinate. Of the approximately 10 million patients diagnosed with nocturia, only about 1.5 million are treated for the condition. One of the leading causes of nocturia is nocturnal polyuria, which is present in up to 88% of nocturia patients. In patients diagnosed with nocturnal polyuria, the kidneys produce too much urine at night. Patients may already be taking medication for overactive bladder (“OAB”) or benign prostatic hyperplasia (“BPH”); however, these medications may not reduce night-time urination because they do not treat NP.

Pharmacological therapy is most useful in treating nocturia due to nocturnal polyuria, including desmopressin, an anti-diuretic hormone therapy. The anti-diuretic effects of desmopressin are mediated by stimulation of vasopressin 2 (“V2”) receptors, thereby increasing water re-absorption in the kidney, and hence reducing urine production. Desmopressin is available as both an oral tablet and a nasal spray. Noctiva[™], an FDA-approved nasal formulation of desmopressin acetate, although not currently marketed in the U.S., is the only other FDA-approved branded desmopressin acetate indicated for the treatment of nocturia.

Epinephrine Injection USP

We are the exclusive supplier of the device, which we developed, for Teva’s generic Epinephrine Injection USP products, indicated for emergency treatment of severe allergic reactions including those that are life threatening (anaphylaxis) in adults and certain pediatric patients. Teva’s Epinephrine Injection, utilizing our patented VIBEX[®] injection technology, was approved by the FDA as a generic drug product with an AB rating, meaning that it is therapeutically equivalent to the branded products EpiPen[®] and EpiPen Jr[®] and therefore, subject to state law, substitutable at the pharmacy. We supply the device and Teva is responsible for the drug, assembly and packaging, distribution and commercialization of the finished product, for which we also receive royalties on Teva’s net sales.

Epinephrine is used for the treatment of severe allergic reactions (anaphylaxis) to insect venom, foods, drugs and other allergens as well as anaphylaxis to unknown substances or exercise-induced anaphylaxis. Viatris’s EpiPen[®], along with its own authorized generic of the product, continues to be the global market leader in the epinephrine auto injector market. In the U.S., sales of generic epinephrine injection products were approximately \$1.66 billion in 2021 based on WAC, according to the IQVIA NSP report. There are other companies and alternative products competing in the U.S. market, including the authorized generic for Adrenaclick[®] marketed by

Amneal Pharmaceuticals, Inc. and Kaléo's AUVI-Q® (Epinephrine Injection, USP). Auto-Injector in the U.S. beginning in February 2017, Adamis Pharmaceuticals also received FDA approval of SYMJEP®[®], an epinephrine injection, which is marketed and distributed in the U.S. by US WorldMeds LLC.

Sumatriptan Injection USP

We, through our partner Teva, sell Sumatriptan Injection USP, indicated in the U.S. for the acute treatment of migraine headaches and cluster headache in adults. Sumatriptan Injection USP is a generic equivalent to Imitrex® STATdose Pen®, and available in the 4 mg/0.5 mL and 6 mg/0.5 mL single-dose pre-filled syringe auto-injectors. We have a license, supply and distribution agreement with Teva, under which Teva is responsible for the manufacture and supply of the drug, and we manufacture the device and complete assembly and packaging of the finished product. Teva is responsible for commercialization and distribution.

The total U.S. retail anti-migraine triptan market was \$4.9 billion in 2021 according to IQVIA's National Prescription Audit® ("NPA") report based on TRx Pharmacy Dollars. The majority of patients who use triptans take oral tablets. Oral drugs accounted for \$4.4 billion of the total, and injectable products accounted for approximately \$257 million of the total market, measured in terms of TRx Pharmacy Dollars. Sumatriptan is currently available in an oral formulation, nasal spray and injectable. There is extensive competition in the anti-migraine marketplace and several manufacturers offer versions of injectable drugs with a delivery device, including GSK (Imitrex STATdose Pen®), Teva (AJOVY®), Pfizer (Alsuma), Endo International plc (Sumavel® DosePro®), Sun Pharma (generic sumatriptan autoinjector) and Upsher-Smith (Zembrace® SymTouch®). Sandoz, Inc. ("Sandoz") also markets an authorized generic version of GSK's Imitrex STATdose Pen®.

Makena® (hydroxyprogesterone caproate injection) Subcutaneous Auto Injector

We are the exclusive supplier of the device, a variation of our VIBEX® QuickShot® subcutaneous auto injector developed by us, for the progestin hormone drug Makena® (hydroxyprogesterone caproate injection). The Makena® subcutaneous auto injector drug-device combination product is a ready-to-administer treatment indicated to reduce the risk of preterm birth in women pregnant with one baby and who spontaneously delivered one preterm baby in the past. The product was approved by the FDA under the accelerated approval pathway. We are the exclusive supplier of the devices and the final assembled and packaged commercial product.

Makena® is a progestin that belongs to a class of drugs called progestogens. Progestogens have been studied to reduce preterm birth and have shown varying results depending upon the subjects enrolled. The active ingredient in Makena®, 17 α hydroxyprogesterone caproate (often referred to as 17P), is the only FDA-approved treatment for pregnant women who have had a prior spontaneous preterm birth (which is a substantial risk factor for recurrent preterm birth) and has been and used for more than a decade by healthcare providers to treat patients with a history of spontaneous preterm birth. The approval of Makena® was based on the landmark Meis trial, conducted by the National Institute of Child Health and Human Development and the Maternal-Fetal Medicine Units Network and published in the New England Journal of Medicine in 2003. The Society for Maternal Fetal Medicine Publications Committee published clinical guidelines for the use of progestogens to reduce the risk of preterm birth in the American Journal of Obstetrics and Gynecology in May 2012, which were affirmed in 2014. Preterm birth is defined as a birth prior to 37 weeks of pregnancy being completed. According to the Centers for Disease Control and Prevention National Center for Health Statistics, the percentage of preterm births affected approximately 10% of births in the U.S. in 2020.

In October 2019, Covis announced that the FDA's Bone, Reproductive and Urologic Drugs Advisory Committee met to better understand and interpret the PROLONG (Progestin's Role in Optimizing Neonatal Gestation) confirmatory clinical trial for Makena® (hydroxyprogesterone caproate) injection. Nine advisory committee members voted to recommend that the FDA pursue withdrawal of approval for Makena® and seven committee members voted to leave the product on the market under accelerated approval and require a new confirmatory trial. In October 2020, Covis received notice that the FDA is proposing to withdraw approval of Makena® (hydroxyprogesterone caproate injection). Covis then formally requested a public hearing in response to the FDA's proposal to withdraw its approval and has stated that it remains committed to working with the FDA to maintain patient access to Makena® as a treatment option to reduce pre-term birth. In August 2021, Covis announced the FDA had granted the request for a public hearing. A date for such meeting has not been set or announced by either the FDA or Covis.

Teriparatide Injection

We are the exclusive supplier of the multi-dose pen, which we developed, used in Teva's generic teriparatide injection product. In 2020, our partner Teva launched Teriparatide Injection, the generic version of Eli Lilly's branded product Forsteo® featuring the Antares multi-dose pen platform, for commercial sale in several countries outside of the U.S. Under an exclusive development, license and supply agreement with Teva, Antares is responsible for the manufacturing and supply of the multi-dose pen used in Teva's generic teriparatide product and Teva is responsible for the sale and distribution of the product. Antares is compensated for devices sold to Teva and is entitled to receive royalties on net product sales by Teva in the territories.

Teriparatide is used for the treatment of osteoporosis in postmenopausal women and men at increased risk of fracture and for glucocorticoid induced osteoporosis in men and women. According to Eli Lilly's annual report, 2021 global sales of Forteo® were \$801.9 million, of which \$441.6 million was generated in the U.S.

Products with Tentative Approval

The following is a discussion of our products with tentative approval from the FDA. For a discussion of other approved and marketed commercial products, including proprietary and partnered products and product candidates currently in development, see the “**Our Products**” and “**Research and Development**” sections above and below, respectively, included in Item 1 of Part I of this Annual Report on Form 10-K.

TLANDO® (testosterone undecanoate) Oral Formulation

TLANDO® (testosterone undecanoate) is a twice daily oral formulation of testosterone for TRT indicated for conditions associated with a deficiency or absence of endogenous testosterone, or hypogonadism in adult males. TLANDO® was granted tentative approval from the FDA in December 2020 and will be eligible for final approval and marketing in the U.S. upon expiration of the exclusivity period previously granted to Clarus for JATENZO® on March 27, 2022. On February 3, 2022, we announced the FDA's acceptance of our NDA resubmission for TLANDO® in which the FDA designated the NDA as a Class 1 resubmission with a two-month review goal period and set a target action date of March 28, 2022. We continue to prepare for the launch of TLANDO® in 2022 pending final FDA approval after the expiration of JATENZO®'s exclusivity period.

In the U.S., there are several different formulations for TRT including intramuscular injection, transdermal patches and gels, oral formulations and nasal gel. According to IQVIA National Sales Perspectives® (“NSP”) reporting of nationally projected sales activities, the overall U.S. TRT market was approximately \$1.4 billion in 2021 based on wholesale acquisition costs (“WAC”). Total prescriptions in the U.S. TRT market grew by 5.1% to 8.0 million prescriptions in 2021 as compared to 2020, entirely driven by an increase in prescriptions of injectables, which increased by 5.4%. The injectable TRT market grew from \$484.4 million in 2020 to \$545.0 million in 2021, an increase of 12.5% based on WAC.

Competition in the U.S. testosterone replacement market includes transdermal formulations such as AbbVie's Androgel® 1% and 1.62%, Perrigo's generic Androgel® Topical Gel, 1.62%, Eli Lilly's Axiron®, Endo's Testim® and Fortesta® and Allergan plc's (“Allergan”) Androderm®. Other forms of TRT include injectables such as Endo's Aveed®, Pfizer's Depo®-Testosterone, and several generic testosterone products sold by Actavis, Sandoz, Viatrix Inc., Teva and others, as well as Testopel® pellets by Endo and JATENZO®, an oral formulation, by Clarus. In addition, Marius Pharmaceuticals has submitted an NDA with the FDA for Kyzatrex, an oral formulation of testosterone that is pending final approval.

Research and Development

We are committed to a strong research and development program, recognizing that the development of new product offerings is important to our future success. An important part of our growth strategy is our continued investment in our evolving research and development activities and new product pipeline. While we are focused on opportunities within urology and endocrinology therapeutic areas, we are also exploring new product opportunities beyond these therapeutic areas that could further grow and diversify our portfolio. Our research and development efforts are focused primarily on leveraging our existing product and technology platforms by broadening their applications for use in other drug/device combination products, as well as exploring new pharmaceutical products, technologies and drug delivery methods. We also have a corporate development team that seeks and evaluates new business and product opportunities to further expand our pipeline.

Our research and development programs consist primarily of clinical, regulatory, formulation development, engineering and device development activities for our current products, next generation versions of current products, product extensions, and new proprietary and partnered products and technologies in development. Our internal research and development team works with external consultants, industry experts, physicians and other medical personnel in an effort to drive our product development pipeline. The following is a discussion of our significant research and development activities.

ATRS - 1901

We have initiated development of a proprietary drug device combination product for the urology oncology market, identified as ATRS-1901, and conducted formulation development work and non-clinical studies to help advance this program. In 2020, we received a response from the FDA regarding our pre-IND (Investigational New Drug) submission and believe we have determined our clinical and regulatory pathway forward. Our pre-clinical safety studies are ongoing.

ATRS - 1902

We have identified a program to develop a proprietary drug device combination product for the endocrinology market, an adrenal crisis pen, identified as ATRS-1902. The development program supports a proposed indication for the treatment of acute adrenal insufficiency, known as adrenal crisis, in adults and adolescents, using a novel proprietary auto-injector platform to deliver a liquid stable formulation of hydrocortisone. We have conducted initial formulation work and developed a working prototype of a new device to support this program.

In June 2021, we submitted an IND application with the FDA for the initiation of a Phase 1 clinical study of ATRS-1902 for adrenal crisis rescue. The IND application includes the protocol for an initial clinical study to compare the pharmacokinetic profile of our novel formulation of hydrocortisone versus Solu-Cortef[®], which is an anti-inflammatory glucocorticoid and is the current standard of care for the management of acute adrenal crises.

In July 2021, the FDA accepted our IND for ATRS-1902 enabling us to initiate our Phase 1 clinical study. The Phase 1 clinical study designed to evaluate the safety, tolerability and pharmacokinetics (“PK”) of a liquid stable formulation of hydrocortisone was initiated in September 2021. The study is a cross-over design to establish the PK profile of ATRS-1902 (100 mg) compared to Solu-Cortef[®] (100 mg), the reference-listed drug, in 32 healthy adults. After this study is completed, we expect to conduct a bioequivalence study and second human factor study utilizing our proprietary auto-injector technology.

In January 2022, we announced the positive results from the Phase 1 clinical study and were granted Fast Track designation by the FDA. The positive results support the advancement of our ATRS-1902 development program to a pivotal study for the treatment of acute adrenal insufficiency, known as adrenal crisis, using our Vai[™] novel proprietary rescue pen platform to deliver a liquid stable formulation of hydrocortisone. We anticipate starting this pivotal study in adults in the second quarter of 2022 and expect to submit a 505(b)(2) NDA with the FDA by the end of 2022 pending the success of the study, a further human factors study and confirmation of the product stability from our ongoing stability program.

ATRS-1903

We have initiated development of a proprietary drug device combination product utilizing our rescue pen technology for a rare immunology disorder, identified as ATRS-1903. Formulation development work has been conducted and we anticipate progressing this towards initial clinical testing to evaluate PK and tolerability in human subjects.

Additional Development Programs

We continue to pursue and evaluate other potential new products and product extensions that address patient needs primarily in targeted therapeutic areas. We explore new development opportunities including innovative delivery technologies and improved formulations of existing therapeutics.

Partnered Development Projects

We, in collaboration with our pharmaceutical partners, are engaged in research and development activities utilizing our auto injectors and disposable pen injectors. The development programs typically consist of determination of the device design, development of prototype tooling, production of prototype devices for testing and clinical studies, and development of commercial tooling and assembly. We expect development related to these products to continue; however, the development timelines are generally controlled by our partners and the extent of near-term and future development will be dependent on decisions made by our partners. The following is a summary of the development stages for select partnered products in development:

Pen Injector with Teriparatide

We are developing with Teva, under a license, development and supply agreement, a multi-dose disposable pen injector device with teriparatide for the treatment of osteoporosis. Teva is working toward a regulatory approval with the FDA for a generic version of Forteo® (teriparatide rDNA origin injection) using the ANDA pathway. See also the “Teriparatide Injection” section above for more information about the product and Teva’s commercialization activities outside the U.S.

Pen Injector with Exenatide

We were developing with Teva a multi-dose pen injector device for use with a generic form of BYETTA® (exenatide injection) for the treatment of diabetes. Teva was working through the U.S. regulatory approval process for its exenatide pen using the ANDA pathway. On February 25, 2022, Teva notified us that it was terminating the exenatide program and related agreement due to a lack of commercial viability. The termination is effective August 23, 2022.

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Rescue Pen (drug undisclosed)

In August 2018, we entered into a development agreement with Pfizer and began developing a combination drug device rescue pen. This rescue pen will use the Antares QuickShot® auto injector and an undisclosed Pfizer drug. In 2021, we continued to work on this development program, and we expect to continue development of this product candidate.

Rescue Device with Selatogrel

In November 2019, we entered into a new global agreement with Idorsia to develop a novel, drug-device product containing selatogrel. A new chemical entity, selatogrel, is being developed for the treatment of a suspected acute myocardial infarction (“AMI”) in adult patients with a history of AMI. Idorsia will pay for the development of the combination product and will be responsible for applying for and obtaining global regulatory approvals for the product. The parties intend to enter into a separate commercial license and supply agreement pursuant to which we will provide fully assembled and labelled product to Idorsia at cost plus mark-up. Idorsia will then be responsible for global commercialization of the product, pending FDA or foreign approval. We will be entitled to receive royalties on net sales of the commercial product.

In 2020, we completed the initial design phase of the selatogrel device and Idorsia conducted a clinical bridging study utilizing these devices. We completed the usability and reliability studies for the device which has been tailored for emergency use ahead of the Phase 3 study.

According to publications by Idorsia, two Phase 2 studies in patients with stable coronary artery disease and acute myocardial infarction, respectively, have met their pharmacodynamic objectives of significantly inhibiting platelet aggregation. Subcutaneous administration of selatogrel 8 mg and 16 mg has demonstrated a rapid onset of action, within 15 minutes, with the height of its effect extending over 4-8 hours, depending on the dose. Selatogrel was safe and well tolerated in both studies and there were no treatment-emergent serious bleeds.

In December 2020, the FDA designated Idorsia’s investigation of selatogrel for the treatment of a suspected AMI in adult patients with a history of AMI as a “fast-track” development program. This designation is intended to promote communication and collaboration between the FDA and pharmaceutical companies for drugs that treat serious conditions and fill an unmet medical need.

In June 2021, Idorsia announced they initiated its Phase 3 registration study to evaluate the efficacy and safety of self-administered subcutaneous selatogrel, Idorsia’s P2Y₁₂ receptor antagonist, in suspected AMI using Antares’ QuickShot® auto-injector. The study is an international, multi-center, double-blind, randomized, placebo-controlled, parallel-group, Phase 3 study to assess the clinical efficacy and safety of 16 mg of selatogrel when self-administered (on top of standard-of-care) upon occurrence of symptoms suggestive of an acute myocardial infarction. The primary efficacy endpoint is the occurrence of death from any cause, or non-fatal AMI after any study treatment self-administration. The study will enroll approximately 14,000 patients who are at high risk of recurrent AMI, at approximately 250 sites in approximately 30 countries. A Special Protocol Assessment has been agreed with the FDA for Idorsia’s selatogrel, which indicates the FDA is in agreement with the adequacy and acceptability of specific critical elements of overall protocol design (e.g., entry criteria, dose selection, endpoints and planned analyses) for a study intended to support a future marketing application.

According to the American Heart Association, the overall prevalence for myocardial infarction in the U.S. is about 7.9 million adults. There are also approximately 805,000 heart attacks in the U.S. annually, of which 605,000 are first heart attacks and 200,000 happen to people who have already had a heart attack according to the Centers for Disease Control and Prevention.

Manufacturing

We use third parties to manufacture our products and product candidates, including the products and related components we supply to our partners. For our products and product candidates, we must ensure they are manufactured in accordance with FDA's current Good Manufacturing Practices ("cGMPs") for drug products and FDA's current Quality System Regulations ("QSRs") for medical devices and equivalent provisions in the European Union ("EU") and elsewhere, which are required as part of the overall obligations necessary. We believe that our third-party manufacturers are currently in compliance with cGMPs, QSRs and foreign equivalents, to the extent applicable. Assembly and packaging of our products and product candidates is performed by third-party service providers under our direction. All manufacturers and suppliers are monitored and evaluated by our quality department to assess compliance with regulatory requirements and our internal quality standards and benchmarks. We perform quality reviews of manufacturing for all of our product candidates and products, and quality releases for all of our product candidates and products that we sponsor or commercialize.

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We use a range of third-party manufacturers to manufacture and supply certain components, drugs, final assembly and finished product. Below is a summary of our key production, manufacturing, assembly and packaging arrangements with third-party manufacturers for products commercialized by us and our partners:

- We have contracted with Phillips-Medisize Corporation (“Phillips”), an international outsource provider of design and manufacturing services, to produce commercial quantities of our QuickShot® auto injector device for XYOSTED®, our QuickShot® auto injector device for the Makena® product with Covis, and our VIBEX® epinephrine auto injector product with Teva.
- We use ComDel Innovation, Inc. (“ComDel”), a domestic provider of integrated solutions for product development, tooling, and manufacturing, to provide manufacturing services for the VIBEX® sumatriptan auto injector product and for the teriparatide pen product with Teva.
- We have contracted with Jabil Healthcare, an international manufacturing development company to supply commercial quantities of our VIBEX® auto injector device for the OTREXUP® product for Otter and the VIBEX® epinephrine auto injector product with Teva.
- We have contracted with Fresenius Kabi to supply commercial quantities of pre-filled syringes of testosterone for XYOSTED®.
- We have contracted with Ferring for the commercial supply of NOCDURNA®.
- We use Sharp Corporation (“Sharp”), an international contract packaging company, to assemble and package XYOSTED®, Sumatriptan Injection USP and the Makena® auto injector products, and the OTREXUP® auto injector product for Otter®.

Below is a summary of our key production, manufacturing, assembly and packaging arrangements with third-party manufacturers for TLANDO®:

- We use Pfizer to supply the active pharmaceutical ingredient (“API”).
- We have contracted with NextPharma, an international pharmaceutical manufacturing company, to supply the bulk capsule product.
- We use PCI Pharma Services (“PCI”), an international contract packaging company, to assemble and package TLANDO®.

We have an experienced quality group that works with and regularly inspects or meets with our manufacturers and suppliers to review the manufacturing process for our products and product candidates, and to provide input on quality matters.

In addition to the above manufacturing capabilities, on July 1, 2019, we entered into a lease for approximately 75,000 square feet of office, laboratory, manufacturing and warehousing space in Minnetonka, Minnesota. We completed the build-out of the facility and began occupying the space in 2020. The new facility supports our administrative functions, product development and quality operations and is intended to provide additional manufacturing and warehousing capabilities in the future.

Commercial Operations

We have built a robust internal commercial organization, consisting of specialty sales representatives, management and support staff, to market and sell our proprietary products XYOSTED®, OTREXUP® and NOCDURNA® in the U.S. As of December 2021, commercialization and distribution of OTREXUP® is the responsibility of Otter in accordance with the Asset Purchase Agreement. In anticipation of final FDA approval, we are preparing to launch TLANDO® in 2022. We have entered into agreements with vendors for

certain commercialization services such as third-party logistics, distribution, data analytics and claims processing. We have and may continue to enter into licensing and or additional distribution arrangements for commercialization of our products outside the U.S.

Distribution – We have contracted with a third-party logistics provider, Cardinal Health 105, Inc., also known as Specialty Pharmaceutical Services (“Cardinal”), for key services related to logistics, warehousing and inventory management, distribution, contract administration and chargeback processing, accounts receivable management and call center management. We also use a division of Cardinal for sample administration. In addition, we use third parties to perform various other services for us relating to regulatory monitoring, including adverse event reporting, safety database management and other product maintenance services.

Trade – We contract with numerous wholesale distributors, including Cardinal, McKesson Corporation (“McKesson”) and AmerisourceBergen Corporation to distribute our proprietary products to retail pharmacies as well as the Veterans Administration and other governmental agencies. In addition to shipping our product, these distributors provide inventory and sales reports as well as other services. In exchange for these services, we pay fees to certain distributors based on a percentage of wholesale acquisition cost. We have also contracted with several specialty pharmacies to support fulfillment of certain prescriptions.

Third Party Reimbursement and Pricing – In the U.S., sales of pharmaceutical products to consumers depend to a significant degree on the availability of coverage and reimbursement by third-party payers, such as government and private insurance plans. Third-party payers are increasingly challenging the pricing of products and services and implementing other cost containment mechanisms, including demanding more aggressive pricing and rebates for favorable formulary placement. This is especially true in markets where generic options exist. Third-party payers often use a tiered reimbursement system and may require step edits or prior authorization. It is time consuming and expensive for us to seek and maintain coverage for our products and to process reimbursements from Medicaid, Medicare and private payers.

Participation in the Medicaid program requires payment of statutory rebates on unit dispenses. Some states have also created Medicaid preferred drug lists and include drugs on those lists only when the manufacturers agree to pay a supplemental rebate. Some States have implemented statutes imposing other consequences for a manufacturer’s failure in certain circumstances to negotiate supplemental rebates, including but not limited to, ordering managed care plans to limit or reduce reimbursement for a drug provided by a medical practitioner. If our products are not included on these preferred drug lists, they may be subject to prior authorization.

Similarly, in order to ensure coverage by Medicare Part D and commercial pharmacy benefit plans, we participate in certain rebate programs, which provide discounted prescriptions to qualified insured patients. Under these rebate programs, we pay a rebate to the third-party administrator of the program. We also provide discounts to authorized users of the Federal Supply Schedule (“FSS”) of the General Services Administration under an FSS contract negotiated by the Department of Veterans Affairs, including discounts mandated by the Veterans Health Care Act, discounted prescriptions to Department of Defense’s (“DoD”) Tricare retail pharmacy program, and statutory discounts to federal grantees and safety net providers referred to as covered entities pursuant to our pharmaceutical pricing agreement with the Department of Health and Human Services and the 340B drug discount program, which is required as a condition of Medicaid coverage. Government agencies ordering under the FSS and covered 340B entities purchase products from the wholesale distributors at the discounted price, and the wholesale distributors then charge back the difference between the current wholesale acquisition cost and the price the entity paid for the product.

We also offer co-pay assistance programs to patients for our proprietary products under which patients covered by commercial pharmacy benefit plans receive discounts on their prescriptions. Our XYOSTED® STEADYCare Co-pay Assistance Program provides financial support to most commercially insured patients to assist with out-of-pocket costs of XYOSTED®. In addition, certain commercially insured patients are eligible for our “first fill free” program for XYOSTED® to assist the patient during the initial claims adjudication process. Similar to XYOSTED®, we offer a co-pay assistance program for NOCDURNA®, which also provides financial support to most commercially insured patients to assist with out-of-pocket costs. We use contract service providers to process and pay claims to patients for actual usage. We also offer the ability for patients who do not have insurance, or whose insurance does not cover our proprietary products, the ability to purchase either XYOSTED® or NOCDURNA® with a valid prescription at a cash price via a specialty pharmacy.

International Distribution – We are contracting with a third-party logistics provider, Cardinal, for key services related to logistics, warehousing and inventory management, international shipping, export and customs administration to support our international distributor, Lunatus. We entered into an exclusive distribution agreement with Lunatus in August 2020 to distribute and promote the sale of XYOSTED® in Saudi Arabia and the United Arab Emirates. Lunatus is responsible for obtaining regulatory approval and, assuming approval, for the promotion and commercialization of the product in the territories.

Sales, Marketing & Distribution of Partnered Products

Our partnered products may encounter some of the same reimbursement issues described above, and although we do not control the reimbursement rate or discounts contracted with third-party payers by our partners, it ultimately affects our royalty payments we receive on net sales. The industry has experienced an increasingly widening gap between gross sales and net sales after discounts.

Epinephrine Injection USP – We are the exclusive supplier of the device used in Teva’s epinephrine injection product. We receive payment for each device sold to Teva and royalties on Teva’s commercial sales of the product. Teva’s epinephrine injection was approved as a generic drug product with an AB rating, meaning that it is therapeutically equivalent to Viatris Inc.’s branded products EpiPen® and EpiPen Jr® and therefore, subject to state law, is substitutable at the pharmacy. Teva is solely responsible for commercialization and distribution of the finished product.

Makena® Subcutaneous Auto Injector – We are the exclusive supplier of the device used in the Makena® subcutaneous auto injector. We receive payment for each device sold to Covis and royalties on Covis’ commercial sales of the product. Covis primarily sells Makena® to specialty pharmacies, specialty distributors, home infusion companies and pharmacies which, in turn, sell Makena® to healthcare providers, hospitals, government agencies and integrated delivery systems. Covis is solely responsible for commercialization and distribution of the finished product.

Sumatriptan Injection USP – We are the exclusive supplier of the product containing sumatriptan which is commercialized by Teva. We are compensated at cost for shipments of product to Teva. In addition, net profits from sales of the product, after deduction of product sales allowances such as discounts, rebates and chargebacks, are split 50/50 between us and Teva. Teva is solely responsible for commercialization and distribution of the finished product.

Teriparatide Injection – We are the exclusive supplier of the pen injection device used in Teva’s Teriparatide Injection product outside the U.S. Teva launched its generic version of Forsteo® in certain territories outside the U.S. in 2020. We receive payment for each device sold to Teva and royalties on Teva’s commercial sales of the product in the territories. Teva is solely responsible for commercialization and distribution of the finished product.

OTREXUP® (methotrexate) Injection – Pursuant to the Asset Purchase Agreement, license agreement and supply agreement, we are the exclusive supplier of the device used in OTREXUP® beginning in December 2021. We receive payment for each device sold to Otter. Otter is solely responsible for commercialization and distribution of the finished product.

Information about Revenues and Customer Concentrations

For information about revenues and customer concentrations, see Item 7 of Part II of this Annual Report on Form 10-K. Significant customers from which we derive 10% or more of our total revenue in each or any of the years in the three-year period ended December 31, 2021 include: Teva, McKesson, AmerisourceBergen Corporation, Cardinal Health and Covis. For more detailed information, see Note 14 – Revenues, Significant Customers and Concentrations of Risk in the Notes to Consolidated Financial Statements included in Item 8 of Part II of this Annual Report on Form 10-K.

Collaborative Arrangements and License Agreements

We have entered into significant partnering arrangements and licensing agreements with Teva, Covis, Pfizer, Idorsia and other pharmaceutical partners. The following is a summary of certain agreements.

Teva License, Development and Supply Agreements

In July 2006, we entered into an exclusive license, development and supply Agreement with Teva for an epinephrine auto injector product to be marketed in the U.S. and Canada. Pursuant to the agreement, Teva is obligated to purchase all of its delivery device requirements from us. We received an upfront cash payment and a milestone payment upon FDA product approval. We also receive a negotiated purchase price for each device sold, as well as royalties on Teva's commercial sales of the product. This agreement has been amended to provide for payment of capital equipment and other ongoing development work that was outside the scope of the original agreement. The agreement will continue until the expiration of the last to expire patent that is filed no later than 12 months after FDA approval. We have multiple patents that have been granted by the United States Patent and Trademark Officer ("USPTO") that cover this product, the latest of which will expire in 2033. We have and plan to continue to file patent applications covering this product.

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In December 2007, we entered into a license, development and supply agreement with Teva under which we developed and will supply a disposable pen injector for two therapeutic products: exenatide and teriparatide. Under the agreement, we received an upfront payment and development milestones, and may receive royalties on future product sales. This agreement has been amended numerous times and provides for payment of capital equipment and other development work that was outside the scope of the original agreement. This agreement will continue until the expiration date of the last to expire patent covering the device or product that is filed no later than 12 months after FDA approval and will be automatically renewed for successive periods of two years each. Currently, the expiration date of the last to expire patent is 2035. On February 25, 2022, Teva notified us that it was terminating the exenatide program and related agreement due to a lack of commercial viability. The termination is effective August 23, 2022.

In November 2012, we entered into a license, supply and distribution agreement with Teva for an auto injector product containing sumatriptan for the treatment of migraines. Under the agreement, we received an upfront payment and a milestone payment upon commercial launch. Teva is responsible for the manufacture and supply of the drug, and we are responsible for the manufacture and supply of the device and assembly and packaging of the finished product. We are compensated at cost for product shipment to Teva and Teva distributes the product in the U.S. Teva also received an option for distribution rights in other territories. In addition, net profits are split 50/50 between us and Teva. The term of the agreement continues seven years from commercial launch, which was in June 2016, with automatic one-year renewals unless terminated sooner by either party in accordance with the terms of the agreement.

Covis Agreements

In September 2014, we entered into a development and license agreement with Lumara Health, Inc., which was subsequently acquired by AMAG, which was subsequently acquired by Covis, to develop and supply an auto injector system for use with Makena[®], a progestin drug (hydroxyprogesterone caproate) indicated to reduce the risk of preterm birth. Under the agreement, we granted an exclusive, worldwide, royalty-bearing license, with the right to sublicense, to certain intellectual property rights, including know-how, patents and trademarks, and received an upfront payment for our license and development activities. We are also entitled to milestone payments upon the achievement of pre-determined amounts of net sales of the product.

Covis was responsible for the clinical development and preparation, submission and maintenance of all regulatory applications, and is responsible for the manufacture and supply of the drug to be used in the product, and to market, distribute and sell the product. We are the exclusive supplier of the auto injection system devices for the product and are responsible for the manufacture and supply of the devices and final assembly and packaging of the finished product. Under the arrangement, we receive payment for each device, and royalties based on net sales of products commencing on product launch in a particular country until the product is no longer developed, marketed, sold or offered for sale in such country. The royalty rates range from high single digit to low double digits and are tiered based on levels of net sales of products and decrease after the expiration of licensed patents or where there are generic equivalents to the auto injector product being sold in a particular country.

In March 2018, we entered into a manufacturing agreement with Covis for the exclusive supply of the devices and fully assembled and packaged final finished product of the Makena[®] subcutaneous auto injector. The term of the agreement is concurrent with the term of the development and license agreement and will continue until such time as commercialization of the product is halted. We receive a contracted price per unit on each product manufactured.

Pfizer Agreement

In August 2018, we entered into a development agreement with Pfizer to jointly develop a combination drug device rescue pen. This rescue pen will use the Antares QuickShot[®] auto injector and an undisclosed Pfizer drug. In 2021, we continued to work on this development program, and we expect to continue development of this product candidate.

Idorsia Agreement

In November 2019, we entered into a new global agreement with Idorsia to develop a novel, drug-device product containing selatogrel. A new chemical entity selatogrel is being developed for the treatment of a suspected AMI in adult patients with a history of AMI. Idorsia will pay for the development of the combination product and will be responsible for applying for and obtaining global regulatory approvals for the product. The parties intend to enter into a separate commercial license and supply agreement pursuant to which Antares will provide fully assembled and labelled product to Idorsia at cost plus mark-up. Idorsia will then be responsible for global commercialization of the product, pending FDA or foreign approval. Antares will be entitled to receive royalties on net sales of the commercial product.

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Ferring Agreement

In October 2020, we entered into an exclusive license and commercial supply agreement with Ferring for the marketed product NOCDURNA[®] (desmopressin acetate) in the U.S., which is indicated for the treatment of nocturia due to nocturnal polyuria (NP) in adults who awaken at least two times per night to urinate. Under the terms of the license agreement, the Company paid Ferring an upfront payment of \$5.0 million upon execution and paid an additional \$2.5 million on October 1, 2021. Ferring is eligible for tiered royalties and additional commercial milestone payments potentially totaling up to \$17.5 million based on our net sales of NOCDURNA[®] in the U.S.

Lipocine Agreement

In October 2021, we entered into an exclusive license agreement with Lipocine for the product TLANDO[®] (testosterone undecanoate) in the U.S., a twice-daily oral formulation of testosterone for testosterone replacement therapy indicated for conditions associated with a deficiency or absence of endogenous testosterone, or hypogonadism in adult males. TLANDO[®] was granted tentative approval from the FDA in December 2020 and will be eligible for final approval and marketing in the U.S. upon expiration of the exclusivity period previously granted to Clarus for JATENZO[®] on March 27, 2022. On February 3, 2022, we announced the FDA's acceptance of our NDA resubmission for TLANDO[®] with a target action date set for March 28, 2022. We continue to prepare for the launch of TLANDO[®] in 2022 pending final FDA approval after the expiration of JATENZO[®]'s exclusivity period. Under the terms of the license agreement, we paid Lipocine an upfront payment of \$11.0 million. Lipocine is eligible for additional milestone payments up to \$10.0 million and tiered royalty and commercial milestones based on net sales of TLANDO[®] in the U.S. We will be responsible for the manufacturing and commercialization of TLANDO[®].

The license agreement also grants us the option to license and develop LPCN 1111 (TLANDO XR) in the U.S., a potential once daily oral testosterone product containing testosterone tridecanoate in development for the treatment of hypogonadism in adult males. Results of the Phase 2b study for TLANDO XR met its primary endpoints, including identifying the dose expected to be tested in a Phase 3 study. TLANDO XR was well tolerated with no drug-related severe or serious adverse events reported and the target Phase 3 dose also met its primary and secondary endpoints in the Phase 2b study. TLANDO XR is an investigational drug containing tridecanoate and has not been approved by the FDA, nor has the name been approved. If elected, upon exercise of the option, we will be required to pay an additional \$4.0 million in license fees in two installments and will be responsible for additional development and commercial milestone payments as well as tiered royalties on net sales of TLANDO XR in the U.S. In addition, we will be responsible for completing the development program including the conduct of a Phase 3 clinical trial and applying for regulatory approval in the U.S.

Otter Agreement

In December 2021, we entered into an Asset Purchase Agreement with Otter to sell certain worldwide assets used in the operation of the OTREXUP[®] product line for \$44.0 million, subject to finalization of changes in closing inventory to be transferred, and a license agreement for rights to commercialize OTREXUP[®]. Simultaneously, we entered into a supply agreement with Otter to manufacture the VIBEX[®] auto-injection system device, designed and developed to incorporate a pre-filled syringe for delivery of methotrexate, assemble, package, label and supply the final OTREXUP[®] product and related samples to Otter at cost plus mark-up. Otter is responsible for manufacturing, formulation and testing of methotrexate and the corresponding pre-filled syringe for assembly with the device manufactured by us, along with the commercialization and distribution of OTREXUP[®].

Seasonality of Business

Certain parts of our business may be affected by seasonality. Customer purchases have historically been lower in the first quarter of the year due to the resetting of high-deductible health insurance plans. Seasonality affects quarterly comparisons within any fiscal year; however, we believe this impact is generally not material to our annual consolidated results. Our revenues may be influenced by many

factors, including regulatory and reimbursement approvals, timing of product launches, acquisitions or divestitures, holiday schedules, and other macro-economic conditions.

Competition

The pharmaceutical and medical device industries are intensely competitive and subject to rapid and significant technological change. We have a wide range of competitors depending upon the branded or generic marketplace, the therapeutic product category, and the product type, including dosage strengths and route of administration. Our competitors include established specialty pharmaceutical companies, major brand name and generic manufacturers of pharmaceuticals such as Teva, Viatris, Eli Lilly and Endo, as well as a wide range of medical device companies that sell a single or limited number of competitive products or participate in only a specific market segment. Our competitors also include third party contract medical device design and development companies such as Scandinavian Health Ltd., Ypsomed AG, West Pharmaceutical and Owen Mumford Ltd. Many of our competitors have greater financial and other resources than we have, such as more commercial resources, larger research and development staffs and more extensive marketing and manufacturing organizations. Smaller or early stage emerging companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

If competitors introduce new products, delivery systems or processes with therapeutic or cost advantages, our products can be subject to progressive price reductions or decreased volume of sales, or both. Branded products not only face competition from other brands, but also from generic versions. Generic versions are generally significantly less expensive than branded versions, and, where available, may be required in preference to the branded version under third-party reimbursement programs, or substituted by pharmacies. Most new products that we introduce must compete with other products already on the market or products that are later developed by competitors. Manufacturers of generic pharmaceuticals typically invest far less in research and development than research-based pharmaceutical companies and therefore can price their products significantly lower than branded products. Accordingly, when a branded product loses its market exclusivity, it normally faces intense price competition from generic forms of the product. To successfully compete for business with managed care and pharmacy benefit management organizations, we must often demonstrate that our products offer not only medical benefits but also cost advantages as compared with other forms of care.

Newly introduced generic products with limited or no other generic competition typically command higher prices initially. At the expiration of the exclusivity period, other generic distributors may enter the market, resulting in a significant price decline for the drug. As a result, the maintenance of profitable operations in generic pharmaceuticals depends, in part, on our ability to select, develop and launch new generic products in a timely and cost-efficient manner and to maintain efficient, high quality manufacturing capabilities.

Industry Trends

Based upon our experience, we believe the following significant trends have important implications for the growth of our business. Recent trends in the pharmaceutical industry include merger and acquisition activity leading to further market consolidation. In many cases, the resulting combined pharmaceutical companies are bigger and have more financial, technical and market strength and greater resources, which increases competitive pressure in the industry.

There is ongoing effort by public and private payers to reduce the cost of drugs and reduce the overall cost of health care. There continues to be greater pressure on drug manufacturers to provide greater discounts and rebates on their products. The drug distribution channels are complex and involve many different parties. Recently, such channels have undergone and continue to undergo consolidation. Drug wholesalers and retail drug chains have merged or consolidated resulting in significantly larger organizations with greater resources and bargaining power controlling multiple levels of the drug distribution network. Consequently, pharmaceutical companies are facing increasing pressure to reduce prices. Additionally, the emergence of large buying groups representing independent retail pharmacies and other drug distributors, and the prevalence and influence of managed care organizations and similar institutions, enable those groups to demand larger price discounts on our products. Large wholesalers and retailer customers have continued to form partnerships. As a result of this consolidation among wholesale distributors as well as the growth of large retail drug store chains, a small number of large wholesale distributors control a significant share of the market.

Government Regulation

Any potential products discovered, developed and manufactured by us or our collaborative partners must comply with comprehensive regulation by the FDA in the U.S. and by comparable authorities in other countries. These national agencies and other federal, state, and local entities regulate, among other things, the pre-clinical and clinical testing, safety, effectiveness, approval, manufacturing operations, quality, labeling, distribution, controlled substance security, export, import, storage, record keeping, safety and other reporting, sampling, advertising, marketing, and promotion of pharmaceutical products and medical devices. Facilities and certain company records are also subject to inspections by the FDA and comparable authorities or their representatives.

The FDA has broad discretion in enforcing the Federal Food, Drug and Cosmetic Act (“FFDCA”) and the regulations thereunder, and noncompliance can result in a variety of regulatory enforcement actions ranging from warning letters, product detentions, device alerts or field corrections to recalls, seizures, manufacturing shut downs, quarantines, refusal of the government to approve NDAs or ANDAs, or supplements to the same, clinical holds, injunctive actions, withdrawal of approvals, civil or criminal actions or penalties, disgorgement, adverse publicity, labeling revisions, dear healthcare provider letters, FDA debarment, exclusion from Federal healthcare programs, contract debarment or refusal of future orders under existing government contracts, consent decrees, and corporate integrity agreements. Furthermore, new government requirements may be established that could delay or prevent regulatory approval of our products under development.

Drug Approval Process

FDA approval of our own and our partners’ products is required before the products may be commercialized in the U.S. Section 505 of the FFDCA describes three regulatory pathways for marketing authorization for a new drug:

- A 505(b)(1) NDA is an application that is used for the approval of a new drug that contains full reports of investigations of safety and effectiveness.
- A 505(b)(2) NDA is an application where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This alternate route for regulatory approval permits the applicant to rely in part upon the FDA’s findings of safety and effectiveness for previously approved products and/or published scientific literature.
- Section 505(j) establishes an abbreviated approval process for generic versions of approved drug products through the submission of an ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths, route of administration, and dosage form as the listed drug, which has the same labeling, performance, characteristics, and intended use as the listed drug, and has been shown to be bioequivalent to the listed drug. ANDA applicants are generally required to conduct bioequivalence testing to confirm pharmaceutical and therapeutic equivalence to the branded reference drug. Generic versions of drugs can often be substituted by pharmacists under prescriptions written for the branded reference drug, pursuant to state laws.

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For both NDAs and ANDAs, the FDA reviews applications to determine, among other things, whether a product is safe and effective for its intended use and whether the manufacturing methods and controls are adequate to assure and preserve the product's identity, strength, quality, safety, potency, and purity. The following table provides a summary description of the various regulatory pathways:

	ANDA	505(b)(2) NDA	505(b)(1) NDA
Clinical Trials/Testing Required	Generally, bioequivalence.	Yes, to address potential differences between the branded reference product and the 505(b)(2) product, as well as bridging studies.	Yes, full reports of safety and efficacy.
Results in Orange Book Listed Patents	No	Yes, for novel formulations, other enhancements and new indications.	Yes
Exclusivity	Potential for 180 days against other generic filers if first generic to file a substantially complete application containing a paragraph IV certification that is lawfully maintained.	Potential for 30-month stay if ANDA or 505(b)(2) applicant citing our or our partners' product as a reference listed drug includes a paragraph IV certification. Also, potential for three- or five-year exclusivity, like 505(b)(1) NDAs.	Potential of five years for a new chemical entity, or three years for new clinical investigations (other than bioavailability and bioequivalence studies) that are essential to approval of the application. Potential for 30-month stay if ANDA or 505(b)(2) applicant citing our or our partners' product as a reference listed drug includes a paragraph IV certification.
Patent Certification Required	Yes	Yes	No
Potential Orphan Drug Designation Drug Status	No	Yes	Yes

NDA Submission

The process required by the FDA before a new drug pharmaceutical product or a change to an already approved pharmaceutical product, may be approved for marketing in the U.S. generally involves:

- pre-clinical laboratory and animal tests;
- submission to the FDA of an Investigational New Drug ("IND") application, which must be in effect before clinical trials may begin;
- adequate and well controlled human clinical trials to establish the safety and efficacy of the drug for its intended indication(s);
- development of manufacturing processes to ensure the drug's identity, strength, quality and purity;
- submission to the FDA of an NDA;
- FDA compliance inspections and/or clearance of all manufacturers and facilities, as well as select clinical trial sites; and

- FDA review of the NDA in order to determine, among other things, whether the drug is safe and effective for its intended uses.

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The preclinical and clinical testing and approval process takes many years and the actual time required to obtain approval, if any, may vary substantially based upon the type, complexity and novelty of the product or disease. Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including cGLPs. The results of preclinical testing are submitted to the FDA as part of an IND, to support human clinical trials along with other information, including information about product chemistry, manufacturing and controls, available scientific literature, and a proposed clinical trial protocol. Some preclinical testing may continue even after the IND is submitted. In the case of drug product candidates for which the sponsor will seek marketing approval via a 505(b)(2) NDA application, some of the above information may be abbreviated or omitted.

IND applications automatically become effective 30 days after receipt by the FDA, unless the FDA places the clinical trial on a clinical hold. If the FDA places a trial on clinical hold, the sponsor must address the issue to the FDA's satisfaction before the trial may begin. In addition, an independent Institutional Review Board ("IRB") must review, approve and monitor the plan for any clinical trial, subject communications, and informed consent information for subjects before the trial commences. The FDA, the IRB or the sponsor may suspend a clinical trial, place a trial on hold or discontinue a trial at any time on various grounds.

Once an IND is in effect, each new clinical protocol and any amendments to the protocols must be submitted to the IND for FDA review, and to the IRB for approval. Progress reports detailing the results of the clinical trials must also be submitted at least annually to the FDA and the IRB and more frequently if serious adverse events or other significant safety information is found.

Sponsors of clinical trials generally must register and report, at the NIH-maintained website ClinicalTrials.gov, key parameters of certain clinical trials, including clinical trial results within set timeframes, with the exception of PK studies. Failure to submit the required information to ClinicalTrials.gov can result in monetary penalties. Investigators must also provide certain information to the clinical trial sponsors to enable sponsors to make certain financial disclosures to the FDA. Moreover, under the 21st Century Cures Act, manufacturers or distributors of investigational drugs for the diagnosis, monitoring or treatment of one or more serious diseases or conditions must have a publicly available policy concerning expanded access to investigational drugs.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients in accordance with the applicable protocol and all applicable laws, rules and regulations. Clinical trials are typically conducted in sequential phases, which may overlap, though in the case of a 505(b)(2) NDA, some study requirements may be abbreviated. Studies, in addition to the below, such as pediatric studies, may also be required by the FDA:

- Phase I – During Phase I, when the drug is initially given to human subjects, the product is tested for safety, dosage tolerance, absorption, distribution, metabolism and excretion. Phase I studies are often conducted with healthy volunteers depending on the drug being tested. If possible, Phase I trials may also be used to gain an initial indication of product effectiveness.
- Phase II – Phase II involves controlled studies in a limited patient population, typically patients with the conditions needing treatment, to evaluate preliminarily the efficacy of the product for specific, targeted indications; determine dosage tolerance and optimal dosage; and identify possible adverse effects and safety risks.
- Pivotal or Phase III – Adequate and well-controlled trials are undertaken in Phase III in order to evaluate efficacy and safety in a comprehensive fashion within an expanded patient population for seeking approval of the new drug. Typically, two Phase III trials are required by FDA for product approval.

In the case of 505(b)(2) NDAs, the above studies may be abbreviated. Following marketing approval, sponsors may also voluntarily or be required to conduct additional studies, called Phase IV studies.

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In some cases, FDA programs may be available to expedite or simplify the process of drug development and FDA marketing application review. For instance, drug products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means the FDA may approve the product based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. A drug candidate approved on this basis is subject to the FDA's prior review of promotional materials. Accelerated approval products are also required to conduct rigorous post-marketing compliance requirements, including the completion of Phase IV or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the drug or biologic from the market on an expedited basis. If the FDA proposes withdrawing an accelerated approval, the agency provides the applicant with an opportunity for a hearing. If the applicant files a timely request for a hearing, the applicant must submit any data and information to the FDA upon which it plans to rely. At the hearing, an advisory committee is asked to review the applicable issues and provide advice and recommendations to the FDA.

Sponsors may also request that a product be designated under the FDA's fast track program. Under this program, products that are intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need, if so designated by the FDA, are eligible for more frequent development meetings and correspondence with the FDA. In addition, the FDA may initiate review of sections of an application before the application is complete. This "rolling review" is available if the applicant provides and the FDA approves a schedule for the remaining information. In some cases, a fast-track product may be eligible for other FDA programs intended to expedite product development and approval for serious and life-threatening diseases. Notably, however, such designations and programs may be withdrawn by the FDA and such designations and programs do not guarantee that a product will ultimately be successfully developed or approved for marketing.

Another program that is intended to facilitate development is the special protocol assessment ("SPA") program. Under this program, a sponsor may be able to request a special protocol assessment, or SPA to reach agreement with the FDA on certain studies. If a written agreement is reached regarding the applicable study protocol, the agreement will be binding on the FDA and the protocol may not be changed by the sponsor or the FDA after the trial begins except with the written agreement of the sponsor and the FDA or if the FDA determines that a substantial scientific issue essential to determining the safety or efficacy of the product candidate was identified after the testing began. An SPA is not binding if new circumstances arise, and there is no guarantee that a study will support an approval even if the study is subject to an SPA.

In addition, under the Pediatric Research Equity Act, or PREA, an NDA or supplement to an NDA for a new active ingredient, indication, dosage form, dosage regimen, or route of administration must contain data that is adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

The results of drug development, pre-clinical studies and clinical trials are submitted to the FDA as part of an NDA. NDAs also must contain extensive chemistry, manufacturing and control information. In most cases, the submission of an NDA is subject to a substantial application user fee. Fee waivers or reductions are available in certain circumstances.

Once the FDA receives an application, it has 60 days to review the NDA to determine if it is substantially complete to permit a substantive review and will be accepted for filing. The FDA may request additional information rather than accept an NDA for filing. Once the submission is accepted for filing, the FDA's goal is to review 90% of all applications for non-New Molecular Entities

("NMEs") within ten months from the submission date. For NMEs, the FDA has the goal of completing its review of 90% of applications within ten months of the 60-day filing date. The FDA, however, may give a priority review designation to drugs that are intended to treat serious conditions and, if approved, would provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of the serious conditions. A priority review means that the goal for the FDA is to review an application within six months of the submission date for non-NMEs and within six months of the 60-day filing date for NMEs. These timeframes, however, are only goals, which the FDA may not meet. Moreover, the review process may also be extended if the FDA requests or the NDA sponsor otherwise provides substantial additional information or clarification regarding the submission.

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The FDA may also choose or be required to refer drugs to advisory committees when it is determined that an advisory committee's expertise would be beneficial to the regulatory decision-making process, including the evaluation of new technology. An advisory committee is a panel that includes clinicians and other experts, which review, evaluate, and make a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

After evaluating the NDA and all related information, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter authorizing marketing for specific conditions, or, in some cases, a Complete Response Letter ("CRL") describing the application deficiencies. If a CRL is issued, the applicant may either resubmit the NDA addressing all of the deficiencies identified in the letter; withdraw the application or request an opportunity for a hearing. The FDA has the goal of reviewing 90% of application resubmissions in either two or six months of the resubmission date, depending on the kind of resubmission.

If a product meets the FDA's approval standards but the approval of the product cannot be made effective before the expiration of patents or exclusivities held by the reference listed drug, the FDA may issue a tentative approval letter to the applicant. Under these circumstances, the FDA delays the final approval of the product until all patent or exclusivity issues have been resolved. Products with tentative approvals may not be marketed until the FDA issues a final approval. Following a tentative approval, applicants may amend their application; however, amendments may delay the FDA's ability to finalize the approval as the FDA must review and approve the amendment. In order to obtain final approval, the applicant must submit a request to the FDA for final approval (which we did for TLANDO® on January 28, 2022 with acceptance by the FDA announced on February 3, 2022). The FDA's review of requests for final approval may take a number of months and depends on the content of the request and the kind of application. Even if a product has received tentative approval, there is no guarantee that the product will receive final approval, as new information may emerge that changes the FDA's prior determination.

ANDA Submissions

A pharmaceutical company seeking to market a generic version of a branded drug must file an ANDA with the FDA. For ANDAs, applicants are not required to conduct complete clinical studies. Such applications, though, normally require bioavailability and/or bioequivalence studies conducted in accordance with Good Clinical Practices ("GCPs") and under the supervision of an IRB.

Like NDAs, ANDAs must be accompanied by user fees. For generic drugs, other fees, such as fees for drug master files, program fees and fees for manufacturing facilities, may also be required to be paid by the applicant, manufacturer, and/or drug master file holder.

Following submission of an ANDA, the FDA has 60 days to evaluate the application to determine if it is substantially complete. If the agency finds that the application is substantially complete, it will receive the application and begin its substantive review. As part of this substantive review, the FDA will determine whether or not the generic version submitted by the company meets the necessary approval standards, including bioequivalence to the reference listed drug, adequate chemistry, manufacturing and controls, and manufacturing facilities and clinical study sites passing pre-approval inspections. Under the FDA's Generic Drug User Fee Act performance goals, the FDA has the goal of reviewing and acting on 90% of standard original ANDAs within ten months of submission; however, certain factors can lengthen or shorten this review timeline.

Following its completion of the review of an ANDA, the FDA will either issue an approval letter authorizing marketing for specific conditions, or a CRL. If a CRL is issued, the applicant may either respond to the FDA addressing all of the deficiencies identified in the letter, withdraw the application or request an opportunity for a hearing. The FDA may also tentatively approve an ANDA application, as described above.

Upon approval, the FDA will rate generic drug products in the Orange Book. Products meeting bioequivalence standards will typically receive an AB rating. Under state law, such generic drug products may be able to be substituted at the pharmacy for the brand-name

drug without the intervention of the prescribing physician, unless otherwise specified by the patient or physician. Many third-party payers of prescription drugs (e.g., health insurance plans, Medicare and Medicaid programs) have adopted policies to encourage the substitution of the lower-priced AB-rated generic drugs for the higher-priced branded drugs when an AB-rated generic drug is available as generic drugs are sold generally at prices below those of the corresponding branded products. Generic drugs may provide a cost-effective alternative for consumers while maintaining the same active ingredient(s), dosage form, strength, route of administration, and conditions of use as the branded product.

Generally Applicable Requirements

Clinical trials for all product candidates must be conducted in accordance with GCPs, which include the requirements that all research subjects provide their informed consent in writing for their participation in any clinical trial as well as review and approval of the study by an IRB. Before approving an application, the FDA may inspect one or more clinical trial sites to assure compliance with GCPs.

Further, during development, the manufacture of investigational drugs for the conduct of human clinical trials is subject to cGMP requirements. Investigational drugs and active pharmaceutical ingredients imported into the U.S. are also subject to regulation by the FDA relating to their labeling and distribution. Further, the export of investigational drug products outside of the U.S. is subject to regulatory requirements of the receiving country as well as U.S. export requirements under the FDCA.

For both NDAs and ANDAs, the FDA also may require submission of a risk evaluation and mitigation strategy (“REMS”) to ensure that the benefits of the drug outweigh the risks of the drug. 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 testing requirements and FDA review and approval. Further, should new safety information arise, additional testing, product labeling or FDA notification may be required.

The Hatch-Waxman Amendments, Regulatory Exclusivity, and Patent Term Extension

Orange Book Patent Listing

When an NDA is submitted to the FDA seeking approval of a drug, including a 505(b)(2) NDA, the applicant is required to list certain patents whose claims cover the applicant’s product or method of use with the FDA. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book. In an effort to clarify which patents must be listed in the Orange Book, in January 2021, Congress passed the Orange Book Transparency Act of 2020, which largely codifies the FDA’s existing practices into the FDCA.

The Orange Book listed NDA products may be cited by potential competitors in support of approval of an ANDA or 505(b)(2) NDA. Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA that: (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires and approval will not be sought until after the patent expiration; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV patent certification. The applicant may also elect to submit a “section viii” statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. Generally, the ANDA or 505(b)(2) NDA approval cannot be made effective by FDA until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through a paragraph IV certification or if the applicant is not seeking approval of a patented method of use.

If the ANDA or 505(b)(2) applicant makes a paragraph IV certification challenging an Orange Book-listed patent, a notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA or 505(b)(2) application refers. If the NDA holder or patent owners of the listed drug asserts infringement of the patent in court within 45 days of the receipt of the paragraph IV certification notice, the FDA is prohibited from making the approval of the ANDA or 505(b)(2) application effective until the earlier of 30 months from the receipt of the paragraph IV certification, the expiration of the patent, the settlement of the lawsuit, a decision in the infringement case that is favorable to the applicant, or such shorter or longer period as may be ordered by a court. The ANDA or 505(b)(2) application approval also will not be made effective until any applicable non-patent exclusivity listed in the Orange Book has expired as described in further detail below.

Recently, Congress, the Administration and administrative agencies have introduced and/or taken certain measures to increase drug competition and thus, decrease drug prices, including with respect to drug importation, making reference product available to facilitate the development and testing of generic and 505(b)(2) products, and shared and individual REMS. New legislative and regulatory efforts could ultimately have an adverse impact on our business and results of operation.

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Non-Patent Exclusivity

The holder of an NDA may be entitled to a period of non-patent exclusivity, during which the FDA cannot make the approval of an ANDA or 505(b)(2) application that relies on the listed drug effective. For example, a pharmaceutical manufacturer may obtain five years of non-patent exclusivity upon NDA approval of a new chemical entity (“NCE”), during which the FDA cannot accept any ANDA or 505(b)(2) application for filing for the same active moiety except that the FDA may accept an application for filing after four years if the follow-on applicant makes a paragraph IV certification.

The holder of an NDA, including one approved under Section 505(b)(2), may obtain a three-year period of exclusivity for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product or a new dosage form or route of administration, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted or sponsored by the applicant. Should this occur, the FDA would be precluded from making the approval of any ANDA or 505(b)(2) application effective for the protected modification until after that three-year exclusivity period has ended. However, unlike NCE exclusivity, the FDA can accept an application and begin the review process during the exclusivity period. Five-year and three-year exclusivity will also not delay the submission or approval of a full NDA.

In addition, an applicant submitting an ANDA to the FDA may be entitled to a 180-day market exclusivity period with respect to subsequently filed generic applications if such applicant is the first to submit a substantially complete application to the FDA and whose filing includes a paragraph IV certification that the applicable patent(s) are invalid, unenforceable and/or not infringed, obtains approval, and launches the product in the marketplace without triggering any statutory forfeiture provisions. An ANDA for a product designated as competitive generic therapy that does not otherwise have patent or exclusivity protections listed in the Orange Book and that is the first approved applicant, is also eligible for a period of 180 days of regulatory exclusivity with respect to other ANDAs. These ANDA exclusivity periods, however, can be lost under certain circumstances. Competitive generic therapies are products for which there is not more than one approved drug included in the Orange Book.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the U.S. and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory and statutory exclusivity for NDA products, including the non-patent exclusivity period described above and patent protections. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data does not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA’s request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the required time frames, whatever statutory or regulatory periods of exclusivity or Orange Book listed patent protection cover the drug are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve an ANDA or 505(b)(2) application owing to regulatory exclusivity or listed patents. Moreover, pediatric exclusivity attaches to all formulations, dosage forms, and indications for products with existing marketing exclusivity or patent life that contain the same active moiety as that which was studied.

If approved, drug products may also be eligible for periods of U.S. patent term restoration if the approval is the first permitted commercial marketing for the product. If granted, patent term restoration extends the patent life of a single unexpired patent, that has not previously been extended, for a maximum of five years. The total patent life of the product with the extension also cannot exceed fourteen years from the product’s approval date. Subject to the prior limitations, the period of the extension is calculated by adding half of the time from the effective date of an IND to the initial submission of a marketing application, and all of the time between the submission of the marketing application and its approval. This period may be reduced by any time that the applicant did not act with due diligence. Whether any of our product candidates will be eligible for patent term restoration is currently unknown. Later, the applicable regulatory authorities may determine that we are not eligible for such restoration periods.

Depending on the drug product, other periods of regulatory exclusivity, such as orphan drug product exclusivity, may also block subsequent applicants.

Orphan Drug Designation

Some jurisdictions, including the U.S., may designate drugs for relatively small patient populations as orphan drugs. Pursuant to the Orphan Drug Act, the FDA grants orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S. or affects more than 200,000 in the U.S. and for which there is no reasonable expectation that the cost of developing and making the product available in the U.S. will be recovered from U.S. sales. Additionally, sponsors must present a plausible hypothesis for clinical superiority to obtain orphan designation if there is a product already approved by the FDA that is intended for the same indication and that is considered by the FDA to be the same as the already approved product. This hypothesis must be demonstrated to obtain orphan exclusivity. Orphan drug designation provides certain benefits, such as the opportunity for grants, tax credits, application user fee waivers, and exemption from program user fees under certain circumstances. The tax advantages, however, were limited in the 2017 Tax Cuts and Jobs Act. If approved for the orphan designation, orphan designated drugs may receive seven years of exclusivity, which, subject to certain exceptions, protects the drug from FDA approval of another drug with the same principal molecular features for the same orphan indication. The FDA may, however, approve a product with the same principal molecular features for the same orphan indication during this time period if such product is able to demonstrate clinical superiority. The FDA may further approve a product with the same principal molecular features for a different indication, or a different product for the same indication during the orphan exclusivity period. Orphan exclusivity can also be lost under certain circumstances, such as the inability of the application holder to ensure sufficient quantities of the product. Orphan drugs are also exempt from the above discussed PREA requirements. Orphan drugs are not, however, exempt from pediatric testing for molecularly targeted oncology drugs.

Combination Drug/Device Regulation

Our products and our products marketed by our partners, as well as our products being developed by our partners are most often categorized as “drug-device combination products” because they contain both a drug and a device to administer the drug. To date, our and our partners’ combination products have been regulated as drug, and are therefore subject to the NDA, ANDA, sNDA, sANDA and 505(b)(2) drug approval process and regulations. Combination drug/device products raise unique scientific, technical and regulatory issues. The FDA has established an Office of Combination Products (“OCP”) to address the challenges associated with the review and regulation of combination products. The OCP assists in determining strategies for the approval of drug/delivery device combinations and assuring agreement within the FDA on review responsibilities. The device specific information is filed with the FDA as part of the drug approval submission or it may be filed separately in the form of a device master file, also known as the master access file (“MAF”). A MAF is not an FDA approval submission but is a filing that can be used to provide supporting data for our partners’ drug approval submissions. A MAF will be reviewed by the FDA only when referenced in an approval submission. By filing a MAF, we are able to provide information directly to the FDA, which can then be referenced by our partners in their drug approval submissions without having to share our proprietary information directly with our partners.

Where common data elements may be part of several submissions for regulatory approval, as in the case of information supporting an injection system, a MAF filing with the FDA may be the preferred route. A delivery device that is applicable to a variety of drug/device combination products, represents another opportunity for such a filing. Another option would be to obtain a 510(k) premarket clearance, *de novo* authorization, or premarket approval (“PMA”) from the FDA for our delivery device as a stand-alone product. The type of premarket submission required is based on the FDA device classification for the delivery device (Class I, II, III, or not yet classified). We intend to pursue such strategies as permitted by the law and as directed by the FDA either through guidance documents or discussions.

Development of a device with a specific drug will likely be handled as part of the marketing application for the drug product, which may be an NDA, ANDA, or supplemental application. Under these circumstances, the device component is only approved if the drug component is approved.

To the extent that our injectors are packaged with the drug as part of a drug delivery system, the entire package will be subject to the requirements for drug/device combination products. These include drug manufacturing requirements, drug adverse reaction and other reporting requirements, and all of the restrictions that apply to drug labeling and advertising. Additionally, such products will also be subject to certain device requirements, including QSRs and certain reporting requirements, such as medical device reports. Sponsors of clinical studies using investigational devices are also required to comply with the FDA's investigational device exemption regulations. These requirements necessitate additional expenditures of time and resources, which could have a substantial adverse impact on our ability to commercialize our products and our operations.

Other Post-Approval Requirements and Promotional Activities

Any product manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements related to manufacturing, recordkeeping, reporting, including adverse experience reporting, drug shortage reporting, periodic reporting, product sampling and distribution, advertising, marketing, promotion, and post-approval obligations imposed as a condition of approval, such as Phase IV clinical trials, REMS and surveillance to assess safety and effectiveness after commercialization.

There also are continuing annual user fee requirements. In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register and, in the case of generic drug products, self-identify their establishments with the FDA and certain state agencies and list their drug products. Device manufacturers must also register their facilities and list the devices that they design, develop, manufacture or import, except those subject to a drug approval. These facilities must also pay annual registration fees. The distribution of prescription pharmaceutical product samples is also subject to the Prescription Drug Marketing Act (“PDMA”).

FDA post-approval requirements are continually evolving. For example, in March 2020, the U.S. Congress passed the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”) which includes various provisions regarding FDA drug shortage and manufacturing volume reporting requirements, as well as provisions regarding supply chain security, such as risk management plan requirements, and the promotion of supply chain redundancy and domestic manufacturing. As part of the CARES Act implementation, the FDA recently issued guidance on the reporting of the volume of drugs produced, which reporting will require additional administrative efforts by drug manufacturers.

The FDA closely regulates the post-approval marketing and promotion of drugs and devices, including standards and regulations for direct-to-consumer advertising, dissemination of off-label information, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to the drug, including changes in indications, labeling or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. Failure to comply with these requirements can result in adverse publicity, Warning Letters, Untitled Letters, corrective advertising and potential civil and criminal penalties, as well as liability under the civil False Claims Act, exclusion from participation in federal healthcare programs, mandatory compliance programs under corporate integrity agreements, debarment, and refusal of government contracts among other consequences.

Physicians may prescribe legally available products for uses that are not described in the product’s labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers’ communications regarding off-label use. Specifically, manufacturers and product sponsors may not promote a product for off-label uses and must also comply with the FDA’s other promotional requirements.

Manufacturing and Quality Regulations

The FDA established regulations to require that the methods used in, and the facilities and controls used for, the manufacture, processing, packing and holding of drugs and medical devices conform to cGMPs and QSRs. The cGMP regulations the FDA enforces are comprehensive, cover all aspects of manufacturing operations and require the conduct of investigations and FDA reporting under certain circumstances. The cGMP regulations for devices, called the Quality System Regulation, are also comprehensive and cover all aspects of device design, quality and manufacturing, including, for example, pre-production design requirements and validation; production and process controls; complaint handling and investigations; corrective and preventative actions; and distribution, installation and servicing. Compliance with the regulations requires a continuous commitment of time, money and effort in all

operational areas. The FDA conducts periodic inspections of drug and device facilities to assess the cGMP/QSR status of marketed products. Before approval of an application, the FDA will typically also conduct facility inspections to ensure cGMP/QSR compliance.

Controlled Substances Regulation

Certain of our drug products are considered “controlled substances” as defined in the Controlled Substances Act (“CSA”) and implementing regulations, which, depending on the controlled substance schedule, establish certain registration, security, monitoring, reporting, storage, distribution, importation, inventory, quota, record keeping, prescribing, dispensing, and other requirements administered by the Drug Enforcement Agency (“DEA”). The DEA regulates controlled substances as Schedule I, II, III, IV or V substances, with Schedule I and II substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. These requirements are directly applicable to us and also applicable to our contract manufacturers and to distributors, prescribers and dispensers of our products.

The DEA regulates the handling of controlled substances through a closed chain of distribution. This control extends to the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce. Annual registration is required for any facility that manufactures, distributes, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule. The DEA typically inspects a facility to review its security measures prior to issuing a registration and on a periodic basis. Certain reports must also be made for controlled substances, such as reports for thefts or significant losses of any controlled substance and reports of suspicious orders. Failure to maintain compliance with applicable requirements, particularly as manifested in loss or diversion, can result in administrative, civil or criminal enforcement action. Individual states may also regulate controlled substances.

Foreign Approval Process

In addition to regulations in the U.S., we (and, where appropriate, our partners marketing medicinal products incorporating our devices) are subject to various foreign regulations governing clinical trials, manufacturing, and the commercial sales and distribution of our medicinal products. We and/or our partners must obtain approval of a medicinal product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The requirements governing the conduct of clinical trials, manufacturing, product licensing, pricing and reimbursement and the regulatory approval process all vary greatly from country to country. Additionally, the time it takes to complete the approval process in foreign countries may be longer or shorter than that required for FDA approval. Foreign regulatory approvals of our products are necessary whether or not we obtain FDA approval for such products. Finally, before a new drug may be exported from the U.S., it must either be approved for marketing in the U.S. or meet the requirements of exportation of an unapproved drug under Section 802 of the Export Reform and Enhancement Act or comply with FDA regulations pertaining to INDs.

In the EU, marketing authorizations for medicinal products can be obtained through several different procedures, principally the centralized procedure, the decentralized procedure and the mutual recognition procedure. The centralized procedure allows a company to submit a single application to the European Medicines Agency (“EMA”), which may provide a positive opinion regarding the application to the effect that it meets certain safety, quality and efficacy requirements. A centralized marketing authorization will be granted based on a positive opinion of the EMA as approved by the European Commission. It is valid in all EU member states and three of the four European Free Trade Association countries (Iceland, Liechtenstein and Norway). The centralized procedure is mandatory for certain medicinal products, including orphan medicinal products and biologic products, and optional for certain other high technology products. The decentralized procedure allows companies to file identical applications for authorization to several EU member states simultaneously for medicinal products that have not yet been authorized in any EU member state. The competent authority of one EU member state, selected by the applicant (the Reference Member State), assesses the application for marketing authorization. The competent authorities of the other EU member states for which marketing authorizations are sought (concerned member states) are subsequently required to grant marketing authorization for their territories on the basis of this assessment except where grounds of potential serious risk to public health require an authorization to be refused. This procedure allows companies that have a medicinal product already authorized in one EU member state to apply for this authorization to be recognized by the competent authorities in other EU member states. The mutual recognition procedure applies in the case where a marketing authorization for the same medicinal

product has already been granted by an EU/European Economic Area (“EEA”) member state, whereas the decentralized procedure is applicable if no marketing authorization exists. Since January 1, 2021, the United Kingdom has separate approval processes to the EU as a consequence of Brexit.

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In so far as our products may be placed on the market as medical devices outside of the U.S. (as opposed to a delivery system of a medicinal product), we are also subject to foreign legal and regulatory requirements. Legal restrictions on the sale of imported medical devices and products vary from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval, and the requirements may differ. We primarily rely upon the companies' marketing our injectors in foreign countries to obtain the necessary regulatory approvals for sales of our products in those countries.

Our Minneapolis Quality Management System has ISO 13485: 2003 certification, the medical device industry standard for our quality systems. This certification shows that our device development and manufacturing comply with standards for quality assurance, design capability and manufacturing process control. Such certification, along with compliance with the EU Medical Devices Regulation 2017/745 (which replaced the European Medical Device Directive 93/42/EC on May 27, 2020), enables us to affix the CE Mark (a certification indicating that a product has met EU consumer safety, health or environmental requirements) to current products and supply the device with a Declaration of Conformity. Regular surveillance audits by our notified body, British Standards Institute, are required to demonstrate continued compliance.

Other Healthcare Laws and Compliance Requirements

In the U.S., the research, manufacturing, distribution, marketing, sale and promotion of drug products and medical devices are subject to numerous regulations by various federal, state and local authorities.

We are subject to various U.S. federal and state laws restricting certain marketing practices in the pharmaceutical industry, including anti-kickback laws and false claims laws. The federal healthcare program Anti-Kickback Statute is a criminal statute that prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce, reward or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs, except for activities protected by narrowly-drawn statutory and regulatory safe harbors. HHS recently promulgated a regulation that is effective in two phases. First, the regulation excludes from the definition of "remuneration" limited categories of (a) PBM rebates or other reductions in price to a plan sponsor under Medicare Part D or a Medicaid Managed Care Organization plan reflected in point-of sale reductions in price and (b) PBM service fees. Second, effective January 1, 2023, the regulation expressly provides that rebates to plan sponsors under Medicare Part D either directly to the plan sponsor under Medicare Part D, or indirectly through a pharmacy benefit manager will not be protected under the anti-kickback discount safe harbor. Liability under the federal Anti-Kickback Statute may be established without a person or entity having actual knowledge of the statute or specific intent to violate it, and a violation of the Anti-Kickback Statute may be grounds for a government or whistleblower claim under the federal False Claims Act. Violations of the federal Anti-Kickback Statute may be punished by civil and criminal fines, imprisonment, and/or exclusion from participation in federal healthcare programs. Separately, the Beneficiary Inducement Civil Monetary Penalties Law imposes similar restrictions on interactions between the biopharmaceutical industry and federal healthcare program beneficiaries.

The federal civil False Claims Act prohibits, among other things, any person from knowingly presenting or causing to be presented a false or fraudulent claim for payment of federal funds; knowingly making or causing to be made, a false statement to get a false claim paid; knowingly making, using or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government; conspiring to defraud the government by getting a false or fraudulent claim paid or approved by the government; or knowingly making, using or causing to be made or used a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government. Claims may be pursued by whistleblowers through qui tam actions, even if the government declines to intervene. Intent to deceive is not necessary to establish civil liability, which may be predicated on reckless disregard for or deliberate ignorance of the truth. The civil False Claims Act authorizes imposition of treble damages and a civil penalty for each false claim, such as an invoice, submitted for payment and may result in significant financial penalties and damages. The criminal federal False Claims Act imposes criminal fines or imprisonment against individuals or entities who make or present a claim to

the government knowing such claim to be false fictitious or fraudulent. Conviction or civil judgment for violation of the False Claims Act can also result in debarment from government procurement programs and exclusion from participation in federal healthcare programs.

The Civil Monetary Penalties Statute further 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 healthcare 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. Federal consumer protection and unfair competition laws also broadly regulate marketplace activities and activities that potentially harm consumers.

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The federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), also created federal criminal 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 the payer (e.g., public or private), 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 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. The ACA amended the intent requirement of certain of these criminal statutes so that a person or entity no longer needs to have actual knowledge of the statute, or the specific intent to violate it.

Various federal and state healthcare programs obligate us to report drug pricing information that is used as the basis for their reimbursement rates for pharmacies and other healthcare providers including under the Medicaid and Medicare programs, prices charged certain federal agencies and non-federal purchasers, and required manufacturer rebates on prescriptions paid by Medicaid and other plans. Payment for a manufacturer’s drugs by these programs is conditioned on submission of this pricing information. States, such as California, have also enacted transparency laws that require manufacturers to report price increases and related information. Some government healthcare programs impose penalties if drug price increases exceed specified percentages or inflation rates, and these penalties can result in mandatory penny prices for certain federal and 340B program customers or rebates equal to 100% of average price. Failure to comply with the rules for calculating and submitting pricing information or otherwise overcharging the government or its beneficiaries may result in criminal, civil, or administrative sanctions or enforcement actions, including False Claims Act liability.

In addition, the Physician Payment Sunshine Act provisions of the Healthcare Reform Act require extensive tracking of certain payments and other transfers of value to physicians (as defined under the Social Security Act), certain other types of healthcare professionals (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives licensed in the U.S.), and U.S. teaching hospitals, as well as ownership and investment interest held by physicians and their immediate family members. Payments made to principal investigators and research institutions at teaching hospitals for clinical trials are also included within this law for reporting purposes. These payments and other transfers of value are required to be reported to the Centers for Medicare and Medicaid Services (“CMS”), which publishes the data publicly on the CMS Open Payments website. Government agencies and private entities may inquire about our marketing practices, and government entities may pursue enforcement activities based on the disclosures in those public reports. Similar state laws also impose reporting requirements for various types of payments and other transfers of value to healthcare providers and organizations, including marketing and promotional expenses, and impose various types of gift bans and other compliance requirements on manufacturers. Failure to comply with required reporting requirements, gift bans and other compliance requirements under these laws could subject manufacturers and others to substantial civil money penalties.

The majority of states also have statutes or regulations similar to the federal consumer protection and unfair competition laws, Anti-Kickback Statute and civil False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply to reimbursement for healthcare items and services regardless of the payer type, including private payers. A number of states now have implemented transparency laws requiring manufacturers to report pricing information and require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in the states. Other states restrict when and where pharmaceutical companies may provide meals to prescribers or engage in other marketing related activities. In addition, some states require pharmaceutical companies to abide by the pharmaceutical industry’s voluntary compliance guidelines and implement compliance programs or marketing codes of conduct. Failure to comply with state laws could result in regulatory enforcement actions, including the assessment of significant administrative penalties.

Although we may not provide financial assistance to Medicare patients taking drugs sold by us, the Office of Inspector General (“OIG”) has established guidelines that permit pharmaceutical manufacturers to make donations to charitable organizations that provide co-pay assistance to Medicare patients, provided that such organizations, among other things, are bona fide charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a first-come basis according to consistent objective financial criteria, and do not link aid to use of a donor’s product. If we, our vendors or donation recipients are deemed to fail to comply with relevant laws, regulations or evolving government guidance in the operation of these programs, we could be subject to damages, fines, penalties or other criminal, civil or administrative sanctions or enforcement actions.

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The Veterans Health Care Act of 1992 requires, as a condition of payment by certain federal agencies and the Medicaid program, that manufacturers of “covered drugs” enter into a Master Agreement, Pharmaceutical Pricing Agreement, and Federal Supply Schedule (“FSS”) contract with the Department of Veterans Affairs through which their covered drugs must be offered for sale at a mandatory ceiling price to certain federal agencies, including the VA and Department of Defense. FSS contracts require compliance with applicable federal procurement laws and regulations, including disclosure of commercial prices during contract negotiations and maintenance of price relationships during the term of the contract, and subject manufacturers to contractual remedies as well as administrative, civil and criminal sanctions. The Veterans Health Care Act also requires manufacturers to enter into pricing agreements with the Department of Health and Human Services to charge no more than a different ceiling price (derived from the Medicaid rebate percentage) to covered entities participating in the 340B drug discount program. Failure to provide the mandatory discount may subject the manufacturer to specific civil monetary penalties, including when subsequent ceiling price recalculations due to pricing data submitted to CMS or new drug price estimations result in a covered entity having paid more than the revised ceiling price and the manufacturer has failed or refused to refund or credit a covered entity. Termination of either of these agreements under the Veterans Health Care Act also jeopardizes payment by Medicaid for the manufacturer’s drugs.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, which we refer to together as the Healthcare Reform Act, expanded healthcare coverage within the U.S., primarily through establishment of state insurance exchanges and expansion of the Medicaid program. This law substantially changed the way healthcare is financed by both governmental and private insurers and significantly impacts the pharmaceutical industry. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, payment of an annual fee by manufacturers of branded drugs and biological products based on their share of the federal market, benefits for patients within a coverage gap in the Medicare Part D prescription drug program (commonly known as the “donut hole”), rules regarding prescription drug benefits under the health insurance exchanges, changes to the Medicaid Drug Rebate program, expansion of the Public Health Service’s 340B drug pricing discount program, and fraud and abuse enforcement. These changes impact existing government healthcare programs and are resulting in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program. The Affordable Care Act has since been amended to repeal the individual health insurance mandate, change price reporting rules for authorized generics, and increase manufacturers’ share of Medicare Part D prescription costs in the donut hole, and other provisions of the law may be repealed and replaced by Congress, which may greatly affect these government and third-party programs and their effect on our business.

In addition, we may be subject to, or our marketing activities may be limited by, data privacy and security regulation by both the federal government and the states in which we conduct our business. One such statute is the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and its implementing regulations, as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”). HIPAA established uniform federal standards for “covered entities,” which are certain healthcare providers, health plans and healthcare clearinghouses, as well as their business associates, governing the conduct of specified electronic healthcare transactions, protecting the security and privacy of protected health information, and mandating security breach notification standards. In addition, other federal and state privacy laws, such as the California Consumer Privacy Act, may govern the privacy and security of personal information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

The Foreign Corrupt Practices Act (“FCPA”) further prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Activities that violate the FCPA,

even if they occur wholly outside the U.S., can result in criminal and civil fines, imprisonment, disgorgement, oversight, and debarment from government contracts.

If our operations are found to be in violation of any of the healthcare regulatory laws described above or any other laws that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, disgorgement, contractual damages, reputational harm, exclusion from participation in government healthcare programs, debarment prohibiting participation in government procurement and non-procurement covered transactions, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private qui tam actions brought by individual whistleblowers in the name of the government or refusal to allow us to enter into supply contracts, including government contracts and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations. In particular, in the EU the data privacy regime (the General Data Protection Regulation which came into effect on May 25, 2018) is regarded as stricter than the U.S. data protection laws. EU laws restrict the export of personal data outside the EU, for instance to the U.S., unless certain safeguards are in place. EU laws and industry codes also restrict certain marketing practices, including inappropriate inducements.

Third-Party Payer Coverage and Reimbursement

The commercial success of the approved products in our portfolio depends, in part, upon the availability of coverage and adequate reimbursement from third-party payers at the federal, state and private levels. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payers to reimburse all or part of the associated healthcare costs. Sales of our product portfolio will therefore depend substantially, both domestically and abroad, on the extent to which the costs of our product portfolio will be paid by health maintenance, managed care, pharmacy benefit and/or similar healthcare management organizations, or are reimbursed by government health administration authorities, such as Medicare and Medicaid, private healthcare coverage insurers and other third-party payers. The market for our product portfolio will depend significantly on access to third-party payers' formularies or lists of treatments for which third-party payers provide coverage and reimbursement.

Also, third-party payers are developing increasingly sophisticated methods of controlling healthcare costs. For example, for high-cost specialty drugs, third party payers have begun demanding value-based pricing in which price is linked to performance metrics. Recent state enactments establish significant negative incentives requiring negotiation of supplemental rebates, and a recent CMS regulation, implemented a most-favored nations pricing model seeking to lower prices under Medicare Part B by tying the costs of certain medicines to cheaper prices in other developed countries. This regulation was rescinded by a final rule published December 29, 2021; however, legislative and executive branch proposals also seek to establish this type of pricing for certain federal healthcare programs. Further, coverage and reimbursement for therapeutic products can differ significantly from payer to payer. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payer separately, with no assurance that adequate coverage and reimbursement will be obtained. The cost of pharmaceuticals and medical devices continues to generate substantial governmental and third-party payer scrutiny. We expect that the pharmaceutical industry will experience continued pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative and administrative proposals. Our results of operations and business could be adversely affected by current and future third-party payer policies as well as healthcare legislative and administrative reforms.

Some third-party payers also require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, these requirements or any announcement or adoption of such proposals could have a material adverse effect on our ability to obtain adequate prices for our product portfolio and to operate profitably.

In international markets, there are health technology assessment regimes with price ceilings and supply and demand side restraints on specific products and therapies and profit controls in most EU member states as well as the United Kingdom. There can be no assurance that our products will be considered medically reasonable and necessary for a specific indication, that our products will be considered

cost-effective by third-party payers, that an adequate level of reimbursement will be available or that the third-party payers' reimbursement policies will not adversely affect our ability to sell our products profitably.

Healthcare Reform

In the U.S. and foreign jurisdictions, the legislative landscape continues to evolve. There have been a number of legislative and regulatory changes to the healthcare system that will likely affect our future operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs, improve access, and improve quality. The Affordable Care Act (“ACA”), passed in 2010, provided more Americans with healthcare coverage while attempting to curb the growth in healthcare spending in the U.S. The legislation included reforms to patient rights and protections, rules for insurance companies, taxes, tax breaks, funding and spending, and amended other laws including the Food, Drug and Cosmetics Act. Since enactment of the ACA, some of its provisions have been repealed or amended, and other provisions may be repealed and replaced by Congress. Some of the main provisions of the ACA that affected the pharmaceutical and biotechnology industry include, among others, the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively, and inclusion of Medicaid managed care plan utilization in manufacturers’ rebate obligations;
- new methodologies by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated;
- a new Medicare Part D coverage gap discount program;
- expansion of eligibility criteria for Medicaid programs thereby potentially increasing manufacturers’ Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- expansion of healthcare fraud and abuse laws, including the federal civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance.

The Drug Supply Chain Security Act imposes on manufacturers of certain pharmaceutical products obligations related to product tracking and tracing, among others. Among the requirements of this legislation, manufacturers are required to provide certain information regarding the drug product to individuals and entities to which product ownership is transferred, label the drug product with a product identifier, and keep certain records regarding the drug product. The transfer of information to subsequent product owners by manufacturers is required to be done electronically. Manufacturers are also required to verify that purchasers of the manufacturers’ products are appropriately licensed. Further, manufacturers have drug product investigation, quarantine, disposition, and FDA and trading partner notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products that would result in serious adverse health consequences or death to humans, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death. Similar requirements are also imposed on other trading partners in the supply chain.

We expect that additional state and federal healthcare reform measures will be adopted in the future. Legislators and regulators at both the federal and state level are increasingly focused on containing the cost of drugs, and there has been increasing legislative and enforcement interest in the U.S. with respect to specialty drug pricing practices. Specifically, there have been recent U.S. congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient support programs, and reform government program reimbursement methodologies for drugs. For example, California enacted a transparency law requiring manufacturers to report drug price increases and related information, including the reasons for the price increases. Congress also amended the Medicaid statute to alter price reporting of branded products sold as authorized generics, which effectively increases the rebates paid on the brand. Recent executive orders focusing on domestic sourcing

also have required government agencies, to the maximum extent practicable, to limit procurement of essential medicines, including epinephrine, to products that are manufactured in the U.S. from U.S. API and other critical inputs. The list of essential medicines is established by the FDA and subject to change. These and any additional healthcare reform and procurement measures could further constrain our business or limit the amounts that federal and state governments will pay for healthcare products and services, which could result in additional pricing pressures.

Other Regulatory Requirements and Considerations

In addition to regulations enforced by the FDA, we must also comply with regulations under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other federal, state and local regulations. We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, the FDA and other government agencies have broad regulatory and enforcement powers, including, among other things, the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect on us. The effects of potential future changes in regulations or new legislation, if any, as a result of the new administration are also unknown.

Available Information

We file with the U.S. Securities and Exchange Commission (“SEC”) annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and other documents as required by applicable law and regulations. The SEC maintains a website (<http://www.sec.gov>) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. We make available free of charge on or through our website (<http://www.antaespharma.com>) our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and if applicable, amendments to those reports filed or furnished pursuant to the Exchange Act, as soon as reasonably practicable after electronically filing those documents with or furnishing them to the SEC. The information on our website is not incorporated into and is not a part of this Annual report on Form 10-K.

ITEM 1A. RISK FACTORS

The following “risk factors” contain important information about us and our business and should be read in their entirety. Additional risks and uncertainties not known to us or that we now believe to be not material could also impair our business. If any of the following risks actually occur, our business, results of operations and financial condition could suffer significantly. As a result, the market price of our common stock could decline, and you could lose all of your investment. In this Section, the terms the “Company,” “we”, “our” and “us” refer to Antares Pharma, Inc.

Risks Related to Our Operations

We have significant outstanding indebtedness under a loan and security agreement. If we do not have sufficient cash available to repay the outstanding indebtedness as it becomes due, or if an event of default were to occur that provides Wells Fargo Bank, National Association the right to accelerate the outstanding balance of the loan and to take possession of some or all of our collateral securing the loan, either situation could have a material adverse effect on our business.

On November 1, 2021, we entered into a Credit Agreement (the “Credit Agreement”) with Wells Fargo Bank, National Association, as administrative agent for the lenders, for credit facilities in an aggregate principal amount of up to \$40.0 million with a maturity date of November 1, 2024. The Credit Agreement consists of a \$20.0 million term loan facility (the “Term Loan Facility”) and a \$20.0 million revolving credit facility, \$5.0 million of which is available for the issuance of letters of credit and \$1.0 million of which is available for swingline loans (the “Revolving Credit Facility”), (collectively the “Credit Facilities”), which are secured by substantially all of our assets. The Term Loan Facility was funded upon execution of the Credit Agreement with the proceeds used to repay our \$20.0 million Term Loan with Hercules Capital and to pay fees and expenses incurred in connection with the early repayment. The Revolving Credit Facility remains available for future use and is expected to be used for ongoing working capital requirements and other general corporate purposes as needed. Payments under the Term Loan Facility are due in consecutive quarterly installments on the last business day of each of March, June, September and December, commencing on March 31, 2022. Interest accrues at either the base rate or

LIBOR plus the applicable margin, which varies based on our consolidated total leverage ratio and will initially be 1.50% for base rate loans and 2.50% for LIBOR loans. The transaction is expected to provide approximately \$1.2 million in annual interest expense savings based on an interest rate of approximately 2.60% (one-month LIBOR rate plus the applicable margin of 2.50%) as of December 31, 2021.

There is no guarantee that healthcare providers and patients will adopt our or our partners' products or continue to use or prescribe our or our partners' products, or that we and our partners will be able to receive and maintain adequate payer coverage and reimbursement.

Successful sales of our products depend on the continued prescription by healthcare providers, adoption by patients, and the availability of adequate coverage and reimbursement from third-party payers. There is no guarantee that healthcare and patients' providers will adopt any newly approved products or continue to prescribe and use products, or that insurers and

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governmental healthcare programs, such as Medicare and Medicaid, will provide adequate coverage and reimbursement, or will not disadvantage our products through imposition of prior authorization, step therapy, high co-payments, or similar formulary management techniques. For instance, coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Additionally, certain third-party payers restrict or block access to patients for new products until a clinical review has occurred or clinical evidence is provided to support the benefits for covered patients. Many states also use formularies and preferred drug lists to obtain supplemental Medicaid rebates in excess of those required for Medicaid coverage. The industry competition to be included in such formularies and not disadvantaged often leads to downward pricing pressures on pharmaceutical companies. Any labeled limitations on the use of a product or warnings could discourage adoption of the product by patients, healthcare providers, and insurers.

To ensure sales, manufacturers often must provide multiple discounts on the same drug in the chain of distribution to the healthcare provider and the payer. Further, manufacturers are required to assume responsibility for a percentage of Medicare Part D prescription costs for innovator drugs and biologics while the beneficiary is in the coverage gap. Increasingly, payers are looking for metrics and performance-based pricing to justify increased costs of therapeutic advancements. Even if coverage is obtained, the net realization from price concessions may negatively impact our profitability. Government health programs also impose inflation penalties that may have adverse consequences if we increase prices in the future. Moreover, we and our partners may experience a delay in receiving coverage and reimbursement for any new products or may not receive adequate levels of coverage or reimbursement at all. New competitive products may be approved, and payers may disadvantage our products in favor of the newly approved products and technologies. If the time to obtain coverage is lengthy, if we are unable to obtain or maintain adequate coverage, or if the rebates we negotiate are higher than anticipated, it may negatively impact our revenue from product sales.

Additionally, if healthcare providers and patients do not adopt any new product, or if insurers restrict patient access or disadvantage our or our partners' products in their formularies or otherwise do not provide adequate coverage and reimbursement, we and our partners may not be able to generate sustainable revenue growth from product sales and royalties which will have a material adverse effect on our business and future product opportunities. We and our partners, accordingly, may need to take steps to assist patients in their ability to afford our products, such as offering bridge programs, free-trials, discounts, rebates and co-pay coupon programs.

New information concerning our or our partners' products learned through required post-approval studies and product use may also result in changes to our or our partners' products. Should any of these events occur, they could have a material and adverse effect on our operations and business.

Any post-approval requirements, including Phase IV studies may also require the dedication of substantial time and resources. By example, as a post-marketing requirement for XYOSTED[®], we must conduct a pediatric study. The FDA has also asked us to conduct a separate label comprehension study that assesses patients' understanding of key risk messages in the Medication Guide for XYOSTED[®] and a study of testosterone replacement therapy in pediatric males ages 14 years and older for conditions associated with a deficiency or absence of endogenous testosterone. The label comprehension study findings may result in revisions to the Medication Guide to optimize patients' understanding of important risks of XYOSTED[®] and potentially other label restrictions or changes. The FDA found that our first label comprehension study did not fulfill the post approval requirement and, thus, we are preparing to conduct a new label comprehension study, which must be completed by the middle of 2023 and will require dedication of funds and resources. Additionally, the outcome of any post-approval studies, including the pediatric study, is uncertain and may not result in an expanded label indication or could result in additional labeling requirements or other post-approval restrictions or regulatory actions.

Additionally, use of our or our partners' products by patients and in Phase IV and post-marketing studies may result in the discovery of new information concerning the products. This may result in regulatory or other actions, including, product liability actions, enforcement actions, distribution and manufacturing restrictions, changes to product labeling and promotional materials, the imposition of post-market requirements, such as REMS or additional Phase IV studies, withdrawal of marketing application approvals, withdrawal of the product from the market, refusal to approve new marketing applications or supplements, product recalls, clinical holds and

suspension of clinical studies, safety alerts, dear healthcare provider letters, adverse publicity, and reimbursement and insurance coverage consequences, among others. Should any of these events occur, they could have a material and adverse effect on our operations and business. By way of example, in October 2020 the FDA proposed that Makena[®] be withdrawn from the market following a review by the FDA's Bone, Reproductive and Urologic Drugs Advisory Committee. Covis subsequently requested an FDA public hearing, and the FDA has granted the request. The FDA has not yet set a date for the public hearing. While, at this time, Makena[®] may still be marketed, we do not yet know what the FDA's ultimate decision will be and whether resources that it dedicated to Makena[®] will be reduced. The uncertainty with

regard to Makena® has negatively impacted our product revenue and royalties from Covis and may adversely impact the business.

Our employees, independent contractors, consultants, commercial partners, manufacturers, principal investigators, or contract research organizations (“CROs”) may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees, independent contractors, consultants, commercial partners, manufacturers, investigators or CROs could include intentional, reckless, negligent, or unintentional failures to comply with FDA regulations, comply with applicable fraud and abuse laws, provide accurate information to the FDA, properly calculate pricing information required by federal programs, comply with federal procurement rules or contract terms, report financial information or data accurately or disclose unauthorized activities to us. This misconduct could also involve the improper use or misrepresentation of information obtained during clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter this type of misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Moreover, it is possible for a whistleblower to pursue a False Claims Act (“FCA”) case against us based on the actions or inactions of these third parties even if the government considers the claim unmeritorious and declines to intervene, which could require us to incur costs defending against such a claim. Further, due to the risk that a judgment in an FCA case could result in exclusion from federal health programs or debarment from procurement programs, whistleblower cases often result in large settlements. 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, financial condition, and results of operations, including the imposition of significant fines or other sanctions.

We rely on third parties to perform many necessary services for our products including services related to the distribution, invoicing, rebates and contract administration, co-pay program administration, sample distribution and administration, storage and transportation of our products.

Depending on the product, we have retained third-party service providers to perform a variety of functions related to the distribution, invoicing, rebates and contract administration, co-pay program administration, sample distribution and administration, storage and transportation of our products, key aspects of which are out of our direct control. We place substantial reliance on these providers as well as other third-party providers that perform services for us, including, depending on the product, entrusting our inventories of products to their care and handling. We also may rely on third parties to administer our drug price reporting and rebate payments and contracting obligations under federal programs. Despite our reliance on third parties, we are responsible for compliance with the applicable legal and program requirements. By example, in certain states, we are required to hold licenses to distribute our products in these states and must comply with the associated state laws. Moreover, if these third-party service providers fail to meet expected deadlines, or otherwise do not carry out their contractual duties to us or encounter physical damage or a natural disaster at their facilities, our ability to deliver products to meet commercial demand would be significantly impaired. In addition, we may use third parties to perform various other services for us relating to regulatory monitoring, including adverse event reporting, safety database management and other product maintenance services. If our employees or any third-party service providers fail to comply with applicable laws and regulations, we and/or they may face regulatory or FCA enforcement actions. Moreover, if the quality or accuracy of the data maintained by these service providers is insufficient, our ability to continue to market our products could be jeopardized or we and/or they could be subject to regulatory sanctions. We do not currently have the internal capacity to perform these important commercial functions, and we may not be able to maintain commercial arrangements for these services on reasonable terms.

We are dependent on numerous third parties in our supply chain for the supply and manufacture of our products and our partners’ products. If we do not develop and maintain relationships with suppliers, manufacturers, assemblers and/or licensees of our and our partners’ drug/device products or product candidates, or if such third parties are unable to supply or manufacture products or assemble

and package the final products, we may be unable to successfully manufacture, assemble, package and sell our and our partners' products, which could have a material adverse effect on our business.

The availability of our products and product candidates depends upon our ability to procure the raw materials, components, packaging materials and finished products that we need from third parties. We have entered into supply agreements with numerous third-party suppliers, many of which are currently our single source for the materials necessary for certain of our products. If any of these or other third parties are unable to supply their respective components for any reason, including due to violations of the FDA's QSR or cGMP requirements, our or our partners' ability to manufacture the finished product will be adversely affected and our ability to meet the supply and demand for any sales of such products and the resulting revenue therefrom will be negatively affected. Additionally, as many of our components are manufactured by sole third-party suppliers, in the event of a failure to supply, we may not be able to find alternative third suppliers in a timely or cost-effective manner.

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Moreover, any failure to comply with the applicable regulatory requirements could subject us, our suppliers, or our collaborators to regulatory enforcement actions or recalls. In the case of product candidates, our and our partners' ability to conduct the necessary studies would also be adversely impacted.

We do not currently use our own facilities to manufacture commercial quantities of our or our partners' drug/device combination products or components. We currently must contract with third parties and/or our partners to produce products, components, and product candidates and to assemble and package finished products and related components according to specifications and that must comply with all applicable manufacturing requirements, including cGMPs for drug products and QSRs for medical devices. The future development and delivery of our and our partners' products and product candidates depend on the capability, as well as the timely, profitable and competitive performance of these third parties and/or our partners, in addition to their initial and continued FDA approval following regulatory authority facility inspections and compliance. There is also no assurance that such third parties and/or our partners will be willing to manufacture, assemble or sell the drug/device products or components or that they will not encounter manufacturing delays, problems, or difficulties. A limited number of manufacturers exist that can manufacture our and our partners' products, components, and product candidates.

In addition, contract manufacturers may use their own technology, technology developed by us, technology developed by our partners, or technology acquired or licensed from third parties. When contract manufacturers develop proprietary process technology, our reliance on such contract manufacturers is increased. A technology transfer from the original contract manufacturer may be required. Any such technology transfer may also require the transfer of requisite data for regulatory purposes, including information contained in a proprietary drug or device master file held by a contract manufacturer. We and/or our partners would be dependent on the contract manufacturer for the maintenance and right of reference to the drug or device master file. If the contract manufacturer fails to maintain a drug or device master file or withdraws our or our partners' right of reference, we and/or our partners may no longer be able to manufacture, develop, market, and sell our or our partners' products or product candidates.

We rely on multiple commercial supply arrangements with third-party manufacturers. Our third-party manufacturers may fail to pass the audits by our or our partners' internal quality and regulatory group. Any of these actions could delay or prevent our development of products, delay or prevent the submission of these products for regulatory approval, delay or prevent marketing approval, or result in insufficient product or product candidate quantity to support commercial demand or development. We may also be required to replace manufacturers, which would be time consuming and expensive, and we may not be able to reach favorable agreements with or FDA approval for alternative manufacturers. As a result, our business, financial condition and results of operations could be seriously harmed.

In addition to the above manufacturing capabilities provided by third party manufacturers, on July 1, 2019, we entered into a lease for office, laboratory, manufacturing and warehousing space in Minnetonka, Minnesota. We completed the build-out of the facility and began occupying the space in 2020. The new facility supports our administrative functions, product development and quality operations, and is intended to provide additional manufacturing and warehousing capabilities in the future. If we begin manufacturing or producing commercial products in the future, we will be subject to the same risks as our third-party manufacturers. We may also not be able to begin product manufacturing and production in a timely manner due to a number of different reasons, including, but not limited, an inability to obtain the necessary supplies, labor and expertise. We may also be delayed if we are not able to obtain necessary licensing and regulatory authority inspections in a timely manner, such as due to inspection restrictions during the Pandemic. Any failure to commence operations at our own facilities could have a material impact on our business.

Some of our suppliers may experience disruption to their respective supply chains due to the effects of the COVID-19 pandemic ("Pandemic"), which could delay, prevent or impair our development or commercialization efforts.

We obtain certain critical materials and components used in manufacturing our products from third-party suppliers whose operations may be directly or indirectly affected by the Pandemic. If we are unable to obtain these critical materials and components in sufficient quantities and in a timely manner, our supply of product for commercialization may be disrupted or delayed which could have a material impact on our revenue and the development, testing and clinical study of our products and product candidates might be delayed or infeasible, and regulatory approval or commercialization of our products and product candidates might be delayed, not obtained or hindered, which could significantly harm our business.

See additional risk factors associated with manufacturing in the section “Risks Related to Regulatory Matters.”

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We rely on many of our partners to manufacture and supply the drug for their product and to distribute and commercialize their products.

We have entered into license and supply agreements with several different partners. Under many of the arrangements, our partners are responsible for supplying the drug product and we are responsible for manufacturing the auto injector and for final assembly and packaging of the final product. Our partners are responsible for the distribution and commercialization of the products in the U.S.

There is no guarantee that our arrangements with any of our partners will be successful. Our partners typically control the manufacture and supply of the drug for their auto-injector product. If, at any time, our partner is unable to source their drug or ceases to manufacture and supply us with their drug or fails to produce sufficient supplies of the drug, we may be unable to produce a finished product or sell our auto injectors designed for their product. In addition, if any of our partners are not able to produce sufficient supplies of the drug in accordance with cGMPs, we also will be unable to produce a finished product and we and/or our partner may be subject to regulatory enforcement action. We also rely on our partners to commercialize and distribute their product within the U.S. and if they are unsuccessful in commercializing the product, the resulting revenue may be lower than expected. In many instances, our partners hold the marketing authorization for their products and should our partner fail to comply with the applicable regulatory requirements, our partner or we may be subject to regulatory enforcement action. There may be instances in which we hold the marketing authorization of the product, and therefore, we may face greater risk of regulatory enforcement should any of our partners fail to comply with the applicable regulatory requirements. Any enforcement action could impact the ability to produce, market, commercialize, sell, and distribute the finished drug product, and in turn, our revenue. Additionally, our partners' control the distribution and commercialization strategies for their products and we may disagree with their decision or business strategies. Such decisions may impact the success of their product commercialization, and we may receive less revenue than desired or expected. Also, as our partners are subject to the same product development and commercialization risks as us, any adverse impact on our partners could have an adverse impact on us.

We may incur significant liability if it is determined that we are promoting or have in the past promoted the "off-label" use of drugs or medical devices, or otherwise promoted or marketed approved products in a manner inconsistent with the FDA's requirements.

In the U.S. and certain other jurisdictions, companies may not promote drugs or medical devices for "off-label" uses, that is, uses that are not described in the product's labeling and that differ from those that were approved or cleared by the FDA or other foreign regulatory agencies. Under what is known in the C's as the "practice of medicine," physicians and other healthcare practitioners may prescribe drug products and use medical devices for off-label or unapproved uses, and such uses are common across some medical specialties. Although the FDA does not regulate a physician's choice of medications, treatments or product uses, the Federal Food, Drug and Cosmetic Act and FDA regulations significantly restrict permissible communications on the subject of off-label uses of drug products and medical devices by pharmaceutical and medical device companies. As the sponsors of FDA approved products, we and our partners will not only be responsible for the actions of the companies but also can be held liable for the actions of employees and contractors, requiring that all employees and contractors engaging in regulated functions, such as product promotion, be adequately trained and monitored, which requires time and monetary expenditures.

If the FDA determines that a company has improperly promoted a product "off label" or otherwise not in accordance with the agency's promotional requirements, the FDA may issue a warning letter or seek other enforcement action to limit or restrict certain promotional activities or materials or seek to have product withdrawn from the market or seize product, among other enforcement requirements. In addition, a company that is found to have improperly promoted off-label uses may be subject to significant liability, including civil fines, criminal fines and penalties, civil damages and exclusion from federal funded healthcare programs such as Medicare and Medicaid and/or government contracting, consent decrees and corporate integrity agreements, as well as potential liability under the federal FCA and applicable state false claims acts. Conduct giving rise to such liability could also form the basis for private civil litigation by third-party payers or other persons allegedly harmed by such conduct.

Moreover, in addition to the regulatory restrictions on off-label promotion, there are other FDA restrictions on and requirements concerning product promotion and advertising, such as requirements that such communications be truthful and non-misleading and adequately supported. The FDA also has requirements concerning the distribution of drug samples. The FDA and other authorities may take the position that we are not in compliance with promotional, advertising, and marketing requirements, and, if such non-compliance is proven, we may be subject to significant liability, including but not limited to administrative, civil and criminal penalties and fines, in addition to regulatory enforcement actions.

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We currently depend on a limited number of customers for the majority of our revenue, and the loss of any one of these customers could substantially reduce our revenue and impact our liquidity.

For the year ended December 31, 2021, we derived approximately 42% of our revenue from Teva. In addition, we derived a significant portion of our product sales revenue from wholesale distributors including McKesson, AmerisourceBergen and Cardinal Health, which each accounted for approximately 13%, 12% and 11% of total revenues in the year ended December 31, 2021, respectively. The loss of any of these significant customers or partners or reduction in our business activities could cause our revenues to decrease significantly and impact our income from operations. If we do not broaden our customer base, we will continue to depend on these few customers for the majority of our revenues. Additionally, if we are unable to negotiate favorable business terms with these customers in the future, our revenues and gross profits may be insufficient to allow us to achieve and/or sustain profitability or continue operations.

The failure of our licensees to perform under any of our existing licensing agreements or the failure of our licensees/partners to develop and obtain regulatory approval for their product candidates or the failure to enter into new licensing agreements could substantially affect our revenue.

One of our business strategies is to enter into license agreements with pharmaceutical companies covering the development, manufacture, use and marketing of our drug delivery devices with specific drug therapies. Under these arrangements, the partners typically assist us in the development of the product and sponsor the collection of the appropriate data for submission for regulatory approval of the use of the drug delivery device with the licensed drug therapy. Our licensees may also be responsible for distribution and marketing of the product or technologies for these therapies either worldwide or in specific territories. We are currently a party to a number of such agreements, all of which are currently in varying stages of development. We may not be able to meet future milestones established in our agreements (such milestones generally being structured around satisfactory completion of certain phases of clinical development, regulatory approvals and commercialization of our product), and thus would not receive the fees expected from such arrangements, related future royalties or product sales. Moreover, there can be no assurance that we will be successful in executing additional collaborative agreements or that existing or future agreements will result in increased sales of our drug delivery technologies or products. In such event, our business, results of operations and financial condition could be adversely affected, and our revenues and gross profits may be insufficient to allow us to achieve and/or sustain profitability.

As a result of our collaborative agreements, we are dependent upon the development, data collection and marketing efforts of our licensees. The amount and timing of resources such licensees devote to these efforts are not within our control, and such licensees could make material decisions regarding these efforts that could adversely affect our future financial condition and results of operations. If one or more of these pharmaceutical company partners fail to pursue the development or marketing of, or are unable to receive marketing approval for our and our partners' products as planned, or fail to perform their contractual obligations in accordance with all regulatory requirements, our revenues and profits may not reach expectations or may decline. In addition, factors that adversely impact the introduction and level of sales of any drug or drug device covered by such licensing arrangements, including competition within the pharmaceutical and medical device industries, the timing of regulatory or other approvals and intellectual property litigation, may also negatively affect sales of our drug delivery technology. For instance, competition in this market could also force us or our partners to reduce the prices of our technologies below currently planned levels, which could adversely affect our revenues and future profitability. Moreover, our partners and licensees will be subject to many of the same regulatory risks as we are. To the extent that they are not able to comply with the applicable regulatory requirements or are not able to obtain or maintain regulatory product approvals, we and they may be subject to regulatory enforcement action, the performance of their obligations under their contracts with us may be inhibited, and we may not be able to realize the benefit of the relationship.

We are relying on partners such as Teva, Covis, Pfizer and Idorsia for future milestone, sales and royalty revenue. Our partners may fail to obtain FDA or foreign approvals of a product with our technologies or may be unsuccessful in commercializing a product. There is no assurance that development of our partners' products will continue or that they will ultimately receive FDA approval in a timely manner or at all, or if FDA approved, they will be a significant revenue source for us. Significant delays in anticipated launches of these

products in development may occur. While we assist our partners in some cases in obtaining regulatory approvals and advancing new products, we depend on these partners and cannot control their decision-making or progress in achieving such goals. Any potential loss of anticipated future revenue could have an adverse effect on our business and the value of your investment.

An increase in the number of competitors targeting generic and 505(b)(2) ANDA opportunities and seeking U.S. market exclusivity may adversely affect our revenues and profits.

Our ability to achieve continued growth and profitability through sales of pharmaceuticals is dependent on our and our partners' continued success in challenging patents, developing non-infringing products or developing products with improved efficacy,

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safety or usability to provide opportunities with U.S. market exclusivity or limited competition. There is substantial competition in the pharmaceutical industry. We and our partners will face competition from generic drug products, drug products that are similar to our or our partners' products, drug products containing the same active ingredient as our or our partners' products, and drug products for the same indication as our or our partners' products.

Our or our partners' products may be eligible for periods of regulatory exclusivity, as described elsewhere in this annual report. This exclusivity, however, may not adequately protect our or our partners' products from competition. If any periods of exclusivity that we or our partners may have not adequately protected the applicable product or if we or they do not receive or lose anticipated periods of regulatory exclusivity, we or they may be subject to abbreviated new drug application ("ANDA") and/or 505(b)(2) competition sooner than we anticipate. We or our partners may also be subject to increased generic competition sooner than anticipated as the FDA, Congress, and the Administration have taken steps to facilitate the approval of generic products and increase competition in the prescription drug market. New legislative and regulatory efforts could ultimately have an adverse impact on our business and results of operation.

Further, regardless of any granted exclusivities, we or our partners may face competition from products or product uses that are not otherwise blocked by our or our partners' patents or exclusivities. For example, exclusivity does not prevent physicians from prescribing a similar product even if it is not approved for the same indication. By further example, in 2019, the FDA approved Clarus's product, JATENZO[®], an oral testosterone undecanoate capsule for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. The introduction of JATENZO[®], which was launched for commercial sale in February 2020, and other oral or competing testosterone products may materially impact our sales of XYOSTED[®]. Moreover, we or our partners may face competition from other products intended for the same use and/or that otherwise contain the same active ingredients, which may be less expensive than our or our partners' products. Any increase or changes in the competitive landscape for our or our partners' products may impact product sales and the amount that can be charged for a given product.

Additionally, the number of generic manufacturers targeting significant new generic opportunities with Hatch-Waxman exclusivity, or which are complex to develop, continues to increase. Other companies may also be developing drugs using the 505(b)(2) pathway that are substantially similar to our products and/or product candidates. The failure to successfully develop and commercialize highly complex products could adversely affect our sales and profitability. For instance, to the extent that another company receives a period of regulatory exclusivity, the FDA may not accept or make our application effective during that company's exclusivity period. This would delay our and our partners' marketing of products and may prevent us or them from establishing a sufficient market share for our product. Similarly, should another company obtain FDA approval for a pharmaceutically equivalent product to one of our product candidates, we may no longer be able to use the 505(b)(2) pathway. In that case, it is the FDA's policy that the appropriate submission would be an ANDA. We may, however, not be able to immediately submit an ANDA or have an ANDA approval made effective, as we could be blocked by others' periods of patent and regulatory exclusivity protection.

Although we have applied for and/or have received several patents and trademarks, we may be unable to protect our intellectual property, which would negatively affect our ability to compete.

Our success depends, in part, on our ability to obtain and enforce patents for our products and device technologies and to preserve our trade secrets and other proprietary information. If we cannot do so, our competitors may exploit our innovations and deprive us of the ability to realize revenues and profits from our developments.

We currently hold numerous patents and have numerous patent applications pending in the U.S. and other countries. Our current patents may not be valid or enforceable and may not protect us against competitors that challenge our patents, obtain their own patents that may have an adverse effect on our ability to conduct business, or are able to otherwise circumvent our patents. Additionally, our products and technologies are complex, and one patent may not be sufficient to protect our products where a series of patents may be needed. Further,

we may not have the necessary financial resources to enforce or defend our patents or patent applications. Even issued patents may later be modified or declared invalid by the U.S. Patent and Trademark Office by analogous foreign offices or in legal proceedings. In addition, any patent applications we may have made or may make relating to inventions for our actual or potential products and technologies may not result in patents being issued or may result in patents that provide insufficient or incomplete coverage for our inventions.

We may seek to protect our patent rights by asserting an allegation of infringement against third parties. For instance, for any products approved via the NDA pathway, we will be required to submit certain patent information for inclusion in the FDA's Orange Book. There is no guarantee, however, that we will be able to obtain patents that may be included in the Orange Book. To the extent that we do not include a patent in the Orange Book, we would not be able to avail ourselves of the

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protections provided in the Hatch Waxman Act, including the possibility of a 30-month stay. To the extent that we include a patent in the Orange Book that should not be included, we could also face legal action.

If third parties identify our products as reference listed drugs in any ANDAs or 505(b)(2) applications, they will be required to provide patent certifications in their applications for our listed patents, and notifications to us. In the event such third parties make paragraph IV certifications, we would be entitled to file a patent infringement lawsuit, and if that is accomplished within 45 days after receiving the notification, it would trigger a 30-month stay against the FDA making the approval of the third party's application effective. Patent litigation is costly and time consuming and the outcome is uncertain. There is no assurance of success with any patent litigation. Depending on the ultimate outcome of the litigation it may have an adverse effect on results of operations and our market penetration. We may also determine that it is not in our business interest to file a patent infringement lawsuit in response to a paragraph IV certification.

To protect our trade secrets and proprietary technologies and processes, we rely, in part, on confidentiality agreements with employees, consultants and advisors. These agreements may not provide adequate protection for our trade secrets and other proprietary information in the event of any unauthorized use or disclosure, or if others lawfully and independently develop the same or similar information. In addition, we may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties. We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we do not prevail, we could be required to pay substantial damages and could lose rights to important intellectual property. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

Others may bring infringement claims against us, which could be time-consuming and expensive to defend and the outcomes could be uncertain.

Third parties may claim that the manufacture, use or sale of our drug delivery technologies infringes their patent rights. As with any litigation where claims may be asserted, we may have to seek licenses, defend infringement actions or challenge the validity of those patents in the U.S. Patent and Trademark Office or the courts. If these claims are not resolved favorably, we may not be able to continue to develop and commercialize our product candidates. Even if we were able to obtain rights to a third party's intellectual property, these rights may be non-exclusive, thereby giving our competitors potential access to the same intellectual property. Moreover, because we are developing and may develop products using the ANDA and/or 505(b)(2) pathways, we may face a greater risk of patent infringement lawsuits and associated 30-month stay in the event that we or our partners make a paragraph IV certification as part of our FDA marketing application. If we are found liable for infringement or are not able to have these patents declared invalid or unenforceable, we may be liable for significant monetary damages, encounter significant delays in bringing products to market or be precluded from participating in the manufacture, use or sale of products or methods of drug delivery covered by others' patents. Any litigation could be costly and time-consuming and could divert the attention of our management and key personnel from our business operations. In addition, there is risk that a court will order us or our partners to pay the other party damages for having violated the other party's patents. We may not have identified, or be able to identify in the future, U.S. or foreign patents that pose a risk of potential infringement claims. In addition, a 505(b)(2) application or ANDA approval will not be made effective until any existing nonpatent exclusivities have expired or, if possible, is carved out from the label. Accordingly, we may invest a significant amount of time and expense in the development of one or more product candidates only to be subject to significant delay and patent litigation. Ultimately, we may be unable to commercialize some of our product candidates as a result of patent infringement claims, which could potentially harm our business.

Product liability, product recalls and related claims could harm our business.

The development, manufacture, testing, marketing and sale of pharmaceutical products and medical devices are associated with significant risks of product liability claims or recalls. Side effects or adverse events known or reported to be associated with, or manufacturing defects in, the products sold by us could exacerbate a patient's condition or could result in serious injury or impairments or even death. This could result in product liability claims and/or recalls of one or more of our products. Product liability claims may be brought by individuals seeking relief for themselves, or by groups seeking to represent a class of injured patients. Further, third party payers, either individually or as a putative class, may bring actions seeking to recover monies spent on one of our products. While we have not had to defend against any product liability claims to date, as sales of our products increase, we may have product liability claims made against us. The risk of product liability claims may also increase if a company receives a warning letter from a regulatory or other enforcement agency. We cannot predict the frequency, outcome or

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cost to defend any such claims. Product liability insurance coverage is expensive, can be difficult to obtain and may not be available in the future on acceptable terms, or at all. Our product liability insurance may not cover all of the future liabilities we might incur in connection with the development, manufacture or sale of our products. In addition, we may not be able to continue to obtain insurance on satisfactory terms or in adequate amounts.

While we maintain product and clinical trial liability insurance and evaluate our insurance requirements on an ongoing basis, a successful claim or claims brought against us in excess of available insurance coverage could subject us to significant liabilities and could have a material adverse effect on our business, financial condition, results of operations and growth prospects. Such claims could also harm our reputation and the reputation of our products, adversely affecting our ability to market our products successfully. Product liability claims can also result in regulatory consequences, including, but not limited to investigations and regulatory enforcement actions, as well as recalls, revocation of approvals, or labeling, marketing or promotional restrictions or changes. In addition, defending a product liability lawsuit is expensive and can divert the attention of key employees from operating our business. Such claims can also impact our ability to initiate or complete clinical trials.

To the extent that a product fails to conform to its specifications or comply with the applicable laws or regulations, we or our partners may be required to or may decide to voluntarily recall the product or regulatory authorities may request or require that we recall a product even if there is no immediate potential harm to a patient. Any recall of our products or products or their components that we supply to our partners could materially adversely affect our business by rendering us unable to sell those products or components for some time and by adversely affecting our reputation. Recalls are costly and take time and effort to administer. Even if a recall only initially relates to a single product, product batch, or a portion of a batch, recalls may later be expanded to additional products or batches or we or our partners may incur additional costs and need to dedicate additional efforts to investigate and rule out the potential for additional impacted products or batches. Moreover, if any of our partners recall a product due to an issue with a product or component that we supplied, they may claim that we are responsible for such issue and may seek to recover the costs related to such recall or be entitled to certain contractual remedies from us. Recalls may further result in decreased demand for our or our partners' products, could cause our partners or distributors to return products to us for which we may be required to provide refunds or replacement products, or could result in product shortages. Recalls may also require regulatory reporting and prompt regulators to conduct additional inspections of our or our partners' or contractors' facilities, which could result in findings of noncompliance and regulatory enforcement actions. A recall could also result in product liability claims by individuals and third-party payers. In addition, product liability claims or other safety issues could result in an investigation of the safety or efficacy of our products, our manufacturing processes and facilities, or our marketing programs conducted by the FDA or the authorities of the EU member states. Such investigations could also potentially lead to a recall of our products or more serious enforcement actions, limitations on the indications for which they may be used, or suspension, variation, or withdrawal of approval. Any such regulatory action by the FDA, the European Medicines Agency ("EMA") or the competent authorities of the EU member states could lead to product liability lawsuits as well.

We depend on information technology and computer systems to operate our business, and any failures or interruptions in our internal computer systems, including a data breach or cybersecurity incident, could have a negative impact on our business.

Despite the implementation of security measures, our internal computer systems and those of our current and any future partners, contractors and consultants are vulnerable to cybersecurity attacks including damage from computer viruses, unauthorized access, attacks by computer hackers and ransomware, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our manufacturing activities, development programs and business operations. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential, protected health or proprietary information, we could incur liability or damage to our reputation, and the further commercialization and development of our products and product candidates could be delayed. Likewise, data privacy or security breaches by employees or others may pose a risk that sensitive data, including our intellectual

property, or trade secrets or the personal information of our employees, patients or other business partners may be exposed to unauthorized persons or to the public. There can be no assurance that our efforts, or the efforts of our partners and vendors, will prevent service interruptions, or identify breaches in our systems, that could adversely affect our business and operations and/or result in the loss of critical or sensitive information, which could result in financial, legal, business or reputational harm to us. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyberattacks and other related breaches.

Our corporate compliance program cannot guarantee that we are in compliance with all potentially applicable laws and regulations, and we have incurred and will continue to incur costs relating to compliance with applicable laws and regulations.

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As a pharmaceutical technology company, we are subject to a large body of legal and regulatory requirements, guidance, and recommendations from a variety of regulatory authorities, such as the FDA, the EMA, and HHS OIG. In addition, as a publicly traded company we are subject to significant regulations, including the Sarbanes-Oxley Act of 2002. While we have developed and instituted a corporate compliance program based on what we believe are the current best practices and continue to update the program in response to newly implemented regulatory requirements and guidance, we cannot ensure that we are or will be in compliance with all potentially applicable regulations. Failure to comply with all potentially applicable laws and regulations could lead to the imposition of fines, cause the value of our common stock to decline, and impede our ability to raise capital or list our securities on certain securities exchanges.

We face uncertainty and risks related to the outbreak of the novel coronavirus disease, COVID-19, which could significantly disrupt our operations and may materially and adversely impact our business and financial conditions.

The Pandemic continues to evolve, including the spread of new more contagious virus strains, and the related risks and uncertainty could materially and adversely affect our business, operating results and financial conditions.

Our sales force has been subject to varying limitations on its ability to visit physicians, and we are utilizing virtual meeting platforms and other forms of social media to connect with our existing and potential customers and healthcare professionals. The restrictions and closures imposed as a result of the Pandemic have also limited patient access to physicians, and we have experienced, and may continue to experience, a decrease in new prescriptions for our proprietary products. Our partners may also experience a decrease in demand for our partnered products due to the Pandemic or the related restrictions. While we have taken measures to help minimize the potential impact of the various government orders, the effects of these restrictions may negatively impact productivity and demand for our products, disrupt our business and delay development programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These restrictions and others in the future, as well as the continued uncertainty on the duration, scope and severity of the Pandemic, could negatively impact our business, operating results and financial condition.

We currently rely on many third parties to source active pharmaceutical ingredient and drug products, manufacture and assemble our devices, distribute finished products and provide various logistics activities for our business. If any of these third parties are adversely impacted by the Pandemic or the restrictions resulting from the outbreak, for example, one of our third party manufacturers' facility had a temporary shutdown as a result of a positive COVID-19 diagnosis by an employee, if they are not able to obtain necessary supplies, or if they need to prioritize other products or customers over us or our partners, we may experience delays or disruptions in our product supply chain which could have a material and adverse impact on our business. Additionally, if we or any of these third parties require a regulatory authority inspection, we or they may be delayed in obtaining such inspection as a result of the Pandemic. These third parties may also need to deviate from their standard manufacturing procedures as a result of the Pandemic, which could adversely impact our or our partners' products. These third parties may also need to deviate from their standard manufacturing procedures as a result of the Pandemic, which could adversely impact our or our partners' products.

In addition, to the extent that we or our partners are conducting clinical trials, the Pandemic could cause delays or disruptions in these or future development programs. The foregoing may require that we consult with relevant review and ethics committees, Institutional Review Boards ("IRBs") and the FDA, and could negatively impact our business. We may also need to make filings to the applicable regulatory authorities to account for changes that are necessary to continue to adapt to the Pandemic.

As the Pandemic continues, it may impact our and our partner's business operations in any number of ways. This has been recognized by the FDA, which has promulgated a number of guidance specific on operations during the Pandemic. As the Pandemic develops, the regulatory guidance may continue to change and evolve, requiring that we and our partners continue to adapt to new requirements.

The full extent to which the Pandemic may impact our business or the economy as a whole is unknown and will depend on future developments, which are highly uncertain and cannot be predicted, such as the ultimate spread and rate of infection, the duration of the

Pandemic, travel restrictions and social distancing requirements, business closures or business disruptions and the effectiveness of actions taken in the U.S. and in other countries to contain and treat the disease and to address its impact, including on financial markets or otherwise. These effects could have a material adverse impact on our business and operations. To the extent the Pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this section and in the “Risk Factor” section in our other filings with the Securities and Exchange Commission. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

We have historically incurred significant losses, and there is no guarantee that we can sustain or grow our profitability.

Although we generated net income of \$46.3 million and \$56.2 million for the years ended December 31, 2021 and 2020, respectively, we incurred net losses of \$2.0 million for the year ended December 31, 2019. In addition, we had an accumulated deficit as of December 31, 2021 of \$176.3 million. The costs for research and development of our products, product candidates and drug delivery technologies, along with marketing and selling expenses and general and administrative expenses, have been the principal causes of our historical losses. Although we have reported net earnings and earnings per share in recent two most recent annual periods, there is no guarantee we will continue to post profitable results of operations or maintain profitability on an annual or quarterly basis.

Risks Related to Regulatory Matters

Our and our partners' product candidates are subject to the inherent risk of product development and clinical trials, in that product development and clinical trials may not be successful, and they may not receive regulatory marketing approval on a timely basis or at all. If we or our partners fail to obtain, or have delays in obtaining, regulatory approvals for any product candidates, our business, financial condition and results of operations may be materially adversely affected.

The design, development, testing, manufacturing and marketing of pharmaceutical compounds and medical devices are subject to regulation by governmental authorities, including the FDA and comparable regulatory authorities in other countries and is an inherently risky and uncertain process. To conduct our and our partners' clinical and preclinical studies, we and they rely on third parties, including CROs and clinical trial sites to carry out the studies in accordance with the written protocol, the instructions, our and our partners' agreements with them, and the applicable regulatory requirements. There is no guarantee that we or our partners will be able to negotiate agreements with these third parties on acceptable terms, on a timely basis, or at all. To the extent that these third parties do not carry out their responsibilities, as is required, or to the extent that we, our partners, or such third parties terminate the applicable agreements, we or our partners may need to replace them, which may take significant time, effort, and expense. Additionally, we or our partners may be subject to regulatory enforcement action for such third parties' and our or our partners' actions, and the FDA or foreign regulatory authorities may find that the study data that is generated cannot form the basis for approval of a marketing application, requiring that we or our partners conduct additional preclinical and clinical studies. Moreover, investigators and CROs may be subject to conflicts of interest that compromise or appear to compromise the resulting data. Such third parties may also have relationships with other entities that they may prioritize over the conduct of our or our partners' studies.

Despite the time and expense associated with preclinical and clinical studies, failure can occur at any stage, and we or our partners could encounter problems that cause us or they to repeat or perform additional preclinical studies, chemistry, manufacturing and controls ("CMC") studies or clinical trials. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates or that may increase the cost of development, including, failure to receive FDA or IRB authorization to begin or continue a trial, negative or inconclusive results, slow or insufficient subject enrollment, failure to obtain adequate clinical supply of product candidates that meet the applicable regulatory quality requirements, and failure by us, our partners, CROs, and clinical trial sites to follow the applicable regulatory requirements, including GCPs. We or our partners may also not have sufficient funding to conduct or complete a clinical trial or pay the substantial FDA application user fees.

The FDA and similar foreign authorities could also delay, limit or deny approval of a product candidate for many reasons, including because they: may not deem a product candidate to be adequately safe and effective or, in the case of a generic drug product, bioequivalent to the reference listed drug; may not find that we have adequately bridged to the reference listed drug, in the case of a 505(b)(2) application; may not find the data, including foreign data, from preclinical studies, CMC studies and clinical trials to be sufficient to support a claim of safety and efficacy; may interpret data from preclinical studies, CMC studies and clinical trials significantly differently than we or our partners do; may not approve the manufacturing processes or facilities associated with our

product candidates; may not agree with the pathway that we or our partners have chosen for our product candidates, requiring us to pursue more difficult approval pathways, including submitting full NDAs, or may not agree with our or our partners' intended indications; may find that our or our partners reliance on a reference listed drug for an ANDA or 505(b)(2) application or literature for a 505(b)(2) application is not appropriate; may not agree with the design and/or implementation of our clinical and/or pre-clinical studies; may require us to conduct additional clinical and/or pre-clinical studies or gather additional information or data; may find safety or efficacy issues with respect to a reference listed drug, either before or after a product candidate's approval; may change approval policies (including with respect to our product candidates' class of drugs), or adopt new regulations; may not meet their review goal dates; or may not accept a submission due to, among other reasons, the content or formatting of the submission. Significant delays also could shorten any periods during which we or our partners may have the exclusive right to commercialize our product candidates, which would allow competitors to bring products to market before we do.

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Undesirable side effects caused by any product candidate that we or our partners develop, a lack of bioequivalence for ANDA product candidates, and/or an inability to demonstrate product candidate efficacy could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications or cause us or our partners to evaluate the future of our development programs. Undesirable side effects could also interrupt, delay, or halt clinical trials. The regulatory review and approval process is lengthy, expensive and inherently uncertain.

Our and our partners' reliance on FDA's 505(b)(2) and ANDA pathways may also impact the risk of development that we would not be subject to under a full NDA. These pathways are continually evolving. Based on evolving regulatory policies, we or our partners may not be able to use the 505(b)(2) or ANDA pathway in the future, requiring that we or they pursue the costlier and time consuming 505(b)(1) full NDA pathway. We or our partners may also face delays or impediments to the approval of any product candidates if a competitor files a citizen petition with the FDA. Moreover, any FDA intervening approvals of drug products that are the same or similar to our or our partners' product candidates could impact our potential market position and prospects, as well as impact the approval of our or our partners' product candidates. By example, should the FDA approve a product that is pharmaceutically equivalent to one of our or our partners' 505(b)(2) NDA product candidates before we or they submit a marketing application, we or they would be required to change the marketing application to an ANDA application. Similarly, should FDA approve a product that is more similar to any of our or our partners' ANDA product candidates than the current reference listed drug, we or our partners may be required to change the reference listed drug for the ANDA. Either of these scenarios could require additional development work, and clinical or preclinical studies. FDA intervening approvals could also delay the timeframe within which we or our partners may submit product applications to the FDA or within which the FDA may make approvals of such applications effective, due to periods of patent protections and regulatory exclusivities for the newly approved product. Because the FDA cannot disclose whether such predicate product is under development or has been submitted at any time during another company's review cycle, we would not know whether there are any intervening products or applications until such product or application is approved.

Should the FDA or another regulatory authority refuse to approve any of our or our partners' product candidates, we or they will be delayed in marketing, may need to conduct additional studies and collect additional data and information, and may need to make changes to the product candidates or their manufacturing processes, any of which could materially harm our business and results of operation. Moreover, if granted, any regulatory approvals may be subject to certain limits or other costly and burdensome requirements, such as labeled warnings, including box warnings, limitations on the indicated use, and post-approval requirements. The FDA also can withdraw product clearances and approvals for failure to comply with regulatory requirements or if unforeseen problems follow initial marketing. Any limitation on use imposed by the FDA or foreign regulatory agencies would adversely affect the marketing of these products and our ability to generate product revenue, which would adversely affect our financial condition and results of operations.

With respect to any new products, we may also face increased risk with respect to regulatory approval, compliance and commercialization. By example, while TLANDO[®] has received tentative FDA approval, it may never receive final approval. Moreover, to the extent that we do not have prior experience with a specific kind of product, such as the TLANDO[®] gel capsules, we will need to acquire the necessary experience and expertise to successfully manufacture and commercialize the product, which we may never be able to do.

In other jurisdictions, we, and the pharmaceutical companies with which we are developing technologies (both drugs and devices), must obtain required regulatory approvals from regulatory agencies and comply with extensive regulations regarding safety and quality. If approvals to market the products are delayed, if we fail to receive these approvals, or if we lose previously received approvals, our revenues may not materialize or may decline. We may not be able to obtain all necessary regulatory approvals. Additionally, clinical data that we generate or obtain from partners from FDA regulatory filings may not be sufficient for regulatory filings in other jurisdictions and we may be required to incur significant costs in obtaining those regulatory approvals.

Because our and our partners' products and product candidates are considered to be drug/device combination products, the approval and post-approval requirements that we and they are required to comply with will be more complex.

Most of our and our partners' products and product candidates are considered to be drug/device combination products by the FDA, consisting of a drug product and a drug delivery device. If marketed individually, each component would be subject to different regulatory pathways and reviewed by different centers within the FDA. A combination product, however, is assigned to a center that will have primary jurisdiction over its pre-market review and regulation based on a determination of the product's primary mode of action, which is the single mode of action that provides the most important therapeutic action. In the case of our and our partners' products and product candidates, the primary mode of action is attributable to the drug component of the products, which means that the Center of Drug Evaluation and Research has primary jurisdiction over the products' premarket development and review. These products and product candidates will be and have been subject to the FDA drug

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approval process and will not require a separate FDA clearance or approval for the device component. Even though these products and product candidates will not require a separate FDA clearance or approval, both the drug and device centers within the FDA will review the marketing application for safety, the efficacy of both the drug and device component, including the design and reliability of the injector, and a number of other different areas, such as to ensure that the drug labeling adequately discloses all relevant information and risks, and to confirm that the instructions for use are accurate and easy to use. These reviews could increase the time needed for review completion of a successful application and may require additional studies, such as usage studies, to establish the validity of the instructions. Such reviews and requirements may extend the time necessary for the approval of drug-device combinations. In the case of combination product candidates for which we or our partners are seeking approval via the ANDA pathway, it is also possible that the agency may decide that the unique nature of combination products leads it to question the claims of bioequivalence and/or same labeling, resulting in the need to refile the application under Section 505(b)(2). This may result in delays in product approval and may cause us or our partners to incur additional costs associated with testing, including clinical trials. Approval via the 505(b)(2) pathway may also result in additional selling expenses and a decrease in market acceptance due to the lack of substitutability by pharmacies or formularies. In addition, approval under the 505(b)(2) or ANDA regulatory pathway is not a guarantee of an exclusive position for the approved product in the marketplace.

Further, although precedent and guidance exist for the approval of such combination products, there is no assurance that the FDA will not change what it requires or how it reviews submissions. Changes in review processes or the requirement for the study of combination products could delay anticipated launch dates or be cost prohibitive. Such delay or failure to launch these products or devices could adversely affect our revenues and future profitability. If our or our partners' combination product candidates are approved, we, our partners, and any of our respective contractors will be required to comply with FDA regulatory requirements related to both drugs and devices. For instance, drug/device combination products must comply with both the drug cGMPs and device QSRs. Depending on whether the drug and device components are at the same facility, however, the FDA regulations provide a streamlined method to comply with both sets of requirements. The FDA has specifically promulgated guidance on injectors, which discuss FDA's requirements with respect to marketing application and post-market injector design controls and reliability analyses. Additionally, drug/device combination products will be subject to additional FDA and constituent part reporting requirements. These requirements will require additional effort and monetary expenditure to ensure that our and our partners' products and product candidates.

We and our partners are subject to ongoing obligations and continued regulatory review, which may result in significant additional expense for our and their approved and unapproved products. Failure to comply with these obligations could result in regulatory and/or legal consequences.

Our and our partners' products and product candidates are subject to extensive and rigorous government regulation by the FDA and foreign regulatory agencies, including requirements related to research, development, pre-clinical and clinical testing before and after product approval, manufacture, safety, effectiveness, recordkeeping, reporting, labeling, packaging, storage, distribution, deviation, approval, facility registration and product listing, the payment of user fees, advertising, marketing, promotion, sale, distribution, sampling, and import and export of pharmaceutical and medical device products. Because our and our partners' products and product candidates are drug/device combination products, we and they will have to comply with more regulatory requirements that would otherwise be required for products that are not combination products. Failure to comply with FDA and other applicable regulatory requirements may, either before or after product approval, subject us to administrative or judicially imposed sanctions. Moreover, were we or our partners to seek regulatory approval for additional indications or uses of any products that we or they may have already received marketing approval for, we or they would be subject to the risks of product development, including the failure to obtain regulatory approval. The applicable FDA, HHS and other governmental policies, laws, and regulations may also change, and additional laws, policies, and regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates or products, or that could impose additional regulatory obligations on us.

The FDA and foreign regulatory agencies will continue to monitor products after approval for continued safety, efficacy, and compliance. We, our partners, and our independent contractors will also be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with regulatory requirements. Later discovery of previously unknown adverse events or that the drug is less effective than previously thought or other problems with our products, manufacturers, or manufacturing processes, or failure to comply with regulatory requirements both before and after approval, may yield various results, including warning letters, untitled letters, cyber letters, manufacturing and distribution restrictions, changes to product labeling, post-marketing study or other requirements such as REMS, refusal to approve marketing applications or supplements, withdrawal of marketing application approvals, removal of the product from the market, labeling or promotional material modifications, product recalls, market withdrawals, field corrections, clinical holds and suspensions of clinical studies, fines, penalties, disgorgement, corporate integrity agreements, consent decrees, seizure, injunctions, prohibition on importing and exporting, dear healthcare provider letters, adverse publicity, FDA debarment, debarment from government procurement programs or

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refusal of orders under existing contracts, and exclusion from federal healthcare programs, among other consequences. Any of these events could have other material adverse effects on our operations and business.

For certain of our products, we and our independent contractors, distributors, prescribers, and dispensers are required to comply with regulatory requirements related to controlled substances, which will require the expenditure of additional time and will incur additional expenses to maintain compliance.

Certain of our products are controlled substances and accordingly, we, and our contractors, distributors, prescribers, and dispensers must comply with Federal controlled substances laws and regulations, enforced by the U.S. Drug Enforcement Administration (“DEA”), as well as state-controlled substances laws and regulations enforced by state authorities. These requirements include, but are not limited to, registration, security, recordkeeping, reporting, storage, distribution, importation, exportation, inventory, and other requirements. These requirements are enforced by the DEA through periodic inspections. Not only must continuous controlled substance registration be maintained, but compliance with the applicable controlled substance requirements will require significant efforts and expenditures, which could also inhibit the successful commercialization. If we and our contractors, distributors, prescribers, and dispensers do not comply with the applicable controlled substance requirements, we or they may be subject to administrative, civil or criminal enforcement, including civil penalties, refusals to renew necessary registrations, revocation of registrations, criminal proceedings, or consent decrees.

Any relationships with healthcare professionals, principal investigators, consultants, customers (actual and potential) and third-party payers in connection with our current and future business activities are and will continue to be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, marketing expenditure tracking and disclosure (or “sunshine”) laws, government price reporting, and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face penalties, contractual damages, reputational harm, diminished profits and future earnings.

Our business operations and activities may be directly, or indirectly, subject to various federal, state and local fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal FCA and similar laws in some state and foreign markets. These laws may impact, among other things, our current activities with principal investigators and research subjects, as well as proposed and future sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by the federal government, state governments and foreign jurisdictions in which we conduct our business. The laws in the U.S. that may affect our ability to operate are further discussed above in the “Government Regulation” section of this Form 10-K.

Changes in healthcare law and implementing regulations, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict, and these changes could have a material adverse effect on our business and financial condition.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (together “the Healthcare Reform Act”) substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. Recently, the law’s individual health insurance mandate was repealed and manufacturers’ responsibility for the cost of prescriptions in the Medicare Part D donut hole has increased. We expect that the Healthcare Reform Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures at the federal and state level that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our existing products or to successfully commercialize our product candidates, if approved. For example, CMS recently finalized (and subsequently rescinded) a rule establishing a pricing model for Medicare Part B drugs based on the average price among other industrialized countries. This type of regulatory development, including if extended to other federal healthcare programs, could have a significant impact on our business.

To help patients afford certain of our products, we offer discount, rebate, and co-pay coupon programs. Co-pay coupon programs have received some negative publicity related to their use to promote branded pharmaceutical products over other less costly alternatives.

CMS recently has issued a regulation imposing additional obligations on manufacturers in order to continue excluding such programs from government pricing calculations to avoid payment of increased Medicaid rebates. In recent years, other pharmaceutical manufacturers have been named in class action lawsuits challenging the legality of their co-pay programs under a variety of federal and state laws. In addition, at least one insurer has directed its network pharmacies to no longer accept co-pay coupons for certain specialty drugs the insurers identified. Our co-pay coupon programs could become the target of similar lawsuits or insurer actions. It is possible that the outcome of litigation against other manufacturers, changes in insurer policies regarding co-pay coupons, and/or the introduction and enactment of new legislation or regulatory action could restrict or otherwise negatively affect these programs.

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We are dependent on third parties to decide to use our and our partners' products and to make them readily available at the point of care throughout their networks of pharmacies.

In addition to extensive internal efforts, the successful commercialization of our and our partners' products require many third parties, over which we have no control, to decide to use them, and to make them readily available at the point of care throughout their networks of pharmacies. These third parties include HMOs, long term care facilities, and pharmacy benefit managers, or PBMs, which use pharmacy and therapeutics committees, commonly referred to as P&T committees, to make purchasing and reimbursement decisions. We cannot guarantee that we and/or our partners will be successful in getting the approvals we need from sufficient P&T committees quickly enough to maintain and grow sales of our or our partners' products.

Risks Related to our Common Stock

The market price of our common stock has been, and may continue to be volatile and fluctuate significantly, which could result in substantial losses for investors.

The trading price for our common stock has been, and we expect it to continue to be, volatile. The price at which our common stock trades depends upon a number of factors, including our historical and anticipated operating results, our financial situation, clinical trial results, announcements of technological innovations or new products by us, our partners or our competitors, our ability or inability to raise the additional capital we may need and the terms on which we raise it, and general market and economic conditions. Some of these factors are beyond our control. Broad market fluctuations may lower the market price of our common stock and affect the volume of trading in our stock, regardless of our financial condition, results of operations, business or prospects.

We are at risk of securities class action and similar litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. For example, on October 23, 2017, Randy Smith filed a complaint in the District of New Jersey, on behalf of a putative class of persons who purchased or otherwise acquired Antares securities against us, Robert F. Apple and Fred M. Powell. In addition, in January 2018, three stockholders filed separate derivative actions, one in the District of New Jersey and two in the Superior Court of New Jersey Chancery Division, Mercer County, purportedly on our behalf, against certain directors and officers, as well as the Company as a nominal defendant. There can be no assurance that we will ultimately prevail in these legal proceedings. Even if we are successful and ultimately prevail, litigation could be costly to defend and divert management's attention and resources, which could further materially harm our financial condition and results of operations.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

If we do not generate sufficient net taxable income in the future, our ability to use our net operating loss carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

Anti-takeover effects of certain certificate of incorporation and bylaw provisions could discourage, delay or prevent a change in control.

Our certificate of incorporation authorizes our board of directors, without action of our stockholders, to designate and issue preferred stock in one or more series, with such rights, preferences and privileges as the board of directors shall determine. In addition, our bylaws grant our board of directors the authority to adopt, amend or repeal all or any of our bylaws, subject to the power of the stockholders to change or repeal the bylaws. In addition, our bylaws limit who may call meetings of our stockholders.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our properties consist of leased office, laboratory, warehouse and manufacturing facilities. We lease our corporate headquarters located in Ewing, New Jersey, primarily consisting of office space. We also lease a building in Minnetonka, Minnesota consisting of office, laboratory, manufacturing and warehousing space. We believe our current facilities are sufficient for our existing needs and to support future anticipated business growth.

Additional information related to lease obligations is included in Item 7 of Part II of this Annual Report on Form 10-K.

ITEM 3. LEGAL PROCEEDINGS

The information set forth under “Note 16. Commitments and Contingencies – *Pending Litigation*” to the Consolidated Financial Statements included in Item 8 of Part II of this Annual Report on Form 10-K is incorporated herein by reference.

Although the results of actual, pending or threatened legal proceedings and litigation cannot be predicted with certainty, we do not believe that there is a reasonable possibility that the final outcome of these matters will have a material adverse effect on our business or financial results. Regardless of the final outcome, litigation could have an adverse impact on us because of defense or settlement costs, diversion of management resources, harm to our reputation and brand, and other factors.

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 trades on the NASDAQ Capital Market under the trading symbol “ATRS”.

Common Shareholders

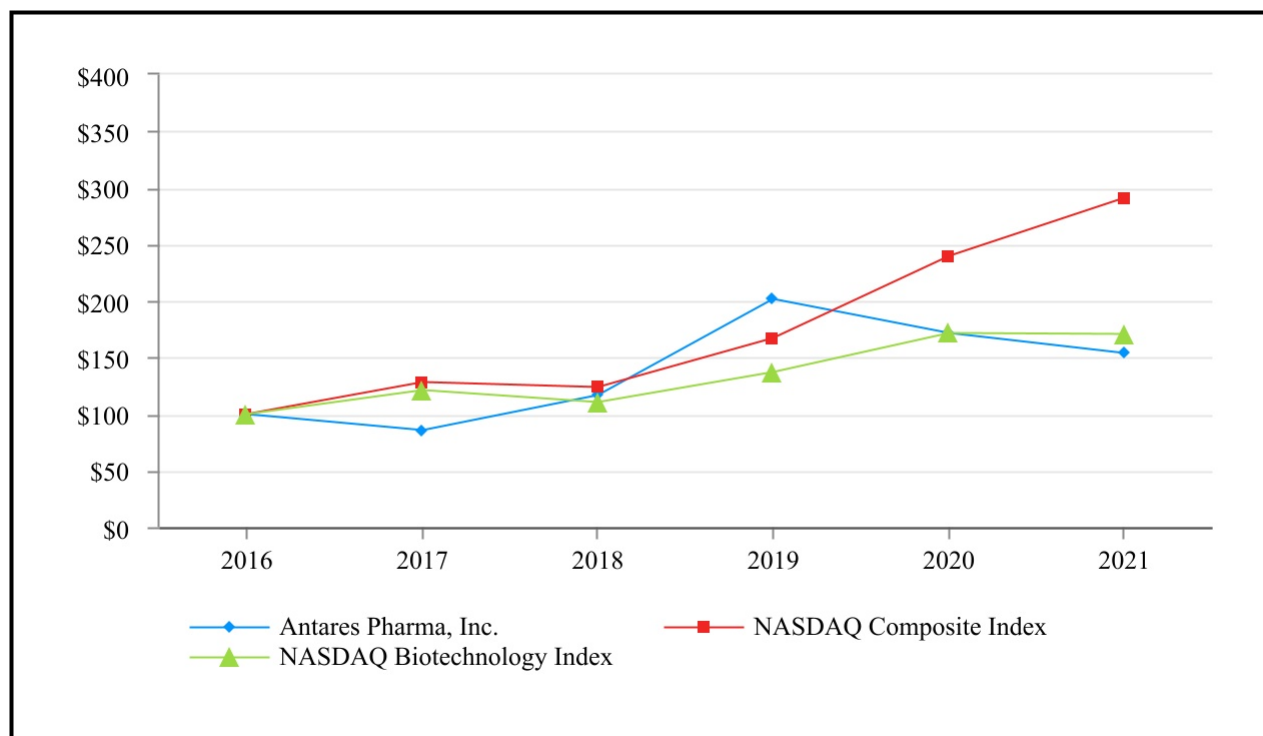
As of February 28, 2022, we had 69 shareholders of record of our common stock and approximately 21,825 shareholders in street name. Information on securities authorized for issuance under our equity compensation plans can be found in Item 12 of Part III of this Annual Report on Form 10-K.

Dividends

We have not paid or declared cash dividends on our common stock during the past ten years and have no intention of paying cash dividends on our common stock in the foreseeable future.

Performance Graph

The graph below provides an indication of cumulative total stockholder returns (“Total Return”) for our common stock as compared with the NASDAQ Composite Index and the NASDAQ Biotechnology Stock Index. The graph covers the period beginning December 31, 2016 through December 31, 2021. The graph assumes \$100 was invested at market close on December 31, 2016 in our common stock, the NASDAQ Composite Index and the NASDAQ Biotechnology Stock Index and that all dividends were reinvested. The graph is not necessarily indicative of future investment performance.



	December 31,					
(in actual dollars)	2016	2017	2018	2019	2020	2021
Antares Pharma, Inc.	\$ 100.00	\$85.41	\$116.74	\$201.72	\$171.24	\$153.22
NASDAQ Composite Index	100.00	128.24	123.26	166.68	239.42	290.63
NASDAQ Biotechnology Index	100.00	121.06	109.77	136.56	171.64	170.55

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

ITEM 6. [RESERVED]

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

Management’s Discussion and Analysis of Financial Condition and Results of Operations (“MD&A”) is designed to provide a reader of our financial statements with a narrative from the perspective of management on our financial condition, results of operations, liquidity and certain other factors that may affect our future results. Our MD&A is presented in five sections.

- Company Overview
- Results of Operations
- Liquidity and Capital Resources
- Critical Accounting Policies and Use of Estimates
- Off-Balance Sheet Arrangements

Our MD&A should be read in conjunction with the consolidated financial statements and related footnotes included in Item 8 of Part II of this Annual Report on Form 10-K and risk factors identified in Item 1A of Part I of this Annual Report on Form 10-K. Some of the statements included below are considered forward-looking statements. See the discussion regarding forward-looking statements preceding Item 1 of Part I of this Annual Report on Form 10-K.

The terms “Antares,” “we,” “our,” “us” or the “Company” in this Annual Report on Form 10-K, unless the context otherwise requires, refer to Antares Pharma, Inc. and its wholly owned subsidiaries.

Company Overview

Antares Pharma, Inc. is a specialty pharmaceutical company focused primarily on the development and commercialization of pharmaceutical products and technologies that address patient needs in targeted therapeutic areas. We develop, manufacture and commercialize, for ourselves or with partners, novel therapeutic products using our advanced drug delivery systems that are designed to provide commercial or functional advantages such as improved safety and efficacy, convenience, improved tolerability, and enhanced patient comfort and adherence. We also seek product opportunities that complement and leverage our commercial platform. We have a portfolio of proprietary and partnered commercial products and ongoing product development programs in various stages of development. We have formed partnership arrangements with several different industry leading pharmaceutical companies.

We market and sell in the U.S. our proprietary product XYOSTED® (testosterone enanthate) injection indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. XYOSTED® is the only FDA approved subcutaneous testosterone enanthate product for once-weekly, at-home self-administration.

In December 2021, we sold certain assets used in the operation of the OTREXUP® product under an asset purchase agreement with Otter for \$44.0 million, subject to finalization of changes in closing inventory to be transferred, with \$18.0 million received at closing

and an additional \$26.0 million to be paid in installments over a one-year period. Prior to the asset sale, we marketed and sold OTREXUP® (methotrexate) injection, a subcutaneous methotrexate injection for once weekly self-administration with an easy-to-use, single dose, disposable auto injector, indicated for adults with severe active rheumatoid arthritis, children with active polyarticular juvenile idiopathic arthritis and adults with severe recalcitrant psoriasis, as a proprietary product in the U.S. In conjunction with the asset sale, we entered into a supply agreement with Otter to manufacture the VIBEX® auto-injection system device at cost plus mark-up. Otter is responsible for manufacturing, formulation and testing of methotrexate and the corresponding prefilled syringe for assembly with the device manufactured by us, along with the commercialization and distribution of OTREXUP® going forward. We also entered into a license agreement with Otter granting them a worldwide, exclusive, royalty-free, fully paid-up, irrevocable, transferable license with the right to sublicense to certain patents relating to the OTREXUP® product that may relate to other products we produce.

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In October 2020, we entered into an exclusive license agreement (the “NOC DURNA[®] License Agreement”) with Ferring for the marketed product NOC DURNA[®] (desmopressin acetate) in the United States, which is indicated for the treatment of nocturia due to nocturnal polyuria (“NP”) in adults who awaken at least two times per night to urinate. We began detailing NOC DURNA[®] with a soft launch in the fourth quarter of 2020 and are currently executing a reintroduction of the product through a comprehensive re-launch strategy to increase awareness and demand.

In October 2021, we entered into an exclusive license agreement (the “TLANDO[®] License Agreement”) with Lipocine for the product TLANDO[®] (testosterone undecanoate) in the U.S., a twice-daily oral formulation of testosterone for testosterone replacement therapy indicated for conditions associated with a deficiency or absence of endogenous testosterone, or hypogonadism in adult males. TLANDO[®] was granted tentative approval from the FDA in December 2020 and will be eligible for final approval and marketing in the U.S. upon expiration of the exclusivity period previously granted to Clarus for JATENZO[®] on March 27, 2022. On February 3, 2022, we announced the FDA’s acceptance of our NDA resubmission for TLANDO[®] with a target action date set for March 28, 2022. We continue to prepare for the launch of TLANDO[®] in 2022 pending final FDA approval after the expiration of JATENZO[®]’s exclusivity period. Under the terms of the TLANDO[®] License Agreement, we paid Lipocine an upfront payment of \$11.0 million. Lipocine is eligible for additional milestone payments up to \$10.0 million and tiered royalty and commercial milestones based on net sales of TLANDO[®] in the U.S. We will be responsible for the manufacturing and commercialization of TLANDO[®].

The TLANDO[®] License Agreement also grants us the option to license and develop LPCN 1111 (TLANDO XR) in the U.S., a potential once daily oral testosterone product containing testosterone tridecanoate in development for the treatment of hypogonadism in adult males. If elected, upon exercise of the option, we will be required to pay an additional \$4.0 million in license fees in two installments and will be responsible for additional development and commercial milestone payments as well as tiered royalties on net sales of TLANDO XR in the U.S. In addition, we will be responsible for completing the development program including the conduct of a Phase 3 clinical trial and applying for regulatory approval in the U.S.

In collaboration with Teva, we developed a version of our VIBEX[®] auto injector for use in a generic epinephrine auto injector product that was approved by the FDA. Teva’s Epinephrine Injection USP is indicated for emergency treatment of severe allergic reactions including those that are life threatening (anaphylaxis) in adults and certain pediatric patients and was approved as a generic drug product with an AB rating, meaning that it is therapeutically equivalent to the branded products EpiPen[®] and EpiPen Jr[®] and therefore, subject to state law, substitutable at the pharmacy. We are the exclusive supplier of the device and Teva is responsible for commercialization and distribution of the finished product, for which we also receive royalties on Teva’s net sales.

Through our commercialization partner Teva, we sell Sumatriptan Injection USP indicated in the U.S. for the acute treatment of migraine and cluster headache in adults.

We are the exclusive supplier of the device, a variation of our VIBEX[®] QuickShot[®] subcutaneous auto injector developed by us, for the progestin hormone drug Makena[®] (hydroxyprogesterone caproate injection), indicated to help reduce the risk of preterm birth in women pregnant with one baby and who spontaneously delivered one preterm baby in the past. As the exclusive supplier, we perform final assembly and packaging of the commercial product and receive royalties on Covis’ net sales of the product. In October 2020, following an FDA advisory committee meeting, Covis in November 2020, received notice that the FDA is proposing to withdraw approval of Makena[®] (hydroxyprogesterone caproate injection). Covis formally requested a public hearing in response to the FDA’s proposal to withdraw its approval and has stated that it remains committed to working with the FDA to maintain patient access to Makena[®] as a treatment option to reduce pre-term birth.

We are also developing with Teva a multi-dose pen for a generic form of Forteo[®] (teriparatide rDNA origin injection) for the treatment of osteoporosis, and were developing another multi-dose pen for a generic form of BYETTA[®] (exenatide injection) for the treatment of type 2 diabetes. On February 25, 2022, Teva notified us that it was terminating the exenatide program and related agreement due to a

lack of commercial viability. The termination is effective August 23, 2022. Teva continues to work through the U.S. regulatory process with the FDA for teriparatide using the ANDA pathway. In 2020, Teva launched Teriparatide Injection (“teriparatide”), the generic version of Eli Lilly’s branded product Forsteo® featuring the Antares multi-dose pen used platform in several countries outside the U.S. We are responsible for the manufacturing and supply of the multi-dose pen utilized in Teva’s generic teriparatide product under an exclusive development, license and supply agreement with Teva, the scope of which is worldwide.

In August 2018, we entered into a development agreement with Pfizer to develop a combination drug device rescue pen. This rescue pen will utilize the Antares QuickShot® auto injector and an undisclosed Pfizer drug. In 2021, we continued to work on this development program, and we expect to continue development of this product candidate.

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In November 2019, we entered into a global agreement with Idorsia to develop a novel, drug-device product containing selatogrel. The new chemical entity selatogrel is being developed for the treatment of a suspected AMI in adult patients with a history of AMI. Idorsia will pay for the development of the combination product and will be responsible for applying for and obtaining global regulatory approvals for the product. The parties intend to enter into a separate commercial license and supply agreement pursuant to which we will provide fully assembled and labelled product to Idorsia at cost plus mark-up. Idorsia will then be responsible for global commercialization of the product, pending FDA or foreign approval. We will be entitled to receive royalties on net sales of the commercial product.

In June 2021, Idorsia announced it had initiated its Phase 3 registration study to evaluate the efficacy and safety of self-administered subcutaneous selatogrel. The study will enroll approximately 14,000 patients who are at high risk of recurrent AMI, at approximately 250 sites in approximately 30 countries.

We are also committed to advancing our internal research and development programs and continue to invest in the development of our proprietary product pipeline. Our research and development efforts are focused primarily on leveraging our existing product and technology platforms by broadening their applications for use in other drug device combination products, as well as exploring new pharmaceutical products, technologies and drug delivery methods.

We have initiated development of a proprietary drug device combination product for the urology oncology market, identified as ATRS-1901, and have conducted formulation development work and non-clinical studies to help advance this program. In 2020, we received a response from the FDA regarding our pre-IND (Investigational New Drug) submission.

We have identified a program to develop a proprietary drug device combination product for the endocrinology market, an adrenal crisis pen, identified as ATRS-1902. The development program supports a proposed indication for the treatment of acute adrenal insufficiency, known as adrenal crisis, in adults and adolescents, using a novel proprietary auto-injector platform to deliver a liquid stable formulation of hydrocortisone. We conducted initial formulation work and developed a working prototype of a new device to support this program. We received a response from the FDA regarding our pre-IND submission and believe we have determined the regulatory and clinical path forward.

In July 2021, the FDA accepted our IND for ATRS-1902 enabling us to initiate our Phase 1 clinical study. In January 2022, we announced the positive results from the Phase 1 clinical study and were granted Fast Track designation by the FDA. The positive results support the advancement of our ATRS-1902 development program to a pivotal clinical study for the treatment of acute adrenal insufficiency, known as adrenal crisis, in adults and adolescents, using our Vai™ novel proprietary rescue pen platform to deliver a liquid stable formulation of hydrocortisone. We anticipate starting this pivotal clinical study in the second quarter of 2022 and expect to submit a 505(b)(2) NDA with the FDA by the end of 2022 pending the success of the pivotal clinical study.

We have initiated development of a proprietary drug device combination product utilizing our rescue pen technology for a rare immunology disorder, identified as ATRS-1903. Formulation development work has been conducted and we anticipate progressing this towards initial clinical testing to evaluate PK and tolerability in human subjects.

COVID-19

In December 2019, a novel strain of coronavirus (COVID-19) emerged in China, and has since spread worldwide, including every state in the U.S. On March 11, 2020, the World Health Organization declared the outbreak a Pandemic and on March 13, 2020, the U.S. declared a national emergency with respect to the outbreak. The Pandemic has impacted global economic activity and lead to disruptions in supply chain, labor shortages, business closures, travel restrictions and other health, safety and social distancing requirements.

We have taken several measures to actively manage and help minimize the impact of the ongoing Pandemic on our business. We have implemented safety measures and protocols to protect the health and safety of our employees and comply with governmental and public health guidelines while working to ensure the sustainability of our business operations and continuity of product supply. We continue to monitor the situation, including COVID-19 variants, and potential effects on our business, suppliers, partners and workforce.

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We have implemented a hybrid work environment with the ability to shift remote as necessary to limit the number of individuals in our facilities to those necessary for essential functions such as research, development, manufacturing and supply. While our field-based team has resumed in-person interaction with fewer restrictions, we believe we are also well-positioned with our virtual capabilities to continue to engage healthcare professionals and patients through the ongoing Pandemic and beyond. Although, we have not experienced significant delays or disruption in our development programs or significant demand reductions for our partnered products due to the Pandemic, we continue monitor the situation, including COVID-19 variants, for potential effects on our or our partners' clinical trials or delays or disruptions in activities with the FDA.

Although, we have taken measures to help minimize the potential impact of the Pandemic on our business, given the fluidity of the Pandemic and other macroeconomic factors, we are unable to estimate the impact the Pandemic has had on our operations or cash flows as of the date of this filing. We also believe there continues to be uncertainty around the timing and duration of any potential future disruptions due to the COVID-19 variants and the magnitude of any potential impact. As a result, we are unable to estimate the potential impact on future operations or cash flows as of the date of this filing. For more information on these risks see "Part I — Item 1A. Risk Factors — *We face uncertainty and risks related to the outbreak of the novel coronavirus disease, COVID-19, which could significantly disrupt our operations and may materially and adversely impact our business and financial conditions.*"

Results of Operations

The following is a discussion and analysis of our financial results, cash flows, and liquidity and capital resources for the years ended December 31, 2021 and 2020. A discussion of changes in our financial results, cash flow comparison and liquidity and capital resources for the years ended December 31, 2020 and 2019 has been omitted from this Form 10-K but may be found in Item 7 of Part II of our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 2, 2021.

Revenue, Net

We generate revenue from proprietary and partnered product sales, license and development activities and royalty arrangements. The following table provides details about the components and drivers of our overall revenue growth:

(in thousands)	Years Ended December 31,		Increased / (Decreased)	
	2021	2020	\$	%
Proprietary product sales, net	\$ 80,016	\$ 62,878	\$ 17,138	27.3 %
Partnered product sales	46,651	50,956	(4,305)	(8.4)%
Total product revenue, net	126,667	113,834	12,833	11.3 %
Licensing and development revenue	19,623	14,466	5,157	35.6 %
Royalties	37,692	21,299	16,393	77.0 %
Total revenue, net	\$ 183,982	\$ 149,599	\$ 34,383	23.0 %

Product Revenue, Net

Net revenue from product sales increased 11.3% primarily due to increased sales of our proprietary products XYOSTED® and NOCDURNA® and partnered sales of OTREXUP® to Otter subsequent to sale of the product line, partially offset by a reduction in sumatriptan sales to Teva and sales of Makena® subcutaneous auto-injectors to Covis.

Sales of our proprietary products are presented net of estimated product returns and sales allowances. The OTREXUP[®] product line was sold to Otter in December 2021 with a supply agreement executed simultaneously; therefore, all revenue generated prior to the date of sale is included in proprietary product sales and all revenue generated subsequent to the date of sale is included in partnered products sales. The increase in propriety product sales of 27.3% was primarily attributable to continued growth in prescriptions and sales of XYOSTED[®], which we launched for commercial sale in 2018, and sales of NOCDURNA[®], which we in-licensed and began detailing in the fourth quarter of 2020, partially offset by a reduction in sales of OTREXUP[®] due to the sale of the product line to Otter in December 2021. We attribute this growth to successful marketing and launch strategies, achieving and maintaining targeted reimbursement coverage, and our ability to leverage our virtual sales capabilities to support the continued growth despite any potential softening or impact due to the global Pandemic in 2021 and 2020.

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We also manufacture and sell devices, components and fully assembled packaged product to our partners Teva, Covis and Otter. Partnered product sales decreased by 8.4% due to a decrease in sumatriptan sales to Teva, lower production and sales volumes of Makena® to Covis and a decrease in shipments of epinephrine auto injectors to Teva, partially offset by revenue generated from production of OTREXUP® for Otter and higher teriparatide sales to Teva.

Licensing and Development Revenue

Licensing and development revenues include license fees received from partners for the right to use our intellectual property and amounts earned in joint development arrangements with partners under which we perform development activities or develop new products on their behalf. Fluctuations in our licensing and development revenue are generally attributable to the development timelines of our various partnered development projects, the timing of which is often controlled by our partner, and the timing of achievement of certain milestones.

Licensing and development revenue increased 35.6% primarily as a result of incremental development and maintenance activities with Teva to support replacement of molds and tooling related to the commercial production of the epinephrine auto injector and continuing development activities under other ongoing partnered development projects, partially offset by a decline in development activities with Pfizer.

Royalties

Royalties are earned in connection with licenses granted to our partners under license and development arrangements. Royalties are generally based upon a percentage of our partners' net sales of the partnered product. Royalty revenue increased 77.0% primarily due to an increase in royalties from Teva on its net sales of generic EpiPens®.

Cost of Revenue

The following table summarizes our cost of product sales and development revenue:

(in thousands)	Years Ended December 31,		Increased / (Decreased)	
	2021	2020	\$	%
Cost of product sales	\$ 54,418	\$ 53,960	\$ 458	0.8 %
Cost of development revenue	13,863	9,140	4,723	51.7 %
Total cost of revenue	\$ 68,281	\$ 63,100	\$ 5,181	8.2 %
% of revenue	37.1 %	42.2 %		

Fluctuations in cost of product sales is generally a function of the product revenue mix. Proprietary products generally have a lower cost of sales as a percentage of revenue than partnered product sales. The year-over-year increase in cost of development revenue is attributable to and relatively consistent with the growth in development revenue from partnered development activities.

Research and Development Expenses

Research and development ("R&D") expenses consist of external costs for clinical studies and analysis activities, formulation development, engineering design work and prototype development, FDA application fees, personnel costs and other general operating expenses associated with our research and development activities.

(in thousands)	Years Ended December 31,		Increased / (Decreased)	
	2021	2020	\$	%
Research and development	\$ 14,502	\$ 10,121	\$ 4,381	43.3 %

R&D expenses increased 43.3% primarily due to our ongoing internal development programs including ATRS-1902 and ATRS-1901, along with higher employee compensation expense. Overall, R&D expense fluctuates based on phases of development and timing of clinical studies, including internal and external development costs incurred. As discussed above, we further advanced our ATRS-1902 development program with positive result from a Phase 1 clinical study for adrenal crisis rescue in January 2022 and were granted Fast Track designation by the FDA. The results support the advancement of our ATRS-1902 development program to a pivotal clinical study which we anticipate starting in the second quarter of 2022.

Selling, General and Administrative

(in thousands)	Years Ended December 31,		Increased / (Decreased)	
	2021	2020	\$	%
Selling, general and administrative	\$ 73,857	\$ 62,759	\$ 11,098	17.7 %

Selling, general and administrative expenses increased 17.7% primarily due to higher sales and marketing costs associated with the relaunch of NOCDURNA[®], which we in-licensed and began detailing in the fourth quarter of 2020. The increase is also attributable to higher sales and marketing costs associated with XYOSTED[®], which were down in 2020 due to the Pandemic as the various restrictions and limitations imposed during the Pandemic led to decreased spending that has returned to pre-Pandemic levels, along with higher employee compensation. General and administrative expenses also increased primarily driven by higher professional service fees, facility costs, insurance expense and employee compensation costs to support the continued growth of the business.

Gain on Sale

In December 2021, we sold certain assets used in the operation of the OTREXUP[®] product to Otter for \$44.0 million, subject to finalization of changes in closing inventory to be transferred, with \$18.0 million received at closing and an additional \$26.0 million to be paid in installments over a one-year period. The gain on sale of assets of \$38.6 million represents the purchase price adjusted for estimated changes in closing inventory to be transferred less net book value of the assets sold and direct transaction costs.

Income Tax Expense (Benefit)

(in thousands)	Years Ended December 31,		Increased / (Decreased)	
	2021	2020	\$	%
Income tax provision (benefit)	\$ 15,982	\$ (46,280)	\$ 62,262	134.5 %
Effective tax rate	25.7 %	(466.5)%		

Income tax expense recorded for the year ended December 31, 2021 was driven by the generation of income before income taxes of \$62.3 million, resulting in an effective tax rate of 25.7%. The effective tax rate is primarily driven by the federal and state tax rates, along with discrete income tax items for compensation expense. For the year ended December 31, 2020, we recorded an income tax benefit of \$46.3 million on pre-tax income of \$9.9 million primarily due to the release of our valuation allowance on our deferred tax assets which favorably impacted our effective tax rate. As of December 31, 2020, we concluded that, as a result of generating pre-tax earnings, utilization of net operating loss carryovers and future projected pre-tax earnings, it is more likely than not that its deferred taxes are realizable and may be utilized to offset future tax liabilities. Excluding the release of our valuation allowance on our deferred tax assets, the effective tax rate for the year ended December 31, 2020 would have been higher than the effective tax rate for the year ended December 31, 2021 primarily due to the impact of permanent tax items on a lower income before income taxes.

Net Income and Earnings Per Common Share

(in thousands, except per share amounts)	Years Ended December 31,		Increased / (Decreased)	
	2021	2020	\$	%
Net income	\$ 46,289	\$ 56,201	\$ (9,912)	(17.6)%
Earnings per common share				
Basic	\$ 0.27	\$ 0.34	\$ (0.07)	(20.6)%
Diluted	\$ 0.26	\$ 0.33	\$ (0.07)	(21.2)%

Liquidity and Capital Resources

As of December 31, 2021 we had cash and cash equivalents of \$65.9 million. We believe that the combination of our current cash and cash equivalents, along with our projected product sales, development revenue and royalties will provide us with sufficient funds to meet our obligations, including debt maturities, and support operations through at least the first quarter of 2023. We reported net income and positive cash flows from operations for the years ended December 31, 2021 and 2020. We had an accumulated deficit as of December 31, 2021 of \$176.3 million. Prior to 2020, we had not historically generated enough operating cash flow to support our operations and funded our operations through equity offerings and debt issuance.

If additional capital is needed to support our operations in the future, we may need to raise additional funds through financing, such as drawing our current credit facility, issuance of additional debt, equity or notes convertible into our common stock. However, we may be unable to obtain such financing, or obtain it on favorable terms, in which case we may be required to curtail development of new products, limit expansion of operations or accept financing terms that are not as attractive as we may desire.

Long-term Debt Financing

As of December 31, 2020, we were party to a loan and security agreement, as amended, with Hercules Capital, Inc. (the “Term Loan”). The amortizing Term Loan was secured by substantially all of our assets, excluding intellectual property, and accrued interest at a prime-based variable rate with a maximum of 9.5%, which was 8.5% in 2021. In 2021, we made principal prepayments of \$20.0 million and paid a 1.0% prepayment fee. On November 1, 2021, we extinguished the Loan Agreement with Hercules Capital, Inc. and repaid the outstanding \$20.0 million principal on the Term Loan, along with a 1.0% prepayment fee and the end of term charge of \$1.7 million. All remaining unamortized debt issuance costs associated with the Term Loan were immediately amortized to interest expense.

On November 1, 2021, we entered into a Credit Agreement (the “Credit Agreement”) with Wells Fargo Bank, National Association, as administrative agent for the lenders, for credit facilities in an aggregate principal amount of up to \$40.0 million with a maturity date of November 1, 2024. The Credit Agreement consists of a \$20.0 million term loan facility (the “Term Loan Facility”) and a \$20.0 million revolving credit facility (the “Revolving Credit Facility”), (collectively the “Credit Facilities”), which are secured by substantially all of our assets. The Term Loan Facility was funded upon execution of the Credit Agreement with the proceeds used to repay our \$20.0 million Term Loan with Hercules Capital, Inc. and to pay fees and expenses incurred in connection with the early repayment.

Total interest-bearing debt as of December 31, 2021 was \$20.0 million and we had \$20.0 million of unused borrowing capacity on our Revolving Credit Facility, which is expected to be used for ongoing working capital requirements and other general corporate purposes as needed. Commitment fees are payable on the unused portion of the Revolving Credit Facility at rates between 0.30% and 0.45% based on our Consolidated Total Leverage Ratio, as defined in the Credit Agreement, remeasured quarterly. Payments under the Term Loan Facility are due in consecutive quarterly installments on the last business day of each of March, June, September and December, commencing on March 31, 2022. At our election, interest accrues at LIBOR plus the applicable margin ranging from 2.25% to 3.00%, which varies based on our Consolidated Total Leverage Ratio. The new Credit Facilities, which replaced the previous Term Loan, are expected to provide approximately \$1.2 million in annual interest expense savings based on an interest rate of approximately 2.60% (one-month LIBOR rate plus the applicable margin of 2.50%) as of December 31, 2021.

Under the Credit Agreement, we are subject to customary affirmative and negative covenants, including, among others, restrictions on our ability to incur debt; create liens; make investments; merge, consolidate or dispose of assets or subsidiaries; enter into transactions with affiliates; modify accounting practices, our year end and organizational documents; pledge assets; revise nature of business; perform sale leasebacks; and enter into any restrictive agreements and customary events of default (including payment defaults, covenant defaults, change of control defaults and bankruptcy defaults). The Credit Agreement also contains financial covenants, including the ratio of consolidated total indebtedness to consolidated earnings before income, taxes, depreciation and amortization (“Consolidated EBITDA”) (“Consolidated Total Leverage Ratio”), as defined in the Credit Agreement” and the ratio of consolidated

senior secured indebtedness to Consolidated EBITDA (“Consolidated Senior Secured Leverage Ratio”), as well as the ratio of Adjusted EBITDA to consolidated fixed charges (“Consolidated Fixed Charge Coverage Ratio”), as defined in the Credit Agreement. These covenants restrict our ability to purchase outstanding shares of our common stock. As of December 31, 2021, we were in compliance with all affirmative, negative and financial covenants.

See Note 8 to the Consolidated Financial Statements included in Item 8 of Part II of this Annual Report on Form 10-K for additional information on our financing arrangements.

Cash Flow Comparisons

The following table summarizes our cash flows:

(in thousands)	Years Ended December 31,	
	2021	2020
Total cash provided by (used in):		
Operating activities	\$ 36,619	\$ 21,320
Investing activities	(3,852)	8,167
Financing activities	(19,990)	447
Effect of exchange rate changes on cash	(1)	2
Increase (decrease) in cash and cash equivalents	12,776	29,936
Cash and cash equivalents, beginning of period	53,137	23,201
Cash and cash equivalents, end of period	\$ 65,913	\$ 53,137

Operating Activities

Operating cash inflows are generated primarily from net product sales, license and development fees and royalties. Operating cash outflows consist principally of expenditures for manufacturing costs, personnel costs, general and administrative expenses, research and development activities, and sales and marketing costs. Fluctuations in cash from operating activities are primarily a result of the timing of cash receipts and disbursements.

The change in the net cash from operating activities was primarily a result of the increase in our net income, excluding non-cash activity, and changes in operating assets and liabilities due to timing of cash receipts and cash disbursements, principally driven by depletion of inventory and an increase in accrued liabilities, partially offset by an increase in accounts receivable and deferred revenue.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2021 was attributable to the purchase of TLANDO® intangible product rights for \$11.3 million, capital expenditures of \$6.7 million, an additional NOCDURNA® intangible product rights contractual payment of \$2.5 million and investment security purchases of \$1.2 million, partially offset by net proceeds of \$17.8 from the sale of the OTREXUP® product line. Net cash provided by investing activities for the year ended December 31, 2020 was attributable to \$22.5 million proceeds from maturities of short-term investments, partially offset by capital expenditures of \$9.6 million primarily for our manufacturing facility and the purchase of NOCDURNA® intangible product rights for \$5.0 million.

Financing Activities

Net cash used in financing activities for the year ended December 31, 2021 consisted of \$40.0 million in principal payments on the extinguishment of our Term Loan with Hercules Capital, Inc., \$2.8 million paid to taxing authorities in connection with net-share settled share-based awards for which we withheld shares equivalent to the value of the employee's tax obligation for the applicable income and other employment taxes, \$2.1 million in prepayment fees and an end of term charge on our Term Loan and \$0.3 million in debt issuance costs, partially offset by \$20.0 million in proceeds from the issuance of our new Term Loan Facility with Wells Fargo and \$5.2 million in proceeds received from exercises of stock options. Net cash provided by financing activities for the year ended December 31, 2020 included \$1.8 million in proceeds from the exercise of stock options, partially offset by \$1.4 million paid to taxing authorities in

connection with net-share settled stock-based awards for which we withheld shares equivalent to the value of the employees' tax obligation for the applicable income and other employment taxes.

Contractual Obligations

As of December 31, 2021, our contractual obligations are as follows:

(in thousands)	Payments Due by Period				
	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Long-term debt obligations ¹	\$ 20,000	\$ 1,500	\$ 18,500	\$ —	\$ —
Interest payable on long-term debt ²	1,350	512	838	—	—
Unused revolving line of credit fee ³	201	71	130	—	—
Operating lease obligations ⁴	8,012	1,334	1,731	1,354	3,593
Purchase commitments ⁵	31,312	31,312	—	—	—
Total	\$ 60,875	\$ 34,729	\$ 21,199	\$ 1,354	\$ 3,593

¹ Long-term debt includes principal installment payments on our Term Loan. Refer to Note 8 to the Consolidated Financial Statements included in Item 8 of Part II of this Annual Report on Form 10-K for additional information regarding our financing arrangements.

² Calculated using the variable interest rate as of December 31, 2021 based on LIBOR plus required spread on our Term Loan. Refer to Note 8 to the Consolidated Financial Statements included in Item 8 of Part II of this Annual Report on Form 10-K for additional information regarding our financing arrangements.

³ Calculated using the commitment fee rate as of December 31, 2021 based on our consolidated total leverage ratio assuming the entire revolving line of credit remains undrawn for the duration of the agreement. Refer to Note 8 to the Consolidated Financial Statements included in Item 8 of Part II of this Annual Report on Form 10-K for additional information regarding our financing arrangements.

⁴ Operating leases are primarily for office space, as well as vehicles and equipment. Refer to Note 5 to the Consolidated Financial Statements included in Item 8 of Part II of this Annual Report on Form 10-K for additional lease information.

⁵ Purchase commitments include open purchase orders with suppliers and inventory to be purchased in accordance with the TLANDO[®] exclusive license agreement entered into with Lipocine in October 2021. Refer to Note 6 to the Consolidated Financial Statements included in Item 8 of Part II of this Annual Report on Form 10-K for additional information on the agreement.

Off Balance Sheet Arrangements

As of December 31, 2021, we did not have any off-balance sheet arrangements, including any arrangements with any structured finance, special purpose or variable interest entities.

Critical Accounting Policies and Use of Estimates

The preceding discussion and analysis of our results of operations and financial condition is based upon our Consolidated Financial Statements. Our Consolidated Financial Statements have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”), which require us to make estimates and assumptions in certain circumstances that, giving due consideration to materiality, affect the reported amounts of assets and liabilities, revenues and expenses and related disclosures as of the date of the financial statements. We regularly review our estimates and assumptions, which are based on historical experience and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the

carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from our estimates, and significant variances could materially impact our financial condition and results of operations under different assumptions or conditions.

We believe that of our significant accounting policies, the following are particularly important to the portrayal of our results of operations and financial position and is subject to an inherent degree of uncertainty as it may require the application of a higher level of subjectivity and judgment by us. Our significant accounting policies are fully described in Note 2 to the Consolidated Financial Statements included in Item 8 of Part II of this Annual Report on Form 10-K.

Revenue Recognition (Variable Consideration)

We generate revenue from proprietary and partnered product sales, license and development activities and royalty arrangements. Revenue is recognized when or as we transfer control of the promised goods or services to our customers in an amount that reflects the consideration to which we expect to be entitled to in exchange for those goods or services.

We enter into contracts with partners that often contain multiple elements such as licensing, development, manufacturing and commercialization components. These arrangements are often complex, and we may receive various types of consideration over the life of the arrangement, including: up-front fees, reimbursements for research and development services, milestone payments, payments on product shipments, margin sharing arrangements, license fees and royalties.

In assessing our revenue arrangements, we must identify the contract, determine the transaction price including an estimation of any variable consideration we expect to receive in connection with the contract, identify the promises of goods or services to the customer and each distinct performance obligation, allocate the transaction price to each of the performance obligations, and recognize revenue when or as the performance obligations are satisfied. Each of these steps in the revenue recognition process requires management to make judgements and/or estimates. The most significant judgements and estimates involve the determination of variable consideration to be included in the transaction price, such as the estimation of product returns and sales allowances in connection with the sale of our proprietary products.

Variable consideration is recognized at an amount we believe is not subject to significant reversal and is adjusted at each reporting period if the most likely amount of expected consideration changes or becomes fixed. For example, we must estimate future product returns and sales allowances at the time of sales to distributors. The expected value is determined based on unit sales data, customer purchasing patterns, product expiration dates and levels of inventory in the distribution channel, contractual terms with customers and third-party payers, historical and expected utilization rates, and any new or anticipated changes in programs or regulations. We believe this provides a reasonable basis for recognizing revenue, however, actual results could differ from estimates and significant changes in estimates could impact our results of operations in future periods.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Foreign Currency Exchange Risk

We are exposed to foreign exchange rate fluctuations of the Swiss Franc to the U.S. dollar as the financial position and operating results of our subsidiaries in Switzerland are translated into U.S. dollars for consolidation. Our exposure to foreign exchange rate fluctuations also arises from transferring funds to our Swiss subsidiaries in Swiss Francs. In addition, we have exposure to exchange rate fluctuations between the Euro and the U.S. dollar for some of our transactions. We do not currently use derivative financial instruments to hedge against exchange rate risk. The effect of foreign exchange rate fluctuations on our financial results for the year ended December 31, 2021 was not material. In addition, a hypothetical 10% appreciation or depreciation in foreign currencies against the U.S. dollar, assuming all other variables are held constant, would not have a material impact on our financial position or operating results for the year ended December 31, 2021.

Interest Rate Risk

We are directly exposed to changes in market interest rates on our long-term debt as our secured floating rate credit facility requires interest payments to be calculated at a floating rate tied in part to LIBOR or, if LIBOR is no longer available, at a replacement rate as defined within the Credit Facility Agreement. As a result, changes in the floating interest rate can affect our operating results and liquidity. As of December 31, 2021, we had floating interest rate debt of \$20.0 million outstanding carrying a floating interest rate of approximately 2.60% (one-month LIBOR rate plus the applicable margin of 2.50%). A hypothetical increase of 1 percentage point in

floating interest rate, assuming principal payments in accordance with the Credit Facility Agreement and all other variables held constant, would result in \$0.2 million increase in future annual interest expense.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

**ANTARES PHARMA, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

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Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Antares Pharma, Inc.:

Opinions on the Consolidated Financial Statements and Internal Control Over Financial Reporting

We have audited the accompanying consolidated balance sheets of Antares Pharma, Inc. and subsidiaries (the Company) as of December 31, 2021 and 2020, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2021, and the related notes (collectively, the consolidated financial statements). We also have audited the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2021, in conformity with U.S. generally accepted accounting principles. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021 based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, 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 consolidated financial statements and an opinion on the Company's internal control over financial reporting 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 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 consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated 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 consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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.

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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.

Critical Audit Matter

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

Government and insurance plan rebate reserves

As discussed in Note 2 to the consolidated financial statements, the Company records estimated reserves for rebates and chargebacks, which includes government and insurance plan rebate reserves. As of December 31, 2021, the reserve for rebates and chargebacks was \$13,301 thousand. The estimated reserves for government and insurance plan rebates are recorded as a reduction to product revenue in the same period that the related revenue is recognized and the reserves are included within current liabilities in the consolidated balance sheets. The government and insurance plan rebate reserves are estimated based on unit sales data, contractual terms with third-party payers, historical and estimated future percentages of rebates incurred on sales, historical and estimated future insurance plan billings, any new or anticipated changes in programs or regulations that would impact the amount of the actual rebates to be paid, and levels of inventory in the distribution channel.

We identified the evaluation of certain government and insurance plan rebate reserves as a critical audit matter. Subjective and challenging auditor judgment was required to evaluate the estimated future percentages of rebates incurred on sales for government plan rebates and the estimated future insurance plan billings for insurance plan rebates due to the unpredictability of those future amounts and the length of time between when the sale occurred and when the rebates are paid to the administrator of the programs.

The following are the primary procedures we performed to address this critical audit matter. We evaluated the design and tested the operating effectiveness of certain internal controls related to the Company's government and insurance plan rebate reserves processes. This included controls related to management's process to develop the estimated future percentages of rebates incurred on sales and the estimated future insurance plan billings. We tested the historical rebates incurred on sales and insurance plan billings, which are used in the determination of estimated future percentages of rebates incurred on sales and insurance plan billings respectively, by comparing samples of the historical rebates incurred on sales and insurance plan billings to underlying invoices and evidence of the cash disbursement. For both government and insurance plan rebate reserves, we assessed management's estimate by evaluating the consistency of the inputs with the trend of actual historical percentages of rebates incurred on sales and insurance plan billings. For the insurance plan rebate reserve, we evaluated management's estimate by comparing insurance plan billings received after period end to the estimated insurance plan billings recorded at year-end. For the government plan rebate reserve, we performed sensitivity analyses over the estimated future percentages of rebates incurred on sales using historical information to assess the impact of changes in those assumptions on management's estimate. We evaluated the Company's ability to estimate government and insurance plan rebate reserves accurately by comparing actual amounts paid for the related rebates to historical estimates.

/s/ KPMG LLP

We have served as the Company's auditor since 1995.

Minneapolis, Minnesota

March 3, 2022

ANTARES PHARMA, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except per share amounts)

	December 31, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	\$ 65,913	\$ 53,137
Short-term investments	1,245	—
Accounts receivable, net	56,697	42,221
Other receivables	26,311	—
Inventories, net	11,544	18,216
Contract assets	8,030	8,140
Prepaid expenses and other current assets	4,532	4,877
Total current assets	174,272	126,591
Deferred tax assets, net	33,043	46,982
Property and equipment, net	26,015	24,020
Operating lease right-of-use assets	3,774	4,621
Intangibles, net	17,879	7,693
Goodwill	1,095	1,095
Other long-term assets	1,427	1,529
Total assets	\$ 257,505	\$ 212,531
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 17,056	\$ 16,194
Accrued expenses and other liabilities	35,043	25,635
Current maturities of long-term debt, net	1,500	16,230
Operating lease liabilities, current	904	1,203
Deferred revenue	4,427	3,943
Total current liabilities	58,930	63,205
Long-term debt, less current maturities	18,241	24,669
Operating lease liabilities, long-term	4,576	4,816
Other long-term liabilities	—	726
Total liabilities	81,747	93,416
Commitments and contingencies (Note 16)		
Stockholders' Equity		
Preferred Stock: \$0.01 par; 3,000 shares authorized, none outstanding	—	—
Common Stock: \$0.01 par; 300,000 shares authorized; 170,072 and 166,836 issued and outstanding as of December 31, 2021 and December 31, 2020, respectively	1,701	1,668
Additional paid-in capital	351,079	340,756
Accumulated deficit	(176,337)	(222,626)
Accumulated other comprehensive loss	(685)	(683)
Total stockholders' equity	175,758	119,115
Total liabilities and stockholders' equity	\$ 257,505	\$ 212,531

The accompanying Notes to Consolidated Financial Statements are an integral part of these consolidated financial statements.

ANTARES PHARMA, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

	Years Ended December 31,		
	2021	2020	2019
Revenue			
Product sales, net	\$ 126,667	\$ 113,834	\$ 92,103
Licensing and development revenue	19,623	14,466	7,529
Royalties	37,692	21,299	24,232
Total revenue, net	183,982	149,599	123,864
Operating expenses			
Cost of product sales	54,418	53,960	46,267
Cost of development revenue	13,863	9,140	4,208
Research and development	14,502	10,121	10,624
Selling, general and administrative	73,857	62,759	61,773
Total operating expenses	156,640	135,980	122,872
Gain on sale of assets	38,591	—	—
Operating income	65,933	13,619	992
Other income (expense)			
Interest expense	(3,611)	(3,787)	(3,549)
Other income (expense), net	(51)	89	530
Total other expense, net	(3,662)	(3,698)	(3,019)
Income (loss) before income taxes	62,271	9,921	(2,027)
Income tax provision (benefit)	15,982	(46,280)	—
Net income (loss)	\$ 46,289	\$ 56,201	\$ (2,027)
Earnings (loss) per common share			
Basic	\$ 0.27	\$ 0.34	\$ (0.01)
Diluted	\$ 0.26	\$ 0.33	\$ (0.01)
Weighted average common shares outstanding			
Basic	169,226	166,066	162,574
Diluted	174,733	170,155	162,574

The accompanying Notes to Consolidated Financial Statements are an integral part of these Consolidated Financial Statements.

ANTARES PHARMA, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(in thousands)

	Years Ended December 31,		
	2021	2020	2019
Net income (loss)	\$ 46,289	\$ 56,201	\$ (2,027)
Foreign currency translation adjustment	(2)	19	1
Comprehensive income (loss)	<u>\$ 46,287</u>	<u>\$ 56,220</u>	<u>\$ (2,026)</u>

The accompanying Notes to Consolidated Financial Statements are an integral part of these Consolidated Financial Statements.

ANTARES PHARMA, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands)

	<u>Common Stock</u>					Accumulated	
	Number		Additional	Accumulated	Other	Total	
	of	Amount	Paid-In	Deficit	Comprehensive	Stockholders'	
	Shares		Capital		Income (Loss)	Equity	
Balance, December 31, 2018	159,721	\$ 1,597	\$ 314,907	\$ (276,800)	\$ (703)	\$ 39,001	
Issuance of common stock	2,307	23	7,758	—	—	7,781	
Common stock issued under equity compensation plan, net of shares withheld for taxes	664	7	(1,138)	—	—	(1,131)	
Exercise of options	2,529	25	4,380	—	—	4,405	
Share-based compensation	—	—	6,470	—	—	6,470	
Net loss	—	—	—	(2,027)	—	(2,027)	
Other comprehensive income	—	—	—	—	1	1	
Balance, December 31, 2019	165,221	1,652	332,377	(278,827)	(702)	54,500	
Common stock issued under equity compensation plan, net of shares withheld for taxes	676	7	(1,374)	—	—	(1,367)	
Exercise of options	939	9	1,805	—	—	1,814	
Share-based compensation	—	—	7,948	—	—	7,948	
Net income	—	—	—	56,201	—	56,201	
Other comprehensive income	—	—	—	—	19	19	
Balance, December 31, 2020	166,836	1,668	340,756	(222,626)	(683)	119,115	
Common stock issued under equity compensation plan, net of shares withheld for taxes	942	10	(2,851)	—	—	(2,841)	
Exercise of options	2,294	23	5,159	—	—	5,182	
Share-based compensation	—	—	8,015	—	—	8,015	
Net income	—	—	—	46,289	—	46,289	
Other comprehensive loss	—	—	—	—	(2)	(2)	
Balance, December 31, 2021	170,072	\$ 1,701	\$ 351,079	\$ (176,337)	\$ (685)	\$ 175,758	

The accompanying Notes to Consolidated Financial Statements are an integral part of these Consolidated Financial Statements.

ANTARES PHARMA, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Years Ended December 31,		
	2021	2020	2019
Cash Flows from Operating Activities			
Net income (loss)	\$ 46,289	\$ 56,201	\$ (2,027)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Deferred taxes	13,939	(47,203)	(371)
Stock-based compensation	8,015	7,948	6,470
Depreciation and amortization	3,901	2,627	2,557
Non-cash interest expense	648	504	405
Increase in inventory reserve	152	511	325
Gain on sale of assets	(38,591)	—	—
Other	671	42	12
Changes in operating assets and liabilities:			
Accounts receivable	(14,476)	(7,128)	(16,095)
Inventories, net	2,748	(2,728)	(4,975)
Contract assets	110	53	(2,793)
Prepaid expenses and other current assets	(1,056)	(1,460)	(655)
Accounts payable	2,189	2,594	926
Accrued expenses and other liabilities	11,596	7,157	4,888
Deferred revenue	484	2,202	718
Net cash provided by (used in) operating activities	36,619	21,320	(10,615)
Cash Flows from Investing Activities			
Purchases of property and equipment	(6,617)	(9,615)	(2,350)
Proceeds from sale of assets, net of transaction costs	17,825	282	5,000
Purchase of intangibles, including transaction costs	(13,815)	(5,000)	—
Purchases of investment securities	(1,245)	—	(22,645)
Proceeds from maturities of investment securities	—	22,500	—
Net cash provided by (used in) investing activities	(3,852)	8,167	(19,995)
Cash Flows from Financing Activities			
Proceeds from issuance of long-term debt	20,000	—	15,000
Principal payments of long-term debt	(40,000)	—	—
Prepayment fees and end of term charge on long-term debt	(2,055)	—	—
Payment of debt issuance costs for long-term debt	(276)	—	(136)
Proceeds from issuance of common stock, net	—	—	7,781
Proceeds from exercise of stock options	5,182	1,814	4,405
Taxes paid related to net share settlement of equity awards	(2,841)	(1,367)	(1,131)
Net cash provided by (used in) financing activities	(19,990)	447	25,919
Effect of exchange rate changes on cash and cash equivalents	(1)	2	—
Cash and cash equivalents			
Net increase (decrease) during the period	12,776	29,936	(4,691)
Beginning of period	53,137	23,201	27,892
End of period	\$ 65,913	\$ 53,137	\$ 23,201

The accompanying Notes to Consolidated Financial Statements are an integral part of these Consolidated Financial Statements.

ANTARES PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(in thousands, except per share amounts)

Note 1. Description of Business

Antares Pharma, Inc. (“Antares,” “we,” “our,” “us” or the “Company”) is a specialty pharmaceutical company focused primarily on the development and commercialization of pharmaceutical products and technologies in targeted therapeutic areas. We develop, manufacture and commercialize, for ourselves or with partners, novel therapeutic products using our advanced drug delivery systems that are designed to provide commercial or functional advantages, such as improved safety and efficacy, convenience, improved tolerability, and enhanced patient comfort and adherence. We also seek product opportunities that complement and leverage our commercial platform. We have a portfolio of proprietary and partnered commercial products and ongoing product development programs in various stages of development. We have formed partnership arrangements with several different industry leading pharmaceutical companies.

Our marketed proprietary products include:

- XYOSTED® (testosterone enanthate) injection, indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone, and is the first and only subcutaneous testosterone enanthate product for once-weekly, at-home self-administration to be approved by the U.S. Food and Drug Administration (“FDA”);
- OTREXUP® (methotrexate) injection, indicated for adults with severe active rheumatoid arthritis, children with active polyarticular juvenile idiopathic arthritis and adults with severe recalcitrant psoriasis, which was sold to Otter Pharmaceuticals, LLC (a subsidiary of Assertio Holdings, Inc., together with Assertio Holdings, Inc., as guarantor, individually and collectively referred to as “Otter”) in December 2021 as discussed in Note 12; and
- NOCDURNA® (desmopressin acetate), marketed in the U.S. for the treatment of nocturia due to nocturnal polyuria (“NP”) in adults who awaken at least two times per night to urinate.

We are also party to various partnered product development and supply arrangements:

- We developed and are the exclusive supplier of devices for Teva Pharmaceutical Industries, Ltd.’ (“Teva”) Epinephrine Injection USP products, the generic equivalent of EpiPen® and EpiPen® Jr., indicated for emergency treatment of severe allergic reactions including those that are life threatening (anaphylaxis) in adults and certain pediatric patients;
- Through our commercialization partner Teva, we sell Sumatriptan Injection USP, a generic equivalent to the Imitrex® STATdose Pen®, in the U.S. indicated for the acute treatment of migraine headaches and cluster headache in adults;
- In collaboration with AMAG Pharmaceuticals, Inc. (“AMAG”), acquired by Covis Group S.a.r.l. (“CG”) (collectively CG and AMAG are herein after referred to as “Covis”) in November 2020, we developed a subcutaneous auto injector and are the exclusive supplier of devices and the final assembled and packaged commercial product of Makena® (hydroxyprogesterone caproate injection) subcutaneous auto injector, which is a ready-to-administer treatment indicated to reduce the risk of preterm birth in women pregnant with one baby and who spontaneously delivered at least one preterm baby in the past.

- We developed and are the exclusive supplier of devices for Teva's generic equivalent of Forsteo[®] (Teriparatide Injection) which is approved and currently sold by Teva in various countries outside the U.S.

Additionally, we are developing other devices in collaboration with various pharmaceutical partners and advancing other internal research and development programs.

We also have a proprietary product, TLANDO[®] (testosterone undecanoate) is a twice-day oral formulation of testosterone for TRT indicated for conditions associated with a deficiency or absence of endogenous testosterone, or hypogonadism in adult males, with tentative FDA approval.

ANTARES PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(in thousands, except per share amounts)

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements include the accounts of Antares Pharma, Inc. and its two wholly-owned foreign subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in accordance with U.S. generally accepted accounting principles (“GAAP”) requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the date of the financial statements and reported amounts of revenues and expenses during the reporting period. Our most significant accounting estimates relate to revenue recognition and variable consideration, inventory valuation, the carrying value of deferred tax assets and the valuation of equity instruments used in the computation of share-based compensation. Actual results could differ from these estimates, and significant variances could materially impact our financial condition and results of operations.

Reclassifications

Certain reclassifications have been made to prior year amounts to conform with the current year presentation. As of and for the year ended December 31, 2020, the cost of product sales and the cost of development revenue were classified under the heading *Operating expenses* in the Consolidated Statements of Operations, and the corresponding prior period amount was reclassified to conform to this presentation. The reclassifications had no impact on our operating income (loss), net income (loss) or cash flows as previously reported.

Accounting Pronouncements Recently Adopted

We adopted FASB ASU No. 2018-15, *Customers’ Accounting for Implementation Costs Incurred in Cloud Computing Arrangement that is a Service Contract*, effective January 1, 2020, which provides new guidance on a customer’s accounting for implementation, set-up, and other upfront costs incurred in a cloud computing arrangement that is hosted by the vendor (i.e., a service contract). Under the new guidance, entities apply the same criteria for capitalizing implementation costs as they would for an arrangement that has a software license. Adoption of this standard did not have a material impact on our financial condition, results of operations or disclosures.

We adopted FASB ASU No. 2018-18, *Clarifying the Interaction Between Topic 808 and 606*, effective January 1, 2020, which clarifies that certain transactions between collaborative arrangement participants should be accounted for under the revenue guidance, adds unit of account guidance to the collaborative arrangement guidance to align with the revenue standard, and clarifies presentation guidance for transactions with a collaborative arrangement participant that is not accounted for under the revenue standard. Adoption of this standard did not have a material impact on our financial condition, results of operations or disclosures.

Recently Issued Accounting Pronouncements Not Yet Adopted as December 31, 2021

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, followed by related amendments, which changes the accounting for credit losses on instruments measured at amortized cost by adding an impairment model that is based on expected losses rather than incurred losses. Any entity will recognize as an allowance its estimate of expected credit losses, which is believed to result in more timely recognition of such losses as the standard eliminates the probable initial recognition threshold. The new guidance is required to be adopted using a modified retrospective

approach with a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period of adoption. Adoption of the new guidance was originally required for annual periods beginning after December 15, 2019, including interim periods within the annual period.

ANTARES PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(in thousands, except per share amounts)

In October 2019, the FASB issued ASU 2019-10, *Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates*, which deferred the effective date of ASU 2016-13 for certain entities, including those that are eligible for smaller reporting company classification. Determination of eligibility for deferral was a one-time assessment as of November 15, 2019 based on the entity's most recent smaller reporting company eligibility determination as of the last business day of its most recently completed second quarter. Based on this determination, we qualified as a smaller reporting entity and was therefore eligible for the adoption deferral resulting in a new effective date of January 1, 2023. The impact on our financial condition, results of operations and disclosures is being evaluated but is not expected to be significant as we have historically had minimal credit losses on financial instruments.

In April 2020, the FASB issued ASU No. 2020-04, *Facilitation of the Effects of Reference Rate Reform on Financial Reporting*, which provides relief for companies preparing for discontinuation of interest rates such as LIBOR. The standard can be applied immediately through December 31, 2022. We have not yet evaluated the impact the adoption of this guidance may have on our financial condition, results of operations or disclosures.

Foreign Currency Translation

The majority of our foreign subsidiaries' revenues are denominated in U.S. dollars, and any required funding of the subsidiaries is provided by the U.S. parent. Nearly all operating expenses of our foreign subsidiaries are denominated in Swiss Francs. Additionally, bank accounts held by foreign subsidiaries are denominated in Swiss Francs, there is a low volume of intercompany transactions and there is not an extensive interrelationship between the operations of the subsidiaries and the parent company. As such, we have determined that the Swiss Franc is the functional currency for our foreign subsidiaries. Our reporting currency is the United States Dollar ("USD"). The financial statements of our foreign subsidiaries are translated into USD for consolidation purposes. All assets and liabilities are translated using period-end exchange rates. Statements of operations items are translated using average exchange rates for the period. The resulting translation adjustments are recorded as a separate component of stockholders' equity, comprising all of the accumulated other comprehensive income (loss). Sales to certain customers and purchases from certain vendors by the U.S. parent are in currencies other than USD and are subject to foreign currency exchange rate fluctuations. Foreign currency transaction gains and losses are included in other income (expense) in the Consolidated Statements of Operations.

Cash and Cash Equivalents

Cash and cash equivalents represent demand deposits at commercial banks and highly liquid investments with an original maturity of three months or less. Cash equivalents, consisting of investments in money market funds and bank certificate of deposits, are remeasured and reported at fair value each reporting period based on quoted market prices, which is a Level 1 input within the three-level valuation hierarchy for disclosure of fair value measurements, and totaled \$26,889 and \$36,133 as of December 31, 2021 and 2020, respectively.

Investments

From time to time, we also invest in bank certificates of deposit that are classified as held-to-maturity because of our intent and ability to hold securities to maturity. Investments with original maturities greater than three months but less than one year are classified as short-term investments on the Consolidated Balance Sheets. The investment securities are carried at their amortized cost and fair value is determined by quoted market prices for identical or similar securities. The carrying value of our short-term investments as of December 31, 2021 approximate fair value.

Fair Value Measurements

Financial assets and liabilities are required to be measured and reported at fair value each reporting period. Fair value is defined 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. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. When considering market participant assumptions in fair value measurement, the following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in one of the following levels.

- **Level 1:** Unadjusted quoted prices which are available in active markets for identical assets or liabilities accessible to us at the measurement date.

ANTARES PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(in thousands, except per share amounts)

- **Level 2:** Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- **Level 3:** Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The hierarchy gives the highest priority to Level 1, as this level provides the most reliable measure of fair value, while given the lowest priority to Level 3.

Financial assets and liabilities that are not measured at fair value on a recurring basis include held-to-maturity investments and long-term debt as the carrying values of which approximate fair value. The estimated fair value of debt is based on Level 2 inputs, including our understanding of current market rates we could obtain for similar loans. The fair value of our cash and cash equivalents, accounts receivable, other receivables, contract assets, accounts payable and accrued liabilities approximate fair value due to their short-term nature.

We measure certain financial instruments at fair value on a nonrecurring basis. These assets primarily include goodwill and intangible assets, as well as property and equipment and right-of-use lease assets. These assets were initially measured and recognized at amounts equal to the fair value determined as of the date of acquisition or purchase. Periodically, these assets are tested for impairment, by comparing their respective carrying values to the estimated fair value of the reporting unit or asset group in which they reside. In the event any of these assets were to become impaired, we would recognize an impairment loss equal to the amount by which the carrying value of the reporting unit, impaired asset or asset group exceeds its estimated fair value. Fair value measurement of the reporting unit associated with our goodwill balance is estimated at least annually in the fourth quarter of each calendar year for purposes of impairment testing if a quantitative analysis is performed. Fair value measurements associated with our intangible assets, other long-lived assets and property and equipment are estimated when events or changes in circumstances such as market value, asset utilization, physical change, legal factors or other matters indicate that the carrying value may not be recoverable.

Accounts Receivable

Trade accounts receivable represents amounts billed to customers and are stated at the amount we expect to collect. Customer creditworthiness, past transaction history with the customer and changes in customer payment terms are factors considered when determining collectability of specific customer accounts. As of December 31, 2021, our trade accounts receivable balance was due primarily from Teva and major wholesale distributors. Each of these customers have historically paid in a timely manner and demonstrated creditworthiness. Accordingly, we believe the risk of accounts being uncollectible is minimal and no significant allowances for doubtful accounts was established as of December 31, 2021 or 2020. If the financial condition of our customers were to deteriorate, adversely affecting their ability to make payments, additional allowances may be required. We had no material write-offs to bad debt expense in the years ended December 31, 2021, 2020 or 2019.

Royalties receivable from partners are included in accounts receivable and are typically payable to us within 45 to 60 days after the end of each quarter in which they were earned.

Inventories

Inventories are stated at the lower of cost or net realizable value with cost determined on a first-in, first-out basis. Certain components of our products are provided by a limited number of vendors, and our production, assembly, warehousing and distribution operations are outsourced to third-party suppliers where substantially all of our inventory is located. Disruption of supply from key vendors or third-party suppliers may have a material adverse impact on our operations and financial results.

We record reserves for potentially excess, dated or obsolete inventories based on forecasted product demand estimates and the likelihood of consumption in the normal course of business, considering the expiration dates of the inventories on hand, planned production volumes and lead times required for restocking of customer inventories. Although every effort is made to ensure that forecasts and assessments are reasonable, changes to these assumptions are possible. In such cases, estimates may prove inaccurate and result in an understatement or overstatement of the reserves required to fairly state such inventories.

ANTARES PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(in thousands, except per share amounts)

Contract Assets

Contract assets are recognized when control of goods or services has transferred to the customer, and corresponding revenue is recognized on an over time basis but is not yet billable to the customer in accordance with the terms of the contract. Costs that have been incurred in connection with development services provided to partners for which the associated revenue has not yet been recognized are also recorded as contract assets and totaled \$564 and \$1,685 as of December 31, 2021 and 2020, respectively.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation is computed using the straight-line method over an asset's estimated useful life as follows:

	Useful Life
Computer equipment and software	3-5 years
Furniture, fixtures and office equipment	5-7 years
Production molds, tooling and equipment	3-10 years
Leasehold improvements	Lesser of useful life or lease term

Expenditures, including interest costs, for assets under construction and internal-use software that are not yet ready for their intended use are capitalized and will be depreciated based on the above guidelines when placed in service. Costs associated with repairs and maintenance activities are expensed as incurred.

Leases

We recognize right-of-use ("ROU") assets and lease liabilities when we obtain the right to control the asset under a leasing arrangement with an initial term greater than twelve months. We evaluate the nature of each lease at the inception of an arrangement to determine whether it is an operating or financing lease and recognize the ROU asset and lease liability based on the present value of future minimum lease payments over the expected lease term. Our leases do not generally contain an implicit interest rate; therefore, we use the incremental borrowing rate we would expect to pay to borrow on a similar collateralized basis over a similar term in order to determine the present value of our lease payments. The incremental borrowing rate is used in determining the present value of lease payments, unless an implicit rate is specified. Certain lease arrangements contain renewal options that have not been included in the determination of the lease term, as they are not reasonably certain of exercise. For contracts that contain lease and non-lease components, we account for both components as a single lease component. Variable lease payments are expensed as incurred.

Intangible Assets

We capitalize and include the costs of acquired product licenses and trademark rights as intangible assets. These intangible assets with finite useful lives are presented net of accumulated amortization. Amortization is computed on a straight-line basis over the shorter of the contractual or estimated economic life of the underlying contract, which generally ranges from five to ten years.

Impairment of Long-Lived Assets and Intangible Assets

Long-lived assets and intangible assets are reviewed for impairment whenever events or changes in circumstances such as market value, asset utilization, physical change, legal factors or other matters indicate that the carrying value of an asset or asset group may not be

recoverable. The impairment test is based on a comparison of the undiscounted cash flows expected to be generated from the use of the asset or asset group and its eventual disposition to the carrying value of the asset. If impairment is indicated, the asset is written down by the amount by which the carrying value of the asset exceeds the related fair value of the asset with the related impairment charge recognized within the Consolidated Statement of Operations. The determination of an asset's fair value requires management to make certain estimates and judgements.

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Goodwill

Goodwill is evaluated for impairment annually as of December 31, or more frequently if an event occurs or circumstances change such as market value, asset utilization, legal factors or other matters that indicate the carrying value may not be recoverable. Evaluating goodwill for impairment involves the determination of the fair value of each reporting unit in which goodwill is recorded using a qualitative or quantitative analysis. A reporting unit is an operating segment or a component of an operating segment for which discrete financial information is available and reviewed by management on a regular basis.

As of December 31, 2021 and 2020, we have goodwill with a carrying value of \$1,095, attributable to our single reporting unit. Based on the results of our qualitative analysis, we determined that goodwill was not impaired, and no impairment loss was recognized in the years ended December 31, 2021, 2020, and 2019, respectively.

Revenue Recognition

We generate revenue from proprietary and partnered product sales, license and development activities and royalty arrangements. Revenue is recognized when or as we transfer control of the promised goods or services to the customer at the transaction price, which is the amount that reflects the consideration to which we expect to be entitled to in exchange for those goods or services.

At inception of each contract, we identify the goods and services that have been promised to the customer and each of those that represent a distinct performance obligation, determine the transaction price including any variable consideration, allocate the transaction price to the distinct performance obligations and determine whether control transfers to the customer at a point in time or over time. Variable consideration is included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. We reassess our reserves for variable consideration at each reporting date and make adjustments, if necessary, which may affect revenue and earnings in periods in which any such changes become known.

We have elected to recognize the cost for freight and shipping activities as a fulfillment cost. Amounts billed to customers for shipping and handling are included as part of the transaction price and recognized as revenue when control of underlying goods are transferred to the customer. The related shipping and freight charges incurred are included in cost of product sales in the Consolidated Statements of Operations.

Proprietary Product Sales

We sell our proprietary commercial products primarily to wholesale and specialty distributors. Revenue is recognized when control has transferred to the customer, which is typically upon delivery, at the net selling price, which reflects the variable consideration for which reserves and sales allowances are established for estimated returns, wholesale distribution fees, prompt payment discounts, government rebates and chargebacks, plan rebate arrangements and patient discount and support programs.

The determination of certain reserves and sales allowances requires us to make a number of judgements and estimates to reflect our best estimate of the transaction price and the amount of consideration to which we believe we would be ultimately entitled to receive. The expected value is determined based on unit sales data, contractual terms with customers and third-party payers, historical and estimated future percentage of rebates incurred on sales, historical and future insurance plan billings, any new or anticipated changes in programs or regulations that would impact the amount of the actual rebates, customer purchasing patterns, product expiration dates and levels of inventory in the distribution channel. Reserves for prompt payment discounts are recorded as a reduction in accounts receivable in the

Consolidated Balance Sheets. Reserves for returns, distributor fees, rebates and customer co-pay support programs are included within current liabilities in the Consolidated Balance Sheets.

Wholesaler Distribution Fees – Distribution fees are paid to certain wholesalers based on contractually determined rates and units purchased. Since the fee paid to the customer is not for a distinct good or service, the consideration is recognized as a reduction of the transaction price of the goods delivered. We accrue the estimated fee due at the time of sale based on the contracted price and adjust the accrual at each reporting period, if necessary, to reflect actual experience.

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Prompt Pay Discounts – We offer cash discounts to our customers, generally 2% of the sales price, as an incentive for prompt payment. Based on historical experience, customers take advantage of this discount and accordingly we accrue 100% of the cash discounts offered by reducing accounts receivable and recognizing the discount as a reduction of revenue in the same period the related sales are made. The accrual is reviewed at each reporting period and adjusted if actual experience differs from estimates.

Chargebacks – We provide discounts primarily to authorized users of the Federal Supply Schedule (“FSS”) of the General Services Administration under an FSS contract negotiated by the Department of Veterans Affairs and various organizations under Medicaid contracts and regulations. These entities purchase products from the wholesale distributors at a discounted price, and the wholesale distributors then charge us back the difference between the current wholesale acquisition cost and the price the entity paid for the product. We estimate and accrue chargebacks based on estimated wholesaler inventory levels, current contract prices and historical chargeback activity. Chargebacks are recognized as a reduction of revenue in the same period the related revenue is recognized.

Rebates – We participate in certain government and insurance plan rebate programs, which provide discounted prescriptions to qualified insured patients. Under these rebate programs, we pay a rebate to the third-party administrators of the programs. The rebate payments are generally made in periods subsequent to the quarter in which prescriptions subject to the rebate are filled, generally on a two- to three-month lag for insurance plan rebates and three- to six-month lag for government plan rebates. We estimate and accrue for these rebates based on unit sales data, contractual terms with third-party payers, historical and estimated future percentage of rebates incurred on sales, historical and future insurance plan billings, any new or anticipated changes in programs or regulations that would impact the amount of the actual rebates to be paid, and levels of inventory in the distribution channel. Rebates are recognized as a reduction of revenue in the same period the related revenue is recognized.

Patient Discount Programs – We offer discount cards, co-pay coupons and free trial programs to off-set the cost of prescriptions to patients. We estimate the total amount that will be redeemed or used based on historical redemption experience and on levels of inventory in the distribution and retail channels, and recognize the discount as a reduction of revenue in the same period the related revenue is recognized.

Product Returns – Consistent with industry practice, we generally offer wholesalers and specialty distributors a limited right to return products, generally within six months prior to and 12 months following the product’s expiration date. Our proprietary products generally have expiration dates ranging from 24 to 33 months. Product returns are estimated and recorded at the time of sale based on historical return patterns. Actual returns are tracked by individual production lots and charged against reserves. Returns reserves may be adjusted, if necessary, if actual returns differ from historical estimates. We also monitor and take into consideration the amount of estimated product inventory in the distribution channel, product dating and any known or expected changes in the marketplace when establishing the estimated rate of returns.

Changes in reserves for product returns and sales allowances are as follows:

	Rebates and Chargebacks	Patient Discount Programs	Returns	Wholesaler Distribution Fees	Prompt Payment Discounts
Balance as of December 31, 2019	\$ 6,308	\$ 845	\$ 370	\$ 1,683	\$ 320
Accruals and adjustments	34,947	12,422	2,657	11,619	2,494
Payments and other reserve reductions	(34,068)	(11,975)	(2,569)	(10,804)	(2,378)
Balance as of December 31, 2020	7,187	1,292	458	2,498	436
Accruals and adjustments	52,243	15,629	4,163	15,683	3,423
Payments and other reserve reductions	(46,129)	(13,971)	(3,992)	(14,498)	(3,222)
Balance as of December 31, 2021	<u>\$ 13,301</u>	<u>\$ 2,950</u>	<u>\$ 629</u>	<u>\$ 3,683</u>	<u>\$ 637</u>

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Partnered Product Sales

We are party to several license, development, supply and distribution arrangements with pharmaceutical partners, under which we produce and are the exclusive supplier of certain products, devices and/or components. Revenue is recognized when or as control of the goods transfers to the customer as discussed below.

We are the exclusive supplier of the Makena[®] subcutaneous auto injector product to Covis and beginning in December 2021, OTREXUP[®] to Otter. Because these products are custom manufactured for each customer with no alternative use and we have a contractual right to payment for performance completed to date, control is continuously transferred to the customer as the product is produced pursuant to firm purchase orders. Revenue is recognized over time using the output method based on the contractual selling price and number of units produced. The amount of revenue recognized in excess of the amount shipped/billed to the customer, if any, is recorded as contract assets in the Consolidated Balance Sheets due to the short-term nature in which the amount is ultimately expected to be billed and collected from the customer.

All other partnered product sales are recognized at the point in time in which control is transferred to the customer, which is typically upon shipment. Sales terms and pricing are governed by the respective supply and distribution agreements, and there is generally no right of return. Revenue is recognized at the transaction price, which includes the contractual per unit selling price and estimated variable consideration, such as volume-based pricing arrangements or profit-sharing arrangements, if any. We recognize revenue, including the estimated variable consideration we expect to receive for contract margin on future commercial sales, upon shipment of the goods to our partner. The estimated variable consideration is recognized at an amount we believe is not subject to significant reversal based on historical experience and is adjusted at each reporting period if the most likely amount of expected consideration changes or becomes fixed.

Licensing and Development Revenue

We have entered into several license, development and supply arrangements with pharmaceutical partners under which we grant a license to our device technology and know-how and provide research and development services that often involve multiple performance obligations and highly customized deliverables. For such arrangements, we identify each of the promised goods and services within the contract and the distinct performance obligations at inception and allocate consideration to each performance obligation based on relative standalone selling price, which is generally determined based on the expected cost plus mark-up.

If the contract includes an enforceable right to payment for performance completed to date and performance obligations are satisfied over time, we recognize revenue over the development period using either the input or output method depending on which is most appropriate given the nature of the distinct deliverable. For other contracts that do not contain an enforceable right to payment for performance completed to date, revenue is recognized when control is transferred to the customer. Factors that may indicate that the transfer of control has occurred include the transfer of legal title, transfer of physical possession, the customer has obtained the significant risks and rewards of ownership of the assets and we have a present right to payment.

Our typical payment terms for development contracts may include an upfront payment equal to a percentage of the total contract value with the remaining portion to be billed upon completion and transfer of the individual deliverables or satisfaction of the individual performance obligations. We record a liability for cash received in advance of performance, which is presented within deferred revenue in the Consolidated Balance Sheets and recognized as revenue when the associated performance obligations have been satisfied. We

recognized \$3,889 in licensing and development revenue in connection with contract liabilities that were outstanding as of December 31, 2020 and satisfied during the year ended December 31, 2021.

License fees and milestones received in exchange for the grant of a license to our functional intellectual property (“IP”) such as patented technology and know-how in connection with a partnered development arrangement are generally recognized at inception of the arrangement, or over the development period depending on the facts and circumstances, as the license is generally not distinct from the non-licensed goods or services to be provided under the contract. Milestone payments that are contingent upon the occurrence of future events, are evaluated and recorded at the most likely amount, and to the extent that it is probable that a significant reversal will not occur when the associated uncertainty is resolved.

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Royalties

We earn royalties in connection with licenses granted under license and development arrangements with partners. Royalties are based upon a percentage of commercial sales of partnered products with rates ranging from mid-single digits to low double digits and are tiered based on levels of net sales. These sales-based royalties, for which the license was deemed the predominant element to which the royalties relate, are estimated and recognized in the period in which the partners' commercial sales occur. The royalties are generally reported and payable to us within 45 to 60 days of the end of the period in which the commercial sales are made. We base our estimates of royalties earned on actual sales information from our partners when available or estimated prescription sales from external sources and estimated net selling price. If actual royalties received are different than amounts estimated, we would adjust the royalty revenue in the period in which the adjustment becomes known.

Remaining Performance Obligations

Remaining performance obligations represent the transaction price of firm orders and development contract deliverables for which work has not been completed or orders fulfilled, and excludes potential purchase orders under ordering-type supply contracts with indefinite delivery or quantity. As of December 31, 2021, the aggregate value of remaining performance obligations, excluding contracts with an original expected length of one year or less, was \$14,879. We expect to recognize revenue on the remaining performance obligations over the next three years, with the majority being recognized in the next twelve months.

Share-Based Compensation

We use share-based compensation in the form of stock options, restricted stock units ("RSUs") and performance-based restricted stock units ("PSUs"). We record compensation expense associated with share-based awards granted to employees at the fair value of the award on the date of grant. The Black-Scholes option valuation model is used to determine the fair value of stock options. The fair values of RSU and PSU grants containing service or performance conditions are based on the market value of our common stock on the date of grant. The fair value of PSUs containing a market condition are estimated using a Monte Carlo simulation. The value of the portion of the award that is ultimately expected to vest is expensed ratably over the requisite service period as compensation expense in the Consolidated Statements of Operations. Forfeitures are recorded as incurred. Assumptions concerning our stock price volatility and projected employee exercise behavior over the contractual life of the award impact the estimated fair value of the stock option awards.

Research and Development

Research and development expenses include costs directly attributable to the conduct of research and development programs including personnel costs, materials and supplies associated with design work and prototype development, FDA filing fees and the cost of services provided by outside contractors such as expenses related to clinical trials. All costs associated with research and development activities are expensed as incurred.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

We account for uncertain tax positions in accordance with ASC 740, *Income Taxes* (“ASC 740”), which applies to all tax positions related to income taxes. Tax benefits are recognized when it is more-likely-than-not that a tax position will be sustained upon examination by the authorities. Interest and penalties accrued related to uncertain tax benefits are recognized as a component of income tax expense in the Consolidated Statements of Operations.

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Earnings (Loss) Per Common Share

Basic earnings (loss) per common share is computed by dividing the net income (loss) applicable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted earnings (loss) per common share is computed in a similar manner, except that the weighted average number of shares outstanding is increased to reflect the potential dilution from the exercise or conversion of securities into common stock. Diluted earnings (loss) per common share contemplate a complete conversion to common shares of all convertible instruments only if such instruments are dilutive in nature with respect to earnings (loss) per common share.

Segments

Operating segments are components of an enterprise for which separate financial information is available and is evaluated regularly by the Chief Operating Decision Maker (“CODM”), our Chief Executive Officer, in deciding how to allocate resources and assess performance. Our CODM currently evaluates our operations as a whole from a number of different operational perspectives, including but not limited to, on a product-by-product, customer and partner basis. We derive all significant revenues from pharmaceutical products and development services, and have a single reportable, operating segment of business.

Going Concern

We are responsible for evaluating, and providing disclosure of uncertainties about, our ability to continue as a going concern. As of December 31, 2021, we had cash and cash equivalents of \$65,913. Based on our evaluation, we concluded there is no substantial doubt or uncertainty about our ability to meet our obligations within one year from the date the Consolidated Financial Statements were issued.

Note 3. Inventories

Inventories consisted of the following:

	December 31, 2021	December 31, 2020
Raw materials	\$ 325	\$ 325
Work in process	6,784	7,120
Finished goods	4,435	10,771
Total inventories, net	<u>\$ 11,544</u>	<u>\$ 18,216</u>

A reserve is recorded for potentially excess, dated or obsolete inventory based on an analysis of inventory on hand compared to forecasted future sales, which was \$214 and \$619 as of December 31, 2021 and 2020, respectively. In 2021, we wrote off \$359 of inventory and reduced the reserve for excess, dated or obsolete inventory by \$46. In 2020, we wrote off \$356 of inventory and increased the reserve for excess, dated or obsolete inventory by \$511.

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Note 4. Property and Equipment

Property and equipment, net consisted of the following:

	December 31, 2021	December 31, 2020
Production molds, tooling and equipment	\$ 22,069	\$ 20,260
Leasehold improvements	7,559	6,298
Furniture, fixtures and office equipment	907	865
Computer equipment and software	1,717	756
Construction and tooling in process	6,942	6,214
Total property and equipment	39,194	34,393
Less: Accumulated depreciation	(13,179)	(10,373)
Total property and equipment, net	\$ 26,015	\$ 24,020

Depreciation expense was \$2,864, \$2,341 and \$2,205 for the years ended December 31, 2021, 2020 and 2019, respectively. In 2021 and 2020, we disposed of certain property and equipment that was fully depreciated and no longer used. We capitalized \$52 and \$231 of interest costs associated with construction of property and equipment during the years ended December 31, 2021 and 2020, respectively.

Note 5. Leases

We are party to non-cancellable operating leases for our corporate headquarters facilities in Ewing, New Jersey, and two facilities in the suburbs of Minneapolis, Minnesota used for research and development, manufacturing and administrative functions. We have also entered into a master operating lease arrangement for a fleet of vehicles for use by our sales force and other operating leases for various office and warehouse equipment. Our lease agreements do not contain any material residual value guarantees, material bargain purchase options or material restrictive covenants. We have no material sublease arrangements with third parties or lease transactions with related parties.

On November 1, 2021, January 1, 2022 and March 1, 2022, we entered into two-month lease extensions on our operating lease for our corporate headquarters in Ewing, New Jersey. The three extensions set new lease expiration dates of December 31, 2021, February 28, 2022 and April 30, 2022, respectively, and maintained the same conditions as the original lease.

On July 1, 2019, we entered into an operating lease for approximately 75,000 square feet of office, laboratory, manufacturing and warehousing space in Minnetonka, Minnesota. The initial lease term is 12.5 years with an option to renew the lease for one additional renewal period of three years. The landlord delivered possession of the premises to us on July 1, 2019 and payment of rent commenced on January 1, 2020. The lease provides for the payment of fixed base rent and additional rent for operating expenses, insurance premiums and taxes. We are completing the build-out of the premises at our cost with an allowance for tenant improvement to be reimbursed by the landlord up to \$1,200.

The operating leases require payment of all executory costs such as maintenance and property taxes. Operating lease costs were \$2,176, \$2,174 and \$1,391 for the years ended December 31, 2021, 2020 and 2019 respectively. Cash paid for amounts included in the

measurement of operating lease liabilities was \$2,005, \$1,884 and \$1,401 and non-cash operating lease ROU assets obtained in exchange for operating lease obligations were \$850, \$778 and \$6,511 for the years ended December 31, 2021, 2020 and 2019 respectively. As of and for the years ended December 31, 2021, 2020 and 2019 the weighted average discount rate was approximately 8.9%, 8.6% and 8.3% respectively, and the weighted average remaining lease term was 8.3 years, 8.3 years and 8.4 years respectively.

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Future lease payments under non-cancelable leases for the next five years and thereafter as of December 31, 2021 are as follows:

	Future Lease Payments
2022	\$ 1,334
2023	969
2024	762
2025	676
2026	678
Thereafter	3,593
Total remaining lease payments	8,012
Less: Imputed interest	(2,532)
Present value of lease liabilities	<u>\$ 5,480</u>

As of December 31, 2021, we have no material additional operating leases that have not yet commenced.

Note 6. Intangible Assets

Intangible assets are as follows:

	Useful Life (in Years)	December 31, 2021			December 31, 2020		
		Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization	Net Book Value
TLANDO [®] product rights	10	\$ 11,315	\$ —	\$ 11,315	\$ —	\$ —	\$ —
NOC DURNA [®] product rights	10	7,500	(937)	6,563	7,500	(188)	7,312
Patents ¹	5 - 10	1,048	(1,047)	1	3,995	(3,614)	381
Total intangibles, net		<u>\$ 19,863</u>	<u>\$ (1,984)</u>	<u>\$ 17,879</u>	<u>\$ 11,495</u>	<u>\$ (3,802)</u>	<u>\$ 7,693</u>

¹ Patents related to OTREXUP[®] were sold as part of the Asset Purchase Agreement entered into with Otter in December 2021. See Note 12 for further discussion regarding the sale of assets.

In October 2021, we entered into an exclusive license agreement (the “TLANDO[®] License Agreement”) with Lipocine, Inc. (“Lipocine”) for the right to commercialize the product TLANDO[®] (testosterone undecanoate) in the U.S., a twice-daily oral formulation of testosterone for testosterone replacement therapy indicated for conditions associated with a deficiency or absence of endogenous testosterone, or hypogonadism in adult males. TLANDO[®] was granted tentative approval from the FDA in December 2020 and will be eligible for final approval and marketing in the U.S. upon expiration of the exclusivity period previously granted to Clarus for JATENZO[®] on March 27, 2022. Under the terms of the TLANDO[®] License Agreement, we paid Lipocine an upfront payment of \$11,000 upon execution of agreement. Lipocine is eligible for additional milestone payments up to \$10,000, minimum tiered royalty payments of \$4,500 over the first three years after commercialization and commercial milestones potentially totaling up to \$160,000

based on net sales of TLANDO® in the U.S. We are also obligated to purchase \$2,002 of TLANDO® inventory from Lipocine of which \$1,056 was purchased as of December 31, 2021. We accounted for the transaction as an asset purchase. Amortization of the product rights intangible asset, including direct transaction costs of \$315, will commence and be included in selling, general and administrative expenses upon commercialization of TLANDO® once final approval is obtained from the FDA after the exclusivity period previously granted to Clarus Therapeutics, Inc. (“Clarus”) for JATENZO® expires on March 27, 2022. The additional milestone and commercial milestone payments associated with TLANDO® are contingent on future events and will be accrued when they are both probable and estimable. Royalty payments will be accrued and included in costs of product sales as incurred.

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In connection with the NOCDURNA[®] license and commercial supply agreement entered into with Ferring International Center S.A. and its affiliates (“Ferring”) in October 2020, we paid Ferring an upfront payment of \$5,000 upon execution and an additional \$2,500 in October 2021. Ferring is eligible for tiered royalties and additional commercial milestone payments potentially totaling up to \$17,500 based on net sales of NOCDURNA[®] in the U.S. We accounted for the transaction as an asset purchase. Amortization of the product rights intangible asset is included in selling, general and administrative expenses. The royalty payments are accrued and included in the cost of product sales as incurred. The commercial milestones were determined to be contingent liabilities and will be accrued when they are both probable and estimable.

Amortization expense for the years ended December 31, 2021, 2020 and 2019 was \$1,037, \$286 and \$352, respectively, and is recorded in selling, general and administrative expenses in the Consolidated Statements of Operations. Estimated future aggregate amortization expense is as follows:

	Estimated Amortization Expense
2022	\$ 1,600
2023	1,882
2024	1,882
2025	1,882
2026	1,882
Thereafter	8,751
Total future amortization expense	<u>\$ 17,879</u>

Future amortization amounts presented above are estimates. Actual future amortization expense may be different due to future acquisitions, impairments, changes in amortization periods or other factors.

Note 7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other liabilities consisted of the following:

	December 31, 2021	December 31, 2020
Product returns and sales allowances	\$ 20,563	\$ 11,435
Accrued employee compensation and benefits	5,648	4,555
License fees payable	—	2,500
Other accrued expenses and liabilities	8,832	7,145
Total accrued expense and other liabilities	<u>\$ 35,043</u>	<u>\$ 25,635</u>

Note 8. Long-Term Debt

Term Loan

On June 6, 2017, we entered into a loan and security agreement (the “Loan Agreement”) with Hercules Capital, Inc., for a term loan of up to \$35,000 (the “Term Loan”), under which we initially borrowed \$25,000 (“Tranche I”), the proceeds of which are being used for working capital and general corporate purposes. The Term Loan was secured by substantially all of our assets, excluding intellectual property and accrued interest at a calculated prime-based variable rate with a maximum interest rate of 9.50%. The interest rate in effect as of December 31, 2020 was 8.50%. Payments under the loan were interest-only until the first principal payment was due.

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On June 26, 2019, we entered into a First Amendment (the “Amendment”) to the Loan Agreement, which increased the aggregate principal amount available under the Term Loan from \$35,000 to \$50,000 and extended the interest-only payment period of the Term Loan to August 1, 2021. The interest only period could be further extended to August 1, 2022 if we achieved a certain loan extension milestone, requested such extension, and paid an extension fee equal to one half of one percent of the principal amount outstanding. Upon signing of the Amendment, an additional \$15,000 (“Tranche II”) was funded to us. The Term Loan maturity date remained July 1, 2022; however, the Term Loan maturity date could be extended to July 1, 2024 contingent upon satisfaction of a certain loan extension milestone. We were eligible, but not obligated, to request one or more additional advances of at least \$5,000, not to exceed \$10,000 in the aggregate (“Tranche III”). Our option to request additional advances expired on October 31, 2020.

We were required to pay an end of term fee (“End of Term Charge”) equal to 4.25% of Tranche I and 3.95% of the borrowings under Tranche II, payable upon the earlier of July 1, 2022 or repayment of the Term Loan. The Loan Agreement also imposed a prepayment fee of 1.0% to 3.0% if any or all of the balance were prepaid prior to the maturity date.

As of December 31, 2020, the carrying value of the Term Loan was \$40,899, which consisted of the principal balance outstanding and the End of Term Charge accrual, less unamortized debt issuance costs that are being amortized/accrued to interest expense over the term of the Term Loan using the effective interest method. The fair value of our debt was estimated to approximate the carrying value based on our understanding of current market conditions and rates we could obtain for similar loans at that time.

In July 2021, having previously met the loan extension milestone, we requested that the interest-only period be extended to August 1, 2022 and the maturity date be extended to July 1, 2024 in accordance with the terms of the Amendment. The Lender granted the extension of the interest-only period and maturity date and waived the extension fee. In 2021, we made principal prepayments of \$20,000 and paid a 1.0% prepayment fee.

On November 1, 2021, we extinguished the Loan Agreement with Hercules Capital, Inc. and repaid the outstanding \$20,000 principal on the Term Loan, along with the 1.0% prepayment fee of \$200 and the End of Term Charge of \$1,655. All remaining unamortized debt issuance costs associated with the Term Loan were immediately amortized to interest expense.

Credit Facilities

On November 1, 2021, we entered into a Credit Agreement (the “Credit Agreement”) with Wells Fargo Bank, National Association, as administrative agent for the lenders, (“Administrative Agent”) for credit facilities in an aggregate principal amount of up to \$40,000 with a maturity date of November 1, 2024. The Credit Agreement provides for a \$20,000 term loan facility (the “Term Loan Facility”) and a \$20,000 revolving credit facility, \$5,000 of which is available for the issuance of letters of credit and \$1,000 of which is available for Swingline loans (the “Revolving Credit Facility”), (collectively the “Credit Facilities”), which are secured by substantially all of our assets. The Term Loan Facility was funded upon execution of the Credit Agreement with the proceeds used to repay our \$20,000 Term Loan with Hercules Capital, Inc. and to pay fees and expenses incurred in connection with the early repayment. The Revolving Credit Facility remains available for future use and can be drawn upon for ongoing working capital requirements and other general corporate purposes as needed.

As of December 31, 2021, we had \$20,000 outstanding under our Term Loan Facility with a carrying value of \$19,741 which consisted of the principal balance outstanding, less unamortized debt issuance costs that are being amortized/accrued to interest expense over the term of the Term Loan Facility using the effective interest rate method. The fair value of our debt is estimated to approximate the carrying value based on our understanding of current market conditions and rates we could obtain for similar loans.

As of December 31, 2021, there were no outstanding borrowings under the Revolving Credit Facility, including no outstanding letters of credit drawn from the Revolving Credit Facility or Swingline loans. Commitment fees are payable on the unused portion of the Revolving Credit Facility at rates between 0.30% and 0.45% based on our Consolidated Total Leverage Ratio, as defined in the Credit Agreement and below, remeasured quarterly. For the year ended December 31, 2021, commitment fees incurred totaled \$12.

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As defined in the Credit Agreement governing the Term Loan Facility, principal payments of the outstanding term loans are due in consecutive quarterly installments on the last business day of each of March, June, September and December, commencing on March 31, 2022. The Credit Agreement also requires prepayment of the outstanding loans under the Term Loan Facility, subject to certain exceptions, with (a) 100% of the net cash proceeds of (i) any incurrence or issuance of certain debt, other than debt permitted under the Credit Agreement; (ii) issuance of equity other than that associated with employee compensation; and (iii) certain asset sales and casualty and condemnation events, subject to reinvestment rights and certain other exceptions. We may voluntarily prepay outstanding loans under the Term Facility at any time without premium or penalty. All obligations under the Term Facility are secured, subject to certain exceptions, by substantially all of our assets and the assets of our subsidiaries.

Borrowings made under the Credit Agreement bear interest at a rate per annum equal to either the Base Rate or LIBOR plus the Applicable Margin, as defined in the Credit Agreement. Swingline loans bear interest at a rate per annum equal to the Base Rate plus the Applicable Margin. The Applicable Margin is based on the Consolidated Total Leverage Ratio, as defined in the Credit Agreement and below, remeasured quarterly. Base Rate is defined as the highest of (a) the Prime Rate, (b) the Federal Funds Rate plus 0.50% and (c) LIBOR for an interest period of one month plus 1%. In the event of default, we no longer have the option to request LIBOR rate loans, Swingline Loans or Letters of Credit and all outstanding financial instruments will bear interest at a rate per annum of 2% in excess of the calculated interest rate.

We have the option to select either the Base Rate or LIBOR as the rate of interest for the Term Loan and Revolving Credit Facilities, along with an interest period of either 1-month, 3-months or 6-months. Upon cessation of LIBOR on June 30, 2023, an appropriate benchmark replacement will be determined pursuant to the terms of the Credit Agreement. We have not yet evaluated the impact the cessation of LIBOR will have on our financial condition and results of operations. As of December 31, 2021, the Applicable Margin was 1.50% for Base Rate loans and 2.50% for LIBOR loans with a 1-month LIBOR selected as the rate of interest for the Term Loan Facility. The weighted average interest rate on the Term Loan Facility outstanding balance during the year ended December 31, 2021 was approximately 2.59%.

Under the Credit Agreement, we are subject to customary affirmative and negative covenants, including, among others, restrictions on our ability to incur debt; create liens; make investments; merge, consolidate or dispose of assets or subsidiaries; enter into transactions with affiliates; modify accounting practices, our year end and organizational documents; pledge assets; revise nature of business; perform sale leasebacks; and enter into any restrictive agreements and customary events of default (including payment defaults, covenant defaults, change of control defaults and bankruptcy defaults). The Credit Agreement also contains financial covenants, including the ratio of consolidated total indebtedness to consolidated earnings before income, taxes, depreciation and amortization (“Consolidated EBITDA”) (“Consolidated Total Leverage Ratio”), as defined in the Credit Agreement” and the ratio of consolidated senior secured indebtedness to Consolidated EBITDA (“Consolidated Senior Secured Leverage Ratio”), as well as the ratio of Adjusted EBITDA to consolidated fixed charges (“Consolidated Fixed Charge Coverage Ratio”), as defined in the Credit Agreement. These covenants restrict our ability to purchase outstanding shares of our common stock. As of December 31, 2021, we were in compliance with all affirmative, negative and financial covenants.

Future principal payments under the Term Loan Facility are as follows:

	Future Principal Payments
2022	\$ 1,500
2023	1,500
2024	17,000
Total future principal payments	<u>\$ 20,000</u>

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Note 9. Stockholders' Equity

In August 2017, we entered into a sales agreement (the "Sales Agreement") with Cowen and Company, LLC ("Cowen") under which we could offer and sell, from time to time and at our sole discretion, shares of our common stock having an aggregate offering price of up to \$30,000 through Cowen as our sales agent and/or as principal. Cowen could sell the common stock by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415 of the Securities Act of 1933, as amended (the "ATM Facility"). The Sales Agreement requires us to pay a commission of 3.0% of the gross sales proceeds of any common stock sold through Cowen.

During year ended December 31, 2019, we sold 2,307 shares of common stock under the ATM Facility, resulting in net offering proceeds of \$7,781. On June 26, 2019, the Company delivered written notice to Cowen that it was terminating the Sales Agreement effective July 6, 2019, and accordingly the ATM Facility is no longer available for use.

Note 10. Share-Based Compensation

We have an Equity Compensation Plan (the "Plan"), which allows for grants in the form of incentive stock options, non-qualified stock options, stock units, stock awards, stock appreciation rights, and other stock-based awards. The Plan was amended and restated in June 2021 to increase the total number of shares available for grant under the Plan by 10,000 shares. The cumulative number of shares that have been authorized for issuance under the Plan to date is 50,200 shares and the maximum number of shares of stock that may be granted to any one participant during a calendar year is 4,000 shares. Options to purchase shares of common stock are granted at exercise prices not less than 100% of fair market value on the date of grant. The term of each option is ten years, and the options typically vest over a three-year period with a minimum vesting period of one year. As of December 31, 2021, the Plan had approximately 366 shares available for grant. Stock option exercises, and the vesting of restricted stock and performance stock awards, are satisfied through the issuance of new shares.

Stock Options

Stock option activity under the Plan is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2018	14,079	\$ 2.19		
Granted	2,489	3.01		
Exercised	(2,572)	1.76		\$ 6,477
Cancelled / Forfeited	(135)	2.81		
Outstanding as of December 31, 2019	13,861	2.41	6.7	31,713
Granted	3,335	2.73		
Exercised	(939)	1.93		1,072
Cancelled / Forfeited	(736)	2.83		
Outstanding as of December 31, 2020	15,521	2.49	6.6	23,407
Granted	2,660	4.37		
Exercised	(2,307)	2.27		5,052
Cancelled / Forfeited	(297)	3.02		
Outstanding as of December 31, 2021	15,577	2.83	6.5	13,839
Exercisable as of December 31, 2021	10,644	\$ 2.46	5.4	\$ 12,028

The per share weighted average fair value of options granted during 2021, 2020 and 2019 was estimated as \$2.29, \$1.42 and \$1.54, respectively, on the date of grant using the Black-Scholes option pricing model based on the assumptions noted in the table below. Expected volatilities are based on the historical volatility of our stock. The weighted average expected life is based on both historical and anticipated employee behavior.

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	Years Ended December 31,		
	2021	2020	2019
Risk-free interest rate	0.8 %	0.4 %	1.9 %
Annualized volatility	59.3 %	59.4 %	55.7 %
Weighted average expected life (in years)	5.4	5.5	5.5
Expected dividend yield	0.0 %	0.0 %	0.0 %

Option exercises during 2021, 2020 and 2019 resulted in proceeds of \$5,182, \$1,814 and \$4,405, respectively, and the issuance of shares of common stock of 2,294 in 2021, 939 in 2020 and 2,529 in 2019. In 2021 and 2019, certain options were net exercised, whereby we withheld 13 and 43 shares, respectively, the fair value of which was equivalent to the aggregate exercise price and tax withholding on the date of exercise.

Long Term Incentive Program

Our Board of Directors has approved a long-term incentive program (“LTIP”) for the benefit of our senior executives. Pursuant to the LTIP, our senior executives are awarded stock options, restricted stock units (“RSU”) and performance stock units (“PSU”) with targeted values based on similar award structures granted by our peer group. The stock options have a ten-year term, an exercise price equal to the closing price of our common stock on the date of grant, vest in quarterly installments over three years, were otherwise granted on the same standard terms and conditions as other stock options granted pursuant to the Plan and are included in the stock options table above. The RSUs generally vest in three equal annual installments, and the PSUs vest and convert into shares of our common stock based on our attainment of certain performance goals over a performance period, which is typically three years.

PSUs and RSUs granted under the LTIP are summarized as follows:

	Performance Stock Units		Restricted Stock Units	
	Number of Shares	Weighted Average Grant Date Fair Value	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding as of December 31, 2018	1,842	\$ 2.41	1,226	\$ 2.44
Granted	593	2.99	789	2.92
Incremental shares earned	59	1.25	—	—
Vested / Settled	(415)	1.18	(614)	2.19
Forfeited / Expired	(238)	1.12	—	—
Outstanding as of December 31, 2019	1,841	3.00	1,401	2.82
Granted	605	2.00	1,078	2.73
Incremental shares earned	77	3.10	—	—
Vested / Settled	(388)	3.11	(785)	2.80
Forfeited / Expired	(494)	3.02	(127)	2.83
Outstanding as of December 31, 2020	1,641	2.61	1,567	2.77
Granted	243	5.55	769	4.42
Incremental shares earned	210	3.18	—	—
Vested / Settled	(766)	2.86	(832)	2.76
Outstanding as of December 31, 2021	1,328	\$ 3.04	1,504	\$ 3.62

The outstanding balance of PSUs is stated at the target number of shares to be awarded upon attainment of certain performance goals. Depending on the outcome of the related performance goals, a recipient may ultimately earn a number of shares that is greater or less than the target number of units granted, ranging from 0% to 150%. The balance of PSUs outstanding as of December 31, 2021 included 308 units granted in 2019 with a performance period ended December 31, 2021 that were subsequently deemed to be achieved and approved for settlement in the first quarter of 2022 for a total of 304 shares.

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In each of the years in the three-year period ended December 31, 2021, the LTIP awards include PSUs that will be earned based on our total shareholder return (“TSR”) as compared to the Nasdaq Biotechnology Index (“NBI”) at the end of the respective annual performance periods. The fair values of the TSR PSUs granted were determined using a Monte Carlo simulation and used the following inputs and assumptions:

	2021 Award	2020 Award	2019 Award
Closing stock price on grant date	\$ 4.42	\$ 2.73	\$ 2.92
Performance period starting price	\$ 3.70	\$ 4.78	\$ 3.01
Term of award (in years)	2.56	2.55	2.55
Volatility	54.4 %	57.5 %	63.7 %
Risk-free interest rate	0.23 %	0.21 %	1.79 %
Expected dividend yield	0.00 %	0.00 %	0.00 %
Fair value per TSR PSU	\$ 5.55	\$ 2.00	\$ 3.18

The performance period starting price is measured as the average closing price over the last 20 trading days prior to the performance period start. The Monte Carlo simulation model also assumed correlations of returns of the prices of our common stock and the common stocks of the NBI companies and stock price volatilities of the NBI companies. The fair value of the target number of shares that can be earned under the TSR PSUs is being recognized as compensation expense over the term of the award. Other PSUs that are not market-based awards are expensed using the grant date fair value of shares expected to vest over the remaining performance period when it becomes probable that the related performance goal will be achieved.

LTIP awards are generally net-share settled such that we withhold shares with value equivalent to the employees’ minimum statutory obligation for the applicable income and other employment taxes, and remit cash to the appropriate taxing authorities. Total shares withheld for net-settled awards were 626, 425 and 409 in 2021, 2020 and 2019, respectively, and were based on the value of the shares on their vesting date as determined by our closing stock price. Total payments for the employees’ tax obligations to the taxing authorities were \$2,841, \$1,367 and \$1,131 in 2021, 2020 and 2019, respectively, and are reflected as a financing activity within the Consolidated Statements of Cash Flows. These net-share settlements reduced the number of shares that would have otherwise been issued as a result of the vesting.

Members of our Board of Directors also receive grants of RSUs that vest one year from the date of grant. Certain Directors have elected to defer receipt of vested shares until retirement or separation from the Board of Directors, for which 30, 72 and no shares vested with deferral as of and for the years ended December 31, 2021, 2020 and 2019, respectively.

Share-based Compensation Expense

Compensation costs incurred in connection with share-based awards are as follows:

	Years Ended December 31,		
	2021	2020	2019
Stock options	\$ 4,102	\$ 3,709	\$ 3,436
Restricted stock units	\$ 2,620	2,239	1,830
Performance stock units	\$ 1,293	2,000	1,204
Total share-based compensation expense	\$ 8,015	\$ 7,948	\$ 6,470

As of December 31, 2021, there was \$6,838 of total unrecognized compensation costs related to non-vested stock option awards that are expected to be recognized over a weighted average period of approximately 1.95 years.

Note 11. Employee 401(k) Savings Plan

We sponsor a 401(k) defined contribution retirement savings plan that covers all U.S. employees who have met minimum age and service requirements subject to the provisions of the Employee Retirement Income Security Act. Under the plan, eligible employees may contribute a portion of their annual compensation into the plan up to the IRS annual limits on a pre-tax or after-

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tax basis. We have elected to make matching contributions to the plan based on a percentage of employee contributions. The total amount contributed by us is determined by plan provisions for matching contributions, as well as at our discretion. Employer matching and discretionary contributions were \$1,151, \$1,097 and \$993 for the years ended December 31, 2021, 2020 and 2019, respectively.

Note 12. Sale of Assets

In December 2021, we entered into an asset purchase agreement (the “Asset Purchase Agreement”) with Otter Pharmaceuticals, LLC (a subsidiary of Assertio Holdings, Inc., together with Assertio Holdings, Inc., as guarantor, individually and collectively referred to as “Otter”) to sell certain worldwide assets used in the operation of the OTREXUP[®] product line for \$44,021 of which we received a \$18,000 at closing and will receive the remaining \$26,021 in installments over a one-year period. As of December 31, 2021, we recorded an increase to the purchase price for estimated changes in closing inventory to be transferred. The Asset Purchase Agreement included the transfer of OTREXUP[®] patents, trademark and intellectual property, product finished goods and sample inventory, and certain other contracts associated with the OTREXUP[®] product line. Subject to the terms of the OTREXUP[®] Asset Purchase Agreement, we generally retained ownership (and related liabilities) of assets not solely related to the OTREXUP[®] product line. We also agreed via the execution of a separate supply agreement to continue to manufacture and supply OTREXUP[®] and sample products to Otter at cost plus mark-up. Further, we entered into a license agreement with Otter pursuant to which we granted Otter a worldwide, exclusive, fully paid-up license to certain patents relating to OTREXUP[®] that may relate to our other products.

We recorded the entire \$38,591 gain on sale of assets in the Consolidated Statements of Operations for the year ended December 31, 2021 as all requirements of the agreement were determined to have been met and it was probable that a significant reversal of the gain would not occur. The gain includes the purchase price of \$44,021 adjusted for estimated changes in closing inventory to be transferred less the net book value of the assets sold and direct transaction costs. The remaining \$26,311 purchase price to be received is classified as other receivables in the Consolidated Balance Sheets as of December 31, 2021, and we recognized \$17,825 of net proceeds from the sale of assets in the Statements of Cash Flows for the year ended December 31, 2021.

Note 13. Income Taxes

We were subject to taxes in both the U.S. and Switzerland in each of the years ended December 31, 2021, 2020 and 2019. Income (loss) before income taxes was derived from the following jurisdictions:

	Years Ended December 31,		
	2021	2020	2019
U.S.	\$ 62,626	\$ 10,284	\$ (1,734)
Switzerland	(355)	(363)	(293)
Total income (loss) before income taxes	<u>\$ 62,271</u>	<u>\$ 9,921</u>	<u>\$ (2,027)</u>

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The income tax provision (benefit) was comprised of:

	Years Ended December 31,		
	2021	2020	2019
Current			
Federal	\$ —	\$ —	\$ —
State	2,041	700	—
Foreign	2	2	—
Total current income tax provision (benefit)	2,043	702	—
Deferred			
Federal	11,918	(39,542)	—
State	2,021	(7,440)	—
Foreign	—	—	—
Total deferred income tax provision (benefit)	13,939	(46,982)	—
Total income tax provision (benefit)	\$ 15,982	\$ (46,280)	\$ —

Effective tax rates differ from statutory income tax rates as follows:

	Years Ended December 31,		
	2021	2020	2019
Statutory income tax rate	21.0 %	21.0 %	21.0 %
State income taxes	5.5	7.1	14.4
Effect of foreign operations	0.1	0.2	(1.0)
Changes in valuation allowance	(0.2)	(516.5)	(59.9)
Change in unused net operating loss and credit carryforwards	—	—	24.7
Change in uncertain tax positions	(0.1)	21.4	—
Research and development credit	(0.7)	(6.0)	—
Stock-based compensation	(2.0)	3.7	22.3
162(m) limitation	2.1	1.9	(18.2)
Nondeductible items	—	1.6	(1.8)
Impact of Tax Cuts and Jobs Act	—	—	(1.5)
Other	—	(0.9)	—
Effective income tax rate	25.7 %	(466.5)%	— %

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Deferred tax assets (liabilities) consist of the following:

	December 31, 2021	December 31, 2020
Gross deferred tax assets		
Net operating loss carryforward – U.S.	\$ 24,738	\$ 36,071
Net operating loss carryforward – Switzerland	162	106
Research and development tax credit carryforward	5,836	5,418
Deferred revenue	14	219
Stock-based compensation	3,423	2,954
Inventory reserve	56	159
Compensation accruals	1,426	1,304
Product reserves	5,235	2,820
Operating lease liabilities	1,436	1,546
Amortization	64	607
Other	188	145
Total deferred tax assets	42,578	51,349
Deferred tax liabilities		
Depreciation	(1,753)	(1,838)
Operating lease right-of-use asset	(1,048)	(1,303)
Installment sale	(5,580)	—
Total deferred tax liabilities	(8,381)	(3,141)
Net deferred tax asset before valuation allowance	34,197	48,208
Less: Valuation allowance	(1,154)	(1,226)
Net deferred tax asset	\$ 33,043	\$ 46,982

In assessing the realizability of deferred tax assets, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which temporary differences become deductible or in which net operating loss or tax credit carryforwards can be used. As of each reporting date, we consider new evidence, both positive and negative, that could affect our view of the future realization of deferred tax assets.

As of December 31, 2021 and 2020, there is sufficient positive evidence to conclude that it is more likely than not that our net U.S. deferred tax assets of \$33,043 and \$46,982, respectively, are realizable as a result of generating pretax earnings, utilizing net operating loss carryovers and projecting pre-tax earnings. For the year ended December 31, 2020, we recorded a net valuation allowance release of \$53,383 based on our reassessment of the amount of our deferred tax assets that are more likely than not to be realized. The valuation

allowances of \$1,154 and \$1,226 as of December 31, 2021 and 2020, respectively, relate to certain state and foreign carryovers for which projected income cannot support utilization.

We have a U.S. federal net operating loss carryforward as of December 31, 2021 of \$99,939, which, subject to limitations of Internal Revenue Code (“IRC”) Section 382, is available to reduce income taxes payable in future years. As of December 31, 2021, we have performed a full analysis of IRC Section 382 and concluded that net operating losses and credits will be able to be used without limitation. If not used, the portion of the carryforward generated before 2018 will expire in the years 2033 through 2037, and the net operating loss carryforward generated in 2018 and any future years will carry forward indefinitely. Additionally, we have U.S. Research Credit carryforwards of \$7,328 which will expire in years 2022 through 2041 if unused.

We also have a Swiss net operating loss carryforward as of December 31, 2021, of \$1,130, which is available to reduce income taxes payable in future years. If not used, this carryforward will begin to expire in 2023.

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A summary of changes to our liability for unrecognized tax benefits is as follows:

	December 31, 2021	December 31, 2020
Beginning liability for unrecognized tax benefits	\$ 2,127	\$ —
Increase (decrease) due to tax positions related to prior years	(70)	2,067
Increase due to tax positions related to the current year	—	60
Ending liability for unrecognized tax benefits	\$ 2,057	\$ 2,127

Included in the balance of unrecognized tax benefits as of December 31, 2021 and 2020, are \$2,057 and \$2,127, respectively, that if recognized would impact the effective tax rate. There is no interest or penalties charged or accrued in relation to unrecognized tax benefits. We will classify any future interest and penalties as a component of income tax expense. We do not anticipate that the total amount of unrecognized tax benefits will change significantly in the next twelve months. We are subject to federal and state examinations for the years 2017 and thereafter.

Note 14. Revenues, Significant Customers and Concentrations of Risk

We disaggregate our revenue by type of goods and services and customer location.

	Years Ended December 31,		
	2021	2020	2019
Types of Goods and Services			
Proprietary product sales, net	\$ 80,016	\$ 62,878	\$ 39,215
Partnered product sales	46,651	50,956	52,888
Total product revenue, net	126,667	113,834	92,103
Licensing and development revenue	19,623	14,466	7,529
Royalties	37,692	21,299	24,232
Total revenue, net	\$ 183,982	\$ 149,599	\$ 123,864
Customer Location			
U.S.	\$ 178,290	\$ 145,789	\$ 120,231
Europe	5,692	3,810	3,463
Other	—	—	170
Total revenue, net	\$ 183,982	\$ 149,599	\$ 123,864

Customers from which we derive 10% or more of our total revenue are as follows:

	Years Ended December 31,		
	2021	2020	2019
Teva	42%	40%	41%
McKesson ¹	13%	12%	10%
AmerisourceBergen Corporation ¹	12%	12%	<10%
Cardinal Health ¹	11%	11%	<10%
Covis	<10%	<10%	20%

¹ Revenue from sales to distributors, net of estimated sales returns and allowances based on shipments.

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Note 15. Earnings (Loss) per Share

Basic earnings (loss) per common share is computed by dividing net income applicable to common stockholders by the daily weighted-average number of common shares outstanding for the applicable period. Diluted earnings (loss) per common share is computed in a similar manner, except that the weighted average number of shares outstanding is increased to reflect the potential dilution from the exercise or conversion of securities into common stock. Diluted earnings (loss) per share contemplates a complete conversion to common shares of all convertible instruments only if such instruments are dilutive in nature with respect to earnings per common share. The following table sets forth the computation for basic and diluted earnings (loss) per common share:

	Years Ended December 31,		
	2021	2020	2019
Net income (loss)	\$ 46,289	\$ 56,201	\$ (2,027)
Weighted average common shares outstanding	169,226	166,066	162,574
Dilutive effects of stock options and share-based awards issuable under equity compensation plans	5,507	4,089	—
Weighted average dilutive common shares outstanding	174,733	170,155	162,574
Earnings (loss) per common share			
Basic	\$ 0.27	\$ 0.34	\$ (0.01)
Diluted	\$ 0.26	\$ 0.33	\$ (0.01)
Anti-dilutive common stock equivalents ¹	2,224	7,092	17,103

¹ These common stock equivalents were outstanding for the period but were not included in the computation of diluted earnings (loss) per common share for those periods as their inclusion would have had an anti-dilutive effect.

Note 16. Commitments and Contingencies

Contingent Considerations

In connection with the TLANDO[®] exclusive license agreement and asset purchase entered into with Lipocine in October 2021, we paid Lipocine and upfront payment of \$11,000 upon execution of agreement. Lipocine is eligible for additional milestone payments up to \$10,000, minimum tiered royalty payments of \$4,500 over the first three years after commercialization has occurred and commercial milestones up to \$160,000 based on net sales of TLANDO[®] in the U.S. The additional milestone and commercial milestone payments are contingent on future events and will be accrued when they are both probable and estimable. We also have the option to license and develop LPCN 1111 (TLANDO XR) for an additional \$4,000 in license fees to be paid in two installments upon exercise of the option, if exercised. The option to license and develop LPCN 111 (TLANDO XR) will be accrued and expensed to research and development when and only if we decide to exercise our option. No decision had been made as of December 31, 2021 to exercise the option; therefore, no accrual was recorded.

In connection with the NOCDURNA[®] license agreement and asset purchase entered into with Ferring in October 2020, we paid Ferring an upfront payment of \$5,000 upon execution and paid an additional \$2,500 in October 2021. Ferring is eligible for additional commercial milestone payments potentially totaling up to \$17,500 based on our net sales of NOCDURNA[®] in the U.S.

Pending Litigation

From time to time, we may be involved in various legal matters generally incidental to our business. Although the results of litigation and claims cannot be predicted with certainty, after discussion with legal counsel, we are not aware of any matters for which the likelihood of a loss is probable and reasonably estimable and which could have a material impact on our consolidated financial condition, liquidity, or results of operations.

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On October 23, 2017, Randy Smith filed a complaint in the District of New Jersey, captioned *Randy Smith, Individually and on Behalf of All Others Similarly Situated v. Antares Pharma, Inc., Robert F. Apple and Fred M. Powell* (“*Smith*”), Case No. 3:17-cv-8945-MAS-DEA, on behalf of a putative class of persons who purchased or otherwise acquired Antares securities between December 21, 2016 and October 12, 2017, inclusive, asserting claims for purported violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, against Antares, Robert F. Apple and Fred M. Powell. The Smith complaint contends that defendants made false and/or misleading statements and/or failed to disclose that: (i) Antares had provided insufficient data to the FDA in connection with the NDA for XYOSTED®; and (ii) accordingly, Antares had overstated the approval prospects for XYOSTED®. On July 27, 2018, the court entered an order appointing Serghei Lungu as lead plaintiff, Pomerantz LLP as lead counsel, and Lite DePalma Greenberg, LLC as liaison counsel for plaintiff. On August 3, 2018, the parties submitted a stipulation and proposed order, setting forth an agreed-upon schedule for responding to the complaint, which the court granted. Pursuant to that order, plaintiff filed a Consolidated Amended Class Action Complaint on October 9, 2018. On November 26, 2018, defendants filed a motion to dismiss. Plaintiff filed an opposition to the motion on January 10, 2019 and defendants filed a reply in support of their motion on February 25, 2019. On July 2, 2019, the court dismissed the complaint in its entirety without prejudice. On July 29, 2019, plaintiff filed a Consolidated Second Amended Class Action Complaint against the same parties alleging substantially similar claims. On September 12, 2019, defendants filed a motion to dismiss the Consolidated Second Amended Class Action Complaint. Plaintiffs’ opposition was filed on October 28, 2019 and defendants’ reply in support of their motion was filed on November 27, 2019. On April 28, 2020, the court dismissed the Consolidated Second Amended Class Action Complaint in its entirety. The court further ordered that plaintiff may file an amended complaint by May 29, 2020 and provide the court with a form of the amended complaint that indicates in what respect(s) it differs from the complaint which it proposes to amend. On May 29, 2020, plaintiff filed a Consolidated Third Amended Class Action Complaint and defendants filed a motion to dismiss on July 10, 2020. Briefing on defendants’ motion was complete on August 25, 2020. On February 26, 2021, the court granted defendants’ motion to dismiss with prejudice, and on March 29, 2021 the plaintiff filed a notice of appeal. On June 21, 2021, plaintiff-appellant filed his opening brief. Defendants-appellees’ response brief was filed on August 4, 2021 and plaintiff-appellant’s reply was filed on September 8, 2021. On January 25, 2022, the Third Circuit ruled in defendants’ favor affirming dismissal. If plaintiffs choose to appeal, they have ninety days to file a petition for writ of certiorari to the U.S. Supreme Court. We believe the claims in the *Smith* action lack merit and intend to continue to defend them vigorously.

On January 12, 2018, a stockholder of the Company filed a derivative civil action, captioned *Chiru Mackert, derivatively on behalf of Antares Pharma, Inc., v. Robert F. Apple, et al.*, in the Superior Court of New Jersey Chancery Division, Mercer County (Case No. C-11-18). On January 17, 2018, another stockholder filed a derivative action in the same court, captioned *Vikram Rao, Derivatively on Behalf of Antares Pharma, Inc. v. Robert F. Apple, et al.* (Case No. C-4-18). Both complaints name Robert F. Apple, Fred M. Powell, Thomas J. Garrity, Jacques Gonella, Anton Gueth, Leonard S. Jacob, Marvin Samson and Robert P. Roche, Jr. as defendants, and the Company as nominal defendant, and they assert claims for breach of fiduciary duties, unjust enrichment, abuse of control, gross mismanagement, and waste of corporate assets arising from the same facts underlying the *Smith* securities class action. The plaintiffs seek damages, corporate governance and internal procedure reforms and improvements, restitution, reasonable attorneys’ fees, experts’ fees, costs, and expenses. The parties have filed a stipulation and order consolidating the two actions and staying the proceedings pending the court’s decision on defendants’ motion to dismiss the *Smith* action; the motion to dismiss in *Smith* was granted on February 26, 2021 and notice of appeal was filed on March 29, 2021. On January 25, 2022, the Third Circuit ruled in defendants’ favor affirming dismissal of the securities fraud class action. If plaintiffs in the securities action choose to appeal, they have ninety days to file a petition for writ of certiorari to the U.S. Supreme Court.

ANTARES PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(in thousands, except per share amounts)

On January 17, 2018, a stockholder of the Company filed a derivative civil action, captioned *Robert Clark, Derivatively on Behalf of Antares Pharma, Inc. v. Robert F. Apple, et al.* (“*Clark*”) (Case No. 3:18-cv-703-MAS-DEA), against Robert F. Apple, Thomas J. Garrity, Jacques Gonella, Leonard S. Jacob, Marvin Samson, Anton G. Gueth and Robert P. Roche, Jr. as defendants, and Company as a nominal defendant. The action was filed in the U.S. District Court for the District of New Jersey and asserts claims for breach of fiduciary duties, unjust enrichment, abuse of control, waste of corporate assets, and a violation of Section 14(a) of the Securities Exchange Act of 1934. This complaint relates to the same facts underlying the *Smith* securities class action and the other derivative actions. The plaintiff in *Clark* seeks damages, corporate governance and internal procedure reforms and improvements, reasonable attorneys’ fees, accountants’ and experts’ fees, costs, and expenses. The parties have filed a stipulation and order staying the action pending the court’s decision on defendants’ motion to dismiss the *Smith* action; the motion to dismiss in *Smith* was granted on February 26, 2021 and notice of appeal was filed on March 29, 2021. After the expiration of all appeals related to the *Smith* dismissal, the parties shall submit a proposed order regarding the derivative action. On January 25, 2022, the Third Circuit ruled in defendants’ favor affirming dismissal of the securities fraud class action. If plaintiffs in the securities action choose to appeal, they have ninety days to file a petition for writ of certiorari to the U.S. Supreme Court.

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

Our management evaluated, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this report. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2021, our disclosure controls and procedures were effective.

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) under the Securities Exchange Act of 1934, as amended). Under the supervision and with the participation of our Chief Executive Officer and the Chief Financial Officer, management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2021. This assessment was based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in *Internal Control-Integrated Framework (2013)*.

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:

- (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and dispositions of the company's assets;
- (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that the company's receipts and expenditures are being made only in accordance with authorizations of the company's management and board of directors; and
- (iii) 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.

Based on management's assessment using the COSO *Internal Control-Integrated Framework (2013)* criteria, management has concluded that its internal control over financial reporting was effective as of December 31, 2021 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. generally accepted accounting principles.

KPMG LLP, an independent registered public accounting firm, has audited the effectiveness of our internal control over financial reporting as of December 31, 2021, and has issued an audit report on our internal control over financial reporting, which appears in Item 8 of this Annual Report on Form 10-K.

Changes in internal control over financial reporting.

There was no change in our internal control over financial reporting that occurred during the quarter ended December 31, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information required by this item concerning our directors will be set forth under the caption “Election of Directors” in our Definitive Proxy Statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K for our 2022 Annual Meeting of Stockholders and is incorporated herein by reference.

Information required by this item concerning our executive officers will be set forth under the caption “Executive Officers of the Company” in our Definitive Proxy Statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K for our 2022 Annual Meeting of Stockholders and is incorporated herein by reference.

Information required by this item concerning compliance with Section 16(a) of the Exchange Act, as amended, will be set forth under the caption “Section 16(a) Beneficial Ownership Reporting Compliance” in our Definitive Proxy Statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K for our 2022 Annual Meeting of Stockholders and is incorporated herein by reference.

Information required by this item concerning our audit committee, the audit committee as our financial expert and any material changes to the way in which security holders may recommend nominees to our Board of Directors will be set forth under the caption “Corporate Governance” in our Definitive Proxy Statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K for our 2022 Annual Meeting of Stockholders and is incorporated herein by reference.

The Board of Directors adopted a Code of Business Conduct and Ethics applicable to all employees and directors, which is posted on our website at www.antareshpharma.com. We will provide copies of our Code of Business Conduct and Ethics without charge upon request. To obtain a copy, please visit our website or send your written request to Antares Pharma, Inc., 100 Princeton South, Suite 300, Ewing, NJ 08628, Attn: Corporate Secretary. With respect to any amendments or waivers of this Code of Business Conduct and Ethics (to the extent applicable to our chief executive officer, principal accounting officer or controller, or persons performing similar functions) we intend to either post such amendments or waivers on our website or disclose such amendments or waivers pursuant to a Current Report on Form 8-K.

ITEM 11. EXECUTIVE COMPENSATION

Information required by this item will be set forth under the caption “Executive Compensation” in our Definitive Proxy Statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K for our 2022 Annual Meeting of Stockholders and is incorporated herein by reference.

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

Information required by this item concerning ownership will be set forth under the caption “Security Ownership of Certain Beneficial Owners” and “Security Ownership of Directors and Executive Officers” in our Definitive Proxy Statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K for our 2022 Annual Meeting of Stockholders and is incorporated herein by reference. The following table provides information about our equity compensation plans as of December 31, 2021 (in thousands, except exercise price):

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding shares reflected in the first column)
Equity compensation plans approved by security holders	15,577	\$2.83	366
Equity compensation plans not approved by security holders	None	None	None

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

Information required by this item will be set forth under the captions “Certain Relationships and Related Transactions” and “Corporate Governance” in our Definitive Proxy Statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K for our 2022 Annual Meeting of Stockholders and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item will be set forth under the caption “Ratification of Selection of Independent Registered Public Accountants” in our Definitive Proxy Statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K for our 2022 Annual Meeting of Stockholders and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

- (1) Financial Statements - see Item 8 of Part II in this Annual Report on Form 10-K.
- (2) Financial Statement Schedules

All schedules have been omitted because they are not applicable, are immaterial or are not required because the information is included in the consolidated financial statements or the notes thereto.

- (3) Item 601 Exhibits - see list of Exhibits below.

(b) Exhibits

The following is a list of exhibits filed as part of, or incorporated by reference into, this Annual Report on Form 10-K.

Exhibit No.	Description
3.1	Certificate of Incorporation of Antares Pharma, Inc. (filed as Exhibit 4.1 to Form S-3 on April 12, 2006 and incorporated herein by reference).
3.2	Certificate of Amendment to Certificate of Incorporation of Antares Pharma, Inc. (filed as Exhibit 3.1 to Form 8-K on May 19, 2008 and incorporated herein by reference).
3.3	Amended and Restated By-laws of Antares Pharma, Inc. (filed as Exhibit 3.1 to Form 8-K on May 15, 2007 and incorporated herein by reference).
3.4	Certificate of Amendment to Certificate of Incorporation of Antares Pharma, Inc. (filed as Exhibit 3.1 to Form 8-K on May 28, 2013 and incorporated herein by reference).
3.5	Certificate of Amendment to Certificate of Incorporation of Antares Pharma, Inc. (filed as Exhibit 10.3 to Form 10-Q on August 9, 2016 and incorporated herein by reference).
4.1	Form of Certificate of Common Stock (filed as Exhibit 4.1 to Form S-1/A on August 15, 1996 and incorporated herein by reference).
4.2	Registration Rights Agreement with Permtec Holding AG dated January 31, 2001 (filed as Exhibit 10.2 to Form 10-K on April 16, 2001 and incorporated herein by reference).
4.3	Stock Purchase Agreement with Sicor Pharmaceuticals, Inc., dated November 23, 2005 (filed as Exhibit 10.55 to Form 10-K on March 20, 2006 and incorporated herein by reference).
4.4*	Antares Pharma, Inc. Equity Compensation Plan, as amended and restated, and approved by stockholders (filed as Exhibit 4.1 to the Company's Form S-8 filed July 23, 2019 and incorporated herein by reference).
4.5	Description of Company's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 (filed as Exhibit 4.5 to Form 10-K on March 3, 2020 and incorporated herein by reference).
10.0	Stock Purchase Agreement with Permtec Holding AG, Permtec Pharma AG, Permtec Technologie AG and Permtec NV with First and Second Amendments dated July 14, 2000 (filed as an Exhibit to Schedule 14A on December 28, 2000 and incorporated herein by reference).
10.1	Third Amendment of Stock Purchase Agreement, dated January 31, 2001 (filed as Exhibit 10.1 to Form 10-K on April 16, 2001 and incorporated herein by reference).

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Exhibit No.	Description
10.2	Lease Agreement between Princeton South Investors, LLC and Antares Pharma, Inc., dated February 3, 2012 (filed as Exhibit 10.21 to Form 10-K for the year ended December 31, 2011 and incorporated herein by reference).
10.3	First Amendment to Lease between Princeton South Investors, LLC and Antares Pharma, Inc., dated January 28, 2013 (filed as Exhibit 10.22 to Form 10-K for the year ended December 31, 2012 and incorporated herein by reference).
10.4	Second Amendment to Lease between Princeton South Investors, LLC and Antares Pharma, Inc., dated December 4, 2013 (filed as Exhibit 10.22 to Form 10-K for the year ended December 31, 2013 and incorporated herein by reference).
10.5	Third Amendment to Lease between Princeton Office Center, LLC and Antares Pharma, Inc., dated May 7, 2019 (filed as Exhibit 10.1 to Form 10-Q on August 6, 2019 and incorporated herein by reference).
10.6	Lease Agreement between St. Paul Fire and Marine Insurance Company and Antares Pharma, Inc., dated December 20, 2013 (filed as Exhibit 10.23 to Form 10-K for the year ended December 31, 2013 and incorporated herein by reference).
10.7	Lease Agreement by and between Antares Pharma, Inc. and Whitewater Properties I, LLC dated July 1, 2019 (filed as Exhibit 10.1 to Form 8-K on July 5, 2019 and incorporated herein by reference).
10.8*	Antares Pharma, Inc. Severance Plan, dated May 29, 2014 (filed as Exhibit 10.4 to Form 10-Q on August 7, 2014 and incorporated herein by reference).
10.9	Form of Indemnification Agreement between Antares Pharma, Inc. and each of its directors and executive officers (filed as Exhibit 10.9 to Form 10-K on March 12, 2019 and incorporated herein by reference).
10.10*	Antares Pharma, Inc. Annual Incentive Plan, effective December 2, 2015 (filed as Exhibit 99.1 to Form 8-K on December 8, 2015 and incorporated herein by reference).
10.11*	Employment Agreement dated March 4, 2016 between Antares Pharma, Inc. and Robert F. Apple (filed as Exhibit 10.1 to Form 10-Q on May 9, 2016 and incorporated herein by reference).
10.12*	Amended and Restated Employment Agreement dated June 30, 2016 between Antares Pharma, Inc. and Peter J. Graham (filed as Exhibit 10.2 to Form 10-Q on August 9, 2016 and incorporated herein by reference).
10.13*	Employment Agreement effective October 31, 2016 between Antares Pharma, Inc. and Fred M. Powell (filed as Exhibit 10.1 to Form 10-Q on November 9, 2016 and incorporated herein by reference).
10.14*	Employment Agreement effective April 26, 2021 between Antares Pharma, Inc. and Dr. Peter C. Richardson (filed herewith).
10.15*	Form of Nonqualified Stock Option Grant Agreement (filed as exhibit 10.4 to Form 10-Q on August 6, 2019 and incorporated herein by reference).
10.16*	Form of Restricted Stock Unit Grant Agreement (filed as Exhibit 10.5 to Form 10-Q on August 6, 2019 and incorporated herein by reference).
10.17*	Form of Restricted Stock Grant Agreement (filed as Exhibit 10.6 to Form 10-Q on August 9, 2016 and incorporated herein by reference).
10.18*	Form of Performance Stock Unit Grant Agreement (filed as Exhibit 10.6 to Form 10-Q on August 6, 2019 and incorporated herein by reference).
10.19*	Form of Nonqualified Stock Option Grant Agreement (Non-Employee Director) (filed as Exhibit 10.7 to Form 10-Q on August 6, 2019 and incorporated herein by reference).

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Exhibit No.	Description
10.20*	Form of Restricted Stock Unit Grant Agreement (Non-Employee Director) (filed as Exhibit 10.8 to Form 10-Q on August 6, 2019 and incorporated herein by reference).
10.21*	Antares Pharma, Inc. Equity Compensation Plan, as amended and restated, and approved by stockholders (filed as Exhibit 4.1 to Form S-8 filed June 24, 2021 and incorporated herein by reference).
10.22	Credit Agreement, dated November 1, 2021, by and among Antares Pharma, Inc., Wells Fargo Bank, National Association, and the lenders from time to time party thereto (filed as Exhibit 10.1 to Form 8-K filed November 2, 2021 and incorporated herein by reference).
10.23	Asset Purchase Agreement, dated December 15, 2021, by and between Antares Pharma, Inc., Otter Pharmaceuticals, LLC, a subsidiary of Assertio Holdings, Inc., and Assertio Holdings, Inc., as guarantor (filed herewith).
23.1	Consent of KPMG LLP, Independent Registered Public Accounting Firm (filed herewith).
31.1	Certification of the Chief Executive Officer of Antares Pharma, Inc. required by Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended (filed herewith).
31.2	Certification of the Chief Financial Officer of Antares Pharma, Inc. required by Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended (filed herewith).
32.1	Certification of the Chief Executive Officer of Antares Pharma, Inc. required by Rule 13a-14(b) under the Securities Exchange Act of 1934, as amended (furnished herewith).
32.2	Certification of the Chief Financial Officer of Antares Pharma, Inc. required by Rule 13a-14(b) under the Securities Exchange Act of 1934, as amended (furnished herewith).
101.INS	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) (filed herewith).
101.SCH	Inline XBRL Taxonomy Extension Schema Document (filed herewith).
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document (filed herewith).
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document (filed herewith).
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document (filed herewith).
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document (filed herewith).
104	Cover Page Interactive Data File (the cover page interactive data does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document) (filed herewith).
<p>* Denotes a management contract or compensatory plan or arrangement required to be filed as an exhibit pursuant to Item 15 of Part IV of this Annual Report on Form 10-K.</p>	

ITEM 16. FORM 10-K SUMMARY

None.

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.

ANTARES PHARMA, INC.

(Registrant)

Date: March 3, 2022

/s/ Robert F. Apple

Robert F. Apple

President and Chief Executive Officer

(Principal Executive Officer)

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

<u>Signature</u>	<u>Capacity</u>	<u>Date</u>
<u>/s/ Robert F. Apple</u> Robert F. Apple	President and Chief Executive Officer, Director (Principal Executive Officer)	March 3, 2022
<u>/s/ Fred M. Powell</u> Fred M. Powell	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 3, 2022
<u>/s/ Leonard S. Jacob</u> Dr. Leonard S. Jacob	Director, Chairman of the Board	March 3, 2022
<u>/s/ Thomas J. Garrity</u> Thomas J. Garrity	Director	March 3, 2022
<u>/s/ Peter S. Greenleaf</u> Peter S. Greenleaf	Director	March 3, 2022
<u>/s/ Anton G. Gueth</u> Anton G. Gueth	Director	March 3, 2022
<u>/s/ Robert P. Roche, Jr.</u> Robert P. Roche, Jr.	Director	March 3, 2022
<u>/s/ Karen L. Smith</u> Dr. Karen L. Smith	Director	March 3, 2022
<u>/s/ Carmen B. Volkart</u> Carmen B. Volkart	Director	March 3, 2022

ANTARES PHARMA, INC.

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (this “*Agreement*”) is made and entered into on this 22nd day of April, 2021, effective as of the 26th day of April 2021 (the “*Effective Date*”) by and between Antares Pharma, Inc., a Delaware corporation (the “*Company*”), and Dr. Peter C. Richardson. (the “*Executive*”).

WITNESSETH:

WHEREAS, the Company desires to secure for itself the services of the Executive, and the Executive wishes to furnish such services to the Company, pursuant to the terms and subject to the conditions hereinafter set forth.

NOW, THEREFORE, in consideration of the premises and of the mutual promises and covenants contained herein, the Company and the Executive, intending to be legally bound, hereby agree as follows:

1. Employment.

(a) Term. This Agreement shall be effective as of the Effective Date and continue until the one-year anniversary thereof, unless sooner terminated by either party as hereinafter provided. In addition, this Agreement shall automatically renew for periods of one (1) year unless either party gives written notice to the other party at least ninety (90) days prior to the end of the Term (as defined below) or at least ninety (90) days prior to the end of any one (1) year renewal period that the Agreement shall not be further extended. The period commencing on the Effective Date and ending on the date on which the term of the Executive’s employment under this Agreement terminates is referred to herein as the “*Term*.”

(b) Duties. During the Term, the Executive shall be employed by the Company as the Executive Vice President, Head of Research and Development, Chief Medical Officer, with the duties, responsibilities and authority commensurate therewith. The Executive shall report to the Chief Executive Officer (the “*CEO*”) and shall perform all duties and accept all responsibilities incident to such position as may be reasonably assigned to him by the CEO.

(c) Best Efforts. During the Term, the Executive shall devote his best efforts and full time and attention to promote the business and affairs of the Company, and may not, without the prior written consent of the Company, operate, participate in the management, operations or control of, or act as an employee, officer, consultant, agent or representative of, any type of business or service (other than as an employee of the Company). It shall not be deemed a violation of the foregoing for the Executive to (i) act or serve as a director, trustee or committee member of any civic or charitable organization; (ii) manage his personal, financial and legal affairs; or (iii) serve as a director of an organization that is not a civic or charitable organization with the prior consent of the Board of Directors of the Company (the “*Board*”), which consent shall not be unreasonably withheld, in all cases so long as such activities (described in clauses (i), (ii) and (iii)) are permitted under the Company’s code of conduct and employment policies and do not materially interfere with or conflict with his

obligations to the Company hereunder, including, without limitation, obligations pursuant to Section 6 below. Effective as of the Effective Date and ending May 31, 2021, Executive currently participates in the outside activities specified on Schedule 1, Executive fully disclosed and described those activities to the Company

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and the parties agree that his participation in such activities as described to the Company do not and will not violate the terms of this Agreement, including, without limitation, the terms set forth in this Section 1(c) and Section 6 below.

(d) Location. The Executive's principal place of employment shall be the Company's principal corporate offices located in Ewing, New Jersey. The Executive may be required to travel for business from time to time in the course of performing his duties for the Company.

2. Compensation.

(a) Base Salary. During the Term, the Company shall pay the Executive a base salary ("**Base Salary**") at the annual rate of \$400,000, which shall be paid in accordance with the Company's normal payroll practices. The Executive's Base Salary shall be subject to review, and at the approval of the Compensation Committee of the Board (the "**Compensation Committee**"), subject to increase (but not decrease) during the Term, based upon the performance of the Executive and the Company, as determined by the Compensation Committee with input from the CEO, in accordance with the Company's normal compensation and performance review policies for senior executives generally. Notwithstanding the foregoing, any increase in the Executive's Base Salary for calendar year 2022 will be multiplied by a fraction, the numerator of which is the number of whole months during which the Executive was employed by the Company during calendar year 2021 and the denominator of which is twelve (12).

(b) Bonus. In addition to the Executive's Base Salary, the Executive shall be eligible to receive a bonus for each calendar year during the Term, based on attainment of certain individual and corporate performance goals and targets (the "**Annual Bonus**") in accordance with the terms of the Company's Annual Incentive Plan, as amended from time to time (or successor plan). The target amount of the Executive's Annual Bonus shall be fifty percent (50%) of Base Salary. The performance goals and targets shall be determined by the Compensation Committee in consultation with the CEO. Once determined, the applicable performance goals and targets shall be communicated to the Executive as soon as reasonably practicable following the Compensation Committee's determination of the applicable goals and targets. The actual Annual Bonus amount paid will be based upon the Compensation Committee's determination, in its sole discretion, whether and to what extent the applicable performance goals and targets have been achieved, and such amount may be more or less than the target amount, as determined by the Compensation Committee in its sole discretion. Any Annual Bonus earned and payable to the Executive hereunder shall be paid on or after January 1 but not later than March 15 of the calendar year following the calendar year for which the Annual Bonus is earned. Notwithstanding the foregoing, any Annual Bonus for calendar year 2021 will be multiplied by a fraction, the numerator of which is the number of days during which the Executive was employed by the Company during calendar year 2021 and the denominator of which is three hundred sixty-five (365).

(c) Equity Compensation.

(i) On the Effective Date, pursuant to the Antares Pharma, Inc. Equity Compensation Plan, as amended from time to time (the "**Equity Plan**"), the Executive shall be granted a stock option to purchase shares of common stock of the Company, \$0.01 par value (the "**Stock**"), with a targeted grant date fair value of \$125,000 and at an exercise price equal to the closing price of the Stock on the date of grant, subject in all respects to the terms and conditions of the Equity Plan and the Stock Option Agreement evidencing the terms and

conditions of the grant (“***Initial Option***”). Provided that the Executive is employed by the Company on the applicable vesting dates, the Initial Option shall vest and become exercisable as to thirty-three

and one-third percent (33-1/3%) of the shares subject to the Initial Option on each of the first three anniversaries of the date of grant.

(ii) In addition, during the Term, the Executive shall be eligible to participate in any long-term equity incentive programs established by the Company for its senior level executives generally, including the Equity Plan (or successor plan), at levels determined by the Compensation Committee in its sole discretion, commensurate with the Executive's position. Subject to the terms and conditions set by the Compensation Committee and as set forth in the applicable award agreements and the Equity Plan, the Executive shall be granted a long-term incentive award in June 2021 with an aggregate targeted grant date fair value of \$400,000, which award shall be in the same combination of stock options, time-vesting restricted stock units, and performance stock units, and in the same proportions and with the same vesting schedules, as shall apply to the long-term incentive awards granted to other senior level executives of the Company in June 2021.

(d) Vacation. During the Term, the Executive shall be entitled to vacation, holiday and sick leave at levels generally commensurate with those provided to other senior executives of the Company, in accordance with the Company's vacation, holiday and other pay-for-time-not worked policies; provided, however, that the Executive shall be entitled to not less than five (5) weeks of paid vacation each calendar year, prorated from any period of employment of less than twelve (12) months in a calendar year. Such paid time off may be carried over from year to year to the extent permitted in accordance with standard Company policy and shall be paid to the extent accrued (and to the extent not used) as of the Executive's termination of employment.

(e) Employee Benefits. The Executive shall be entitled to participate in the Company's health, life insurance, long and short-term disability, dental, retirement, savings, flexible spending accounts and medical programs, if any, pursuant to their respective terms and conditions. Nothing in this Agreement shall preclude the Company or any parent, subsidiary or affiliate of the Company from terminating or amending any employee benefit plan or program from time to time after the Effective Date.

(f) Expense Reimbursement. During the Term, the Company shall reimburse the Executive, in accordance with the policies and practices of the Company in effect from time to time, for all reasonable and necessary business expenses and other disbursements incurred by him for or on behalf of the Company in connection with the performance of his duties hereunder upon presentation by the Executive to the Company of appropriate documentation thereof.

3. Termination of Employment.

(a) Employment at Will. Executive's employment with the Company is on an at-will basis, meaning the Company or Executive may terminate Executive's employment at any time, with or without cause.

(b) Termination for Cause. The Company may terminate the Executive's employment hereunder at any time for Cause (as defined below) upon written notice to the Executive (as described below), in which event all payments under this Agreement shall cease, except for any amounts earned, accrued and owing, but not yet paid under Section 2 above and any benefits accrued and due under any applicable benefit plans and programs of the Company.

For purposes of this Agreement, the term “***Cause***” shall mean any of the following grounds for termination of the Executive’s employment: (i) the Executive’s knowing and material dishonesty or fraud committed in connection with the Executive’s employment; (ii) theft, misappropriation

or embezzlement by the Executive of the Company's funds; (iii) the Executive's conviction of or a plea of guilty or *nolo contendere* to any felony, a crime involving fraud or misrepresentation, or any other crime (whether or not connected with his employment) the effect of which is likely to adversely affect the Company or its parents, subsidiaries or affiliates; (iv) the Executive commits any act or omission that would constitute a breach of a fiduciary duty of an officer of a Delaware corporation; (v) the Executive's material failure to comply with the Company's code of conduct or significant employment policies; or (vi) a material breach by the Executive of any of the provisions or covenants set forth in this Agreement.

(c) Voluntary Resignation. The Executive may voluntarily terminate his employment without Good Reason (as defined below) upon thirty (30) days advance written notice to the Company. In such event, after the effective date of such termination, no payments shall be due under this Agreement, except that the Executive shall be entitled to any amounts earned, accrued and owing, but not yet paid under Section 2 above and any benefits accrued and due under any applicable benefit plans and programs of the Company.

For purposes of this Agreement, "**Good Reason**" shall mean the occurrence of one or more of the following without the prior written consent of the Executive: (i) a material reduction in Executive's Base Salary; (ii) the Company's material breach of terms of this Agreement (which for purposes of this Agreement shall include (A) the failure of the Company to require any successor to the Company to assume the obligations of the Company to Executive under this Agreement and any other agreement between the Company and Executive then in effect or (B) the Company's reduction in the target annual bonus opportunity below fifty percent (50%) of Base Salary for any calendar year during the Term) (for the avoidance of doubt for purposes of this clause (ii), both of the events described in subclauses (A) and (B) do not need to occur for a material breach of this Agreement to be triggered); (iii) a change in the Executive's designation of title from Executive Vice President, Head of Research and Development, Chief Medical Officer of the Company or successor entity (unless such change is to a higher title and level of responsibility) that results in a material diminution in Executive's authority, duties and responsibilities (for the avoidance of doubt, a change in Executive's title that removes either Head of Research and Development or Chief Medical Officer responsibilities shall not give rise to the right to resign for Good Reason hereunder); (iv) a material change in the geographic location at which Executive must perform services that results in the relocation of Executive's principal business location to a location that is sixty (60) miles or more from Ewing, New Jersey; or (v) the Company's delivery to the Executive of a notice of its intent not to renew the Term pursuant to Section 1(a) above; provided that the Executive is willing and able to execute a new contract providing terms and conditions substantially similar to those in this Agreement and to continue providing services to the Company.

Notwithstanding any provision of this definition of Good Reason to the contrary, the Executive shall not have Good Reason for termination unless the Executive gives written notice of termination for Good Reason within thirty (30) days after the event giving rise to Good Reason occurs, the Company does not correct the action or failure to act that constitutes the grounds for Good Reason, as set forth in the Executive's notice of termination, within thirty (30) days after the date on which the Executive gives written notice of termination, and the Executive terminates employment within sixty (60) days after the event that constitutes Good Reason. If the Executive's resignation occurs after such time, the resignation shall be treated as a voluntary resignation other than for Good Reason and the Executive will not be entitled to severance benefits under this Agreement.

(d) Termination without Cause; Resignation for Good Reason. Except as provided in Section 4(a) below, if the Executive's employment is terminated by the Company (or the

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surviving company following a Change of Control (as defined in Section 4(c) below)) without Cause or by the Executive for Good Reason, either before or after a Change of Control, the provisions of this Section 3(d) shall apply (subject to the modifications of Section 4(a) below, if applicable). The Company may terminate the Executive's employment with the Company at any time without Cause upon not less than thirty (30) days' prior written notice to the Executive. The Company may, in its sole and absolute discretion, pay the Executive his Base Salary in lieu of any unexpired period of notice and terminate his employment immediately. Except as provided in Section 4(a) below, upon termination of the Executive's employment by the Company under this Section 3(d) or by the Executive for Good Reason, either before or after a Change of Control, if the Executive executes and does not revoke a written release, in substantially the form attached hereto as Exhibit A, of any and all claims against the Company and all related parties with respect to all matters arising out of the Executive's employment by the Company, or the termination thereof (other than claims for any entitlements under the terms of this Agreement or under any plans or programs of the Company under which the Executive has accrued and is due a benefit) (the "**Release**"), and continues to comply with the provisions of the Proprietary Information and Invention Assignment Agreement (as defined in Section 6(a) below) and covenants and representations in Section 6 below, the Executive shall be entitled to receive the payments and benefits set forth in subsections 3(d)(i), (ii), (iii) and (iv), in lieu of any other payments and benefits due under any severance plan or program for employees or executives (subject to the modifications of Section 4(a) below, if applicable).

(i) The Company will pay to the Executive severance as follows: the rate of the Executive's Base Salary as in effect at the time of termination will be added together with the dollar value of the Executive's target Annual Bonus for the year in which termination occurs and the sum of the foregoing amounts will be divided by twelve (12) (the "**Monthly Severance Amount**"). The Monthly Severance Amount will be paid each month over the twelve (12) month period following the termination date, beginning within the sixty (60)-day period following the date of the Executive's termination of employment and continuing on each payroll date thereafter until fully paid, in accordance with the Company's regular payroll practices. The first severance payment will include any missed payments during such sixty (60)-day period.

(ii) The Company will pay to the Executive a pro rata Annual Bonus for the year in which the termination of employment occurs, which shall be determined based on Executive's actual Annual Bonus earned for the year in which termination of employment occurs (if any), based on actual performance, multiplied by a fraction, the numerator of which is the number of days in which the Executive was employed by Company during the year in which the termination of employment occurs, and the denominator of which is three hundred sixty-five (365). The pro rata Annual Bonus described in this subsection 3(d)(ii) will be paid at the same time and under the same terms and conditions as bonuses are paid to other executives of the Company, on or after January 1 but not later than March 15 of the calendar year following the calendar year in which the Executive's employment terminates, subject to Section 5(b) below.

(iii) For the twelve (12) month period following the Executive's termination of employment, provided that the Executive timely elects COBRA, the Company will reimburse the Executive for the monthly COBRA cost of continued medical and dental coverage for the Executive and, where applicable, his spouse and dependents, at the level in effect as of the date of the Executive's termination of employment, less the employee portion of the applicable premiums that the Executive would have paid had he remained employed during the such twelve (12) month period (the COBRA continuation coverage period shall run concurrently with the twelve (12) month period that the Executive is provided with reimbursement for medical and dental coverage under this

subsection 3(d)(iii)). These reimbursements will commence within the sixty (60)-day period following the date of the Executive's termination of employment and will

be paid on the first payroll date of each month, provided that the Executive demonstrates proof of payment of the applicable premiums prior to the applicable reimbursement payment date. Notwithstanding the foregoing, the Company's reimbursement of the monthly COBRA premiums in accordance with this subsection 3(d)(iii) shall cease immediately upon the earlier of: (A) the end of the twelve (12) month period following the Executive's termination of employment, or (B) the date that the Executive is eligible for comparable coverage with a subsequent employer. Notwithstanding the foregoing, the Company reserves the right to restructure the foregoing COBRA premium reimbursement arrangement in any manner necessary or appropriate to avoid fines, penalties or negative tax consequences to the Company or the Executive (including, without limitation, to avoid any penalty imposed for violation of the nondiscrimination requirements under the Patient Protection and Affordable Care Act or the guidance issued thereunder), as determined by the Company in its sole and absolute discretion.

(iv) Notwithstanding any provision to the contrary in the Equity Plan (or a successor plan) or any applicable agreement (including this Agreement), all outstanding equity grants held by the Executive immediately prior to the Executive's termination date which vest based upon the Executive's continued service over time that would have become vested during the twelve (12) month period following the Executive's termination date had the Executive remained employed during such twelve (12) month period shall accelerate, become fully vested and/or exercisable, as the case may be, as of the Executive's termination date. All outstanding equity grants held by the Executive immediately prior to the Executive's termination date which vest based upon attainment of performance criteria shall remain subject to the terms and conditions of the agreement evidencing such performance-based award.

(v) The Executive shall also be entitled to any amounts earned, accrued and owing but not yet paid under Section 2 above and any benefits accrued and due under any applicable benefit plans and programs of the Company without regard to whether the Executive executes or revokes the Release.

(e) Death or Disability. The Executive's employment hereunder shall terminate upon the Executive's death or involuntary termination of employment by the Company on account of his Disability (as defined below), subject to the requirements of applicable law. If the Executive's employment terminates due to death or involuntary termination by the Company on account of the Executive's Disability, no payments shall be due under this Agreement, except that the Executive (or in the event of the Executive's death, the Executive's executor, legal representative, administrator or designated beneficiary, as applicable), shall be entitled to receive any amounts earned, accrued and owing but not yet paid under Section 2 above and any benefits accrued and due under any applicable benefit plans and programs of the Company. For purposes of this Agreement, the term "**Disability**" shall mean such physical or mental illness or incapacity of the Executive as shall (i) prevent him from substantially performing his customary services and duties to the Company, with or without reasonable accommodation, and (ii) continue for periods aggregating more than sixty (60) days in any six (6)-month period. The Company shall determine whether there is a Disability after consultation with a qualified, independent physician. The Executive shall cooperate with the Company, including making himself reasonably available for examination by physicians at the Company's request, to determine whether or not he has incurred a Disability. The Executive's failure (other than a failure caused by the Disability) to cooperate with the Company in a determination of Disability shall be treated as the Executive's voluntary resignation from the Company without Good Reason.

4. Change of Control.

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(a) Termination without Cause or Resignation for Good Reason Within Sixty Days Before or Eighteen Months Following a Change of Control. Notwithstanding anything to the contrary herein, if there is both a Change of Control and the Executive's employment is terminated without Cause or by the Executive for Good Reason within sixty (60) days before or within eighteen (18) months following such Change of Control (a "**CIC Termination**"), the Executive shall be entitled to (i) the payments set forth under subsection 3(d)(i), except that the Monthly Severance Amount will be multiplied by eighteen (18) months, (ii) the payment described in subsection 3(d)(ii) on the same terms and conditions described in subsection 3(d)(ii), (iii) the payments set forth under subsection 3(d)(iii), except that twelve (12) months shall be replaced with eighteen (18) months, and (iv) in lieu of the benefit described in subsection 3(d)(iv), notwithstanding any provision to the contrary in the Equity Plan (or a successor plan) or any applicable agreement (including this Agreement), all outstanding equity grants held by the Executive immediately prior to the CIC Termination which vest based upon the Executive's continued service over time shall accelerate, become fully vested and/or exercisable, as the case may be, as of the date of the CIC Termination and all outstanding equity grants held by the Executive immediately prior to the CIC Termination which vest based upon attainment of performance criteria shall remain subject to the terms and conditions of the agreement evidencing such performance based award. Notwithstanding the foregoing in this Section 4(a), no amounts under this Section 4(a) will be paid or benefits under this Section 4(a) will be provided, in each case, upon a CIC Termination unless the Executive executes and does not revoke a Release and continues to comply with the covenants set forth in Section 6 below and the provisions of any confidentiality, non-competition, non-solicitation or invention assignment agreement with the Company to which the Executive is subject.

(b) Application of Section 280G. In the event that it shall be determined that any payment or distribution in the nature of compensation (within the meaning of section 280G(b)(2) of the Internal Revenue Code of 1986, as amended (the "**Code**")) to or for the benefit of the Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise (a "**Payment**"), would constitute an "excess parachute payment" within the meaning of section 280G of the Code, the aggregate present value of the Payments under the Agreement shall be reduced (but not below zero) to the Reduced Amount (defined below), provided that the reduction shall be made only if the Accounting Firm (described below) determines that the reduction will provide the Executive with a greater net after-tax benefit than would no reduction. The "**Reduced Amount**" shall be an amount expressed in present value which maximizes the aggregate present value of Payments under this Agreement without causing any Payment under this Agreement to be subject to the Excise Tax (defined below), determined in accordance with section 280G(d)(4) of the Code. The term "**Excise Tax**" means the excise tax imposed under section 4999 of the Code, together with any interest or penalties imposed with respect to such excise tax. Payments under this Agreement shall be reduced on a nondiscretionary basis in such a way as to minimize the reduction in the economic value deliverable to the Executive. Where more than one payment has the same value for this purpose and they are payable at different times they will be reduced on a pro rata basis. Only amounts payable under this Agreement shall be reduced pursuant to this Section 4(b). All determinations to be made under this Section 4(b) shall be made by an independent certified public accounting firm selected by the Company immediately prior to the Change of Control (the "**Accounting Firm**"), which shall provide its determinations and any supporting calculations both to the Company and the Executive within ten (10) days of the Change of Control. Any such determination by the Accounting Firm shall be binding upon the Company and the Executive. All of the fees and expenses of the Accounting Firm in performing the determinations referred to in this Section 4(b) shall be borne solely by the Company.

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(c) Definition of a Change of Control. For purposes of this Agreement, the term “Change of Control” shall have the same meaning ascribed to such term under the Equity Plan, as in effect on the date hereof and as it may be amended from time to time, or if the Equity Plan is no longer in effect, a successor plan thereto.

5. Section 409A.

(a) Compliance with Section 409A. This Agreement is intended to comply with section 409A of the Code and its corresponding regulations, or an exemption, and payments may only be made under this Agreement upon an event and in a manner permitted by section 409A of the Code, to the extent applicable. Severance benefits under the Agreement are intended to be exempt from section 409A of the Code under the “short-term deferral” exception, to the maximum extent applicable, and then under the “separation pay” exception, to the maximum extent applicable. For purposes of section 409A of the Code, all payments to be made upon a termination of employment under this Agreement may only be made upon a “separation from service” within the meaning of such term under section 409A of the Code, each payment made under this Agreement shall be treated as a separate payment and the right to a series of installment payments under this Agreement is to be treated as a right to a series of separate payments. In no event shall the Executive, directly or indirectly, designate the calendar year of payment. Notwithstanding any provision of this Agreement to the contrary, in no event shall the timing of the Executive’s execution of the Release, directly or indirectly, result in the Executive designating the calendar year of payment of nonqualified deferred compensation subject to section 409A of the Code, and if a payment of nonqualified deferred compensation subject to section 409A of the Code is subject to execution of the Release could be made in more than one taxable year, payment shall be made in the later taxable year. All reimbursements and in-kind benefits provided under this Agreement shall be made or provided in accordance with the requirements of section 409A of the Code, including, where applicable, the requirement that (i) any reimbursement is for expenses incurred during the Executive’s lifetime (or during a shorter period of time specified in this Agreement), (ii) the amount of expenses eligible for reimbursement, or in-kind benefits provided, during a calendar year may not affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other calendar year, (iii) the reimbursement of an eligible expense will be made on or before the last day of the calendar year following the year in which the expense is incurred, and (iv) the right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

(b) Payment Delay. Notwithstanding any provision in this Agreement to the contrary, if at the time of the Executive’s separation from service with the Company, the Company has securities which are publicly traded on an established securities market and the Executive is a “specified employee” (as defined in section 409A of the Code) and it is necessary to postpone the commencement of any severance payments otherwise payable pursuant to this Agreement as a result of such separation from service to prevent any accelerated or additional tax under section 409A of the Code, then the Company will postpone the commencement of the payment of any such payments hereunder (without any reduction in such payments ultimately paid or provided to the Executive) that are not otherwise exempt from section 409A of the Code, until the first payroll date that occurs after the date that is six (6) months following the Executive’s separation from service with the Company. If any payments are postponed due to such requirements, such postponed amounts will be paid in a lump sum to the Executive on the first payroll date that occurs after the date that is six (6) months following the Executive’s separation from service with the Company. If the Executive dies during the postponement period prior to the payment of the postponed amount, the amounts withheld on account of section 409A of the Code shall be paid to the personal representative of the Executive’s estate within sixty (60) days after the date of the Executive’s death.

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6. Covenants and Representations.

(a) Confidential Information. Contemporaneously with this Agreement, the Executive executed the Company's standard Proprietary Information and Invention Assignment Agreement, attached hereto as Exhibit B (the "***Proprietary Information and Invention Assignment Agreement***"), all of the terms of which are hereby incorporated into this Agreement by reference. The Executive hereby agrees that, during the Term and thereafter, the Executive shall hold in strict confidence any proprietary or Confidential Information (as defined below) related to the Company and its parents, subsidiaries and affiliates, except that he may disclose such information pursuant to law, court order, regulation or similar order or in accordance with Section 6(g) below. For purposes of this Agreement, the term "***Confidential Information***" shall mean all information of the Company or any of its parents, subsidiaries and affiliates (in whatever form), which is not generally known to the public, including without limitation any inventions, processes, methods of distribution, customer lists or trade secrets. The Executive hereby agrees that, upon the termination of this Agreement, he shall not take any document (in whatever form) of the Company or its parents, subsidiaries or affiliates, which is of a confidential nature relating to the Company or its parents, subsidiaries or affiliates, or, without limitation, relating to its or their methods of distribution, or any description of any formulas or secret processes and will return any such information (in whatever form) then in his possession.

(b) Non-Competition. The Executive hereby acknowledges that during his employment with the Company, the Executive will become familiar with trade secrets and other Confidential Information concerning the Company, its subsidiaries and their respective predecessors, and that the Executive's services will be of special, unique and extraordinary value to the Company. Accordingly, the Executive hereby agrees that, subject to the requirements of applicable law, at any time during the Term, and for a period of twelve (12) months after the Executive's date of termination of employment for any reason except a CIC Termination, or eighteen (18) months after a CIC Termination (such twelve (12) month period or eighteen (18) month period, as applicable, shall be referred to as the "***Restriction Period***"), the Executive will not, directly or indirectly, own, manage, control, participate in, consult with, render services for, or in any manner engage in any business involving or related to (directly or indirectly) the research, development, marketing and/or sale or other delivery of injection devices, within any geographical area in which, as of the date of the Executive's termination of employment, the Company or its subsidiaries engage in business or demonstrably plan to engage in business (the "***Business***"). It will not be considered a violation of this Section 6(b) for the Executive to be a passive owner of not more than one percent (1%) of the outstanding stock of any class of a corporation which is publicly traded, so long as the Executive has no active participation in the business of such corporation. Further, it shall not be deemed a violation of this Section 6(b) for the Executive to (i) act or serve as a director, trustee, or committee member of any civic or charitable organization; (ii) manage his personal, financial, and legal affairs; or (iii) serve as a director of an organization that is not a civic or charitable organization with the prior consent of the Board, which consent shall not be unreasonably withheld, in all cases so long as such activities (described in clauses (i), (ii) and (iii)) are permitted under the Company's code of conduct and employment policies and do not materially interfere with or conflict with his obligations to the Company hereunder, including, without limitation, obligations pursuant to this Section 6. In addition, the restrictions contained in this section 6(b) shall not prevent the Executive from accepting employment following termination of employment with the Company with a large diversified organization with separate and distinct divisions that do not compete, directly or indirectly, with the Business, as long as prior to accepting such employment, the Company receives separate written assurances from the prospective employer and from the Executive, satisfactory to the Company, to the effect that Executive will

not render any services, directly or indirectly, to any division or business unit that competes, directly or indirectly, with

the Business. During the period set forth in the section, Executive will inform any new employer, prior to accepting employment, of the existence of this Agreement and provide such employer with a copy of this Agreement.

(c) Non-Solicitation. The Executive hereby agrees that during the Term and the Restriction Period, (i) the Executive will not, directly or indirectly through another entity, induce or attempt to induce any employee of the Company or its subsidiaries to leave the employ of the Company or its subsidiaries, or in any way interfere with the relationship between the Company or its subsidiaries and any employee thereof or otherwise employ or receive the services of an individual who was an employee of the Company or its subsidiaries at any time during such Restriction Period, except any such individual whose employment has been terminated by the Company and (ii) the Executive will not induce or attempt to induce any customer, supplier, client, broker, licensee or other business relation of the Company or its subsidiaries to cease doing business with the Company or its subsidiaries.

(d) Return of Property. Upon termination of the Executive's employment with the Company for any reason whatsoever, voluntarily or involuntarily (and in all events within five (5) days of the Executive's date of termination), and at any earlier time the Company requests, the Executive will deliver to the person designated by the Company all originals and copies of all documents and property of the Company in the Executive's possession, under the Executive's control or to which the Executive may have access, including but not limited to, any office, computing or communications equipment (e.g., laptop computer, facsimile machine, printer, cellular phone, etc.) that he has had or has been using, and any business or business-related files that he has had in his possession, except as otherwise permitted in accordance with Section 6(g) below. The Executive will not reproduce or appropriate for the Executive's own use, or for the use of others, any property, Confidential Information or Company inventions, and shall remove from any personal computing or communications equipment all information relating to the Company. The Executive further agrees that, to the extent any Company-related information is stored in hard or electronic copy in any of the Executive's personal properties, devices or accounts, including in the Executive's home, cellphone, PDA or other personal device, email account, cloud, thumb drive or other storage device, the Executive will fully cooperate with the Company in the permanent removal of such information from any such location, device or account.

(e) Non-Disparagement. The Executive agrees that the Executive will not disparage the Company, its subsidiaries and parents, and their respective executives, directors, investors, employees, and agents, and its and their respective successors and assigns, heirs, executors, and administrators, or make any public statement reflecting negatively on the Company, its subsidiaries and parents, and their respective officers, directors, investors, employees, and agents, and its and their respective successors and assigns, heirs, executors, and administrators, to third parties, including, but not limited to, any matters relating to the operation or management of the Company, irrespective of the truthfulness or falsity of such statement, except as may otherwise be required by applicable law or compelled by process of law, or except as otherwise permitted in accordance with Section 6(g) below. The Company shall instruct the members of the Board and members of executive management not make any disparaging or negative remarks, either oral or in writing, regarding the Executive.

(f) Cooperation. During the Term and thereafter, the Executive shall cooperate with the Company and its parents, subsidiaries and affiliates, upon the Company's reasonable request, with respect to any internal investigation or administrative, regulatory or judicial proceeding involving matters within the scope of the Executive's duties and responsibilities to the Company during the Term (including, without limitation, the Executive being available to the Company

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upon reasonable notice for interviews and factual investigations, appearing at the Company's reasonable request to give testimony without requiring service of a subpoena or other legal process, and turning over to the Company all relevant Company documents which are or may come into the Executive's possession during the Term); provided, however, that any such request by the Company shall not be unduly burdensome or unreasonably interfere with the Executive's personal schedule or ability to engage in gainful employment. In the event the Company requires the Executive's cooperation in accordance with this Section 6(f), the Company shall reimburse the Executive for reasonable and approved out-of-pocket expenses (including travel, lodging and meals and reasonable attorneys' fees) incurred by the Executive in connection with such cooperation, subject to reasonable documentation.

(g) Reports to Government Entities. Nothing in this Agreement or the Proprietary Information and Invention Assignment Agreement, restricts or prohibits the Executive from initiating communications directly with, responding to any inquiries from, providing testimony before, providing Confidential Information to, reporting possible violations of law or regulation to, or from filing a claim or assisting with an investigation directly with a self-regulatory authority or a government agency or entity, including the U.S. Equal Employment Opportunity Commission, the Department of Labor, the National Labor Relations Board, the Department of Justice, the Securities and Exchange Commission, the Congress, and any agency Inspector General, or from making other disclosures that are protected under the whistleblower provisions of state or federal law or regulation. The Executive does not need the prior authorization of the Company to engage in conduct protected by this paragraph, and the Executive does not need to notify the Company that the Executive has engaged in such conduct.

Please take notice that federal law provides criminal and civil immunity to federal and state claims for trade secret misappropriation to individuals who disclose a trade secret to their attorney, a court, or a government official in certain, confidential circumstances that are set forth at 18 U.S.C. §§ 1833(b)(1) and 1833(b)(2), related to the reporting or investigation of a suspected violation of the law, or in connection with a lawsuit for retaliation for reporting a suspected violation of the law.

(h) Executive Representations.

(i) The Executive represents and warrants to the Company that there are no restrictions, agreements or understandings whatsoever to which the Executive is a party which would prevent or make unlawful the Executive's execution of this Agreement or the Executive's employment hereunder, which is or would be inconsistent or in conflict with this Agreement or the Executive's employment hereunder, or would prevent, limit or impair in any way the performance by the Executive of the obligations hereunder. In addition, the Executive has disclosed to the Company all restraints, confidentiality commitments, and other employment restrictions that he has with any other employer, person or entity. The Executive covenants that in connection with his provision of services to the Company, the Executive shall not breach any obligation (legal, statutory, contractual or otherwise) to any former employer or other person, including, but not limited to, obligations relating to confidentiality and proprietary rights.

(ii) Upon and after the Executive's termination or cessation of employment with the Company and until such time as no obligations of the Executive to the Company hereunder exist, the Executive shall (A) provide a complete copy of this Agreement to any person, entity or association engaged in a competing business

with whom or which the Executive proposes to be employed, affiliated, engaged, associated or to establish any business or remunerative relationship prior to the commencement of any such relationship and (B) shall

notify the Company of the name and address of any such person, entity or association prior to the commencement of such relationship.

7. Legal and Equitable Remedies. Because the Executive's services are personal and unique and the Executive has had and will continue to have access to and has become and will continue to become acquainted with the proprietary information of the Company, and because any breach by the Executive of any of the covenants contained in Section 6 would result in irreparable injury and damage for which money damages would not provide an adequate remedy, the Company shall have the right to enforce Section 6 and any of its provisions by injunction, specific performance or other equitable relief, without bond and without prejudice to any other rights and remedies that the Company may have for a breach, or threatened breach, of the covenants set forth in Section 6. The Executive agrees that in any action in which the Company seeks injunction, specific performance or other equitable relief, the Executive will not assert or contend that any of the provisions of Section 6 are unreasonable or otherwise unenforceable. The Executive irrevocably and unconditionally (a) agrees that any legal proceeding arising out of this paragraph may be brought in the United States District Court for the District of New Jersey, or if such court does not have jurisdiction or will not accept jurisdiction, in any court of general jurisdiction in Mercer County, New Jersey, (b) consents to the non-exclusive jurisdiction of such court in any such proceeding, and (c) waives any objection to the laying of venue of any such proceeding in any such court. The Executive also irrevocably and unconditionally consents to the service of any process, pleadings, notices or other papers.

8. Arbitration; Expenses. In the event of any dispute under the provisions of this Agreement, other than a dispute in which the primary relief sought is an equitable remedy such as an injunction, the parties shall be required to have the dispute, controversy or claim settled by arbitration in Trenton, New Jersey in accordance with the National Rules for the Resolution of Employment Disputes then in effect of the American Arbitration Association, before an arbitrator agreed to by both parties. If the parties cannot agree upon the choice of arbitrator, the Company and the Executive will each choose an arbitrator. The two arbitrators will then select a third arbitrator who will serve as the actual arbitrator for the dispute, controversy or claim. Any award entered by the arbitrators shall be final, binding and nonappealable and judgment may be entered thereon by either party in accordance with applicable law in any court of competent jurisdiction. This arbitration provision shall be specifically enforceable. The arbitrators shall have no authority to modify any provision of this Agreement or to award a remedy for a dispute involving this Agreement other than a benefit specifically provided under or by virtue of the Agreement. Each party shall be responsible for its own expenses, unless the Executive shall prevail in an arbitration proceeding as to any material issue, in which case the Company shall reimburse the Executive for all reasonable costs, expenses and fees relating to the conduct of the arbitration, and shall share the fees of the American Arbitration Association. The Company shall pay the reasonable costs, expenses and fees relating to the conduct of the arbitration to the Executive within thirty (30) days after the date on which it is finally determined that the Executive has prevailed on any material issue which is the subject of such arbitration.

9. Survivability. The respective rights and obligations of the parties under this Agreement shall survive any termination of the Executive's employment to the extent necessary to the intended preservation of such rights and obligations.

10. Assignment. All of the terms and provisions of this Agreement shall be binding upon and inure to the benefit of and be enforceable by the respective heirs, executors, administrators, legal representatives, successors and assigns of the parties hereto, except that the duties and responsibilities of the Executive under this Agreement

are of a personal nature and shall not be assignable or delegable in whole or in part by the Executive. The Company shall require any

successor (whether direct or indirect, by purchase, merger, consolidation, reorganization or otherwise) to all or substantially all of the business or assets of the Company, within fifteen (15) days of such succession, expressly to assume and agree to perform this Agreement in the same manner and to the same extent as the Company would be required to perform if no such succession had taken place and the Executive acknowledges that in such event the obligations of the Executive hereunder, including but not limited to those under Section 6, will continue to apply in favor of the successor.

11. Entire Agreement; Amendment, Waiver. This Agreement, together with the Proprietary Information and Invention Assignment Agreement and that certain Indemnification Agreement by and between the Executive and the Company, effective on the Effective Date, sets forth the entire understanding between the parties hereto with respect to the subject matter hereof and cannot be changed, modified, extended or terminated except upon written amendment approved by the Board and executed on its behalf by a duly authorized officer (other than the Executive) and by the Executive. This Agreement supersedes the provisions of the Prior Agreement (such that the Prior Agreement shall be void and of no further force and effect) and any other agreement between the Executive and the Company that relate to any matter that is also the subject of this Agreement.

12. Remedies Cumulative; No Waiver. No remedy conferred upon a party by this Agreement is intended to be exclusive of any other remedy, and each and every such remedy shall be cumulative and shall be in addition to any other remedy given under this Agreement or now or hereafter existing at law or in equity. No delay or omission by a party in exercising any right, remedy or power under this Agreement or existing at law or in equity shall be construed as a waiver thereof, and any such right, remedy or power may be exercised by such party from time to time and as often as may be deemed expedient or necessary by such party in its sole discretion.

13. Beneficiaries/References. The Executive shall be entitled, to the extent permitted under any applicable law, to select and change a beneficiary or beneficiaries to receive any compensation or benefit payable under this Agreement following the Executive's death by giving the Employer written notice thereof. In the event of the Executive's death or a judicial determination of the Executive's incompetence, reference in this Agreement to the Executive shall be deemed, where appropriate, to refer to the Executive's beneficiary, estate or other legal representative.

14. Withholding. All payments under this Agreement shall be made subject to applicable tax withholding, and the Company shall withhold from any payments under this Agreement all federal, state and local taxes as the Company is required to withhold pursuant to any law or governmental rule or regulation. The Executive shall bear all expense of, and be solely responsible for, all federal, state and local taxes due with respect to any payment received under this Agreement.

15. Indemnification. In the event the Executive is made, or threatened to be made, a party to any legal action or proceeding, whether civil or criminal, including any governmental or regulatory proceedings or investigations, by reason of the fact that the Executive is or was a director or officer of the Company or any of its affiliates, the Company agrees to indemnify and hold the Executive harmless to the fullest extent permitted by the laws of the State of Delaware and under the bylaws of the Company, both as in effect at the time of the subject act or omission. In connection therewith, the Executive shall be entitled to the protection of any insurance policies which the Company elects to maintain generally for the benefit of the Company's directors and officers, against all costs, charges and expenses whatsoever incurred or sustained by the Executive in connection with any action, suit or proceeding to which the Executive may

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be made a party by reason of his being or having been a director, officer or employee of the Company. This provision shall survive any termination of the Executive's employment hereunder.

16. Notices. Any notice or communication required or permitted under the terms of this Agreement shall be in writing and shall be delivered personally, or sent by registered or certified mail, return receipt requested, postage prepaid, or sent by nationally recognized overnight carrier, postage prepaid, or sent by facsimile transmission to the Company at the Company's principal office and facsimile number or to the Executive at the address and facsimile number, if any, appearing on the books and records of the Company. Such notice or communication shall be deemed given (a) when delivered if personally delivered; (b) five (5) mailing days after having been placed in the mail, if delivered by registered or certified mail; (c) the business day after having been placed with a nationally recognized overnight carrier, if delivered by nationally recognized overnight carrier, and (d) the business day after transmittal when transmitted with electronic confirmation of receipt, if transmitted by facsimile. Any party may change the address or facsimile number to which notices or communications are to be sent to it by giving notice of such change in the manner herein provided for giving notice. Until changed by notice, the following shall be the address and facsimile number to which notices shall be sent:

If to the Company, to:

Antares Pharma, Inc.
Princeton Crossroads Corporate Center
100 Princeton South, Suite 300
Ewing, New Jersey 08628
Attn: Chief Executive Officer
(609) 359-3015 (facsimile)

With a copy to:

Morgan, Lewis and Bockius LLP
1701 Market Street
Philadelphia, PA 19103
Attn: Joanne R. Soslow, Esq.
(215) 963-5001 (facsimile)

If to the Executive, to the most recent address on file with the Company or to such other names or addresses as the Company or the Executive, as the case may be, shall designate by notice to each other person entitled to receive notices in the manner specified in this Section 16.

17. Company Policies. This Agreement and the compensation payable hereunder shall be subject to any applicable clawback or recoupment policies, share trading policies, and other policies that may be implemented by the Board from time to time with respect to officers of the Company.

18. Governing Law. This Agreement will be governed by and construed in accordance with the laws of the State of New Jersey, without regard to conflict of law principles.

19. Counterparts. This Agreement may be executed in counterparts (including facsimile counterparts or as a “pdf” or similar attachment to an email), each of which shall be deemed to be an original as against any party whose signature appears thereon, but all of which together shall constitute but one and the same instrument.
20. Headings; Gender. The headings of sections and subsections herein are included solely for convenience of reference and shall not control the meaning or interpretation of any of the provisions of this Agreement.
21. Severability. If any provision of this Agreement or application thereof to anyone or under any circumstances is adjudicated to be invalid or unenforceable in any jurisdiction, such invalidity or unenforceability shall not affect any other provision or application of this Agreement which can be given effect without the invalid or unenforceable provision or application and shall not invalidate or render unenforceable such provision or application in any other jurisdiction. If any provision is held void, invalid or unenforceable with respect to particular circumstances, it shall nevertheless remain in full force and effect in all other circumstances.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the day and year first above written.

ANTARES PHARMA, INC.

By: /s/ Robert F. Apple

Name: Robert F. Apple

Its President & CEO

EXECUTIVE:

/s/ P.C. Richardson

Dr. Peter C. Richardson.

Schedule 1

Outside Activities

Consulting in connection with COVID-related management issues for Adare Pharmaceuticals, not to exceed five hours per month. (engagement ending May 31, 2021)

Non-active consulting role with Ellodi Pharmaceuticals, not to exceed one hour per month (engagement ending May 31, 2021)

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Exhibit A

CONFIDENTIAL SEPARATION AGREEMENT AND GENERAL RELEASE

This CONFIDENTIAL SEPARATION AGREEMENT AND GENERAL RELEASE (this “Agreement”) is entered into as of [____], 20[___] to be effective on the Effective Date (as defined in Section 1(a) below), by and between Antares Pharma, Inc. (the “Company”) and Dr. Peter C. Richardson (the “Executive”).

RECITALS

WHEREAS, pursuant to the terms of an Employment Agreement, effective as of April 26, 2021, entered into by and between the Company and Executive (the “Employment Agreement”), Executive has been employed as the Company’s Executive Vice President, Head of Research and Development, Chief Medical Officer;

WHEREAS, the Company and Executive have come to a mutual agreement with respect to Executive’s termination from employment with the Company on [____] (the “Termination Date”);

WHEREAS, in connection with Executive’s termination from employment with the Company, at the request of the Board of Directors of the Company, Executive resigned as an officer of the Company effective as of the Termination Date; and

WHEREAS, as consideration for Executive’s execution and non-revocation of a release of all claims against the Company and its affiliates upon the Termination Date, the Company desires to provide Executive with the severance payments and benefits set forth in Section 1(a) below following the Termination Date.

NOW, THEREFORE, in consideration of the mutual promises hereinafter set forth and intending to be legally bound hereby, the parties hereby agree as follows:

1. **Termination from Employment.** Executive resigns as an officer of the Company as of the Termination Date. Executive’s termination from employment with the Company shall be effective on the Termination Date. Consistent with Section 3(d) of the Employment Agreement and provided that the terms and conditions set forth herein are satisfied, Executive shall be entitled to the following:

(a) **Severance Payments and Benefits.** **[Based on Non-CIC Related Severance. To be modified if termination is following a CIC.]** In consideration of the payments in this Section 1(a), Executive hereby agrees to execute and not revoke the General Release of Claims attached hereto as Exhibit A (the “Release”). Provided that the Release becomes effective in accordance with the terms set forth therein (such date the Release becomes effective, the “Effective Date”), and so long as Executive continues to comply with the provisions of the Proprietary Information and Invention Assignment Agreement (defined in Section 6(a) of the Employment Agreement) and the covenants and representations in Section 6 of the Employment Agreement, Executive will receive the following severance payments:

(i) **Continued Base Salary Plus Target Annual Bonus.** The Company will pay Executive severance as follows: the rate of the Executive’s Base Salary as in effect at the time of termination will be added together with the dollar value of the Executive’s target Annual Bonus for the year in which termination occurs and the sum of the foregoing amounts

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will be divided by twelve (12) (the “Monthly Severance Amount”). The Monthly Severance Amount will be paid each month over the twelve (12) month period following the Termination Date, beginning within the sixty (60)-day period following the date of the Executive’s termination of employment and continuing on each payroll date thereafter until fully paid, in accordance with the Company’s regular payroll practices. The first severance payment will include any missed payments during such sixty (60)-day period.

(ii) Health Benefits. For the twelve (12) month period following the Termination Date, provided that Executive is eligible for, and timely elects COBRA continuation coverage, the Company will pay on Executive’s behalf, the monthly cost of COBRA continuation coverage under the Company’s group health plan for Executive and, where applicable, his spouse and dependents, at the level in effect as of the Termination Date, less the employee portion of the applicable premiums that Executive would have paid had he remained employed during the such twelve (12) month period (the COBRA continuation coverage period shall run concurrently with the twelve (12) month period that COBRA premium reimbursement payments are made on Executive’s behalf under this subsection 1(a)(ii)). These payments on Executive’s behalf will commence within the sixty (60)-day period following the Termination Date and will be paid on the first payroll date of each month through the twelfth (12th) month following the Termination Date. Notwithstanding the foregoing, the Company’s payment of the monthly COBRA premiums in accordance with this subsection 1(a)(ii) shall cease immediately upon the earlier of: (A) the end of twelve (12) month period following the Termination Date, or (B) the date that Executive is eligible for comparable coverage with a subsequent employer. Executive agrees to notify the Company in writing immediately if subsequent employment is accepted prior to the end of the twelve (12) month period following the Termination Date and Executive agrees to repay to the Company any COBRA premium amount paid on Executive’s behalf during such period for any period of employment during which group health coverage is available through a subsequent employer. Notwithstanding the foregoing, the Company reserves the right to restructure the foregoing COBRA premium payment arrangement in any manner necessary or appropriate to avoid fines, penalties or negative tax consequences to the Company or Executive (including, without limitation, to avoid any penalty imposed for violation of the nondiscrimination requirements under the Patient Protection and Affordable Care Act or the guidance issued thereunder), as determined by the Company in its sole and absolute discretion.

(iii) Time-Based Equity Award Acceleration. All outstanding equity awards held by Executive immediately prior to the Termination Date granted under the Antares Pharma, Inc. Equity Incentive Plan, as amended from time to time or a successor plan, which vest based on Executive’s continued services over time that would have become vested during the twelve (12) month period following the Termination Date had Executive remained employed during such twelve (12) month period following Executive’s Termination Date, shall accelerate, become fully vested and exercisable as of the Termination Date. All equity awards that have not vested as of the Termination Date will automatically terminate and be canceled on the Termination Date, and Executive hereby fully and forever waives and releases any and all right to such terminated and canceled equity awards.

(iv) 20 Annual Bonus. The Company will pay Executive the amount of Executive’s bonus earned for any fiscal year ended prior to Executive’s Termination Date but for which any bonus earned for such fiscal year has not yet been paid, if any, which will be determined in accordance with Section 2(b) of the Employment Agreement and will be paid to Executive at the same time and under the same terms and conditions

as such bonus is paid to other executives of the Company who participate in the Company's Annual Incentive Plan.

(v) **20 Annual Bonus.** The Company will pay to Executive a pro rata annual bonus for fiscal year 20[] (the fiscal year in which the Termination Date occurs), which shall be determined based on Executive's actual annual bonus earned for fiscal year 20[], if any, based on actual performance, multiplied by a fraction, the numerator of which is (representing the number of days in which Executive was employed by Company during fiscal year 20[]), and the denominator of which is three hundred sixty-five (365). The pro rata annual bonus for fiscal year 20[] will be paid at the same time and under the same terms and conditions as bonuses are paid to other executives of the Company who participate in the Company's Annual Incentive Plan, on or after January 1, 20[] but not later than March 15, 20[].

(b) **Payment in lieu of Notice.** Without regard to whether Executive executes or revokes the Release, the Company will pay Executive an amount equal to \$[] which equals thirty (30) days of base salary, in lieu of the Company's obligation to provide notice of termination pursuant to Section 3(d) of the Employment Agreement. Such amount will be paid to Executive on the Company's next regular payroll date after the Termination Date.

(c) **Accrued Wages and Benefits.** Without regard to whether Executive executes or revokes the Release, the Company will pay or provide Executive with any amounts earned, accrued and owing but not yet paid under Section 2 of the Employment Agreement including but not limited to base salary for services rendered through the Termination Date and any benefits accrued and due under any applicable benefit plans and programs of the Company. The Company will pay Executive the amount of \$[] based on [] hours of accrued but unused vacation. Upon the Executive's receipt of his final paycheck, which includes payment for services through the Termination Date and the amount set forth in the preceding sentence for accrued but unused vacation, Executive will have received all wages and benefits owed to him by virtue of his employment with the Company or termination thereof.

(d) Executive is not eligible for any other payments or benefits by virtue of his employment with the Company or termination thereof except for those expressly described in this Agreement. Employee will receive the payments described in Sections 1(b) and 1(c) whether or not he signs this Agreement. Employee will not receive the separation pay or benefits described in Section 1(a) of this Agreement if he (i) does not sign this Agreement and the Release, (ii) revokes the release of claims in accordance with the Release, or (iii) violates any of the terms and conditions set forth in this Agreement.

2. **Covenants in Section 6 of Employment Agreement.** Executive and the Company agree that Section 6 of the Employment Agreement continues to remain in full force and effect in accordance with the terms therein and are hereby incorporated by reference.

3. **Non-Admission.** It is expressly understood that this Agreement does not constitute, nor will it be construed as an admission by the Company of any liability or unlawful conduct whatsoever. The Company specifically denies any liability or unlawful conduct.

4. **Section 409A.** This Agreement is intended to comply with section 409A of the Internal Revenue Code of 1986, as amended (the "Code") and its corresponding regulations, or an exemption, and payments may only be made under this Agreement upon an event and in a manner permitted by section 409A of the Code, to the extent applicable. For purposes of section 409A of the Code, all payments to be made upon a termination of employment under this Agreement may only be made upon a "separation from service" within the meaning of

such term under section 409A of the Code, each payment made under this Agreement shall be treated as a separate payment and the right to a series of installment payments under this Agreement is to be

treated as a right to a series of separate payments. In no event shall Executive, directly or indirectly, designate the calendar year of payment of any severance benefits. All reimbursements and in-kind benefits provided under this Agreement shall be made or provided in accordance with the requirements of section 409A of the Code.

5. **Entire Agreement, Amendment and Assignment.** Except as otherwise provided in a separate writing between the Company and Executive, this Agreement, including the attachments hereto, is the sole agreement between the Company and Executive with respect to the subject matter hereof and it supersedes all prior agreements and understandings with respect thereto, and all prior agreements and understandings with respect to his employment with the Company prior to the Termination Date, whether oral or written, including, but not limited to, the Employment Agreement (except for Section 6 (including the Proprietary Information and Invention Assignment Agreement) and 15 therein). No modification to any provision of this Agreement shall be binding unless in writing and signed by the Company and Executive. All of the terms and provisions of this Agreement shall be binding upon and inure to the benefit of and be enforceable by the respective heirs, executors, administrators, legal representatives, successors and permitted assigns of the parties hereto, except that the duties and responsibilities of Executive hereunder are of a personal nature and shall not be assignable or delegable in whole or in part by Executive.

6. **Waiver.** No waiver of any rights under this Agreement shall be effective unless in writing signed by the party to be charged. A waiver by any of the parties hereto of a breach of any provision of this Agreement by another party shall not operate or be construed as a waiver of any subsequent breach.

7. **Taxes.** All payments under this Agreement shall be made subject to applicable tax withholding, and the Company shall withhold from any payments under this Agreement, all federal, state and local taxes as the Company is required to withhold pursuant to any law or governmental rule or regulation. Executive shall bear all expense of, and be solely responsible for, all federal, state and local taxes due with respect to any payment received under this Agreement.

8. **Governing Law; Venue.** This Agreement shall be governed in accordance with the laws of the State of New Jersey, without regard to the conflicts of law or choice of law principles thereof. If any dispute between the parties leads to litigation, the parties agree that the courts of the State of New Jersey or the federal courts in New Jersey shall have the exclusive jurisdiction and venue over such litigation. All parties consent to personal jurisdiction in the State of New Jersey, and agree to accept service of process outside of the State of New Jersey as if service had been made in that state.

9. **Notices.** All notices, demands or other communications to be given or delivered under or by reason of the provisions of this Agreement shall be in writing and shall be deemed to have been given when delivered personally to the recipient, two business days after the date when sent to the recipient by reputable express courier service (charges prepaid) or four (4) business days after the date when mailed to the recipient by certified or registered mail, return receipt requested and postage prepaid. Such notices, demands and other communications shall be sent to Executive and to the Company at the addresses set forth below,

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If to Executive: The most recent address in the Company's files.

If to the Company: Antares Pharma, Inc.
100 Princeton South
Suite 300
Ewing, NJ 08628
Attn: Peter J. Graham, Executive Vice President, General
Counsel, Chief Compliance Officer, Human Resources and
Secretary

With a copy to:
Morgan, Lewis and Bockius LLP
1701 Market Street
Philadelphia, PA 19103
Attn: Joanne R. Soslow, Esq.
(215) 963-5001 (facsimile)

or to such other address or to the attention of such other person as the recipient party has specified by prior written notice to the sending party.

10. **Confidentiality of this Agreement.** Executive agrees not disclose to others the fact or terms of this Agreement, *except* Executive may disclose such information to his spouse or domestic/civil union partner and to his attorney or accountant (in order for such individuals to render professional services to Executive), so long as such individuals agree to keep such information confidential. Nothing in this Section 10, or elsewhere in this Agreement, is intended to prevent or prohibit Executive from (a) providing information regarding Executive's former employment relationship with the Company, as may be required by law or legal process, or (b) cooperating, participating or assisting in any government entity investigation or proceeding.

11. **Reports to Government Entities.**

(a) Nothing in this Agreement, including the covenants incorporated herein or the "**Confidentiality of this Agreement**" clause, restricts or prohibits Executive from initiating communications directly with, responding to any inquiries from, providing testimony before, providing confidential information to, reporting possible violations of law or regulation to, or from filing a claim or assisting with an investigation directly with a self-regulatory authority or a government agency or entity, including but not limited to the U.S. Equal Employment Opportunity Commission, the Department of Labor, the National Labor Relations Board, the Department of Justice, the Securities and Exchange Commission, the Congress, and any agency Inspector General (collectively, the "**Regulators**"), or from making other disclosures that are protected under the whistleblower provisions of state or federal law or regulation. However, to the maximum extent permitted by law, the Executive is waiving his right to receive any individual monetary relief from the Company or any others covered by the Release resulting from such claims or conduct, regardless of whether the Executive or another

party has filed them, and in the event the Executive obtains such monetary relief the Company will be entitled to an offset for the payments made pursuant to this Agreement. This Agreement does not limit the Executive's right to receive an award from any Regulator that provides awards for providing

information relating to a potential violation of law. The Executive does not need the prior authorization of the Company to engage in conduct protected by this paragraph, and the Executive does not need to notify the Company that the Executive has engaged in such conduct.

Please take notice that federal law provides criminal and civil immunity to federal and state claims for trade secret misappropriation to individuals who disclose a trade secret to their attorney, a court, or a government official in certain, confidential circumstances that are set forth at 18 U.S.C. §§ 1833(b)(1) and 1833(b)(2), related to the reporting or investigation of a suspected violation of the law, or in connection with a lawsuit for retaliation for reporting a suspected violation of the law.

(b) Executive recognizes and agrees that, in connection with any such activity outlined above, Executive must inform the Regulators, Executive's attorney, a court or a government official that the information Executive is providing is confidential. Despite the foregoing, Executive is not permitted to reveal to any third-party, including any governmental, law enforcement, or regulatory authority, information Executive came to learn during the course of Executive's employment with the Company that is protected from disclosure by any applicable privilege, including but not limited to the attorney-client privilege and/or attorney work product doctrine. The Company does not waive any applicable privileges or the right to continue to protect its privileged attorney-client information, attorney work product, and other privileged information.

12. **Survivability.** The respective rights and obligations of the parties under this Agreement shall survive termination of Executive's services hereunder to the extent necessary to the intended preservation of such rights and obligations.

13. **Counterparts and Electronic Signatures.** This Agreement shall become binding when any one or more counterparts hereof, individually or taken together, shall bear the signatures of Executive and the Company. This Agreement may be executed in two or more counterparts (including facsimile counterparts or as a "pdf" or similar attachment to an email), each of which shall be deemed to be an original as against any party whose signature appears thereon, but all of which together shall constitute but one and the same instrument.

14. **Severability.** If any provision of this Agreement or application thereof to anyone or under any circumstances is adjudicated to be invalid or unenforceable in any jurisdiction, such invalidity or unenforceability shall not affect any other provision or application of this Agreement which can be given effect without the invalid or unenforceable provision or application and shall not invalidate or render unenforceable such provision or application in any other jurisdiction.

15. **Headings.** The headings of sections and subsections appearing in this Agreement are inserted for convenience only and shall not control the meaning or interpretation of any provisions of this Agreement.

[Signature Page Follows]

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IN WITNESS WHEREOF, the undersigned, intending to be legally bound, have duly executed this Agreement as of the date first above written.

ANTARES PHARMA, INC.

By: _____

Name:

Title:

Dr. PETER C. RICHARDSON

Exhibit A

GENERAL RELEASE OF CLAIMS

In consideration of the severance benefits payable to Dr. Peter C. Richardson (“Executive”) under Section 1(a) of the attached Separation Agreement dated as of [____], 20[___], by and between Antares Pharma, Inc. (the “Company”) and Executive (the “Agreement”), the terms of which are incorporated by reference to this General Release of Claims (this “Release”), Executive hereby executes this Release on his own behalf and also on behalf of any heirs, agents, representatives, successors and assigns that he has now or may have in the future.

1. **General Waiver & Release.** Executive hereby waives and releases any and all claims, subject to and without waiving any rights identified in Section 1(c), whether or not now known to Executive, whether legal, equitable or otherwise, against the Company, its parent, subsidiary and affiliated companies, and all of their past and present officers, directors, employees, agents and assigns (collectively, “Releasees”), arising on or before the date Executive signs this Release.

(a) **Included Claims.** The claims being waived and released include, without limitation:

(i) any and all claims arising from or relating to Executive’s recruitment, hire, employment and termination of employment with the Company;

(ii) any and all claims of wrongful discharge, emotional distress, defamation, misrepresentation, fraud, detrimental reliance, breach of contractual obligations, promissory estoppel, negligence, assault and battery, violation of public policy;

(iii) any and all claims for monetary damages arising under the Age Discrimination in Employment Act of 1967 (“ADEA”) as amended, the Older Workers Benefit Protection Act of 1990 (“OWBPA”), Title VII of the Civil Rights Act of 1964 as amended, and the Americans with Disabilities Act of 1990 as amended;

(iv) any and all claims, outside of those identified in Section (1)(a)(iii), of unlawful discrimination, harassment and retaliation under applicable federal, state and local laws and regulations;

(v) any and all claims, outside of those identified in Section (1)(a)(iii), of violation of any federal, state and local law relating to recruitment, hiring, terms and conditions of employment, and termination of employment; and

(vi) any and all claims for monetary damages and any other form of personal relief.

(b) **Unknown Claims.** In waiving and releasing any and all claims, subject to and without waiving any rights identified in Section 1(c), against the Releasees, *whether or not now known* to Executive, Executive understands that this means that, if Executive later discovers facts different from or in addition to those facts currently known by Executive, or believed by Executive to be true, the waivers and releases of this Release shall remain effective in all respects -- despite such different or additional facts and Executive’s later discovery of such facts, even if Executive would not have agreed to this Release if Executive had prior knowledge of such facts.

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(c) **Exceptions.** Executive may still bring claims:

(i) for unemployment, state disability and/or paid family leave insurance benefits pursuant to the terms of applicable state law;

(ii) for continuation of existing participation in Company-sponsored group health benefit plans, at Executive's full expense, under the federal law known as "COBRA" and/or under an applicable state counterpart law;

(iii) for any benefit entitlements that are vested as of the Termination Date pursuant to the terms of a Company-sponsored benefit plan governed by the federal law known as "ERISA;"

(iv) for any vested stock and/or vested option shares pursuant to the written terms and conditions of Executive's existing stock and stock option grants and agreements, existing as of the Termination Date and for all such rights that are granted in and survive the Agreement, including accelerated vesting rights;

(v) for violation of any federal, state or local statutory and/or public policy right or entitlement that, by applicable law, is not waivable;

(vi) for any wrongful act or omission occurring after the date Executive signs this Release;

(vii) for any continuing rights to indemnification and defense under Section 13 of the Employment Agreement and under the Company's governing documents, by-laws, policies and insurance policies; and

(viii) in his capacity as a stockholder of the Company.

2. **Entire Agreement.** This Release and the Agreement contain the entire agreement of Executive and the Company with respect to the subject matter hereof and supersede and render null and void any and all prior or contemporaneous oral or written understandings, statements, representations or promises pertaining to the matters set forth herein and in the Agreement.

3. **Governing Law; Venue.** This Release shall be governed in accordance with the laws of the State of New Jersey, without regard to the conflicts of law or choice of law principles thereof. If any dispute between the parties leads to litigation, the parties agree that the courts of the State of New Jersey or the federal courts in New Jersey shall have the exclusive jurisdiction and venue over such litigation. All parties consent to personal jurisdiction in the State of New Jersey, and agree to accept service of process outside of the State of New Jersey as if service had been made in that state.

4. **Further Acknowledgements.** Executive acknowledges that:

(i) Executive has been offered a period of at least twenty-one (21)¹ calendar days from the date he received this Release within which to review and consider its terms before signing it;

¹ If the Executive's employment is terminated as part of a group termination, then the Executive must be provided with 45 calendar days to consider the Release, and provided with additional information about the employees considered and selected for the group termination.

- (ii) The Company hereby advises the Executive to consult with an attorney prior to executing this Release, and he fully understands this right;
- (iii) Executive has carefully read and understands all of the provisions of this Release and that he is entering into this Release freely, knowingly, and voluntarily;
- (iv) Executive is not waiving any rights or claims that may arise after this Release is executed or any other claims that cannot be waived as a matter of law;
- (v) The consideration provided to Executive in consideration for his execution of this Release is greater than any benefits to which Executive would have been entitled had he not executed this Release;
- (vi) Any changes made to this Release before Executive signs it will not entitle him to an additional twenty-one (21) calendar days to review the new version of this Release;
- (vii) Executive is not entitled to the severance benefits set forth in Section 1(a) of the Agreement, unless he signs and does not revoke this Release;
- (viii) Executive may revoke this Release within seven (7) calendar days following its execution (the “Revocation Period”) by notifying the Company in writing, by certified letter delivered to the attention of Peter J. Graham, Executive Vice President, General Counsel, Chief Compliance Officer, Human Resources, and Secretary, Antares Pharma, Inc., 100 Princeton South, Suite 300, Ewing, NJ 08628, and the terms of this Release shall not become effective or enforceable until the day after the expiration of the Revocation Period; and
- (ix) Executive is not relying upon any promises, inducements, representations, or statements that are not expressly set forth in this Release or the Agreement.

IN WITNESS WHEREOF, Executive, acknowledging that he is acting of his own free will after receiving a reasonable period of time to consider the terms of this Release, has caused the execution of this Release as of this day and year written below.

Agreed and Accepted:

Dr. Peter C. Richardson

Date

12

DB1/ 120506350.4

Exhibit B

ANTARES PHARMA, INC. PROPRIETARY INFORMATION AND INVENTION ASSIGNMENT AGREEMENT

As an employee of Antares Pharma, Inc. (the “Company”), I acknowledge that the Company operates in a competitive environment and that it enhances its opportunities to succeed by establishing policies designed to identify and secure the Company’s Intellectual Property and Proprietary Information. This Agreement is designed to make clear that:

- i) I will maintain the confidentiality of the Company’s Proprietary Information and use such Proprietary Information for the exclusive benefit of the Company;
- ii) Inventions that I create will be owned by the Company; and
- iii) My activities separate from the Company will not conflict with the Company’s development of its proprietary rights.

In consideration of my employment and/or the continuation of my employment by the Company, I hereby agree as follows:

1. Provisions Related to Trade Secrets

- (a) I acknowledge that the Company possesses and will continue to develop and acquire valuable Proprietary Information (as defined below), including information that I may develop or discover as a result of my employment with the Company.
- (b) As used in this Agreement, “Proprietary Information” means any information (including any compilation, device, method, technique or process) that derives independent economic value, actual or potential, from not being generally known to the public or other persons who can obtain economic value from its disclosure or use, and includes information of the Company, its customers, suppliers, joint ventures, licensors, licensees, distributors and other persons and entities with whom the Company does business.
- (c) I will not disclose or use at any time, either during or after my employment with the Company, any Proprietary Information except for the exclusive benefit of the Company as required by my duties for the Company, as the Company expressly may consent to in writing or in accordance with Section 1(d) below. I will cooperate with the Company to implement reasonable measures to maintain the secrecy of, and will use my best efforts to prevent the unauthorized disclosure, use or reproduction of, all Proprietary Information.
- (d) I understand that nothing in this Agreement restricts or prohibits me from initiating communications directly with, responding to any inquiries from, providing testimony before,

providing confidential information to, reporting possible violations of law or regulation to, or from filing a claim or assisting with an investigation directly with a self-regulatory authority or a government agency or entity, including the U.S. Equal Employment Opportunity Commission, the Department of Labor, the National Labor Relations Board, the Department of

Justice, the Securities and Exchange Commission, the Congress, and any agency Inspector General, or from making other disclosures that are protected under the whistleblower provisions of state or federal law or regulation. I do not need the prior authorization of the Company to engage in conduct protected by this paragraph, and I do not need to notify the Company that I have engaged in such conduct.

Please take notice that federal law provides criminal and civil immunity to federal and state claims for trade secret misappropriation to individuals who disclose a trade secret to their attorney, a court, or a government official in certain, confidential circumstances that are set forth at 18 U.S.C. §§ 1833(b)(1) and 1833(b)(2), related to the reporting or investigation of a suspected violation of the law, or in connection with a lawsuit for retaliation for reporting a suspected violation of the law.

- (e) Upon leaving employment with the Company for any reason, I immediately will deliver to the Company any property, records, documents and other tangible materials (including all copies) in my possession or under my control, including data incorporated in word processing, computer and other data storage media, containing or disclosing Proprietary Information.

2. Ownership of Inventions

- (a) I agree to communicate to the Company as promptly and fully as practicable all Inventions (as defined below) conceived or reduced to practice by me (alone or jointly by others) at any time during my employment with the Company. I hereby assign to the Company and/or its nominees all my right, title and interest in such Inventions, and all my right, title and interest in any patents, copyrights, patent applications or copyright applications based thereon. I will give the Company and/or its nominees (at no expense to me) any assistance it reasonably requires to perfect, protect and use its rights to all such Inventions anywhere in the world.
- (b) As used in this Agreement, the term “Inventions” includes, but is not limited to, all discoveries, improvements, processes, developments, designs, know-how, data, computer programs and formulae, whether patentable or unpatentable or protectable by copyright or other intellectual property law.
- (c) Any provision in this Agreement requiring me to assign my rights in any Invention does not apply to an Invention for which no equipment, supplies, facility or trade secret information of the Company was used, and which was developed entirely on my own time, and which:
 - (i) does not relate directly to the Company’s business or to the Company’s anticipated research or development, or
 - (ii) does not result from any work performed by me for the Company.
- (d) I hereby designate and appoint the Company and each of its duly authorized officers as my agent and attorney-in-fact to act for and in my behalf to execute and file any document, and to do all other lawfully permitted acts to further the prosecution, issuance and enforcement of patents,

copyrights and other proprietary rights with the same force and effect as if executed and delivered by me.

3. Conflicts With Other Activities

I understand that my employment with the Company and my compliance with this Agreement do not and will not breach any agreement to keep in confidence any information acquired by me prior to or outside of my employment with the Company. I have not brought and will not bring with me to the Company for use in the performance of my duties at the Company any materials, documents or information of a former employer or any third party that are not generally available to the public unless I have obtained express written authorization from the owner for their possession and use by or for the Company. I have not entered into and will not enter into any agreement, either oral or written, in conflict with this Agreement.

4. Miscellaneous

- (a) My obligations under this Agreement may not be modified or terminated, in whole or in any part, except in a writing signed by the Company. Any waiver by the Company of a breach of any provision of this Agreement will not operate or be construed as a waiver of any subsequent breach.
- (b) Each provision of this Agreement will be treated as a separate and independent clause, and the unenforceability of any one provision will in no way impair the enforceability of any other provision. If any provision is held to be unenforceable, such provision will be construed by the appropriate judicial body by limiting or reducing it to the minimum extent necessary to make it legally enforceable.
- (c) My obligations under this Agreement will survive the termination of my employment, regardless of the manner of such termination. This Agreement will inure to the benefit of and will be binding upon the successors and assigns of the Company.
- (d) I understand that the provisions of this Agreement are a material condition to my employment and/or continued employment with the Company. I also understand that this Agreement is not an employment contract, and nothing in this Agreement creates any right to my continuous employment by the Company, or to my employment for any particular term.
- (e) Any breach of this Agreement likely will cause irreparable harm to the Company for which money damages could not reasonably or adequately compensate the Company. Accordingly, I agree that the Company will be entitled to injunctive relief to enforce this Agreement, in addition to damages and other available remedies.

SIGNING THIS AGREEMENT CREATES IMPORTANT OBLIGATIONS OF TRUST AND AFFECTS THE EMPLOYEE'S RIGHTS TO INVENTIONS THE EMPLOYEE MAY MAKE DURING HIS/HER EMPLOYMENT.

Dated: 23 April 2021

Effective

Date: 26 April 2021

Employee Signature: /s/ P.C. Richardson

Employee Name: Peter C. Richardson

Printed or typed

ACCEPTED AND AGREED TO:

ANTARES PHARMA, INC.

By: /s/ Peter J. Graham

Authorized Signer

Exhibit 10.23

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS OF THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

ASSET PURCHASE AGREEMENT

by and between

OTTER PHARMACEUTICALS, LLC,

ANTARES PHARMA, INC.,

and

ASSERTIO HOLDINGS, INC.

Dated as of December 15, 2021

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Exhibit F	Form of Buyer FDA Letter
Exhibit G	Assumption Agreement
Exhibit H	Supply Agreement
Exhibit I	Quality Agreement
Exhibit J	Safety Data Exchange Agreement
Exhibit K	Allocation of Purchase Price

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Number	Description
Schedule 1.16	***]
Schedule 1.21	Product Inventory
Schedule 2.1(b)	Transferred Patents
Schedule 2.1(c)	Transferred Trademark
Schedule 2.1(d)	Transferred Domain Names
Schedule 2.1(e)	Regulatory Approvals
Schedule 2.1(f)(i)	Contracts
Schedule 2.1(f)(ii)	Assumed Commercial Contracts
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Schedule 3.13(k)	Recalls, Suspensions or Discountenance of Product
Schedule 3.14	Sales Practices
Schedule 3.15	Title to Acquired Assets
Schedule 3.16	Customers and Suppliers
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Schedule 6.5(a)(ii)	***]
Schedule 4.4	Brokers (Buyer)

ASSET PURCHASE AGREEMENT

THIS ASSET PURCHASE AGREEMENT (this “Agreement”) is entered into as of December 15, 2021 (“Execution Date”), by and between Otter Pharmaceuticals, LLC, a Delaware limited liability company (the “Buyer”), Antares Pharma, Inc., a Delaware corporation (the “Seller”), and Assertio Holdings, Inc., a Delaware corporation (the “Guarantor”). Each of the Buyer and the Seller is referred to herein as a “Party” and collectively as the “Parties.”

PRELIMINARY STATEMENT

WHEREAS, the Seller desires to sell, transfer and assign to the Buyer, and the Buyer desires to purchase from the Seller, the Acquired Assets (as defined below) subject to the assumption by the Buyer of the Assumed Liabilities (as defined below), upon the terms and subject to the conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the foregoing and the respective representations, warranties, covenants and agreements set forth below, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Buyer and the Seller agree as follows:

ARTICLE I DEFINITIONS

1.1 “Business Day” means any day except Saturday, Sunday or any other day on which commercial banks located in the States of New York and Delaware are authorized or required by Law to close.

1.2 [***]

1.3 [***]

1.4 “Cutover Date” means [***].

1.5 “FDA Fees” means the FDA annual program fees for the period beginning on October 1, 2021 and ending on September 30, 2022.

1.6 “Fixed Payments” means each of the First Fixed Payment and the Second Fixed Payment, and collectively, the First Fixed Payment and the Second Fixed Payment.

1.7 “Fraud” means, with respect to any Party hereto, an actual and intentional fraud with respect to the making of the representations and warranties contained in ARTICLE III or ARTICLE IV (as applicable), provided that such actual and intentional fraud of such Party shall be deemed to exist only if any of the individuals listed in the definition of “Seller’s Knowledge” (in the case of the Seller) or “Buyer’s Knowledge” (in the case of the Buyer) had actual knowledge (as opposed to imputed or constructive knowledge) that the representations and warranties made by such Party were actually untrue when made, with the express intention that the Buyer (in the case of the Seller) or the Seller (in the case of the Buyer) rely thereon to its detriment.

1.8 “GAAP” means generally accepted accounting principles in the United States.

1.9 “IND(s)” means all investigational new drug applications in effect, as defined in the Act, as amended, and the regulations promulgated thereunder, and other related registrations and approvals required by any Governmental Entity associated with the conduct of nonclinical and clinical studies of pharmaceutical products.

1.10 “Indications” means (i) management of patients with severe, active rheumatoid arthritis (RA) and polyarticular juvenile idiopathic arthritis (pJIA), who are intolerant of or had an inadequate response to first-line therapy, and (ii) symptomatic control of severe, recalcitrant, disabling psoriasis in adults who are not adequately responsive to other forms of therapy.

1.11 “Know-How” means all proprietary know-how, updates, enhancements, improvements, discoveries, developments, trade secrets, information, data and materials, operating records, development reports, instructions, processes, methods, techniques, formulas, inventions (whether or not patentable), discoveries, ideas, concepts, assays, practices, software, devices, procedures, compositions, constructs, compounds, plans, applications, research, formulation information, manufacturing technology, validations, package specifications, copies of the master batch records (manufacturing and packaging), chemical specifications, chemical and finished goods analytical test methods, data, stability samples and prototypes, non-clinical, pre-clinical and clinical data, regulatory information, product and raw material specifications and test methods, scale-up and other technical data, reports, documentation and samples, including: biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols; assays and biological methodology, packaging component specifications, labeling specifications, manufacturing in-process and finished product specifications and test methods, drawings and technology, and all other manufacturing data and information, source code, documentation, technology, customer lists, business and marketing plans, inventions, marketing information, systems architecture, research in progress, algorithms, data, designs, schematics, drawings, blueprints, flow charts, and models.

1.12 [***]

1.13 “Methotrexate” means the compound known as methotrexate (including its geometric isomers and stereoisomers, and any pharmaceutically acceptable salts, esters, or metabolites thereof).

1.14 “Molds and Equipment” means the molds and equipment related to the Sub-Assembly Component [***].

1.15 “NDA(s)” means all new drug applications and supplemental new drug applications, as defined in the Act, as amended, and the regulations promulgated thereunder, and other registrations and approvals required by any Governmental Entity associated with the sale of pharmaceutical products.

1.16 [***].

1.17 [***]

1.18 “Pre-Closing Tax Period” means any taxable period ending on or before the Closing Date and, with respect to any taxable period beginning before and ending after the Closing Date, the portion of such taxable period ending on and including the Closing Date.

1.19 “Product” means all of the pharmaceutical products (including all dosages) approved by the U.S. Food and Drug Administration under NDA N204824 (the “Product NDA”) and currently sold under the trademark of Otrexup®, together with any improvements, enhancements, modifications or extensions of said products and any new uses, kits, formulations, dosage forms or strengths included in the Product NDA. For clarity, Product does not include the Sub-Assembly Component on a standalone basis or any other device identified in any device master file, device design history file or master access file whether referenced in the Product NDA or otherwise and held by the Seller, its Affiliates or a third party.

1.20 “Product Business” means the Seller’s business of manufacturing or having made, marketing, promoting, distributing, selling, offering for sale and otherwise commercializing the Product for the approved Indications.

1.21 “Product Inventory” means all of (i) the Seller’s inventory of the Product in finished quantities, (ii) samples of the Product and (iii) WIP Product Inventory, in each case, whether held by the Seller or by a third party on behalf of the Seller, and as set forth on Schedule 1.21.

1.22 “Regulatory Approvals” means all federal regulatory filings, marketing authorizations, permits, licenses, registrations, regulatory clearances and approvals issued by the United States Food and Drug Administration (the “FDA”), and all correspondence with the FDA related thereto, including any NDAs, NDA supplements and any INDs, in each case solely related to the Product. For clarity, Regulatory Approvals do not include any device master file, device design history file or master access file referenced in the Product NDA or otherwise and held by the Seller, its Affiliates or a third party for the Sub-Assembly Component or any other device listed in such files.

1.23 “Regulatory Documentation” means all (i) documentation comprising the Regulatory Approvals, and (ii) material correspondence and reports submitted to or received from Governmental Entities in the United States (including minutes and official contact reports relating to any material communications with any such Governmental Entity) and all supporting documents with respect thereto solely related to the Product, including any safety reports or updates, Product Adverse Drug Event Reports (PADER’s) and adverse event files, complaint files and product quality reviews, Corrective and Preventive Actions (CAPAs), clinical or pre-clinical data derived from clinical studies conducted or sponsored by or on behalf of the Seller or its Affiliates, Development Safety Update Reports (DSURs), reports and materials relating to any post-marketing requirements and post-marketing commitments imposed by the FDA or the subject of a post-marketing requirement or commitment to the FDA, and medical device reports (MDR), but excluding Marketing Assets. For clarity, Regulatory Documentation does not include any documentation comprising any device master file, device design history file or master access file referenced in the Product NDA or otherwise and held by the Seller, its Affiliates or a third party, and any correspondence or reports submitted to or received from Governmental Entities related to any device master file, device design history file, or master access file for the Sub-Assembly Component or any other device listed in such files.

1.24 “Sub-Assembly Component” means the auto-injector sub-assembly component related to the Product and supplied to the Seller from [***].

1.25 “WIP Product Inventory” [***].

1.26 Other Defined Terms. The following defined terms shall have the meaning ascribed to such term in the corresponding section set forth below:

Defined Term	Section
Acquired Assets	2.1
Act	3.13(b)
Affiliate	5.7(b)
Agreement	Preamble
***]	***]
Ancillary Documents	2.6(b)(ix)
Anti-Kickback Statute	3.13(f)
Assumed Commercial Contracts	2.1(f)
Assumed Liabilities	2.3(d)
Assumption Agreement	2.6(b)(vi)
Bill of Sale	2.6(b)(ii)
Books and Records	2.1(g)
Business Day	1.1
***]	***]
Buyer	Preamble
Buyer's Knowledge	7.16
Buyer FDA Letter	5.5(a)
***]	***]
cGMP	3.9
***]	***]
***]	***]
Claim Notice	6.3(b)
Closing	2.6(a)
Closing Date	2.6(a)
Closing Payment	2.5(a)(i)
***]	***]
***]	***]
***]	***]
Confidential Information	5.1
Contract	2.1(f)
Copyrights	3.5(a)
***]	***]

Defined Term	Section
Damages	6.1
DDR	5.9(a)
Definitions	ARTICLE I
Disclosure Schedule	ARTICLE III
Domain Names	3.5(a)
Excluded Assets	2.2
Excluded Liabilities	2.4
Execution Date	Preamble
***]	***]
FDA	1.22
FDA Fees	1.5
***]	***]
***]	***]
***]	***]
First Fixed Payment	2.5(a)(ii)
Fixed Payments	1.6
Fraud	1.7
GAAP	1.8
Governmental Entity	3.2(c)
Guarantor	Preamble
HCR Fees	3.13(l)
Health Authorities	3.13(b)
Health Laws	3.13(b)
HIPAA	3.13(b)
HITECH	3.13(b)
IND(s)	1.9
Indemnified Party	6.3(a)
Indemnifying Party	6.3(a)
***]	***]
Indications	1.10
Intellectual Property	3.5(a)
***]	***]
Know-How	1.11

Defined Term	Section
Law(s)	3.10
Legal Proceeding	3.7
Liabilities	2.3(d)
License Agreement	2.6(b)(v)
Licensed Intellectual Property	3.5(a)
Licensed Know-How	3.5(a)
Licensed Patent Rights	3.5(a)
Liens	3.2(b)
Marketing Assets	2.1(g)
Material Adverse Effect	3.1(b)
Methotrexate	1.13
Molds and Equipment	1.14
NDAs	1.15
***]	***]
***]	***]
Order	3.5(f)
Ordinary Course of Business	3.2(b)
***]	***]
Other Financial Data	1.16
Party(ies)	Preamble
Patent Rights	3.5(a)
Patent Rights Assignment	2.6(b)(iii)
Permitted Liens	3.2(b)
Person	3.5(e)
***]	***]
***]	***]
Pre-Closing Tax Period	1.18
Product	1.19
Product Business	1.20
Product Inventory	1.21
Product NDA	1.19
Purchase Price	2.5(a)
Quality Agreement	2.6(b)(viii)
***]	***]
Regulatory Approvals	1.22

Regulatory Documentation	1.23
Defined Term	Section
***]	***]
Safety Data Exchange Agreement	2.6(b)(ix)
***]	***]
Second Fixed Payment	2.5(a)(iii)
Seller	Preamble
Seller Brands	5.6(a)
Seller FDA Letter	5.5(a)
Seller Permits	3.11
Seller's Knowledge	7.16
Seller's Taxes	2.4(d)
***]	***]
***]	***]
Sub-Assembly Component	1.24
Subject Court	7.12
Supply Agreement	2.6(b)(vii)
Tax Returns	3.4(a)
Taxes	3.4(a)
Taxing Authority	3.4(a)
Third Party Claim Notice	6.3(a)
Trademark Assignment	2.6(b)(iv)
Trademark Period	5.6(b)
Trademarks	3.5(a)
Transferred Copyrights	2.1(g)(v)
Transferred Domain Names	2.1(d)
Transferred Intellectual Property	3.5(a)
Transferred Patents	2.1(b)
Transferred Trademark	2.1(c)
Transfer Taxes	2.7
***]	***]
***]	***]
***]	***]
***]	***]

ARTICLE II PURCHASE AND SALE OF THE ASSETS

2.1 Purchase and Sale of Assets. Upon the terms and subject to the conditions set forth in this Agreement, at the Closing, the Seller shall sell, convey, transfer, assign and deliver to the Buyer, and the Buyer shall purchase from the Seller, all of the Seller's right, title and interest in and to the Acquired Assets, free and clear of any Liens, other than Permitted Liens. For purposes of this Agreement, the term "Acquired Assets" means:

(a) the Product Inventory, to be delivered [***] in accordance with Section 2.11 following the Closing Date;

(b) all of the Seller's patents set forth on Schedule 2.1(b) and all rights therein (the "Transferred Patents");

(c) the Seller's Otrexup® Trademark and all rights therein and all applications and registrations for such Trademark including those set forth on Schedule 2.1(c) (the "Transferred Trademark");

(d) all Domain Names set forth on Schedule 2.1(d)(i) (the "Transferred Domain Names") and that certain website solely related to the Product Business set forth on Schedule 2.1(d)(ii);

(e) all Regulatory Approvals listed on Schedule 2.1(e) and all Regulatory Documentation (but excluding records or files not reasonably separable from documents or databases that do not relate solely to the Product or the Acquired Assets) to be delivered within [***] following the Closing Date to a reasonable location provided by Buyer in writing; provided, however, that the Seller may retain copies of the Regulatory Approvals and Regulatory Documentation or may retain originals of the Regulatory Approvals and Regulatory Documentation and provide the Buyer with copies in their place;

(f) those legally binding contracts, agreements, instruments, commitments, obligations, understandings, or undertakings of any nature (including licenses, notes, guarantees, sublicenses, subcontracts, covenants not to compete, and covenants not to sue) ("Contracts") set forth on Schedule 2.1(f)(i), [***] (collectively, the "Assumed Commercial Contracts");

(g) the following current and, for the last [***] from the Execution Date, historical records, files and lists relating solely to the Product or the Acquired Assets to the extent owned, maintained, and in the possession of the Seller or any of its Affiliates (but excluding records or files not reasonably separable from documents or databases that do not relate solely to the Product or the Acquired Assets, including any stock images):

(i) customer and physician target and detail lists and records;

(ii) a list of the distributors for the Product;

(iii) pricing lists, calculations and the related pricing submissions for the Product;

(iv) records relating to Transferred Intellectual Property that is registered or pending registration and not otherwise publicly available;

(v) the marketing assets set forth on Schedule 2.1(g) (the “Marketing Assets”), including all of the Seller’s Copyrights in such Marketing Assets (the “Transferred Copyrights”) to be delivered to Buyer in the data room within [***] following Closing; and

(vi) development, quality control and pharmacovigilance records;

in each case, to the extent that such records are permitted to be transferred under applicable Law and do not relate to the Sub-Assembly Component (the foregoing records and documents described in this Section 2.1(g), collectively, the “Books and Records”); provided, however, that the Seller may retain copies of the Books and Records or may retain originals of the Books and Records and provide the Buyer with copies in their place; and provided, further that the Books and Records shall exclude, in all cases, (A) all books, documents, records and files prepared in connection with or relating to the negotiation, preparation, execution and delivery of this Agreement or the consummation of transactions contemplated by this Agreement, including bids received from third parties and strategic, financial or tax analyses relating to the divestiture of the Acquired Assets, the Assumed Liabilities, the Product or the Product Business; (B) trade secrets of third parties in which Seller has no legal right to disclose; (C) any books or records relating to the manufacturing of the Product or the Product Business; (D) any attorney work product, attorney-client communications and other items protected by established legal privilege; and (E) any tax records or tax workpapers;

(h) all claims, counterclaims, defenses, causes of action, rights under express or implied warranties, rights of recovery, rights of set-off, rights of subrogation, judgements, demands, and all other rights of any kind against any third party (other than rights to assert claims with respect to any insurance recoveries), to the extent solely relating to any Assumed Liabilities or Acquired Assets;

(i) all rights of indemnification, warranty, contribution, credits, refunds, reimbursement and other rights of recovery (regardless of whether such rights are currently exercisable) possessed by the Seller against third parties (excluding any form of insurance recovery from insurance carriers or otherwise) that arise out of or relate to any of the Acquired Assets to the extent such rights of indemnification, warranty, contribution, credits, refunds, reimbursement or other rights of recovery relate solely to the Product and are not Excluded Assets;

(j) [***]; and

(k) all goodwill relating to the Acquired Assets.

2.2 Excluded Assets. Notwithstanding anything to the contrary in this Agreement, the Acquired Assets shall not include any Excluded Assets. For purposes of this Agreement, the term “Excluded Assets” means all assets, property, rights and interests of the Seller and its Affiliates other than the Acquired Assets including:

(a) all of the Seller’s or any Affiliate’s accounts receivable related to the Product or the Product Business sold prior to the Closing Date;

- (b) all cash, checks, money orders, marketable securities, short-term investments and other cash equivalents, funds in time and demand deposits or similar accounts, of the Seller or any Affiliate;
- (c) any Contract (or rights therein or thereunder) of the Seller or any Affiliate that is not an Assumed Commercial Contract;
- (d) all Intellectual Property of the Seller or any Affiliate other than the Transferred Intellectual Property;
- (e) all of the Seller's or any Affiliate's inventory of the Sub-Assembly Component and the Molds and Equipment;
- (f) all employees of the Seller or any Affiliate and independent contractor personnel of the Seller or its Affiliates (excluding, for the avoidance of doubt, contractors under [***] Assumed Commercial Contracts);
- (g) all real property (whether owned or leased) of the Seller or its Affiliates;
- (h) all Tax assets (including refunds, rebates or credits) of the Seller or its Affiliates;
- (i) any regulatory documentation related to any device (including the Sub-Assembly Component) identified in any device master file, device design history file or master access file referenced in the Product NDA or otherwise and held by the Seller, its Affiliates or a third party;
- (j) any current and prior insurance policies of the Seller or its Affiliates and all rights of any nature with respect thereto, including all insurance recoveries thereunder and rights to assert claims with respect to any such insurance recoveries;
- (k) any rights, refunds, reimbursements, claims, credits and other rights of recovery (regardless of whether such rights are currently exercisable) of the Seller or any of its Affiliates that arise out of or relate to any Excluded Asset or any Excluded Liability, including any contribution, guarantees, warranties, indemnities and similar rights in favor of the Seller or any of its Affiliates relating to any Excluded Asset or any Excluded Liability; and
- (l) all other assets, rights and properties of the Seller or any Affiliate other than those listed in the definition of Acquired Assets.

2.3 Assumption of Liabilities. Upon the terms and subject to the conditions set forth in this Agreement, at the Closing, the Buyer shall assume and timely satisfy and discharge all Liabilities of the Seller and its Affiliates under, or in respect of or relating, to the Acquired Assets or the Product to the extent that they:

- (a) arise out of or relate to the Buyer's or its Affiliates' ownership, operation, development, commercialization, manufacturing, packaging, importing, marketing, distribution, supply or sale of the Product or the Product Business or use of the Acquired Assets from and after the Closing (even if ordered prior to the Closing) and regardless of whether such Liabilities are based on allegations of the design or development of the Product or the Acquired Assets before Closing;

(b) arise out of or relate to Legal Proceedings, regardless of when such Legal Proceeding was commenced or made, and irrespective of the legal theory asserted (including product liability claims, including claims alleging defects in the Product and claims involving the death of or injury to any individual relating to the Product), to the extent arising from the development, commercialization, manufacturing, packaging, importing, marketing, distribution or sale of any unit of the Product or the use of the Acquired Assets (even if ordered prior to Closing), in each case, by or on behalf of the Buyer or its Affiliates from and after the Closing, including all Legal Proceedings relating to the alleged infringement or misappropriation by the Buyer of any third party intellectual property rights for the development, commercialization, manufacture, packaging, import, marketing, distribution, sale or use of the Product from and after Closing, and in each case, regardless of whether such Liabilities are based on allegations of the design or development of the Product or the Acquired Assets before Closing;

(c) arise under the Assumed Commercial Contracts from and after the Closing, except as such Liabilities relate to a breach of such Assumed Commercial Contracts by Seller that occurred on or before the Closing (which are Excluded Liabilities); or

(d) arise or are expressly assumed or borne by the Buyer pursuant to the terms of this Agreement or any Ancillary Documents [***] (collectively, the “Assumed Liabilities”). For purposes of this Agreement, the term “Liabilities” means all liabilities and obligations of every kind, nature, character and description (whether known or unknown, whether accrued or fixed, whether absolute, contingent or otherwise, whether liquidated or unliquidated, whether asserted or unasserted, matured or unmatured and whether due or to become due).

2.4 Excluded Liabilities. It is expressly understood and agreed that, other than the Assumed Liabilities, the Buyer shall not assume, nor shall it be liable for, any Liabilities of the Seller or its Affiliates (collectively, the “Excluded Liabilities”), and the Seller hereby acknowledges that it is retaining, and is and shall be liable for, the Excluded Liabilities. Excluded Liabilities means:

(a) all Liabilities arising out of or relating to Legal Proceedings, regardless of when such Legal Proceeding was commenced or made, and irrespective of the legal theory asserted (including product liability claims, including claims alleging defects in the Product and claims involving the death of or injury to any individual relating to the Product), to the extent arising from the development, commercialization, manufacturing, packaging, importing, marketing, distribution or sale of the Product or the use of the Acquired Assets, in each case, by or on behalf of the Seller or its Affiliates prior to the Closing, including all Legal Proceedings relating to the alleged infringement or misappropriation by the Seller of any third party intellectual property rights for the development, commercialization, manufacture, packaging, import, marketing, distribution, sale or use of the Product before the Closing (provided, that for the avoidance of doubt, this Section 2.4(a) does not include Liabilities from such Legal Proceedings arising from Buyer’s or its Affiliates’ operation of the Product Business or use of the Acquired Assets from and after the Closing Date regardless of whether such Liabilities are based on allegations of the design or development of the Product or Acquired Assets before the Closing, all of which are Assumed Liabilities);

(b) all Liabilities arising out of or relating to any Assumed Commercial Contract, to the extent relating to the period of time prior to the Closing, [***];

(c) all Liabilities related to any invoices, bills, accounts payable or other payables due and owed to any third party arising prior to the Closing out of or in connection with developing, commercializing, manufacturing (or having manufactured), packaging, importing, exploiting, marketing, distributing or selling the Products by or on behalf of the Seller or its Affiliates prior to the Closing [***];

(d) any Liability for (i) expenses, fees or Taxes incident to or arising out of the negotiation, preparation, approval or authorization of this Agreement or the consummation (or preparation for the consummation) of the transactions contemplated hereby (including all attorneys' and accountants' fees and transfer Taxes) [***], (ii) Taxes of the Seller (or any stockholder or Affiliate of the Seller) relating to the Product, the Product Business or the Acquired Assets which are attributable to any Pre-Closing Tax Period, or (iii) other Taxes of the Seller (or any stockholder or Affiliate of the Seller) of any kind that becomes a Liability of the Buyer under any doctrine of *de facto* merger or transferee or successor liability (clauses (i)-(iii) collectively, "Seller's Taxes");

(e) any Liability with respect to any employee of the Seller or any Affiliate or independent contractor personnel of the Seller or its Affiliates to the extent services from such independent contractor personnel were provided prior to Closing;

(f) [***]

(g) any Liability in respect of any of the Excluded Assets; and

(h) except as otherwise set forth in this Agreement or any Ancillary Document, any other Liability to the extent arising out of or relating to the ownership, operation, development, commercialization, manufacture, packaging, import, marketing, distribution or sale of the Product or the Product Business or the use of the Acquired Assets prior to the Closing Date (provided, that for the avoidance of doubt, this Section 2.4(h) does not include Liabilities arising from Buyer's or its Affiliate's operation of the Product Business or use of the Acquired Assets from and after the Closing Date regardless of whether such Liabilities are based on allegations of the design or development of the Product or Acquired Assets before the Closing, all of which are Assumed Liabilities).

2.5 Consideration.

(a) Purchase Price. As consideration for the Acquired Assets and the license of the Licensed Intellectual Property, in addition to assuming the Assumed Liabilities, subject to the terms and conditions of this Agreement, the Buyer shall pay to the Seller \$44,021,327 (the "Purchase Price") in cash as follows:

(i) \$18,000,000 (the "Closing Payment");

(ii) \$16,021,327 on May 31, 2022 by wire transfer of immediately available funds to the account designated by the Seller prior to May 31, 2022 (the “First Fixed Payment”); and

(iii) \$10,000,000 on December 15, 2022 by wire transfer of immediately available funds to the account designated by the Seller prior to December 15, 2022 (the “Second Fixed Payment”).

(b) Late Payments. In addition to any other remedies available to the Seller pursuant to this Agreement, any failure by the Buyer to make a payment within [***] after the date when due shall obligate the Buyer to pay computed interest, the interest period commencing on the due date and ending on the actual payment date, to the Seller at a rate of [***] calculated for the period of the delinquent payment, or the highest rate allowed by applicable Law, whichever is lower. [***]

2.6 Closing; Delivery and Payment.

(a) Closing Date. The Closing of the sale and transfer of the Acquired Assets and the assumption of the Assumed Liabilities (the “Closing”) shall occur by means of exchange of signature pages by facsimile or other electronic means (to be followed by delivery of hard copies of all Closing deliveries) or at the offices of Seller’s counsel or other location as the Parties may agree on the Execution Date (the “Closing Date”) simultaneously with the execution of this Agreement by the Seller, the Buyer and the Guarantor. All transactions contemplated hereby to be effective as of the Closing shall be deemed effective at 12:01 a.m. Eastern Time on the Closing Date.

(b) Closing Deliveries. At the Closing:

(i) the Buyer shall pay the Closing Payment to the Seller, by wire transfer of immediately available funds to such account or accounts as the Seller shall designate in writing to the Buyer;

(ii) the Seller shall have executed and delivered a Bill of Sale attached hereto as Exhibit A (the “Bill of Sale”);

(iii) the Seller shall have executed and delivered a Patent Rights Assignment attached hereto as Exhibit B (the “Patent Rights Assignment”);

(iv) the Seller shall have executed and delivered a Trademark Assignment attached hereto as Exhibit C (the “Trademark Assignment”);

(v) the Seller and the Buyer shall have executed and delivered a License Agreement attached hereto as Exhibit D (the “License Agreement”);

(vi) the Buyer shall have executed and delivered to the Seller an Assumption Agreement, attached hereto as Exhibit G (the “Assumption Agreement”);

(vii) the Seller and the Buyer shall have executed and delivered a supply agreement attached hereto as Exhibit H (the “Supply Agreement”);

(viii) the Seller and the Buyer shall have executed and delivered a quality agreement attached hereto as Exhibit I (the “Quality Agreement”);

(ix) the Seller and the Buyer shall have executed and delivered a safety data exchange agreement attached hereto as Exhibit J (the “Safety Data Exchange Agreement”, and together with the Bill of Sale, the Patent Rights Assignment, the Trademark Assignment, the License Agreement, the Seller FDA Letter, the Buyer FDA Letter, the Supply Agreement, the Quality Agreement, and the Assumption Agreement and any other agreements entered into by the Parties pursuant hereto, collectively, the “Ancillary Documents”)

(x) the Seller shall have delivered to Buyer evidence of collateral release of that certain Lien (other than Permitted Liens) set forth on Schedule 2.6(b)(x) related to the Acquired Assets;

(xi) the Buyer shall have received a certificate pursuant to Treasury Regulations Section 1.1445-2(b)(2) in form and substance reasonably satisfactory to the Buyer, which certificate shall have been duly executed by the Seller certifying that the Seller is not a foreign person within the meaning of Section 1445 of the Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder;

(xii) the Buyer shall have delivered to the Seller a certificate of its and the Guarantor’s Chief Executive Officer dated as of the Closing Date and certifying that attached thereto are (1) true and complete copies of the correct certificate of incorporation and bylaws (or limited liability company agreement, as applicable) of the Buyer and the Guarantor, and all amendments thereto, (2) true copies of all corporate actions taken by it, including resolutions adopted by its respective Board of Directors authorizing the consummation of the transactions contemplated hereby and the execution, delivery and performance of this Agreement and the Ancillary Documents, and that all such resolutions are in full force and effect and are all the resolutions adopted by the Buyer or the Guarantor, as applicable, in connection with the transactions contemplated by this Agreement, and (3) certificates of good standing from the Secretary of State of Delaware, dated as of a date not more than ten (10) days prior to Closing, certifying that each of the Buyer and the Guarantor is in good standing in Delaware; and

(xiii) the Seller shall have delivered to the Buyer a certificate of its Secretary dated as of the Closing Date and certifying that attached thereto are (1) true and complete copies of the correct certificate of incorporation and bylaws of the Seller, and all amendments thereto, (2) true copies of all corporate actions taken by it, including resolutions adopted by its respective Board of Directors, authorizing the consummation of the transactions contemplated hereby and the execution, delivery and performance of this Agreement and the Ancillary Documents, and that all such resolutions are in full force and effect and are all the resolutions adopted by the Seller, in connection with the transactions contemplated by this Agreement, and (3) a certificate of good standing from the Secretary of State of Delaware, dated as of a date not more than ten (10) days prior to Closing, certifying that the Seller is in good standing in Delaware.

2.7 Taxes and Fees. Sales/use taxes, transfer taxes, excise taxes, tariffs, stamp taxes, conveyance taxes, mortgage taxes, intangible taxes, documentary recording taxes, license and registration fees, value added taxes, recording fees and other similar taxes, charges and fees (including any penalties and interest) imposed by any Governmental Entity, if any, upon the transfer of the Acquired Assets hereunder (“Transfer Taxes”) shall be borne by [***]. The Buyer and the Seller shall file all necessary Tax Returns and other documentation with respect to such Transfer Taxes required by a Governmental Entity to be filed by the Buyer and the Seller, respectively. The Buyer, on the one hand, and the Seller, on the other hand, agree to timely sign and deliver such certificates or forms as may be necessary or appropriate to establish an exemption from (or otherwise reduce), or file Tax Returns with respect to, Transfer Taxes. Each party shall provide the other party with copies of all Tax Returns and other documentation for Transfer Taxes and evidence that such Transfer Taxes have been paid.

2.8 Allocation of Purchase Price. The Buyer shall prepare and deliver the allocation of the Purchase Price and the Assumed Liabilities among the Acquired Assets in accordance with Exhibit K to the Seller within [***] of the Closing. The Purchase Price shall be allocated in accordance with applicable Law and the principles set forth in Exhibit K. The Buyer and the Seller each agree (a) to file any Tax Returns and any other governmental filings on a basis consistent with such allocation and in accordance with Section 1060 of the Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder, and (b) not to take any position inconsistent therewith in any Tax Return, in any Tax refund claim, in any litigation or otherwise.

2.9 Nonassignable Contracts. To the extent that the assignment hereunder by the Seller to the Buyer of any Assumed Commercial Contract is not permitted or is not permitted without the consent of any other party to such Assumed Commercial Contract, this Agreement shall not be deemed to constitute an assignment of any such Assumed Commercial Contract if such consent is not given or if such assignment otherwise would constitute a breach of, or cause a loss of contractual benefits under, any such Assumed Commercial Contract. If any assignment of an Assumed Commercial Contract is not permitted and the Closing hereunder is consummated, the Seller shall, for a period of [***] following the Closing Date, cooperate with the Buyer in any reasonable arrangement designed to provide the Buyer with the rights and benefits (subject to the obligations) under any such Assumed Commercial Contract, including, upon the request of the Buyer, enforcement for the benefit of the Buyer of any and all rights of the Seller against any other party arising out of any breach or cancellation of any such Assumed Commercial Contract by such other party and, if requested by the Buyer, acting as an agent on behalf of the Buyer or as the Buyer shall otherwise reasonably request, at the Buyer’s expense; provided, that none of the Seller or any of its Affiliates shall be required to pay money to any third party, commence any litigation or offer or grant any material accommodation (financial or otherwise) to any third party in connection with such efforts. For the avoidance of doubt, the Buyer acknowledges and agrees that, to the extent that any of the Transferred Copyrights or materials in connection therewith or any transferred websites contain (i) any Seller Brands, no ownership or transfer of the Seller Brands shall occur and the Seller retains full right, title and interest in and to any such Seller Brands and the Buyer shall only have the limited right to use such Seller Brands pursuant to Section 5.6, or (ii) any marks, images, information or other items of a third party for which the Seller received a right to use from a third party, no right, title or interest in any such third party mark, image, information or item is being transferred or assigned to the Buyer and the Buyer shall have no right to use any such third party mark, image, information or item unless and until the Buyer, in its sole discretion, obtains a license from any such third party for any such use.

2.10 Withholding. Each of the Buyer and its Affiliates, as the case may be, shall be entitled to deduct and withhold from any consideration otherwise payable to any Person pursuant to this Agreement such Taxes as it is required to deduct and withhold under any provision of applicable Law with respect to the making of such payment. To the extent that such amounts are so withheld and paid over to the relevant Governmental Entity by the Buyer or its Affiliates, as the case may be, such withheld amounts shall be treated for all purposes of this Agreement as having been paid to the applicable Person in respect to which such deduction and withholding was made.

2.11 Product Inventory Delivery. Notwithstanding anything to the contrary contained herein, as soon as reasonably practicable, but in any event no later than [***] following the Closing Date, the Buyer shall notify the Seller in writing of the storage location the Buyer desires the Product Inventory to be delivered. The Seller agrees to transfer or cause to be transferred such Product Inventory to such storage location directed by Buyer [***] following Buyer's notice of such location. [***]. Notwithstanding anything to the contrary contained herein, in no event shall the Seller or any of its Affiliates or third party storage facilities be required to transfer the Product Inventory to any location other than Buyer's third party storage facility (and not, for the avoidance of doubt, to any Person to whom such Product Inventory may have been sold).

ARTICLE III REPRESENTATIONS AND WARRANTIES OF THE SELLER

The Seller represents and warrants to the Buyer that the statements contained in this ARTICLE III are true and correct as of the Execution Date, except as set forth in the disclosure schedule delivered by the Seller to the Buyer (the "Disclosure Schedule") as contemplated by Section 7.14.

3.1 Organization, Standing and Power.

(a) The Seller is a corporation duly organized, validly existing and in good standing under the Laws of the State of Delaware, has all requisite corporate power and authority to own, lease and operate the Acquired Assets and to carry on the Product Business as now being conducted and to license the Licensed Intellectual Property under the License Agreement.

(b) The Seller is duly qualified to do business and, where applicable as a legal concept, is in good standing as a foreign corporation in each jurisdiction in which the character of the properties it owns, operates or leases or the nature of its activities makes such qualification necessary, except for such failures to be so qualified or in good standing, individually or in the aggregate, would not result in a Material Adverse Effect. For the purposes of this Agreement, "Material Adverse Effect" means [***].

3.2 Authority; No Conflict; Required Filings and Consents.

(a) The Seller has all requisite corporate power and authority to enter into this Agreement and each of the Ancillary Documents to which it will be a party and to consummate the transactions contemplated hereby and thereby. The execution, delivery and performance by the Seller of this Agreement and each of the Ancillary Documents to which it will be a party and the consummation of the transactions contemplated hereby and thereby by the Seller have been duly authorized by all necessary corporate action on the part of the Seller. This Agreement has been, and each such Ancillary Document will be, duly executed and delivered by the Seller, and

this Agreement is, and each such Ancillary Document when so duly executed and delivered by the Seller and, if applicable, the Buyer, will be, the legal, valid and binding obligation of the Seller, enforceable against the Seller in accordance with its terms, except as enforceability may

be limited by bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium or other similar Laws affecting the rights of creditors generally and by equitable principles.

(b) Except as set forth in Schedule 3.2(b), the execution, delivery and performance by the Seller of this Agreement and each of the Ancillary Documents to which it will be a party, and the consummation by the Seller of the transactions contemplated hereby and thereby, do not and will not, (i) conflict with, or result in any violation or breach of, any provision of the Certificate of Incorporation or By-laws of the Seller, (ii) conflict with, or result in any material violation or breach of, or constitute (with or without notice or lapse of time, or both) a material default (or give rise to a right of termination, cancellation or acceleration of any obligation or loss of any material benefit) under, require a consent or waiver under, or result in the imposition of any mortgage, security interest, pledge, conditional sale or other title retention agreement, lien, charge or encumbrance (“Liens”), other than Permitted Liens, on or with respect to (1) any of the Acquired Assets, (2) any Assumed Commercial Contract or (3) any material permit, concession, franchise, license or Law applicable to the Seller or any of its properties or assets that would, solely with respect to clause (3), prevent the consummation of the transactions contemplated hereby. For the purposes of this Agreement, the term “Permitted Liens” means (A) inchoate mechanic’s, materialmen’s, worker’s, landlord’s, laborer’s, carrier’s, warehouseman’s, supplier’s, vendor’s and similar liens incurred in the Ordinary Course of Business and (B) all statutory or other liens for Taxes, assessments and other charges which are not yet due and payable or delinquent, or the validity or amount of which is being contested in good faith by appropriate proceedings that operate to stay the enforcement of any Lien and for which adequate reserves or accruals have been established in accordance with GAAP. For purposes of this Agreement, “Ordinary Course of Business” shall mean such actions taken in the ordinary course of its normal operations and consistent with its past practices.

(c) Except as set forth in Schedule 3.2(c) and with respect to the notice required to be given to the FDA in connection with the transactions contemplated by this Agreement, no material consent, approval, license, permit, order or authorization of, or registration, declaration, notice or filing with, any Governmental Entity is required by or with respect to the Seller in connection with the execution, delivery and performance by the Seller of this Agreement and each of the Ancillary Documents to which it will be a party or the consummation by the Seller of the transactions contemplated hereby and thereby. For the purposes of this Agreement, “Governmental Entity” means any court, administrative agency or commission or other governmental authority or instrumentality of applicable jurisdiction, whether domestic or foreign.

3.3 Reserved.

3.4 Taxes.

(a) The Seller has timely filed all material Tax Returns that it was required to file that would result in Tax liability to the Buyer or affect the Product or the Acquired Assets, and all such Tax Returns were correct and complete in all material respects. The Seller has paid in full on a timely basis all material Taxes attributable to the Product and the Acquired Assets to the extent failure to do so would result in the Buyer becoming liable or responsible therefor or would affect the Product or the Acquired Assets after the Closing Date. The Seller has complied in all material respects with all applicable Laws relating to the filing of Tax Returns, the payment of Taxes, and the withholding and deposit of Taxes that would result in Tax liability to the Buyer or affect the Product or the Acquired Assets after the Closing Date. None of the Acquired Assets is property treated as owned in any part by persons other than the Seller for income Tax purposes. For the purposes of this Agreement,

(i) “Taxes” means (A) (1) all taxes, charges, surcharges, fees, levies or other similar assessments or liabilities in the nature of a tax, including income, gross receipts, ad valorem, premium, value-added, excise, license, real property,

personal property, unclaimed property, escheat, sales, use, service, transfer, withholding, employment, unemployment, payroll and franchise taxes imposed by any Taxing Authority and (2) any liability of the Seller for the payment of amounts with respect to payments of a type described in clause (1) as a result of being a member of an affiliated, consolidated, combined or unitary group, or as a result of any obligation of the Seller under any Tax sharing arrangement or Tax indemnity agreement and (B) any interest, fines, penalties, assessments or additions to tax resulting from, attributable to or incurred in connection with any tax described in clause (A) or any contest or dispute thereof; (ii) “Taxing Authority” means the Internal Revenue Service and any other Governmental Entity or any subdivision, agency, commission or entity thereof or any quasi-governmental entity having or purporting to have jurisdiction with respect to any Tax, and (iii) “Tax Returns” means all reports, returns, declarations, statements or other information actually supplied to or required to be supplied to any Taxing Authority in connection with Taxes (including any attachments thereto and, in each case, including any amendments thereof).

(b) There are no Liens (other than Permitted Liens) with respect to Taxes upon any of the Acquired Assets, other than with respect to Taxes not yet due and payable.

(c) There is no Tax audit, litigation, proceeding or other claim ongoing, pending or, to the Seller’s Knowledge, threatened by any Taxing Authority that could result in Tax liability to the Buyer or affect the Product or the Acquired Assets after the Closing Date.

(d) There is not currently in effect any extension or waiver of any statute of limitations with respect to the assessment or collection of any Taxes that could result in Tax liability to the Buyer or affect the Product or the Acquired Assets after the Closing Date.

(e) The Seller has conducted all aspects of the Product Business in all material respects in accordance with the terms and conditions of any Tax abatements, concessions and exemptions received with respect to the Product or the Acquired Assets prior to Closing that are potentially available to Buyer after the Closing. With respect to any Tax abatements, exemptions or concessions that were provided prior to the Closing by any relevant Taxing Authority with respect to the Product or the Acquired Assets, no default of such terms and conditions has been alleged by any Taxing Authority, and no default, recapture, or other payments are owing pursuant to such terms and conditions or will result from the purchase and sale pursuant to this Agreement, in each case that could result in liability to Buyer or otherwise adversely impact any such abatements, exemptions or concessions potentially available to Buyer after the Closing, which for the avoidance of doubt, only include abatements, exemptions or concessions that may be transferred under applicable Law and which are Acquired Assets.

3.5 Intellectual Property.

(a) Other than (x) any Intellectual Property that are licenses for commercial click through, “off-the-shelf” or “shrink-wrap” software, (y) administrative, finance and other back office infrastructure and information technology systems, networks and software, and (z) Intellectual Property relating to (1) the manufacturing or supply of the Product or (2) commercial operations used in connection with other products of Seller that are not the Product, the Transferred Intellectual Property, Licensed Intellectual Property and Assumed Commercial Contracts constitute all Intellectual Property owned or used by the Seller or any of its Affiliates in connection with the promotion, sale, offer for sale, distribution and commercialization of the Product. The Seller

is the sole owner of and has good and valid title to all of the Transferred Intellectual Property and any Licensed Intellectual Property, free and clear of all Liens, other than Permitted Liens, and the Transferred Intellectual Property and Licensed Intellectual Property in each case, is enforceable, valid and subsisting. [***] For purposes of this Agreement: (A) the term “Intellectual Property” means collectively, Copyrights, Patent Rights, Trademarks, Know-How and Domain Names; (B) the term “Copyrights” means United States copyrights and

mask works (as defined in 17 U.S.C. §901), whether registered or unregistered, and pending applications to register the same in the United States and all other nations throughout the world, works of authorship in any media now known or hereafter created and whether or not completed, published, or used (including computer programs, software, databases, compilations, files, applications, and Internet site content), moral rights, mask works, drafts, writings, plans, sketches, layouts, designs, artwork, printed or graphic matter, video, films, photographs, illustrations, slides, audio and video recordings and other audiovisual works, software development documentation and programming tools, literary and artistic works, and all derivative works, translations, adaptations, or combinations of any of the foregoing, all of the foregoing whether or not registered, and registrations and applications for registrations for any of the foregoing; (C) the term “Patent Rights” means (i) any national, regional and international patents and patent applications, including United States and foreign patents and provisional patent applications; (ii) any patent applications claiming priority or filed from such patents, patent applications or provisional applications or from an application claiming priority to either of these, including continuations, continuations-in-part, divisions, provisionals, converted provisionals, continued prosecution applications, and substitutions; (iii) any patents that have issued or in the future issue from the foregoing patent applications described in clauses (i) and (ii), including utility models, patents of addition, petty patents and design patents and certificates of invention; and (iv) any patent term extension under 35 U.S.C. §156 or any non-U.S. counterpart or equivalent of the foregoing, including supplementary protection certificates, inventors’ certificates, patent term extensions, pediatric data package exclusivity extensions, patent disclosures, industrial designs, inventions (whether or not patentable or reduced to practice) and improvements thereto, and any other extensions that are now available or become available in the future, or any restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions of the foregoing patents or patent applications described in clauses (i), (ii) and (iii); (D) the term “Trademarks” means United States, foreign, and state trademarks, service marks, trade names, trade dress, designs, logos, slogans, 800-numbers, URLs, Domain Names, and other source identifiers, whether registered or unregistered, and pending registrations and applications to register the foregoing; (E) the term “Domain Names” means domain names in the United States and all other nations throughout the world, whether registered or unregistered and pending applications to register the same in the United States and all other nations throughout the world, including all variations, derivations, and combinations thereof, and all common law rights, registrations and applications for registration or renewals of the foregoing and all goodwill associated therewith; (F) the term “Transferred Intellectual Property” means the Transferred Copyrights, Transferred Patents, Transferred Domain Names, Transferred Trademark; (G) the term “Licensed Know-How” shall have the meaning set forth in the License Agreement; (H) the term “Licensed Patent Rights” shall have the meaning set forth in the License Agreement; (I) collectively the Licensed Patent Rights and the Licensed Know-How, means the “Licensed Intellectual Property”; and (J) [***].

(b) Schedule 3.5(b) contains a list and description of all Contracts that are material to the Product or the Product Business and relate to: (i) any Transferred Intellectual Property; (ii) any Licensed Intellectual Property; and (iii) any material Intellectual Property licensed to or used by the Seller or any of its Affiliates solely in connection with the Product or the Product Business (other than, for the avoidance of doubt, manufacturing and supply agreements relating to the Product that are not Assumed Commercial Contracts, click-through and off-the-shelf shrink-wrap agreements).

(c) Except as otherwise set forth on Schedule 3.5(c)(i), the Seller is not a party to any Contract pursuant to which the Seller has purchased or otherwise acquired or licensed any Transferred Intellectual Property or Licensed Intellectual Property from a third party. Except as otherwise set forth on Schedule 3.5(c)(ii), to the

Seller's Knowledge, all registrations, issuances and applications for the Transferred Intellectual Property and Licensed Intellectual Property,

including the Transferred Patents, Transferred Trademark and the Transferred Domain Names: (A) have been duly filed or registered (as applicable) with the applicable Governmental Entity and properly maintained, including the timely submission of all necessary filings and payment of fees in accordance with the legal and administrative requirements in the appropriate jurisdictions; (B) have not lapsed or expired or been cancelled, disclaimed or abandoned; and (C) are valid and in force and, with respect to all applications, are pending and in good standing, all without challenge of any kind. The Seller has the sole and exclusive right to bring actions for infringement, misappropriation, dilution, violation or unauthorized use of the Transferred Intellectual Property and the Seller has the right to bring actions for infringement, misappropriation, dilution, violation or unauthorized use of the Licensed Intellectual Property.

(d) To the Seller's Knowledge, each Person who was involved in, or who has participated in or contributed to, the conception, development, authoring, creation, or reduction to practice of the Transferred Patents or the Licensed Patent Rights has been accurately identified to applicable government agencies in all countries where such Transferred Patents or Licensed Patent Rights are nationalized, validated or registered, and all such Persons have, to the Seller's Knowledge, executed valid and enforceable agreements that presently and irrevocably assign all right, title and interest in such Patent Rights to the Seller.

(e) To the Seller's Knowledge, no third party is infringing or violating or misappropriating any of the Transferred Intellectual Property or Licensed Intellectual Property in any material respect. The Seller has not sent nor has the Seller received any written notice to or asserted or threatened in writing any action or claim against any Person nor has any Person asserted or threatened any action or claim against the Seller in writing involving or relating to any of the Transferred Intellectual Property or Licensed Intellectual Property except as set forth on Schedule 3.5(e). There are no claims or proceedings pending by the Seller or any of its Affiliates against any Person involving or relating to any of the Transferred Intellectual Property or Licensed Intellectual Property except as set forth on Schedule 3.5(e). For the purposes of this Agreement, "Person" means any individual, corporation, partnership, limited liability company, joint venture, trust, business association, organization, Governmental Entity or other entity.

(f) Except as otherwise set forth on Schedule 3.5(f), to the Seller's Knowledge, the use, manufacture or having made, marketing, promotion, distribution, sale, offer for sale and commercialization of the Product, as well as the conduct of the Product Business, do not infringe or violate or constitute a misappropriation of any Intellectual Property of any third party existing as of the Execution Date. During the past [***] prior to the Execution Date, the Seller has not received any written claim or notice alleging any such infringement, violation or misappropriation or received any written offer from a third party to take a license to any Intellectual Property of any third party in connection with the Product or the Product Business. Except as otherwise set forth on Schedule 3.5(f), there is no pending or, to the Seller's Knowledge, threatened claim, interference, opposition or demand of any third party challenging the ownership, validity or scope of any Transferred Intellectual Property or Licensed Intellectual Property. The Seller has not been served with or provided written notice that any Transferred Intellectual Property or Licensed Intellectual Property is the subject of any judicial, administrative or arbitral order, award, decree, injunction, lawsuit, proceeding or stipulation ("Order"), and the Seller is not subject to any Order barring or limiting the Seller's use of any Transferred Intellectual Property or Licensed Intellectual Property.

(g) The Seller takes and has taken commercially reasonable and adequate action to protect, preserve, and prevent the unauthorized disclosure or use of the Confidential Information and trade secrets included in the Transferred Intellectual Property or Licensed Intellectual Property, including having all officers, directors,

employees and other Persons with access to such trade secrets enter into appropriate confidentiality agreements or otherwise be subject to binding confidentiality obligations. To the Seller's Knowledge, there has been no

unauthorized disclosure or use of the Confidential Information and trade secrets included in the Transferred Intellectual Property or Licensed Intellectual Property.

(h) All past and currently due maintenance fees or annuities for the Transferred Patents and the Licensed Patent Rights, and all past and currently due renewal fees, taxes, or maintenance fees for the Transferred Trademark have been paid and all necessary documents and certificates in connection with such Intellectual Property have been filed with the relevant Governmental Entities in the United States or foreign jurisdictions, as the case may be, for the purposes of maintaining such Intellectual Property.

3.6 Contracts. The Seller has made available to the Buyer a complete and accurate copy of each Assumed Commercial Contract, except to the extent such Assumed Commercial Contracts have been redacted to (i) enable compliance with Laws relating the safeguarding of data privacy or (ii) exclude information not related solely to the Product or the Product Business. Each Assumed Commercial Contract is the legal, valid and binding obligation of the Seller and is in full force and effect with respect to the Seller and, to the Seller's Knowledge, with respect to each other party thereto, except as enforcement may be limited by bankruptcy, insolvency, reorganization, moratorium and other similar Laws affecting the rights of creditors generally and by equitable principles. Neither the Seller nor, to the Seller's Knowledge, any other party to any Assumed Commercial Contract is in material violation of or in material default under any Assumed Commercial Contract, and no event has occurred that, with the giving of notice or lapse of time or both, would constitute a material breach or material default thereunder. As of the Execution Date, the Seller has received no written notice of any material adverse change in the price or availability of any supplies or services provided under any Assumed Commercial Contract that are used in the manufacture, distribution or sale of the Product, except as otherwise provided for in any Assumed Commercial Contract.

3.7 Litigation. Except as set forth on Schedule 3.7, no action, suit, proceeding, claim, arbitration or investigation by or before any Governmental Entity, arbitrator or mediator (each, a "Legal Proceeding") is currently pending against the Seller with respect to the Product or the Product Business and, to the Seller's Knowledge, no Legal Proceeding has been threatened or otherwise asserted in writing against the Seller. There are no unsatisfied judgments or outstanding Orders, against any of the Acquired Assets or against the Seller with respect to the Product or the Product Business.

3.8 Financial Statements. Schedule 3.8 sets forth [***]

3.9 Inventory. All of the Product Inventory [***] .

3.10 Compliance With Laws. The Seller is currently in compliance in all material respects with, is not in material violation of, and has not in the past [***] received any written notice alleging any material violation with respect to, any applicable Law with respect to the manufacture, marketing and sale of the Product, the Product Business or the ownership or operation of the Acquired Assets. For the purposes of this Agreement, "Law" or "Laws" means any federal, state or local law, statute or ordinance, common law or any rule, regulation, judgment, order, writ, injunction, decree, license or permit of any Governmental Entity, including any ruling, directive, pronouncement, requirement, specification, determination, decision or opinion issued, enacted, adopted, passed, approved, promulgated, made, implemented or otherwise binding and put into effect by or under the authority of any Governmental Entity. In the past [***], the Seller has not received any written notice from a Governmental

Entity alleging that the Seller has materially violated, or inquiring into allegations related to the material violation of, any Laws applicable to the Product, the Product Business or the Acquired Assets.

3.11 Permits. The Seller has all material permits necessary for the Seller to own, lease or operate the Acquired Assets and operate the Product Business in the manner currently conducted and in which the Product Business has been conducted during the [***] prior to the date of this Agreement. Schedule 3.11 contains a complete listing of all such permits solely relating to the Product (the “Seller Permits”). The Seller is in compliance in all material respects with the terms of the Seller Permits, and has not received any notices that it is in violation of any of the terms or conditions of such Seller Permits. All such Seller Permits are in full force and effect and no action or claim is pending or, to the Seller’s Knowledge, threatened or otherwise asserted to revoke, suspend, adversely modify or terminate any such Seller Permit or declare any such Seller Permit invalid in any respect.

3.12 Product Liability. Except as set forth on Schedule 3.12, no product liability, recall or warranty claims are pending or have been settled, terminated or received by the Seller in the [***] prior to the Execution Date and, to the Seller’s Knowledge, no such claims have been threatened or otherwise asserted against the Seller, in each case, relating to, or arising from, the sale or use of the Product prior to the Closing. There is no judgment, order or decree outstanding against the Seller (or to Seller’s Knowledge, any other Person or entity) relating to product liability or manufacturing defect claims with respect to the Product.

3.13 Regulatory Matters.

(a) Schedule 3.13(a) sets forth, as of the Execution Date, a list of the marketing approvals, clearances or other authorizations necessary to market or sell the Product in the United States and granted to the Seller by, or pending with, any Governmental Entity, including all Regulatory Approvals for the Product. All such marketing approvals, clearances or other authorizations are solely owned by the Seller and registered in the name of the Seller and are in full force and effect. To the Seller’s Knowledge, there are no INDs, NDAs or other marketing approvals, clearances or other authorizations in any country held by a third party solely related to the Product. The Seller has paid the FDA Fees and all FDA annual program fees for prior years.

(b) The Product has been researched, developed, tested, manufactured, handled, labeled, packaged, supplied, promoted, co-promoted, distributed, marketed, commercialized, stored and sold by or on behalf of the Seller, as applicable, in compliance in all material respects with applicable Health Laws, and the Product has not been adulterated or misbranded within the meaning of applicable Health Laws. For purposes of this Agreement, (i) the term “Health Laws” means the applicable Laws and legally binding rules, regulations, codes, policies and guidelines of all Governmental Entities relating to the research, development, testing, manufacture, handling, production, preparation, propagation, compounding, conversion, pricing, labeling, packaging, marketing, promotion, sale, distribution, coverage, or reimbursement of a drug, device or other medical or pharmaceutical item, supply or service, including the federal Food, Drug, and Cosmetic Act (21 U.S.C. § 321 et seq.) (the “Act”), the Controlled Substances Act (21 U.S.C. § 801 et seq.), the federal False Claims Act (31 U.S.C. § 3729 et seq.), the federal healthcare program Anti-Kickback Statute (42 U.S.C. § 1320a-7b), the healthcare fraud, false statement and health information privacy and security provisions of the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health (“HITECH”) Act, and its implementing regulations (collectively, “HIPAA”), the federal healthcare program civil money penalty and exclusion authorities, the applicable requirements of Medicare, Medicaid and other Governmental Entity healthcare programs, including the Veterans Health Administration and U.S. Department of Defense healthcare and contracting programs, and the analogous Laws of any federal, state, local, or foreign jurisdiction applicable to the Buyer or the Seller, and (ii) the term “Health Authorities” means the Governmental

Entities which administer Health Laws, including the FDA and US Customs and Border Protection. The Product has not been seized,

detained, or subject to any suspension of manufacturing, distribution, marketing, or sale by the FDA or any other Governmental Entity which administers applicable Health Laws. In the [***] prior to the Execution Date, the Product has been manufactured in all material respects in accordance with cGMP and has not been adulterated or misbranded.

(c) In the [***] prior to the Execution Date, the Seller has not received any written or oral notice from the FDA or any other Governmental Entity or third party alleging that its research, development, manufacture, distribution, marketing, offering for sale, selling, labeling, storing or testing practices are unlawful or threatening to revoke, suspend, cancel, withdraw, curtail, or seek damages related to any existing certification, license, or approval, including any Regulatory Approvals, necessary to the Product Business.

(d) The Seller has made available to the Buyer complete and correct copies of each NDA and each IND submitted to the FDA with respect to the Product, including all supplements and amendments thereto, and all other material correspondence with and reports and notices from any relevant Health Authorities, including the FDA and U.S. Customs and Border Protection, in each case solely related to the Product. In the [***] prior to the Execution Date, all material reports, documents, notices that are required to be maintained or filed with the FDA or any other Governmental Entity under applicable Laws with respect to the Product, including those relating to complaints, adverse events, product pricing, and rebates, have been maintained or filed and are accurate in all material respects.

(e) The clinical, pre-clinical and other studies and tests conducted by or on behalf of the Seller related to the Product, or in which the Seller or the Product has participated, were conducted in all material respects in accordance with all applicable Health Laws.

(f) Except for ordinary course inquiries, the Seller has not received within the past [***] prior to the Execution Date, with respect to the Product, any written notice or communications from the FDA or any other Governmental Entity which administers applicable Health Laws alleging noncompliance with any applicable Laws, and the Seller is not subject to any enforcement proceedings or, to the Seller's Knowledge, any investigations by the FDA or any other Governmental Entity which administers applicable Health Laws, and, to the Seller's Knowledge, no such investigations or enforcement proceedings have been threatened. To the Seller's Knowledge, within the past [***] prior to the Execution Date, the Seller has not been subject to any investigation related to the Product or the Product Business and, to the Seller's Knowledge, no such investigation has been threatened, including by (i) the FDA, (ii) the Department of Health and Human Services Office of Inspector General or Department of Justice pursuant to the Federal Healthcare Program Anti-Kickback Statute (42 U.S.C. §1320a-7b(b) (known as the "Anti-Kickback Statute")) or the federal False Claims Act (31 U.S.C. §3729), or (iii) state attorneys general pursuant to state false claim or fraud laws.

(g) To the Seller's Knowledge, neither the Seller nor its agents has submitted any claim for payment to any government healthcare program related to the Product in material violation of any Laws relating to false claim or fraud, including the Federal False Claims Act, 31 U.S.C. § 3729, or any applicable state false claim or fraud Law.

(h) To the Seller's Knowledge, the Seller has complied in all material respects with all applicable security and privacy standards regarding protected health information under (i) HIPAA, (ii) HITECH, (iii) state Laws governing the confidentiality, privacy, security and protection of individually identifiable personal

information, including state data breach notification Laws, state medical privacy laws and state consumer protection Laws and (iv) other applicable privacy Laws, in each case as related to the Product or the Product Business.

(i) There are no pending or, to the Seller's Knowledge, threatened Legal Proceedings pending or in effect against the Seller for failure to comply with any Health Law, including any pending or threatened Legal Proceeding against the Seller or to the Seller's Knowledge, any of its officers or employees, by or before any Governmental Entity, with respect to the Product or the Product Business, or the Seller's obligations set forth herein, including any which may materially and adversely affect the Seller's ability to perform its obligations under this Agreement. The Seller has not received any written notice that the FDA, any other component of the U.S. Department of Health and Human Services, institutional review board, accreditation body, or any other federal, state or foreign Governmental Entity has recommended, initiated, or threatened to initiate, any action to place on clinical hold, suspend, withdraw approval for, or terminate any investigational new drug application, new drug application, or any comparable foreign regulatory application sponsored by the Seller with respect to the Product or the Product Business. To the Seller's Knowledge, there are no facts that would be reasonably likely to result in such an action of the type described in the preceding sentence by a Governmental Entity under applicable Health Laws which could have a Material Adverse Effect.

(j) Neither the Seller nor any officer or employee, nor, to the Seller's Knowledge, any agent or contractor of the Seller has made an untrue statement of material fact or fraudulent statement to any Health Authority, failed to disclose a material fact required to be disclosed to any Health Authority or any other Governmental Entity, or committed an act, made a statement, or failed to make a statement, including with respect to any scientific data or information, that, at the time such disclosure was made or failure to disclose occurred, would reasonably be expected to provide a basis for the Health Authority or any other Governmental Entity to invoke the FDA Application Integrity Policy respecting "Fraud, Untrue Statements of Material Facts, Bribery and Illegal Gratuities," set forth in FDA's Compliance Policy Guide Sec. 120.100 (CPG 7150.09) or any similar policy. Neither the Seller nor, to the Seller's Knowledge, any officer, employee, agent, or contractor of the Seller has been debarred or convicted of any crime or engaged in any conduct for which debarment is mandated by 21 U.S.C. § 335a(a) or any similar Laws or authorized by 21 U.S.C. § 335a(b) or any similar Laws. Neither the Seller nor, to the Seller's Knowledge, any officer, employee or agent of the Seller has been excluded or convicted of any crime or engaged in any conduct for which such Person could be excluded from participating in the Federal health care programs under Section 1128 of the Social Security Act of 1935, as amended, or any similar Laws.

(k) Neither the Seller nor, to the Seller's Knowledge, any manufacturers of the Product or of the raw materials for the Product have received any Form 483 observations, warning letters, notice of violation letters, or other communications from a Governmental Entity regarding violations or potential violations of Laws related to the raw materials for the Product or the Product Business that would reasonably be expected to adversely impact the manufacture, distribution, marketing, or sale of the Product. Except as set forth on Schedule 3.13(k), during the past [***] prior to the Execution Date, the Product has not been recalled, suspended, or discontinued by the Seller (nor, to the Seller's Knowledge, is there currently under consideration by the Seller, any removal, field correction or recall in respect of any of the Product), nor has the Seller received any written notice from any Health Authority that it has commenced or threatened to initiate, any action to withdraw approval, place sales or marketing restrictions on or request the recall of the Product, or that it has commenced or threatened to initiate any action to enjoin or place restrictions on the Product or distribution of the Product.

(l) The Seller has paid all HCR Fees related to the Product. For purposes of this Agreement, "HCR Fees" means the fees described in Section 9008 of the Patient Protection and Affordable Care Act, Pub. L.

No. 111-148, as amended by Section 1404 of the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152.

3.14 [***] .

3.15 Title to Acquired Assets. The Seller has and at the Closing the Seller will deliver to the Buyer, good, marketable and valid title to, and/or a valid right to use, each of the Acquired Assets, as the case may be, free and clear of all Liens, other than Permitted Liens. Except as set forth on Schedule 3.15, no Affiliate of the Seller owns, beneficially or of record, or has any rights, title or interest in, to or under any Acquired Asset.

3.16 ***

3.17 Brokers. Except as set forth on Schedule 3.17, no broker, investment banker, agent, finder or other intermediary acting on behalf of the Seller or under the authority of the Seller is or will be entitled to any broker's or finder's fee or any other commission or similar fee directly or indirectly in connection with any of the transactions contemplated hereby.

3.18 Exclusivity of Representations. EXCEPT FOR THE EXPRESS REPRESENTATIONS AND WARRANTIES CONTAINED IN THIS ARTICLE III, THE SELLER HAS MADE NO REPRESENTATION OR WARRANTY WHATSOEVER HEREIN OR OTHERWISE, EXPRESS OR IMPLIED (INCLUDING ANY REPRESENTATION OR WARRANTY RELATING TO FINANCIAL CONDITION OR RESULTS OF OPERATIONS OF THE PRODUCT BUSINESS OR MAINTENANCE, REPAIR, CONDITION, DESIGN, PERFORMANCE, VALUE, MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE OF THE ACQUIRED ASSETS) AND THE SELLER HEREBY DISCLAIMS ANY SUCH REPRESENTATIONS AND WARRANTIES.

ARTICLE IV REPRESENTATIONS AND WARRANTIES OF THE BUYER AND GUARANTOR

The Buyer and Guarantor jointly and severally represent and warrant to the Seller that the statements contained in this ARTICLE IV are true and correct as of the Execution Date.

4.1 Organization, Standing and Power. The Buyer is a limited liability company and the Guarantor is a corporation and each are duly organized, validly existing and in good standing under the Laws of the jurisdiction of its formation, has all requisite company power and authority to own, lease and operate its properties and assets and to carry on its respective business as now being conducted, and each is duly qualified to do business and, where applicable as a legal concept, is in good standing as a foreign entity in each jurisdiction in which the character of the properties it owns, operates or leases or the nature of its respective activities makes such qualification necessary, except for such failures to be so qualified, individually or in the aggregate, that would not reasonably be expected to be material to the Buyer or the Guarantor, as applicable.

4.2 Authority; No Conflict; Required Filings and Consents; Regulatory Representation.

(a) Each of the Buyer and the Guarantor has all requisite company power and authority to enter into this Agreement and each of the Ancillary Documents to which each will be a party and to consummate the transactions contemplated hereby and thereby. The execution, delivery and performance by each of the Buyer and the Guarantor of this Agreement and each of the Ancillary Documents to which each will be a party and the consummation of the transactions contemplated hereby and thereby by the Buyer and the Guarantor have been duly authorized by all necessary corporate action on the part of each of the Buyer and the Guarantor. This Agreement has been, and each such Ancillary Document will be, duly executed and delivered by each of the Buyer and the

Guarantor and this Agreement is, and each such Ancillary Document when so duly executed and delivered by each of the Buyer and the Guarantor and, if applicable, the Seller, will be, the valid and binding obligation of each of the Buyer and the Guarantor

enforceable against each of the Buyer and the Guarantor in accordance with its terms, except as enforceability may be limited by bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium or other similar Laws affecting the rights of creditors generally and by equitable principles.

(b) The execution, delivery and performance by each of the Buyer and the Guarantor of this Agreement and each of the Ancillary Documents to which each will be a party, and the consummation by each of the Buyer and the Guarantor of the transactions contemplated hereby and thereby, shall not, (i) conflict with, or result in any violation or breach of, any provision of the organizational documents of each of the Buyer or the Guarantor, (ii) conflict with, or result in any material violation or material breach of, or constitute (with or without notice or lapse of time, or both) a material default (or give rise to a right of termination, cancellation or acceleration of any obligation or loss of any material benefit) under, require a consent or waiver under, constitute a change in control under, or result in the imposition of any Lien, other than Permitted Liens, on or with respect to each of the Buyer's or the Guarantor's assets or under any material Contract to which Buyer or its Affiliates is a party or (iii) conflict with or violate any material permit, concession, franchise, license or Law applicable to each of the Buyer or the Guarantor or any of its respective properties or assets, except for any of the matters referred to in clause (iii) that would not prevent or materially delay performance by the Buyer or the Guarantor of any of its material obligation under this Agreement.

(c) No material consent, approval, license, permit, order or authorization of any Governmental Entity is required by or with respect to the Buyer or the Guarantor in connection with the execution, delivery and performance by the Buyer or the Guarantor of this Agreement and each of the Ancillary Documents to which they will be a party or the consummation by the Buyer or the Guarantor of the transactions contemplated hereby.

(d) Neither the Buyer, the Guarantor, nor any officer or employee, nor, to Buyer's Knowledge, any agent or contractor of the Buyer or the Guarantor, as applicable, has made an untrue statement of material fact or fraudulent statement to any Health Authority, failed to disclose a material fact required to be disclosed to any Health Authority or any other Governmental Entity, or committed an act, made a statement, or failed to make a statement, including with respect to any scientific data or information, that, at the time such disclosure was made or failure to disclose occurred, would reasonably be expected to provide a basis for the Health Authority or any other Governmental Entity to invoke the FDA Application Integrity Policy respecting "Fraud, Untrue Statements of Material Facts, Bribery and Illegal Gratuities," set forth in FDA's Compliance Policy Guide Sec. 120.100 (CPG 7150.09) or any similar policy. Neither the Buyer nor the Guarantor nor, to Buyer's Knowledge, any officer, employee, agent or contractor of the Buyer or the Guarantor has been debarred or convicted of any crime or engaged in any conduct for which debarment is mandated by 21 U.S.C. § 335a(a) or any similar Laws or authorized by 21 U.S.C. § 335a(b) or any similar Laws. Neither the Buyer nor the Guarantor nor, to Buyer's Knowledge, any officer, employee or agent of the Buyer or the Guarantor has been excluded or convicted of any crime or engaged in any conduct for which such Person could be excluded from participating in the Federal health care programs under Section 1128 of the Social Security Act of 1935, as amended, or any similar Laws.

4.3 Litigation. There is no Legal Proceeding pending or, to the knowledge of the Buyer or the Guarantor, threatened, against the Buyer or the Guarantor, and neither the Buyer nor the Guarantor is subject to any outstanding order, writ, judgment, injunction or decree of any Governmental Entity that, in either case, would, individually or in the aggregate, (a) prevent or materially delay the consummation by the Buyer or the Guarantor of the transactions contemplated by this Agreement or (b) otherwise prevent or materially delay performance by the Buyer or the Guarantor of any of its material obligations under this Agreement.

4.4 Brokers. Except as set forth on Schedule 4.4, no broker, investment banker, agent, finder or other intermediary acting on behalf of the Buyer or the Guarantor or under the authority of the Buyer or the Guarantor is or will be entitled to any broker's or finder's fee or any other commission or similar fee directly or indirectly in connection with any of the transactions contemplated hereby.

4.5 Financial Capacity. The Buyer and the Guarantor collectively have immediately available cash sufficient to enable it to complete the transactions contemplated hereby and to perform its respective obligations under its Agreement and the Ancillary Documents, including the payment of each Fixed Payment.

4.6 Solvency. After giving effect to all of the transactions contemplated by this Agreement, including the payment of the Purchase Price, (a) the "fair saleable value" of the assets of the Buyer and the Guarantor will exceed (i) the value of all liabilities of the Buyer and the Guarantor, including contingent and other liabilities as of the Closing Date and (ii) the amount that will be required to pay the liabilities of the Buyer and the Guarantor on its respective existing debts (including contingent liabilities) as such debts become absolute and matured, (b) each of the Buyer and the Guarantor will not have, as of such date, unreasonably small capital for the operation of its respective businesses in which it is engaged or proposed to be engaged following such date and (c) each of the Buyer and the Guarantor will be able to pay its liabilities as they become due.

4.7 No Other Representations; Buyer's Investigation and Reliance. Neither the Buyer nor the Guarantor is relying on any statement or representation made by or on behalf of the Seller with respect to the Acquired Assets or Product Business (including (a) as to the accuracy or completeness of any of the information provided to the Buyer or any of its Affiliates or representatives or (b) with respect to any projections, forecasts, estimates, plans or budgets of future revenues, expenses or expenditures, future results of operations, future cash flows or future financial condition of the Product Business provided to the Buyer or any of its Affiliates or representatives), other than the representations made in ARTICLE III. In entering into this Agreement, except as expressly provided herein, the Buyer has relied solely upon the representations set forth in ARTICLE III and its independent investigation and analysis of the Product Business. The Buyer acknowledges that there are inherent uncertainties in attempting to make such projections, forecasts, estimates, plans or budgets and that it takes full responsibility for making its own evaluation of the adequacy and accuracy of any such projections, forecasts, estimates, plans or budgets (including the reasonableness of the assumptions underlying any such projections, forecasts, estimates, plans or budgets).

ARTICLE V

ADDITIONAL AGREEMENTS; COVENANTS

5.1 Confidentiality. From and after the Closing Date, the Seller shall treat and hold as confidential, and not disclose, any of the Confidential Information to any third party, except (a) as expressly permitted by this Agreement or any Ancillary Document; (b) as necessary to perform this Agreement or any Ancillary Document, including to defend, prosecute, arbitrate any indemnification claim or any Legal Proceeding relating to this Agreement or any Ancillary Document; (c) as required by Law or the rules and regulations of each stock exchange upon which the securities of the Seller or its Affiliates are listed, if any; or (d) with respect to Confidential Information relating to the Product Business, the Acquired Assets or the Assumed Liabilities, as reasonably necessary to operate any of the Seller's business other than the Product Business as conducted as of the Execution Date and without limitation of any of the Seller's rights under this Agreement or any Ancillary Document (provided, that the Seller shall not disclose any such Confidential Information to a third party unless

such third party is subject to a confidentiality obligation in favor of the Seller no less restrictive than this Section 5.1). In the

event that the Seller is requested or required (by oral question or request for information or documents in any legal proceeding, interrogatory, subpoena, civil investigative demand or similar process or as otherwise required by Law) to disclose any Confidential Information (other than in connection with the rules and regulations of each stock exchange upon which the securities of the Seller or its Affiliates are listed, if any), the Seller shall notify the Buyer promptly of the request or requirement so that the Buyer may seek, at its expense, an appropriate protective order or waive compliance with the provisions of this Section 5.1. If, in the absence of a protective order or the receipt of a waiver hereunder the Seller is compelled to disclose any Confidential Information to any Governmental Entity, the Seller may disclose the Confidential Information to the Governmental Entity; provided, however, that the Seller shall (x) disclose only that portion of the Confidential Information that it is advised by counsel is required to be disclosed and (y) use commercially reasonable efforts to obtain, at the request and expense of the Buyer, reliable assurance that confidential treatment will be accorded to such portion of the Confidential Information required to be disclosed. For the purposes of this Agreement, “Confidential Information” shall mean any nonpublic confidential or proprietary information relating solely to the Product or the Product Business for the Indications or Acquired Assets in the possession of the Seller or its Affiliates. “Confidential Information” shall not include any information that (i) was publicly available prior to the date of this Agreement or hereafter becomes publicly available not as a result of any breach of this Agreement by Seller or (ii) becomes available on a non-confidential basis to the Seller or its Affiliates from a Person (other than the Seller or any of its Affiliates) that is not subject to any legally binding obligation to keep such information confidential. The Seller shall be responsible for any use or disclosure of Confidential Information by any of the Seller’s Affiliates or representatives that would breach this Section 5.1 if such Affiliate or representative was a party hereto.

5.2 Post-Closing Access. Except as otherwise set forth in any Ancillary Document, for a period of [***] following the Closing Date (and solely, in the case of access to personnel, for a period of [***] following the Closing Date), the Seller shall afford to the Buyer and the Buyer’s authorized accountants, counsel and other designated representatives, during normal business hours, upon reasonable advance notice in writing, to the extent permitted by applicable Law and at Buyer’s sole cost and expense, access to the books, records, data, files and personnel of the Seller, in each case, to the extent (a) relating primarily to the Product or the Product Business and reasonably requested by the Buyer and (b) not otherwise provided to the Buyer pursuant to Section 2.1 hereof; provided, however, that such access shall not unreasonably interfere with the Seller’s operation of its businesses; provided, further, that the Seller may restrict the foregoing access to the extent that (i) such access or provision of information would result in a violation of confidentiality obligations to a third party or disclosure of a trade secret of the Seller, (ii) any persons fail to execute a customary confidentiality and access agreement with Seller or (iii) disclosure of any such information would result in the loss or waiver of any attorney-client privilege, in which case the Seller shall use commercially reasonable efforts to provide the Buyer with an acceptable alternative means of obtaining such information; provided, further, that the Seller may redact any material provided under this Section 5.2 to the extent such material relates to any assets or products other than such reasonable financial and operating data that is available to the Seller with respect to the Acquired Assets, the Assumed Liabilities or the Product Business as the Buyer may from time to time reasonably request.

5.3 Further Assurances. From time to time, as and when requested by either Party, each of the Parties shall, at its expense (except as otherwise expressly provided in this Agreement), execute such additional documents and take such further actions as may be reasonably requested to carry out the provisions hereof and consummate and evidence the transactions contemplated hereby, including executing and delivering or causing to be executed and delivered to the other Party such additional documents as the other Party or its counsel may

reasonably request as necessary for such purpose; provided, that after the Closing Date, apart from such customary further assurances, Seller shall have no other obligations except as set forth

in and described herein or in the Ancillary Documents, including having any obligation to pay any amount of money or make any material concessions. Without limitation of the foregoing, except as expressly set forth in Section 5.5 or in the Ancillary Documents, the Seller shall have no obligation to assist or otherwise participate in the amendment or supplementation of the Regulatory Approvals or in any filings or other activities relating to the Regulatory Approvals.

5.4 [***]

(a)

5.5 Notification to FDA; Customers.

(a) Notification to FDA. No later than [***] following the date the Seller provides all required Regulatory Approvals and Regulatory Documentation pursuant to Section 2.1(e), (i) the Seller shall execute and deliver to both the FDA contact described therein and the Seller a letter from the Seller to the FDA notifying the FDA of the transfer to the Buyer of the rights to the applicable Regulatory Approvals issued by the FDA, in the form of letter attached hereto as Exhibit E (the “Seller FDA Letter”) and (ii) the Buyer shall execute and deliver to both the FDA contact described therein and the Seller a letter from the Buyer to the FDA of Buyer assuming responsibility for the applicable Regulatory Approvals issued by the FDA, in the form attached hereto as Exhibit F (the “Buyer FDA Letter”). Further, each of the Buyer and the Seller shall work together to make all other filings with and give all other notices to all Governmental Entities, including the FDA, required in connection with the transfer of the Product and the Regulatory Approvals promptly following the Closing.

(b) Notification of Customers. [***], the Buyer shall be responsible for processing customer orders and for shipping and invoicing customers for the Product. [***], the Parties shall jointly issue a letter reasonably satisfactory to both Parties to customers within the trade (wholesalers and distributors) and to commercial Chargeback customers notifying such customers (i) that the Buyer has acquired the rights to market and sell the Product, (ii) that all future Product orders are to be placed with the Buyer, (iii) that all returns of finished goods are to be delivered to the Buyer, (iv) of the Seller’s and the Buyer’s responsibilities in connection with Assumed Commercial Contracts providing for payment of Chargebacks, Rebates, Other Charges, and administrative fees and (v) providing the appropriate contact information for the Buyer’s personnel. After the issuance of such letter, the Parties shall at all times reasonably cooperate in (A) notifying and continuing to notify such customers that all future Product orders are to be placed with the Buyer and that all returns of finished goods are to be delivered to the Buyer and (B) taking such other actions as are reasonably necessary to effect the foregoing, including forwarding to the Buyer any orders placed prior to the Closing Date for the purchase of Product by customers that are unfulfilled as of the Closing Date.

5.6 Use of Seller Brands.

(a) The Seller hereby grants to the Buyer a fully-paid, royalty-free, non-exclusive, non-sublicensable, irrevocable, non-transferable and non-assignable limited right and license to use any universal product codes or Trademarks used on or in connection with the Product that are not included in the Transferred Intellectual Property or Licensed Intellectual Property (the “Seller Brands”) for the purposes expressly set forth below in Section 5.6(b) for the Trademark Period.

(b) The Buyer shall be permitted, for a period commencing on the Closing Date and ending no later than the date of the latest expiration date for any individual units of finished Product included in the Product Inventory that bear or contain the Seller Brands (the “Trademark Period”) to use the Seller Brands only to the extent they appear on Product Inventory and Marketing Assets and only as necessary to sell off the Product Inventory and use up Marketing Assets that in each case exist as of the Closing Date. The Buyer shall use commercially reasonable efforts to stop using the Seller Brands as promptly as reasonably practical following the Closing.

(c) Nothing contained in this Agreement shall be construed as an assignment to the Buyer of any right, title or interest in the Seller Brands; it being understood that all rights, title and interest relating to the Seller Brands are expressly reserved by the Seller.

5.7 Regulatory Matters.

(a) Each of the Seller and the Buyer shall reasonably cooperate and use its commercially reasonable efforts to ensure compliance with all Laws, including FDA regulation 21 C.F.R. 314.72, that may be or become applicable to the performance of its and the other Party’s obligations pursuant to this Agreement. The Seller hereby grants to the Buyer a right of reference to use Seller’s device master file or master access file for any device covered by the Seller’s device master file and/or master access file that is identified in the Product NDA, including the Sub-Assembly Component. Reasonably promptly upon the Buyer’s request in writing, the Seller will provide the Buyer with a right of reference letter to use Seller’s device master file or master access file for any device covered by the Seller’s device master file and/or master access file that is identified in the Product NDA, including the Sub-Assembly Component.

(b) From the Closing Date [***], each Party shall promptly notify the other Party of any communication it or any of its Affiliates receives from any Governmental Entity relating to the matters that are the subject of this Agreement and shall, to the extent permitted by applicable Law, permit the other Party to review in advance any proposed communication by such Party to any Governmental Entity relating to the matters that are the subject of this Agreement. For the purposes of this Agreement, “Affiliate” means, with respect to any Party, any other person, firm, trust, partnership, corporation, company or other entity or combination thereof, which directly or indirectly (i) controls such Party, (ii) is controlled by such Party or (iii) is under common control with such Party. The terms “control” and “controlled” mean ownership of fifty percent (50%) or more, including ownership by trusts with substantially the same beneficial interests, of the voting and equity rights of such Party, firm, trust, corporation or other entity or combination thereof, or the power, indirectly or directly, to direct or cause the direction of the management and policies of such Party, firm, trust, corporation or other entity or combination thereof, whether by Contract or otherwise.

(c) Subject to the terms of the Quality Agreement, as applicable, after the Closing Date, the Buyer shall have all responsibility for investigating and reporting complaints and adverse experiences for the Product arising after the Closing Date to any Governmental Entities and addressing any such Governmental Entities’ inquiries related to the safety of the Product, including those that may arise from Product Inventory manufactured prior to the Closing Date; provided, that after the Closing, the Seller shall use its commercially reasonable efforts to assist the Buyer in the investigation of adverse experiences and product complaints reported after the Closing for Product manufactured or distributed by or for the Seller. [***], the Seller shall forward to

the Buyer all adverse experience reports and product complaints for the Product received after the Closing by the Seller, its Affiliates, or its or their agents, contractors or licensees.

5.8 [***]

(a)

5.9 [***]

(a)

5.10 [***]

5.11 Seller Contact. The contact for the Seller for all matters relating to Sections 5.4, 5.8 through 5.10 is:

Antares Pharma, Inc.
100 Princeton South
Suite 300
Ewing, New Jersey 08628
Facsimile: (609) 359-3015
Attn: Raymond Taylor, Sr. Director of Managed Care, Trade Relations and Government Pricing

With a copy to:

Antares Pharma, Inc.
100 Princeton South
Suite 300
Ewing, New Jersey 08628
Facsimile: (609) 359-3015
Attn: Peter J. Graham, General Counsel

5.12 Taxes.

(a) The Seller shall be liable for and pay, and in accordance with the applicable requirements and limitations of ARTICLE VI shall indemnify and hold harmless the Buyer from and against all of Seller's Taxes. In cases where a taxable period includes but does not end on the Closing Date, the Tax liability attributable to the Pre-Closing Tax Period and, thus, Seller's Taxes, shall be determined (i) in the case of real, personal and intangible property Taxes and similar ad valorem obligations that are imposed on a periodic basis levied with respect to the Acquired Assets, by apportioning such Taxes between the Pre-Closing Tax Period portion of such Tax period, on the one hand, and the portion of such taxable period beginning after the Closing Date, on the other, based on the number of days of such taxable period up to and including the Closing Date and the number of days of such taxable period after the Closing Date and (ii) in the case of any income Taxes, sales or use Taxes, value-added Taxes, employment Taxes, withholding Taxes, and any Tax based on or measured by income or revenues, based on a closing of the books as of the Closing Date. The Seller be liable for the amount of such Taxes that is attributable to Pre-Closing Tax Period, and the Buyer shall be liable for the amount of such Taxes that is attributable to the portion of the taxable period beginning after the Closing Date.

(b) After the Closing, each of the Seller and the Buyer shall: (i) provide reasonable assistance to the other Party in connection with such Party's preparation of any Tax Returns which such Party is responsible for preparing and filing; (ii) provide reasonable cooperation in preparing for any audits of, or disputes with Taxing Authorities regarding, any

Tax Returns relating to the Product, the Product Business or the Acquired Assets; (iii) make available to the other Party and to any Taxing Authority as reasonably requested all information, records, and documents relating to Taxes relating to the Product or the Acquired Assets; (iv) in the case of the Buyer, provide timely notice to the Seller in writing of any pending or threatened (in writing) Tax audits or assessments relating to the Product, the Product Business or the Acquired Assets for Tax periods for which the Seller may have a liability under this Section 5.12; and (v) in the case of the Buyer, furnish the Seller with copies of all correspondence received from any Taxing Authority in connection with any Tax audit or information request in respect of the Product or the Acquired Assets with respect to Tax periods for which the Seller may have a liability under this Section 5.12.

(c) The Buyer shall promptly forward to or reimburse the Seller for any refunds of Taxes for which the Seller is liable pursuant to Section 5.12(a). The Seller shall promptly forward to or reimburse the Buyer for any refunds of Taxes paid by the Buyer and for which the Buyer is liable pursuant to this Agreement.

5.13 Brokers and Other Expenses. Each Party shall be responsible for its own broker's, finder's, financial advisor's or other similar fee or commission in connection with any of the transactions contemplated by this Agreement. All costs and expenses associated with removing and moving any Acquired Asset to a location designated by the Buyer shall be borne and paid solely by the Buyer when due; provided, however, that if any such amount shall be incurred by the Seller at the request of the Buyer or with the Buyer's prior written consent, the Buyer shall, subject to receipt of satisfactory evidence of the Seller's payment thereof, promptly reimburse the Seller for its out-of-pocket costs. All other costs and expenses (including fees and disbursements of counsel and accountants) not otherwise attributable to a Party as set forth herein, and incurred in connection with this Agreement and the transactions contemplated hereby, shall be paid by the Party incurring such costs and expenses. Notwithstanding anything to the contrary contained herein, following the Closing, the Buyer and the Guarantor each hereby agrees that Guarantor will continue to reimburse the Seller for any Fees (as such term is defined in the Carve-Out Financial Letter Agreement) incurred by the Seller whether before or after the Closing in accordance with the terms of the Carve-Out Financial Letter Agreement, including any Fees above any estimates set forth therein.

5.14 Bulk Transfer Laws. The Buyer hereby waives compliance by the Seller with the provisions of any bulk transfer or similar law of any jurisdiction in connection with the sale of the Acquired Assets to the Buyer.

5.15 Safety Data Exchange Agreement. After the Closing, the Buyer shall be responsible for complying with all applicable adverse event reporting obligations to any Governmental Entity with respect to the Product in accordance with the Safety Data Exchange Agreement. In particular, the Buyer shall be responsible for collecting all pharmacovigilance information and for submitting applicable reports and notifying the relevant Governmental Entity of all reportable events relating to the Product in accordance with the Safety Data Exchange Agreement. In the event that the Seller is contacted by a Governmental Entity regarding the Product or any of the Acquired Assets following the Closing Date, the Seller shall be permitted to respond to such communication by directing any such Governmental Entity to the Buyer.

5.16 ***

5.17 Acquired Assets. The Buyer shall not assign, transfer, convey or grant any rights in, or to, any of the Acquired Assets, in whole or in part, to a third party without assigning this Agreement to such third party recipient

of such Acquired Assets in accordance with the provisions of Section 7.6. In connection with any such assignment, the assignee shall provide

written notification to the Seller confirming that such assignee is bound to the Buyer's obligations set forth in this Agreement in connection with such Acquired Assets.

5.18 [***]

5.19 [***]

ARTICLE VI INDEMNIFICATION

6.1 Indemnification by the Seller. Subject to the terms and conditions of this ARTICLE VI, from and after the Closing, the Seller shall indemnify and hold harmless the Buyer and its Affiliates, and its and their respective equityholders, officers, directors, managers, employees, agents, partners, representatives, successors and assigns from and against any and all losses, damages, obligations, liabilities, fines, fees, penalties, interest, awards, judgments and claims of any kind, including reasonable attorneys' and consultants' fees and expenses and other reasonable legal costs and expenses incurred in prosecution, investigation, remediation, defense or settlement (collectively, "Damages") to the extent arising from or relating to:

- (a) any breach of any of the representations or warranties of the Seller contained in this Agreement;
- (b) any breach by the Seller of any covenant or agreement contained in this Agreement;
- (c) any Excluded Liabilities; or
- (d) Seller's Taxes.

6.2 Indemnification by the Buyer. Subject to the terms and conditions of this ARTICLE VI, from and after the Closing, the Buyer shall indemnify and hold harmless the Seller and its Affiliates, and its and their respective equityholders, officers, directors, managers, employees, agents, partners, representatives, successors and assigns from and against any and all Damages to the extent arising from or relating to:

- (a) any breach of any of the representations or warranties of the Buyer contained in this Agreement;
- (b) any breach or failure to perform by the Buyer of any covenant or agreement contained in this Agreement; or
- (c) any Assumed Liabilities.

6.3 Claims for Indemnification.

(a) Third Party Claims. All claims for indemnification made under this Agreement resulting from, related to or arising out of a third party claim against an Indemnified Party shall be made in accordance with the following procedures. A Person entitled to indemnification under this ARTICLE VI (an "Indemnified Party") shall give prompt written notice to the Indemnifying Party (a "Third Party Claim Notice") of the commencement of

any action, suit or proceeding relating to a third party claim for which indemnification may be sought or, if earlier, upon the assertion of any such claim by a third party; provided, however, that failure of the Indemnified Party to timely give the notice provided in this Section 6.3 to the Indemnifying Party shall not preclude the Indemnified Party from recovering Damages unless

and only to the extent that the Indemnifying Party can demonstrate that it was actually prejudiced and directly damaged by such failure. For the purposes of this Agreement, “Indemnifying Party” means (i) in the case of a claim for indemnification by the Buyer, the Seller and (ii) in the case of a claim for indemnification by the Seller, the Buyer. Such Third Party Claim Notice shall include a description in reasonable detail (to the extent known by the Indemnified Party) of the facts constituting the basis for such third party claim and the amount of the Damages claimed. Within [***] after delivery of such Third Party Claim Notice, the Indemnifying Party shall, upon written notice thereof to the Indemnified Party, be entitled to participate in the defense of such action, suit, proceeding or claim at the Indemnifying Party’s expense. The Indemnifying Party shall be entitled to control and appoint lead counsel of such defense with reputable counsel reasonably acceptable to the Indemnified Party; provided that the Indemnifying Party shall not have the right to assume control of such defense and shall pay the reasonable fees and expenses of counsel retained by the Indemnified Party, if the claim which the Indemnifying Party seeks to assume control (A) seeks non-monetary relief, (B) involves criminal allegations, or (C) is one in which the Indemnifying Party is also a party and joint representation would be inappropriate or there may be legal defenses available to the Indemnified Party which are different from or additional to those available to the Indemnifying Party. If the Indemnifying Party does not assume control of such defense, the Indemnified Party shall control such defense. The Party controlling such defense shall keep the other Party advised of the status of such action, suit, proceeding or claim and the defense thereof and shall consider recommendations made by the other Party with respect thereto. The Indemnified Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the Indemnifying Party. The Indemnifying Party shall not agree to any settlement of such action, suit, proceeding or claim that does not include a complete release of the Indemnified Party from all liability with respect thereto or that imposes any liability or obligation on the Indemnified Party (other than the payment of monetary damages for which the Indemnifying Party shall indemnify the Indemnified Party) without the prior written consent of the Indemnified Party.

(b) Procedure for Claims Not Involving Third Parties. An Indemnified Party wishing to assert a claim for indemnification under this ARTICLE VI that does not involve a third party claim shall deliver to the Indemnifying Party a written notice (a “Claim Notice”) which contains (i) a description and the amount of any actual or estimated Damages, (ii) a statement that the Indemnified Party is entitled to indemnification under this ARTICLE VI and a reasonable explanation of the basis therefor and (iii) a demand for payment in the amount of such Damages; provided, however, that failure of the Indemnified Party to timely give the Claim Notice provided in this Section 6.3 to the Indemnifying Party shall not preclude the Indemnified Party from recovering Damages unless and only to the extent that the Indemnifying Party can demonstrate that it was actually prejudiced by such failure. If the Indemnifying Party disputes its liability with respect to any such claim, the Indemnifying Party shall give written notice to the Indemnified Party, promptly but in no event greater than [***] after receipt of written notice of the indemnification sought, of the dispute and describing those portions and the amount (if known and quantifiable) of the claim in dispute, and the basis of the dispute. Upon the Indemnified Party’s receipt of a timely notice of dispute, the Indemnifying Party and the Indemnified Party shall proceed to negotiate a resolution of such dispute. If such dispute is not resolved within [***] following the delivery by the Indemnifying Party of such response, the Indemnifying Party and the Indemnified Party shall each have the right to submit such dispute to a court of competent jurisdiction in accordance with the provisions of Section 7.12.

6.4 Survival.

(a) The representations and warranties of the Seller and the Buyer set forth in this Agreement shall survive the Closing and the consummation of the transactions contemplated hereby and continue until [***]. The representations and warranties in Section 3.4 (Taxes) shall survive for [***]. The representations and warranties in Section 3.5 (Intellectual Property) shall

survive [***]. The Fundamental Reps shall survive for a period of [***]. The covenants and agreements of the Seller and the Buyer set forth in this Agreement shall survive the Closing and the consummation of the transactions until fully performed in accordance with their express terms.

(b) If an indemnification claim is asserted in writing pursuant to Section 6.3 prior to the expiration as provided in Section 6.4(a) of the representation or warranty that is the basis for such claim, then such representation or warranty shall survive until, but only for the purpose of, the resolution of such claim.

6.5 Limitations.

(a) [***]

(i)

(b) The amount of Damages recoverable by an Indemnified Party under this ARTICLE VI with respect to an indemnity claim shall be reduced by the amount of any insurance payment actually received by such Indemnified Party (or an Affiliate thereof) with respect to such indemnity claim less any cost associated with receiving such recovery (including any reasonable expenses incurred by the Indemnified Party, the amount of any deductible and the present value of all increases or adjustments to insurance premiums arising from such insurance claim). The Buyer shall use its commercially reasonable efforts to collect insurance proceeds for any claim made by the Seller to the Buyer or by the Buyer to the Seller. If an Indemnified Party (or an Affiliate) receives any insurance payment in connection with any claim for Damages for which it has already been indemnified by the Indemnifying Party, it shall pay to the Indemnifying Party, within [***] of receiving such insurance payment, an amount equal to the excess of (i) the amount previously received by the Indemnified Party under this ARTICLE VI with respect to such claim plus the amount of the insurance payments received, over (ii) the amount of Damages with respect to such claim which the Indemnified Party has become entitled to receive under this ARTICLE VI.

(c) [***], NEITHER THE BUYER NOR THE SELLER SHALL BE LIABLE TO THE OTHER, OR THEIR AFFILIATES, FOR ANY CLAIMS, DEMANDS OR SUITS FOR CONSEQUENTIAL, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE, INDIRECT OR MULTIPLE DAMAGES, INCLUDING BUT NOT LIMITED TO LOSS OF PROFITS, REVENUE OR INCOME, DIMINUTION IN VALUE OR LOSS OF BUSINESS OPPORTUNITY WHETHER OR NOT FORESEEABLE AT THE DATE OF THIS AGREEMENT CONNECTED WITH OR RESULTING FROM ANY BREACH AFTER THE CLOSING DATE OF THIS AGREEMENT, OR ANY ACTIONS UNDERTAKEN IN CONNECTION WITH, OR RELATED HERETO, INCLUDING ANY SUCH DAMAGES WHICH ARE BASED UPON BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE AND MISREPRESENTATION), BREACH OF WARRANTY, STRICT LIABILITY, STATUTE, OPERATION OF LAW OR ANY OTHER THEORY OF RECOVERY.

(d) [***]the rights of the Indemnified Parties under this ARTICLE VI shall be the sole and exclusive monetary remedies of the Indemnified Parties with respect to claims under, or otherwise relating to the transactions that are the subject of, this Agreement.

6.6 Manner of Payment.

(a) Any payment to any Indemnified Party under this ARTICLE VI for indemnification shall be effected by wire transfer of immediately available funds from or on

behalf of the Indemnifying Party to an account designated by the Indemnified Party within [***]s after the date of the determination of any amounts due and owing under this ARTICLE VI.

(b) The Buyer shall not be entitled to setoff of any amounts due and payable, or any Damages arising, under this Agreement against any amounts due and payable, or any Damages arising, under this Agreement or the Ancillary Documents. The payment obligations under each of this Agreement and the Ancillary Documents remain independent obligations of each Party, irrespective of any amounts owed to any other Party under this Agreement or the respective Ancillary Documents.

6.7 Disclaimers.

(a) Except with respect to claims of Fraud or as expressly set forth in any representation or warranty in ARTICLE III, Buyer acknowledges and agrees that neither it nor any other Buyer Indemnified Parties shall have any claim or right to indemnification pursuant to this ARTICLE VI (or otherwise) with respect to any information, documents, or materials furnished to or for Buyer by Seller or any of its Affiliates or any of their officers, directors, employees, agents or advisors, including any information, documents, or material made available to Buyer in any “data room”, management presentation, or any other form in connection with the transactions contemplated by this Agreement or any Ancillary Document. Any claims Buyer may have for breach of representation or warranty of Seller under this Agreement shall be based solely on the representations and warranties of Seller expressly set forth in this Agreement.

(b) WITHOUT LIMITING THE GENERALITY OF ANYTHING SET FORTH IN THIS AGREEMENT, INCLUDING ARTICLE IV, BUYER ACKNOWLEDGES AND AGREES THAT EXCEPT AS EXPRESSLY PROVIDED IN ARTICLE III, BUYER IS ACQUIRING THE ACQUIRED ASSETS ON AN “AS IS, WHERE IS” BASIS WITHOUT ANY EXPRESS OR IMPLIED WARRANTIES, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, INCLUDING ANY WARRANTY OF QUALITY, THE FITNESS FOR A PARTICULAR PURPOSE, MERCHANTABILITY, CONDITION OF THE ASSETS, AS TO THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF ANY PERSON OR AS TO ANY OTHER MATTER.

6.8 Indemnification Payments. All indemnification payments made hereunder shall be treated by all Parties as adjustments to the Purchase Price for Tax purposes unless otherwise required by Law.

ARTICLE VII MISCELLANEOUS

7.1 Notices. All notices and other communications hereunder shall be in writing and shall be deemed duly delivered (i) on the day of delivery if delivered in person; (ii) one (1) Business Day after being sent for next Business Day delivery, fees prepaid, via a reputable nationwide overnight courier service or (iii) on the date of confirmation of receipt (or, the first Business Day following such receipt if the date of such receipt is not a Business Day) of transmission by e-mail or facsimile, in each case to the intended recipient as set forth below:

(a) if to the Buyer, to

Assertio Therapeutics, Inc.

100 South Saunders Road, Suite 300
Lake Forest, Illinois 60045
Attention: Sam Schlessinger, General Counsel

and

Baker Botts L.L.P.
98 San Jacinto Blvd, #1500
Austin, TX 78701
Email: margaret.sampson@bakerbotts.com
Attn: Margaret Sampson

(b) if to the Seller, to

Antares Pharma, Inc.
100 Princeton South
Suite 300
Ewing, New Jersey 08628
Facsimile: (609) 359-3015
Email: Ed Tykot, Sr. VP Corporate Development

with a copy to:

Antares Pharma, Inc.
100 Princeton South
Suite 300
Ewing, New Jersey 08628
Email: pgraham@antarespharma.com
Attn: Peter J. Graham, General Counsel

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

Morgan, Lewis & Bockius LLP
101 Park Avenue
Suite 40
New York, New York 10178
Facsimile: (212) 309-6001
Email: Allison.gargano@morganlewis.com
Attn: Allison D. Gargano

Any Party may give any notice or other communication hereunder using any other means (including personal delivery, messenger service or ordinary mail), but no such notice or other communication shall be deemed to have been duly given unless and until it actually is received by the Party for whom it is intended. Any Party may change the address to which notices and other communications hereunder are to be delivered by giving the other Parties notice in the manner herein set forth.

7.2 Disclosure. Without limiting any Party's obligations under existing confidentiality agreements, each Party shall not, and shall not permit any of its Affiliates to, issue any press release or make any disclosure regarding the transactions contemplated hereunder unless: (a) the other Party shall have approved such press release or disclosure in writing; or (b) such Party shall have determined in good faith, (i) upon the advice of outside legal counsel, that such disclosure is required by applicable Law, or (ii) disclosure is required under the rules and regulations of each stock exchange upon which the securities of such Party are listed, if any, and, to the extent practicable, before such press release or disclosure is issued or made, such Party advises the other Party of, and consults with the other Party regarding, the text of such

press release or disclosure. Notwithstanding the foregoing, nothing in this Section 7.2 shall prevent a Party from making disclosures: (A) to persons employed or engaged by such Party in evaluating, approving, structuring or administering this Agreement or any Ancillary Document; (B) to such Party's legal counsel or accountants, partners or investors (including outside auditors and legal counsel of such Party's accountants, partners or investors) or to such Party's employees, officers, directors or Affiliates, so long as such persons are notified of, and under confidentiality obligations with respect to, the confidential nature of such information; (C) to any investor, lender or potential investor or lender of such Party, in connection with investment or lending decisions with respect to such Party or otherwise in connection with customary reports to such investors, lenders or potential investors or lenders regarding such Party's portfolio and performance, so long as such persons are notified of the confidential nature of, and under confidentiality obligations with respect to, such information; (D) to any assignee or potential assignee that has agreed to comply with the covenant contained in this Section 7.2 (and any such assignee or potential assignee may disclose such information to persons employed or engaged by it as described in clauses (A) - (C) above) or (E) required by the rules and regulations of the United States Securities and Exchange Commission. Notwithstanding Section 7.2(E) or any other provision above, in the event this Agreement or any Ancillary Document is to be filed with the United States Securities and Exchange Commission, each Party agrees, prior to making any such filing, to provide the other Party and its counsel with a redacted version of this Agreement (and any other Ancillary Document) that it intends to file, and use reasonable efforts to ensure the confidential treatment by the Securities and Exchange Commission of those sections.

7.3 Entire Agreement. This Agreement (including the Ancillary Documents, Disclosure Schedule, the Carve-Out Financial Letter Agreement and the Schedules and Exhibits hereto and the documents and instruments referred to herein that are to be delivered at the Closing) constitutes the entire agreement between the Parties and supersedes any prior understandings, agreements or representations by or between the Parties, written or oral, with respect to the subject matter hereof. In the event of any inconsistency between any such Schedules and Exhibits and this Agreement, the terms of this Agreement shall govern.

7.4 Amendments and Waivers. This Agreement may not be amended except by an instrument in writing signed on behalf of each Party hereto. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. No waiver by either Party of any term or condition of this Agreement, in any one or more instances, shall be deemed to be or construed as a waiver of the same or any other term or condition of this Agreement on any future occasion.

7.5 No Third Party Beneficiaries. This Agreement is not intended, and shall not be deemed, to confer any rights or remedies upon any person other than the Parties and their respective successors and permitted assigns, to create any agreement of employment with any Person or to otherwise create any third party beneficiary hereto.

7.6 Assignment. Neither this Agreement nor any of the rights, interests or obligations under this Agreement may be transferred or assigned, in whole or in part, by operation of Law or otherwise, by either of the Parties without the prior written consent of the other Party [***]. Within [***] after any transfer or assignment by a Party pursuant to this Section 7.6, the transferring or assigning Party shall provide notice to the other Party of such transfer or assignment. Subject to this Section 7.6, this Agreement shall be binding upon, inure to the benefit of, and be enforceable by, the Parties and their respective successors and permitted assigns. Any attempted assignment in violation of this Section 7.6 shall be void and of no effect.

7.7 Severability. Any term or provision of this Agreement that is invalid or unenforceable in any situation in any jurisdiction shall not affect the validity or enforceability of

the remaining terms and provisions hereof or the validity or enforceability of the offending term or provision in any other situation or in any other jurisdiction. If the final judgment of a court of competent jurisdiction declares that any term or provision hereof is invalid or unenforceable, the Parties agree that the court making such determination shall have the power to limit the term or provision, to delete specific words or phrases, or to replace any invalid or unenforceable term or provision with a term or provision that is valid and enforceable and that comes closest to expressing the intention of the invalid or unenforceable term or provision, and this Agreement shall be enforceable as so modified.

7.8 Counterparts and Signature. This Agreement may be executed in two (2) counterparts, each of which shall be deemed an original but all of which together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each of the Parties and delivered to the other Party, it being understood that both Parties need not sign the same counterpart. This Agreement may be executed and delivered by facsimile or .pdf transmission.

7.9 Interpretation. When reference is made in this Agreement to an Article or a Section, such reference shall be to an Article or Section of this Agreement, unless otherwise indicated. The table of contents, table of defined terms and headings contained in this Agreement are for convenience of reference only and shall not affect in any way the meaning or interpretation of this Agreement. The language used in this Agreement shall be deemed to be the language chosen by the Parties to express their mutual intent, and no rule of strict construction shall be applied against any Party. Whenever the context may require, any pronouns used in this Agreement shall include the corresponding masculine, feminine or neuter forms, and the singular form of nouns and pronouns shall include the plural, and vice versa. Unless the context otherwise requires, references herein: (a) to an agreement, instrument or other document means such agreement, instrument or other document as amended, supplemented and modified from time to time to the extent permitted by the provisions thereof and by this Agreement; and (b) to any federal, state or local Law means such statute as amended from time to time and shall be deemed also to refer to all rules and regulations promulgated thereunder. Whenever the words “include,” “includes” or “including” are used in this Agreement, they shall be deemed to be followed by the words “without limitation.” The words “shall” and “will” have the same meaning and are used interchangeably in this Agreement. The word “or” shall not be exclusive when used in this Agreement. Any capitalized terms used in any Schedule or Exhibit attached hereto and not otherwise defined therein shall have the meanings set forth in this Agreement.

7.10 Governing Law. This Agreement shall be governed by and construed in accordance with the Laws of the State of Delaware, without giving effect to any choice or conflict of Law provision or rule that would cause the application of Laws of any jurisdiction other than those of the State of Delaware.

7.11 Remedies. Except as otherwise provided herein, any and all remedies herein expressly conferred upon a Party shall be deemed cumulative with and not exclusive of any other remedy conferred hereby, or by Law or equity upon such Party, and the exercise by a Party of any one (1) remedy shall not preclude the exercise of any other remedy.

7.12 Submission to Jurisdiction. Each of the Parties (a) consents to submit itself to the exclusive personal jurisdiction of the Court of Chancery of the State of Delaware, or if the Court of Chancery of the State of Delaware does not have jurisdiction, the exclusive personal jurisdiction of any state or federal court sitting in the State of Delaware (any such court, the “Subject Court”), in any action or proceeding arising out of or relating to this Agreement or any of the transactions contemplated by this Agreement, (b) agrees that all claims in respect of such

action or proceeding may be heard and determined in the Subject Court, (c) agrees that it shall not attempt to deny or defeat such personal jurisdiction by motion or other request for leave from

the Subject Court and (d) agrees not to bring any action or proceeding arising out of or relating to this Agreement or any of the transactions contemplated by this Agreement in any other court. Each of the Parties waives any defense of inconvenient forum to the maintenance of any action or proceeding so brought and waives any bond, surety or other security that might be required of any other Party with respect thereto. Any Party may make service on another Party by sending or delivering a copy of the process to the Party to be served at the address and in the manner provided for the giving of notices in Section 7.1.

7.13 Waiver of Jury Trial. EACH PARTY HERETO IRREVOCABLY AND UNCONDITIONALLY WAIVES TRIAL BY JURY IN ANY LEGAL ACTION OR PROCEEDING RELATING TO THIS AGREEMENT, THE ANCILLARY DOCUMENTS OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY AND FOR ANY COUNTERCLAIM THEREIN.

7.14 Disclosure Schedule. The Disclosure Schedule shall be arranged in sections corresponding to the numbered Sections contained in ARTICLE III; provided, that any numbering or references in the Disclosure Schedules or Sections of this Agreement are for convenience only and do not in any way limit, and shall not be regarded as limiting the disclosure concerning such numbered or referred to Sections; and provided, further, that any information disclosed under any section number shall be deemed to have been disclosed and incorporated into any other section number under this Agreement where such disclosure would be readily apparent from a reading of the disclosure that such disclosure is applicable to such other sections and subsections. The inclusion of any information in the Disclosure Schedule shall not be deemed to be an admission or acknowledgment, in and of itself, that such information is required by the terms hereof to be disclosed, is material, has resulted in or would reasonably be expected to result in a Material Adverse Effect, or is outside the Ordinary Course of Business.

7.15 Specific Performance. Each of the Parties acknowledges and agrees that the other Party would be damaged irreparably in the event any of the provisions of this Agreement are not performed in accordance with their specific terms or otherwise are breached. Accordingly, each of the Parties agrees that the other Party shall be entitled to seek an injunction or injunctions to prevent breaches of the provisions of this Agreement and to seek specific performance of this Agreement and the terms and provisions hereof in any action instituted in any court of the United States or any state thereof having jurisdiction over the Parties and the matter (subject to the provisions set forth in Section 7.12 above), in addition to any other remedy to which they may be entitled, at Law or in equity.

7.16 Knowledge. For the purposes of this Agreement, the term “Seller’s Knowledge” means the actual knowledge, following reasonable inquiry of such Person’s direct reports concerning such subject matter, of each of [***]. For the purposes of this Agreement, the term “Buyer’s Knowledge” means the actual knowledge, following reasonable inquiry of such Person’s direct reports concerning such subject matter, of each of [***].

7.17 Guarantee. The Guarantor hereby unconditionally and irrevocably guarantees to the Seller the punctual, full and complete performance by the Buyer when due of all the Buyer’s obligations under or arising out of this Agreement or any Ancillary Document, including the payment of the Purchase Price, and undertakes, upon the occurrence and continuance of any default by the Buyer under this Agreement or any Ancillary Document, that the Guarantor will duly and properly perform or procure the performance of such obligations as provided in this Agreement or applicable Ancillary Document. The Guarantor unconditionally and irrevocably waives, to the fullest extent permitted by Law, presentment, demand for payment, notice of non-performance, default, dishonor and protest, and all other notices and defenses of any kind. The Guarantor agrees that this guaranty constitutes a

guaranty of payment and performance when due and not of collection. The liability of the Guarantor as guarantor hereunder shall not be released

or diminished by (a) any amendment of the terms of this Agreement or Ancillary Document pursuant to their respective terms, (b) any delay or neglect in seeking performance of the obligations imposed under this Section 7.17, (c) any release of or granting of time or any other indulgence to the Buyer or any third party, (d) the liquidation, insolvency, receivership or any other analogous event occurring in relation to the Buyer or (e) any other act, event or omission, which but for this paragraph would or might operate to impair or discharge the Guarantor's liability hereunder or under any Ancillary Document. One or more separate actions may be brought and prosecuted against the Guarantor, regardless of whether any action is brought against the Buyer or whether the Buyer or any other Person is joined in any such actions. Guarantor acknowledges that it will receive direct and indirect benefits from the transactions contemplated by this Agreement and the other Ancillary Documents, and that the waivers set forth in this guaranty are knowingly made in contemplation of such benefits.

[Remainder of Page Intentionally Left Blank.]

IN WITNESS WHEREOF, the Buyer, the Seller and the Guarantor have caused this Agreement to be signed by their respective officers thereunto duly authorized as of the date first written above.

OTTER PHARMACEUTICALS, LLC

By: /s/ Dan Peisert
Name: Dan Peisert
Title: Chief Executive Officer

ANTARES PHARMA, INC.

By: /s/ Robert F. Apple
Name: Robert F. Apple
Title: President and Chief Executive Officer

ASSERTIO HOLDINGS, INC.

By: /s/ Dan Peisert
Name: Dan Peisert
Title: Chief Executive Officer

Exhibit A

Bill of Sale

[***]

Exhibit B

Patent Rights Assignment

[***]

Exhibit C

Trademark Assignment

[***]

Exhibit D

License Agreement

[***]

Exhibit E

Form of Seller FDA Letter

[***]

Exhibit F

Form of Buyer FDA Letter

[***]

Exhibit G

Assumption Agreement

[***]

Exhibit H

Supply Agreement

[***]

Exhibit I
Quality Agreement

[***]

Exhibit J

Safety Data Exchange Agreement

[***]

Exhibit K

Allocation of Purchase Price

[***]

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statements (Nos. 333-167457, 333-180832, 333-189172, 333-196644, 333-211782, 333-232775 and 333-257345) on Form S-8, registration statements (Nos. 333-61950, 333-96739, 333-103958, 333-133218, 333-142323, 333-144748, and 333-217808) on Form S-3, and registration statements (Nos. 333-109114 and 333-114098) on Form S-2 of our report dated March 3, 2022, with respect to the consolidated financial statements of Antares Pharma, Inc. and the effectiveness of internal control over financial reporting.

/s/ KPMG LLP

Minneapolis, Minnesota

March 3, 2022

SARBANES-OXLEY SECTION 302 CERTIFICATIONS

I, Robert F. Apple, certify that:

1. I have reviewed this report on Form 10-K of Antares Pharma, 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 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 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: March 3, 2022

/s/ Robert F. Apple

Robert F. Apple

President and Chief Executive Officer

SARBANES-OXLEY SECTION 302 CERTIFICATIONS

I, Fred M. Powell, certify that:

1. I have reviewed this report on Form 10-K of Antares Pharma, 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 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 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: March 3, 2022

/s/ Fred M. Powell

Fred M. Powell

Executive Vice President and Chief Financial Officer

ANTARES PHARMA, INC.
CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002 (18 U.S.C. 1350)

The undersigned, Robert F. Apple, the Chief Executive Officer of Antares Pharma, Inc. (the “Company”), has executed this Certification in connection with the filing with the Securities and Exchange Commission of the Company’s Annual Report on Form 10-K for the year ended December 31, 2021 (the “Report”).

The undersigned hereby certifies that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 3, 2022

/s/ Robert F. Apple

Robert F. Apple

President and Chief Executive Officer

ANTARES PHARMA, INC.
CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002 (18 U.S.C. 1350)

The undersigned, Fred M. Powell, the Chief Financial Officer of Antares Pharma, Inc. (the “Company”), has executed this Certification in connection with the filing with the Securities and Exchange Commission of the Company’s Annual Report on Form 10-K for the year ended December 31, 2021 (the “Report”).

The undersigned hereby certifies that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 3, 2022

/s/ Fred M. Powell

Fred M. Powell

Executive Vice President and Chief Financial Officer

Cover - USD (\$)
\$ in Millions

12 Months Ended

Dec. 31, 2021

Feb. 28,
2022

Jun.
30,
2021

Cover [Abstract]

<u>Document Type</u>	10-K
<u>Document Annual Report</u>	true
<u>Document Period End Date</u>	Dec. 31, 2021
<u>Current Fiscal Year End Date</u>	--12-31
<u>Document Transition Report</u>	false
<u>Entity File Number</u>	001-32302
<u>Entity Registrant Name</u>	ANTARES PHARMA, INC.
<u>Entity Incorporation, State or Country Code</u>	DE
<u>Entity Tax Identification Number</u>	41-1350192
<u>Entity Address, Address Line One</u>	100 Princeton South
<u>Entity Address, Address Line Two</u>	Suite 300
<u>Entity Address, City or Town</u>	Ewing
<u>Entity Address, State or Province</u>	NJ
<u>Entity Address, Postal Zip Code</u>	08628
<u>City Area Code</u>	609
<u>Local Phone Number</u>	359-3020
<u>Title of 12(b) Security</u>	Common Stock, par value \$0.01 per share
<u>Trading Symbol</u>	ATRS
<u>Security Exchange Name</u>	NASDAQ
<u>Entity Well-known Seasoned Issuer</u>	No
<u>Entity Voluntary Filers</u>	No
<u>Entity Current Reporting Status</u>	Yes
<u>Entity Interactive Data Current</u>	Yes
<u>Entity Filer Category</u>	Accelerated Filer
<u>Entity Small Business</u>	false
<u>Entity Emerging Growth Company</u>	false
<u>ICFR Auditor Attestation Flag</u>	true
<u>Entity Shell Company</u>	false
<u>Entity Public Float</u>	

\$
739.4

Entity Common Stock, Shares Outstanding	170,106,346
Documents Incorporated by Reference	Portions of the definitive Proxy Statement to be filed within 120 days after the end of the period covered by this report for the registrant's 2022 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.
Amendment Flag	false
Document Fiscal Year Focus	2021
Document Fiscal Period Focus	FY
Entity Central Index Key	0001016169

Audit Information**12 Months Ended
Dec. 31, 2021****[Audit Information \[Abstract\]](#)**Auditor Firm ID

185

Auditor Name

KPMG LLP

Auditor Location

Minneapolis, MN

Consolidated Balance Sheets
- USD (\$)
\$ in Thousands

	Dec. 31,	Dec. 31,
	2021	2020
<u>Current assets</u>		
<u>Cash and cash equivalents</u>	\$ 65,913	\$ 53,137
<u>Short-term investments</u>	1,245	0
<u>Accounts receivable, net</u>	56,697	42,221
<u>Other receivables</u>	26,311	0
<u>Inventories, net</u>	11,544	18,216
<u>Contract assets</u>	8,030	8,140
<u>Prepaid expenses and other current assets</u>	4,532	4,877
<u>Total current assets</u>	174,272	126,591
<u>Deferred tax assets, net</u>	33,043	46,982
<u>Property and equipment, net</u>	26,015	24,020
<u>Operating lease right-of-use assets</u>	3,774	4,621
<u>Intangibles, net</u>	17,879	7,693
<u>Goodwill</u>	1,095	1,095
<u>Other long-term assets</u>	1,427	1,529
<u>Total assets</u>	257,505	212,531
<u>Current liabilities</u>		
<u>Accounts payable</u>	17,056	16,194
<u>Accrued expenses and other liabilities</u>	35,043	25,635
<u>Current maturities of long-term debt, net</u>	1,500	16,230
<u>Operating lease liabilities, current</u>	904	1,203
<u>Deferred revenue</u>	4,427	3,943
<u>Total current liabilities</u>	58,930	63,205
<u>Long-term debt, less current maturities</u>	18,241	24,669
<u>Operating lease liabilities, long-term</u>	4,576	4,816
<u>Other long-term liabilities</u>	0	726
<u>Total liabilities</u>	81,747	93,416
<u>Commitments and contingencies</u>		
<u>Stockholders' Equity</u>		
<u>Preferred Stock: \$0.01 par; 3,000 shares authorized, none outstanding</u>	0	0
<u>Common Stock: \$0.01 par; 300,000 shares authorized; 170,072 and 166,836 issued and outstanding as of December 31, 2021 and December 31, 2020, respectively</u>	1,701	1,668
<u>Additional paid-in capital</u>	351,079	340,756
<u>Accumulated deficit</u>	(176,337)	(222,626)
<u>Accumulated other comprehensive loss</u>	(685)	(683)
<u>Total stockholders' equity</u>	175,758	119,115
<u>Total liabilities and stockholders' equity</u>	\$ 257,505	\$ 212,531

Consolidated Balance Sheets
(Parenthetical) - \$ / shares

Dec. 31, 2021 Dec. 31, 2020

Statement of Financial Position [Abstract]

<u>Preferred Stock, par value (in dollars per share)</u>	\$ 0.01	\$ 0.01
<u>Preferred Stock, authorized (in shares)</u>	3,000,000	3,000,000
<u>Preferred Stock, outstanding (in shares)</u>	0	0
<u>Common Stock, par value (in dollars per share)</u>	\$ 0.01	\$ 0.01
<u>Common Stock, authorized (in shares)</u>	300,000,000	300,000,000
<u>Common Stock, issued (in shares)</u>	170,072,000	166,836,000
<u>Common Stock, outstanding (in shares)</u>	170,072,000	166,836,000

**Consolidated Statements of
Operations - USD (\$)
shares in Thousands, \$ in
Thousands**

12 Months Ended

Dec. 31, 2021 Dec. 31, 2020 Dec. 31, 2019

Revenue

Total revenue, net \$ 183,982 \$ 149,599 \$ 123,864

Operating expenses

Research and development 14,502 10,121 10,624

Selling, general and administrative 73,857 62,759 61,773

Total operating expenses 156,640 135,980 122,872

Gain on sale of assets 38,591 0 0

Operating income 65,933 13,619 992

Other income (expense)

Interest expense (3,611) (3,787) (3,549)

Other income (expense), net (51) 89 530

Total other expense, net (3,662) (3,698) (3,019)

Income (loss) before income taxes 62,271 9,921 (2,027)

Income tax provision (benefit) 15,982 (46,280) 0

Net income (loss) \$ 46,289 \$ 56,201 \$ (2,027)

Earnings (loss) per common share

Basic (in dollars per share) \$ 0.27 \$ 0.34 \$ (0.01)

Diluted (in dollars per share) \$ 0.26 \$ 0.33 \$ (0.01)

Weighted average common shares outstanding

Basic (in shares) 169,226 166,066 162,574

Diluted (in shares) 174,733 170,155 162,574

Product sales, net

Revenue

Total revenue, net \$ 126,667 \$ 113,834 \$ 92,103

Operating expenses

Cost of product sales 54,418 53,960 46,267

Licensing and development revenue

Revenue

Total revenue, net 19,623 14,466 7,529

Operating expenses

Cost of product sales 13,863 9,140 4,208

Royalties

Revenue

Total revenue, net \$ 37,692 \$ 21,299 \$ 24,232

**Consolidated Statements of
Comprehensive Income
(Loss) - USD (\$)
\$ in Thousands**

12 Months Ended

Dec. 31, 2021 Dec. 31, 2020 Dec. 31, 2019

Statement of Comprehensive Income [Abstract]

<u>Net income (loss)</u>	\$ 46,289	\$ 56,201	\$ (2,027)
<u>Foreign currency translation adjustment</u>	(2)	19	1
<u>Comprehensive income (loss)</u>	\$ 46,287	\$ 56,220	\$ (2,026)

Consolidated Statements of Stockholders' Equity - USD (\$) shares in Thousands, \$ in Thousands	Total	Common Stock	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)
Balance at Dec. 31, 2018	\$ 39,001	\$ 1,597	\$ 314,907	\$ (276,800)	\$ (703)
Balance (in shares) at Dec. 31, 2018		159,721			
Increase (Decrease) in Stockholders' Equity [Roll Forward]					
Issuance of common stock	7,781	\$ 23	7,758		
Issuance of common stock (in shares)		2,307			
Common stock issued under equity compensation plan, net of shares withheld for taxes	(1,131)	\$ 7	(1,138)		
Common stock issued under equity compensation plan, net of shares withheld for taxes (in shares)		664			
Exercise of options	4,405	\$ 25	4,380		
Exercise of options (in shares)		2,529			
Share-based compensation	6,470		6,470		
Net income (loss)	(2,027)			(2,027)	
Other comprehensive income (loss)	1				1
Balance at Dec. 31, 2019	54,500	\$ 1,652	332,377	(278,827)	(702)
Balance (in shares) at Dec. 31, 2019		165,221			
Increase (Decrease) in Stockholders' Equity [Roll Forward]					
Common stock issued under equity compensation plan, net of shares withheld for taxes	(1,367)	\$ 7	(1,374)		
Common stock issued under equity compensation plan, net of shares withheld for taxes (in shares)		676			
Exercise of options	1,814	\$ 9	1,805		
Exercise of options (in shares)		939			
Share-based compensation	7,948		7,948		
Net income (loss)	56,201			56,201	
Other comprehensive income (loss)	19				19
Balance at Dec. 31, 2020	119,115	\$ 1,668	340,756	(222,626)	(683)
Balance (in shares) at Dec. 31, 2020		166,836			
Increase (Decrease) in Stockholders' Equity [Roll Forward]					
Common stock issued under equity compensation plan, net of shares withheld for taxes	(2,841)	\$ 10	(2,851)		

<u>Common stock issued under equity compensation plan, net of shares withheld for taxes (in shares)</u>	942				
<u>Exercise of options</u>	5,182	\$ 23	5,159		
<u>Exercise of options (in shares)</u>		2,294			
<u>Share-based compensation</u>	8,015		8,015		
<u>Net income (loss)</u>	46,289			46,289	
<u>Other comprehensive income (loss)</u>	(2)				(2)
<u>Balance at Dec. 31, 2021</u>	\$ 175,758	\$ 1,701	\$ 351,079	\$ (176,337)	\$ (685)
<u>Balance (in shares) at Dec. 31, 2021</u>	170,072				

**Consolidated Statements of
Cash Flows - USD (\$)
\$ in Thousands**

**12 Months Ended
Dec. 31, 2021 Dec. 31, 2020 Dec. 31, 2019**

Cash Flows from Operating Activities

Net income (loss) \$ 46,289 \$ 56,201 \$ (2,027)

Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:

Deferred taxes 13,939 (47,203) (371)

Stock-based compensation 8,015 7,948 6,470

Depreciation and amortization 3,901 2,627 2,557

Non-cash interest expense 648 504 405

Increase in inventory reserve 152 511 325

Gain on sale of assets (38,591) 0 0

Other 671 42 12

Changes in operating assets and liabilities:

Accounts receivable (14,476) (7,128) (16,095)

Inventories, net 2,748 (2,728) (4,975)

Contract assets 110 53 (2,793)

Prepaid expenses and other current assets (1,056) (1,460) (655)

Accounts payable 2,189 2,594 926

Accrued expenses and other liabilities 11,596 7,157 4,888

Deferred revenue 484 2,202 718

Net cash provided by (used in) operating activities 36,619 21,320 (10,615)

Cash Flows from Investing Activities

Purchases of property and equipment (6,617) (9,615) (2,350)

Proceeds from sale of assets, net of transaction costs 17,825 282 5,000

Purchase of intangibles, including transaction costs (13,815) (5,000) 0

Purchases of investment securities (1,245) 0 (22,645)

Proceeds from maturities of investment securities 0 22,500 0

Net cash provided by (used in) investing activities (3,852) 8,167 (19,995)

Cash Flows from Financing Activities

Proceeds from issuance of long-term debt 20,000 0 15,000

Principal payments of long-term debt (40,000) 0 0

Prepayment fees and end of term charge on long-term debt (2,055) 0 0

Payment of debt issuance costs for long-term debt (276) 0 (136)

Proceeds from issuance of common stock, net 0 0 7,781

Proceeds from exercise of stock options 5,182 1,814 4,405

Taxes paid related to net share settlement of equity awards (2,841) (1,367) (1,131)

Net cash provided by (used in) financing activities (19,990) 447 25,919

Effect of exchange rate changes on cash and cash equivalents (1) 2 0

Cash and cash equivalents

Net increase (decrease) during the period 12,776 29,936 (4,691)

Beginning of period 53,137 23,201 27,892

<u>End of period</u>	65,913	53,137	23,201
<u>Supplemental disclosure of cash flow information</u>			
<u>Cash paid for interest</u>	2,736	3,538	3,025
<u>Cash paid for income taxes</u>	1,783	90	0
<u>Supplemental disclosure of non-cash investing activities</u>			
<u>Purchases of property and equipment recorded in accounts payable and accrued expenses</u>	259	2,017	970
<u>Purchase of intangible assets included in accrued liabilities</u>	0	2,500	0
<u>Gain on sale of assets recognized in excess of cash received</u>	\$ 20,766	\$ 0	\$ 0

Description of Business

**12 Months Ended
Dec. 31, 2021**

Organization, Consolidation and Presentation of

Financial Statements

[Abstract]

Description of Business

Description of Business

Antares Pharma, Inc. (“Antares,” “we,” “our,” “us” or the “Company”) is a specialty pharmaceutical company focused primarily on the development and commercialization of pharmaceutical products and technologies in targeted therapeutic areas. We develop, manufacture and commercialize, for ourselves or with partners, novel therapeutic products using our advanced drug delivery systems that are designed to provide commercial or functional advantages, such as improved safety and efficacy, convenience, improved tolerability, and enhanced patient comfort and adherence. We also seek product opportunities that complement and leverage our commercial platform. We have a portfolio of proprietary and partnered commercial products and ongoing product development programs in various stages of development. We have formed partnership arrangements with several different industry leading pharmaceutical companies.

Our marketed proprietary products include:

- XYOSTED® (testosterone enanthate) injection, indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone, and is the first and only subcutaneous testosterone enanthate product for once-weekly, at-home self-administration to be approved by the U.S. Food and Drug Administration (“FDA”);
- OTREXUP® (methotrexate) injection, indicated for adults with severe active rheumatoid arthritis, children with active polyarticular juvenile idiopathic arthritis and adults with severe recalcitrant psoriasis, which was sold to Otter Pharmaceuticals, LLC (a subsidiary of Assertio Holdings, Inc., together with Assertio Holdings, Inc., as guarantor, individually and collectively referred to as “Otter”) in December 2021 as discussed in Note 12; and
- NOCDURNA® (desmopressin acetate), marketed in the U.S. for the treatment of nocturia due to nocturnal polyuria (“NP”) in adults who awaken at least two times per night to urinate.

We are also party to various partnered product development and supply arrangements:

- We developed and are the exclusive supplier of devices for Teva Pharmaceutical Industries, Ltd.’ (“Teva”) Epinephrine Injection USP products, the generic equivalent of EpiPen® and EpiPen® Jr., indicated for emergency treatment of severe allergic reactions including those that are life threatening (anaphylaxis) in adults and certain pediatric patients;
- Through our commercialization partner Teva, we sell Sumatriptan Injection USP, a generic equivalent to the Imitrex® STATdose Pen®, in the U.S. indicated for the acute treatment of migraine headaches and cluster headache in adults;

- In collaboration with AMAG Pharmaceuticals, Inc. (“AMAG”), acquired by Covis Group S.a.r.l. (“CG”) (collectively CG and AMAG are herein after referred to as “Covis”) in November 2020, we developed a subcutaneous auto injector and are the exclusive supplier of devices and the final assembled and packaged commercial product of Makena® (hydroxyprogesterone caproate injection) subcutaneous auto injector, which is a ready-to-administer treatment indicated to reduce the risk of preterm birth in women pregnant with one baby and who spontaneously delivered at least one preterm baby in the past.
- We developed and are the exclusive supplier of devices for Teva’s generic equivalent of Forsteo® (Teriparatide Injection) which is approved and currently sold by Teva in various countries outside the U.S.

Additionally, we are developing other devices in collaboration with various pharmaceutical partners and advancing other internal research and development programs.

We also have a proprietary product, TLANDO® (testosterone undecanoate) is a twice-day oral formulation of testosterone for TRT indicated for conditions associated with a deficiency or absence of endogenous testosterone, or hypogonadism in adult males, with tentative FDA approval.

Summary of Significant Accounting Policies

12 Months Ended
Dec. 31, 2021

[Accounting Policies](#)

[\[Abstract\]](#)

[Summary of Significant Accounting Policies](#)

Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements include the accounts of Antares Pharma, Inc. and its two wholly-owned foreign subsidiaries. All accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in accordance with U.S. generally accepted accounting principles ("GAAP") requires us to make estimates that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the date of the financial statements and revenues and expenses during the reporting period. Our most significant accounting estimates relate to revenue recognition and variable consideration, inventory carrying value of deferred tax assets and the valuation of equity instruments used in the computation of share-based compensation. Actual results may differ from estimates, and significant variances could materially impact our financial condition and results of operations.

Reclassifications

Certain reclassifications have been made to prior year amounts to conform with the current year presentation. As of and for the year ended December 31, 2020, product sales and the cost of development revenue were classified under the heading *Operating expenses* in the Consolidated Statements of Operations. The corresponding prior period amount was reclassified to conform to this presentation. The reclassifications had no impact on our operating income or cash flows as previously reported.

Accounting Pronouncements Recently Adopted

We adopted FASB ASU No. 2018-15, *Customers' Accounting for Implementation Costs Incurred in Cloud Computing Arrangement that is a Service Contract*, effective January 1, 2020, which provides new guidance on a customer's accounting for implementation, set-up, and other upfront costs incurred in a cloud computing arrangement that is hosted by the vendor (i.e., a service contract). Under the new guidance, entities apply the same criteria for capitalizing implementation costs as for a software arrangement that has a software license. Adoption of this standard did not have a material impact on our financial condition, results of operations or disclosures.

We adopted FASB ASU No. 2018-18, *Clarifying the Interaction Between Topic 808 and 606*, effective January 1, 2020, which clarifies that certain collaborative arrangement participants should be accounted for under the revenue guidance, adds unit of account guidance to the collaborative arrangement standard, aligns with the revenue standard, and clarifies presentation guidance for transactions with a collaborative arrangement participant that is not accounted for under the revenue standard. Adoption of this standard did not have a material impact on our financial condition, results of operations or disclosures.

Recently Issued Accounting Pronouncements Not Yet Adopted as December 31, 2021

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which includes related amendments, which changes the accounting for credit losses on instruments measured at amortized cost by adding an impairment model that measures expected credit losses rather than incurred losses. Any entity will recognize as an allowance its estimate of expected credit losses, which is believed to result in more consistent measurement of such losses as the standard eliminates the probable initial recognition threshold. The new guidance is required to be adopted using a modified retrospective cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period of adoption. Adoption of the new guidance was completed for annual periods beginning after December 15, 2019, including interim periods within the annual period.

In October 2019, the FASB issued ASU 2019-10, *Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates*, which deferred the effective date of ASU 2016-13 for certain entities, including those that are eligible for smaller reporting companies. Determination of eligibility for deferral was a one-time assessment as of November 15, 2019 based on the entity's most recent smaller reporting company determination as of the last business day of its most recently completed second quarter. Based on this determination, we qualified as a smaller reporting company and therefore eligible for the adoption deferral resulting in a new effective date of January 1, 2023. The impact on our financial condition, results of operations or disclosures is being evaluated but is not expected to be significant as we have historically had minimal credit losses on financial instruments.

In April 2020, the FASB issued ASU No. 2020-04, *Facilitation of the Effects of Reference Rate Reform on Financial Reporting*, which provides guidance on preparing for discontinuation of interest rates such as LIBOR. The standard can be applied immediately through December 31, 2022. We have not yet determined the adoption of this guidance may have on our financial condition, results of operations or disclosures.

Foreign Currency Translation

The majority of our foreign subsidiaries' revenues are denominated in U.S. dollars, and any required funding of the subsidiaries is provided by the parent. The operating expenses of our foreign subsidiaries are denominated in Swiss Francs. Additionally, bank accounts held by foreign subsidiaries are denominated in Swiss Francs. As there is a low volume of intercompany transactions and there is not an extensive interrelationship between the operations of the subsidiaries and the parent, we have determined that the Swiss Franc is the functional currency for our foreign subsidiaries. Our reporting currency is the United States dollar. The financial statements of our foreign subsidiaries are translated into USD for consolidation purposes. All assets and liabilities are translated using period-end exchange rates. Statements of operations items are translated using average exchange rates for the period. The resulting translation adjustments are recorded as a component of equity.

stockholders' equity, comprising all of the accumulated other comprehensive income (loss). Sales to certain customers and purchases from certain parent are in currencies other than USD and are subject to foreign currency exchange rate fluctuations. Foreign currency transaction gains and losses are included in income (expense) in the Consolidated Statements of Operations.

Cash and Cash Equivalents

Cash and cash equivalents represent demand deposits at commercial banks and highly liquid investments with an original maturity of three months or less. Cash equivalents, consisting of investments in money market funds and bank certificate of deposits, are remeasured and reported at fair value each reporting period. The fair value of cash equivalents, which is a Level 1 input within the three-level valuation hierarchy for disclosure of fair value measurements, and totaled \$26,889 and \$36,210 as of December 31, 2021 and 2020, respectively.

Investments

From time to time, we also invest in bank certificates of deposit that are classified as held-to-maturity because of our intent and ability to hold securities to maturity. Investments with original maturities greater than three months but less than one year are classified as short-term investments on the Consolidated Balance Sheet. Investment securities are carried at their amortized cost and fair value is determined by quoted market prices for identical or similar securities. The fair value of short-term investments as of December 31, 2021 approximate fair value.

Fair Value Measurements

Financial assets and liabilities are required to be measured and reported at fair value each reporting period. Fair value is defined 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. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. When considering market participant assumptions in fair value measurement, the following fair value hierarchy distinguishes between the three levels of inputs, which are categorized in one of the following levels.

- **Level 1:** Unadjusted quoted prices which are available in active markets for identical assets or liabilities accessible to us at the measurement date.
- **Level 2:** Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities in active markets; that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the asset or liability.
- **Level 3:** Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The hierarchy gives the highest priority to Level 1, as this level provides the most reliable measure of fair value, while given the lowest priority to Level 3.

Financial assets and liabilities that are not measured at fair value on a recurring basis include held-to-maturity investments and long-term debt as of December 31, 2021 and 2020, which approximate fair value. The estimated fair value of debt is based on Level 2 inputs, including our understanding of current market rates we observe for similar loans. The fair value of our cash and cash equivalents, accounts receivable, other receivables, contract assets, accounts payable and accrued liabilities are measured at fair value due to their short-term nature.

We measure certain financial instruments at fair value on a nonrecurring basis. These assets primarily include goodwill and intangible assets, as well as property, plant and equipment and right-of-use lease assets. These assets were initially measured and recognized at amounts equal to the fair value determined as of the date of acquisition. Periodically, these assets are tested for impairment, by comparing their respective carrying values to the estimated fair value of the reporting unit in which they reside. In the event any of these assets were to become impaired, we would recognize an impairment loss equal to the amount by which the carrying value of the reporting unit, impaired asset or asset group exceeds its estimated fair value. Fair value measurement of the reporting unit associated with our goodwill is performed at least annually in the fourth quarter of each calendar year for purposes of impairment testing if a quantitative analysis is performed. Fair value measurements for our intangible assets, other long-lived assets and property and equipment are estimated when events or changes in circumstances such as market conditions, physical change, legal factors or other matters indicate that the carrying value may not be recoverable.

Accounts Receivable

Trade accounts receivable represents amounts billed to customers and are stated at the amount we expect to collect. Customer creditworthiness, payment history, the customer and changes in customer payment terms are factors considered when determining collectability of specific customer accounts. As of December 31, 2021, the trade accounts receivable balance was due primarily from Teva and major wholesale distributors. Each of these customers have historically paid in a timely manner, demonstrating creditworthiness. Accordingly, we believe the risk of accounts being uncollectible is minimal and no significant allowances for doubtful accounts are established as of December 31, 2021 or 2020. If the financial condition of our customers were to deteriorate, adversely affecting their ability to make payments, additional allowances may be required. We had no material write-offs to bad debt expense in the years ended December 31, 2021, 2020 or 2019.

Royalties receivable from partners are included in accounts receivable and are typically payable to us within 45 to 60 days after the end of each quarter. Royalties are earned.

Inventories

Inventories are stated at the lower of cost or net realizable value with cost determined on a first-in, first-out basis. Certain components of our production are sourced from a limited number of vendors, and our production, assembly, warehousing and distribution operations are outsourced to third-party suppliers where significant inventory is located. Disruption of supply from key vendors or third-party suppliers may have a material adverse impact on our operations and financial results.

We record reserves for potentially excess, dated or obsolete inventories based on forecasted product demand estimates and the likelihood of consumptions in the course of business, considering the expiration dates of the inventories on hand, planned production volumes and lead times required for restocking. Although every effort is made to ensure that forecasts and assessments are reasonable, changes to these assumptions are possible. In such cases, estimates may be inaccurate and result in an understatement or overstatement of the reserves required to fairly state such inventories.

Contract Assets

Contract assets are recognized when control of goods or services has transferred to the customer, and corresponding revenue is recognized on an accrual basis, yet billable to the customer in accordance with the terms of the contract. Costs that have been incurred in connection with development services performed under contracts, which the associated revenue has not yet been recognized are also recorded as contract assets and totaled \$564 and \$1,685 as of December 31, 2021 and 2020, respectively.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation is computed using the straight-line method over an asset's estimated useful life as follows:

	Useful Life
Computer equipment and software	3-5 years
Furniture, fixtures and office equipment	5-7 years
Production molds, tooling and equipment	3-10 years
Leasehold improvements	Lesser of useful life or lease term

Expenditures, including interest costs, for assets under construction and internal-use software that are not yet ready for their intended use are capitalized and depreciated based on the above guidelines when placed in service. Costs associated with repairs and maintenance activities are expensed as incurred.

Leases

We recognize right-of-use ("ROU") assets and lease liabilities when we obtain the right to control the asset under a leasing arrangement with an initial term of more than twelve months. We evaluate the nature of each lease at the inception of an arrangement to determine whether it is an operating or financing lease. For operating leases, the asset and lease liability based on the present value of future minimum lease payments over the expected lease term. Our leases do not generally contain variable lease rates; therefore, we use the incremental borrowing rate we would expect to pay to borrow on a similar collateralized basis over a similar term in our market as the discount rate to determine the present value of our lease payments. The incremental borrowing rate is used in determining the present value of lease payments, unless an implicit rate is readily determinable. Lease arrangements contain renewal options that have not been included in the determination of the lease term, as they are not reasonably certain to be exercised. For leases that contain lease and non-lease components, we account for both components as a single lease component. Variable lease payments are expensed as incurred.

Intangible Assets

We capitalize and include the costs of acquired product licenses and trademark rights as intangible assets. These intangible assets with finite useful lives are amortized over their estimated useful lives less accumulated amortization. Amortization is computed on a straight-line basis over the shorter of the contractual or estimated economic life of the intangible asset. The useful life generally ranges from five to ten years.

Impairment of Long-Lived Assets and Intangible Assets

Long-lived assets and intangible assets are reviewed for impairment whenever events or changes in circumstances such as market value, asset utilization, legal factors or other matters indicate that the carrying value of an asset or asset group may not be recoverable. The impairment test is based on a comparison of the undiscounted cash flows expected to be generated from the use of the asset or asset group and its eventual disposition to the carrying value of the asset or asset group. If indicated, the asset is written down by the amount by which the carrying value of the asset exceeds the related fair value of the asset with the related impairment recognized within the Consolidated Statement of Operations. The determination of an asset's fair value requires management to make certain estimates.

Goodwill

Goodwill is evaluated for impairment annually as of December 31, or more frequently if an event occurs or circumstances change such as market conditions, legal factors or other matters that indicate the carrying value may not be recoverable. Evaluating goodwill for impairment involves the determination of the fair value of each reporting unit in which goodwill is recorded using a qualitative or quantitative analysis. A reporting unit is an operating segment or a component of an operating segment for which discrete financial information is available and reviewed by management on a regular basis.

As of December 31, 2021 and 2020, we have goodwill with a carrying value of \$1,095, attributable to our single reporting unit. Based on the results of our impairment analysis, we determined that goodwill was not impaired, and no impairment loss was recognized in the years ended December 31, 2021, 2020, and 2019.

Revenue Recognition

We generate revenue from proprietary and partnered product sales, license and development activities and royalty arrangements. Revenue is recognized when we transfer control of the promised goods or services to the customer at the transaction price, which is the amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services.

At inception of each contract, we identify the goods and services that have been promised to the customer and each of those that represent a distinct performance obligation. We determine the transaction price including any variable consideration, allocate the transaction price to the distinct performance obligations and determine the amount of revenue to recognize when control of the goods or services is transferred to the customer at a point in time or over time. Variable consideration is included in the transaction price to the extent that it is probable that the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. We maintain reserves for variable consideration at each reporting date and make adjustments, if necessary, which may affect revenue and earnings in periods in which the actual amount becomes known.

We have elected to recognize the cost for freight and shipping activities as a fulfillment cost. Amounts billed to customers for shipping and handling are included in the transaction price and recognized as revenue when control of underlying goods are transferred to the customer. The related shipping and freight costs are included in cost of product sales in the Consolidated Statements of Operations.

Proprietary Product Sales

We sell our proprietary commercial products primarily to wholesale and specialty distributors. Revenue is recognized when control has transferred to the customer, typically upon delivery, at the net selling price, which reflects the variable consideration for which reserves and sales allowances are established for discounts, wholesale distribution fees, prompt payment discounts, government rebates and chargebacks, plan rebate arrangements and patient discount and sales commissions.

The determination of certain reserves and sales allowances requires us to make a number of judgements and estimates to reflect our best estimate of the amount of consideration to which we believe we would be ultimately entitled to receive. The expected value is determined based on unit sales volume, contracts with customers and third-party payers, historical and estimated future percentage of rebates incurred on sales, historical and future insurance plan billings, anticipated changes in programs or regulations that would impact the amount of the actual rebates, customer purchasing patterns, product expiration dates and inventory in the distribution channel. Reserves for prompt payment discounts are recorded as a reduction in accounts receivable in the Consolidated Balance Sheet. Reserves for returns, distributor fees, rebates and customer co-pay support programs are included within current liabilities in the Consolidated Balance Sheet.

Wholesaler Distribution Fees – Distribution fees are paid to certain wholesalers based on contractually determined rates and units purchased. Since the fee is not for a distinct good or service, the consideration is recognized as a reduction of the transaction price of the goods delivered. We accrue the fee at the time of sale based on the contracted price and adjust the accrual at each reporting period, if necessary, to reflect actual experience.

Prompt Pay Discounts – We offer cash discounts to our customers, generally 2% of the sales price, as an incentive for prompt payment. Based on historical experience, if customers take advantage of this discount and accordingly we accrue 100% of the cash discounts offered by reducing accounts receivable and revenue. The reduction of revenue in the same period the related sales are made. The accrual is reviewed at each reporting period and adjusted if actual experience differs from the estimate.

Chargebacks – We provide discounts primarily to authorized users of the Federal Supply Schedule (“FSS”) of the General Services Administration. These entities purchase products from distributors at a discounted price, and the wholesale distributors then charge us back the difference between the current wholesale acquisition cost and the price paid for the product. We estimate and accrue chargebacks based on estimated wholesaler inventory levels, current contract prices and historical chargeback experience. Chargebacks are recognized as a reduction of revenue in the same period the related revenue is recognized.

Rebates – We participate in certain government and insurance plan rebate programs, which provide discounted prescriptions to qualified insured persons. In these programs, we pay a rebate to the third-party administrators of the programs. The rebate payments are generally made in periods subsequent to the period the prescriptions subject to the rebate are filled, generally on a two- to three-month lag for insurance plan rebates and three- to six-month lag for government programs. We estimate and accrue for these rebates based on unit sales data, contractual terms with third-party payers, historical and estimated future percentage of prescriptions filled, sales, historical and future insurance plan billings, any new or anticipated changes in programs or regulations that would impact the amount of the rebates and levels of inventory in the distribution channel. Rebates are recognized as a reduction of revenue in the same period the related revenue is recognized.

Patient Discount Programs – We offer discount cards, co-pay coupons and free trial programs to off-set the cost of prescriptions to patients. We estimate the amount of discounts that will be redeemed or used based on historical redemption experience and on levels of inventory in the distribution and retail channels, and recognize the reduction of revenue in the same period the related revenue is recognized.

Product Returns – Consistent with industry practice, we generally offer wholesalers and specialty distributors a limited right to return products, generally within 30 days prior to and 12 months following the product’s expiration date. Our proprietary products generally have expiration dates ranging from 24 to 33 months. We estimate and accrue for product returns based on historical return patterns. Actual returns are tracked by individual production lots and charged to the related revenue. Reserves may be adjusted, if necessary, if actual returns differ from historical estimates. We also monitor and take into consideration the amount of inventory in the distribution channel, product dating and any known or expected changes in the marketplace when establishing the estimated rate of returns.

Changes in reserves for product returns and sales allowances are as follows:

	Rebates and Chargebacks	Patient Discount Programs	Returns	Wholesale Distribution Fees
Balance as of December 31, 2019	\$ 6,308	\$ 845	\$ 370	\$ 1
Accruals and adjustments	34,947	12,422	2,657	11
Payments and other reserve reductions	(34,068)	(11,975)	(2,569)	(10)
Balance as of December 31, 2020	7,187	1,292	458	2
Accruals and adjustments	52,243	15,629	4,163	15
Payments and other reserve reductions	(46,129)	(13,971)	(3,992)	(14)
Balance as of December 31, 2021	\$ 13,301	\$ 2,950	\$ 629	\$ 3

Partnered Product Sales

We are party to several license, development, supply and distribution arrangements with pharmaceutical partners, under which we produce and/or distribute certain products, devices and/or components. Revenue is recognized when or as control of the goods transfers to the customer as discussed below.

We are the exclusive supplier of the Makena[®] subcutaneous auto injector product to Covis and beginning in December 2021, OTREXUP[®] to Otis. These products are custom manufactured for each customer with no alternative use and we have a contractual right to payment for performance completed to date. Revenue is transferred to the customer as the product is produced pursuant to firm purchase orders. Revenue is recognized over time using the output method, based on the selling price and number of units produced. The amount of revenue recognized in excess of the amount shipped/billed to the customer, if any, is recorded in the Consolidated Balance Sheets due to the short-term nature in which the amount is ultimately expected to be billed and collected from the customer.

All other partnered product sales are recognized at the point in time in which control is transferred to the customer, which is typically upon shipment. Pricing arrangements are governed by the respective supply and distribution agreements, and there is generally no right of return. Revenue is recognized at the time control is transferred to the customer, which includes the contractual per unit selling price and estimated variable consideration, such as volume-based pricing arrangements or profit-sharing arrangements. To recognize revenue, including the estimated variable consideration we expect to receive for contract margin on future commercial sales, upon shipment to the customer, we partner. The estimated variable consideration is recognized at an amount we believe is not subject to significant reversal based on historical experience. Each reporting period if the most likely amount of expected consideration changes or becomes fixed.

Licensing and Development Revenue

We have entered into several license, development and supply arrangements with pharmaceutical partners under which we grant a license to our drug products, know-how and provide research and development services that often involve multiple performance obligations and highly customized deliverables. In these arrangements, we identify each of the promised goods and services within the contract and the distinct performance obligations at inception and allocate consideration to each obligation based on relative standalone selling price, which is generally determined based on the expected cost plus mark-up.

If the contract includes an enforceable right to payment for performance completed to date and performance obligations are satisfied over time, we recognize revenue over the development period using either the input or output method depending on which is most appropriate given the nature of the distinct deliverables. If the contract does not contain an enforceable right to payment for performance completed to date, revenue is recognized when control is transferred to the customer. Indicators that the transfer of control has occurred include the transfer of legal title, transfer of physical possession, the customer has obtained the significant benefits of ownership of the assets and we have a present right to payment.

Our typical payment terms for development contracts may include an upfront payment equal to a percentage of the total contract value with the remainder billed upon completion and transfer of the individual deliverables or satisfaction of the individual performance obligations. We record a liability for the upfront payment in advance of performance, which is presented within deferred revenue in the Consolidated Balance Sheets and recognized as revenue when the associated performance obligations have been satisfied. We recognized \$3,889 in licensing and development revenue in connection with contract liabilities that were outstanding at December 31, 2020 and satisfied during the year ended December 31, 2021.

License fees and milestones received in exchange for the grant of a license to our functional intellectual property ("IP") such as patented technology, in connection with a partnered development arrangement are generally recognized at inception of the arrangement, or over the development period depending on the circumstances, as the license is generally not distinct from the non-licensed goods or services to be provided under the contract. Milestone payments, which are upon the occurrence of future events, are evaluated and recorded at the most likely amount, and to the extent that it is probable that a significant reversal of the associated uncertainty is resolved.

Royalties

We earn royalties in connection with licenses granted under license and development arrangements with partners. Royalties are based upon a percentage of net sales of partnered products with rates ranging from mid-single digits to low double digits and are tiered based on levels of net sales. These sales-based royalties, which are based on the license was deemed the predominant element to which the royalties relate, are estimated and recognized in the period in which the partners' commercial sales of the products are generally reported and payable to us within 45 to 60 days of the end of the period in which the commercial sales are made. We base our estimate of royalties earned on actual sales information from our partners when available or estimated prescription sales from external sources and estimated net selling price. If actual sales received are different than amounts estimated, we would adjust the royalty revenue in the period in which the adjustment becomes known.

Remaining Performance Obligations

Remaining performance obligations represent the transaction price of firm orders and development contract deliverables for which work has not been fulfilled, and excludes potential purchase orders under ordering-type supply contracts with indefinite delivery or quantity. As of December 31, 2021, remaining performance obligations, excluding contracts with an original expected length of one year or less, was \$14,879. We expect to recognize performance obligations over the next three years, with the majority being recognized in the next twelve months.

Share-Based Compensation

We use share-based compensation in the form of stock options, restricted stock units (“RSUs”) and performance-based restricted stock units (“PSUs”). Compensation expense associated with share-based awards granted to employees at the fair value of the award on the date of grant. The Black-Scholes model is used to determine the fair value of stock options. The fair values of RSU and PSU grants containing service or performance conditions are based on the fair value of our common stock on the date of grant. The fair value of PSUs containing a market condition are estimated using a Monte Carlo simulation. The portion of the award that is ultimately expected to vest is expensed ratably over the requisite service period as compensation expense in the Consolidated Statements of Operations. Forfeitures are recorded as incurred. Assumptions concerning our stock price volatility and projected employee exercise behavior over the term of the award impact the estimated fair value of the stock option awards.

Research and Development

Research and development expenses include costs directly attributable to the conduct of research and development programs including personnel salaries, supplies associated with design work and prototype development, FDA filing fees and the cost of services provided by outside contractors such as clinical trials. All costs associated with research and development activities are expensed as incurred.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the periods in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that includes the enactment date. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

We account for uncertain tax positions in accordance with ASC 740, *Income Taxes* (“ASC 740”), which applies to all tax positions related to income taxes. A tax position is recognized when it is more-likely-than-not that a tax position will be sustained upon examination by the authorities. Interest and penalties accrued on unrecognized tax benefits are recognized as a component of income tax expense in the Consolidated Statements of Operations.

Earnings (Loss) Per Common Share

Basic earnings (loss) per common share is computed by dividing the net income (loss) applicable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted earnings (loss) per common share is computed in a similar manner, except that the weighted average number of common shares is increased to reflect the potential dilution from the exercise or conversion of securities into common stock. Diluted earnings (loss) per common share is computed assuming the complete conversion to common shares of all convertible instruments only if such instruments are dilutive in nature with respect to earnings (loss).

Segments

Operating segments are components of an enterprise for which separate financial information is available and is evaluated regularly by the Chief Financial Officer (“CODM”), our Chief Executive Officer, in deciding how to allocate resources and assess performance. Our CODM currently evaluates our operations from a number of different operational perspectives, including but not limited to, on a product-by-product, customer and partner basis. We derive all significant revenue from pharmaceutical products and development services, and have a single reportable, operating segment of business.

Going Concern

We are responsible for evaluating, and providing disclosure of uncertainties about, our ability to continue as a going concern. As of December 31, 2021, we had cash equivalents of \$65,913. Based on our evaluation, we concluded there is no substantial doubt or uncertainty about our ability to meet our obligations for the next twelve months from the date the Consolidated Financial Statements were issued.

Inventories

12 Months Ended
Dec. 31, 2021

[Inventory Disclosure](#)

[\[Abstract\]](#)

[Inventories](#)

Inventories

Inventories consisted of the following:

	December 31, 20
Raw materials	\$ 2,619
Work in process	6,356
Finished goods	4,356
Total inventories, net	\$ 11,331

A reserve is recorded for potentially excess, dated or obsolete inventory based on an analysis of inventory on hand compared to forecasted future demand. As of December 31, 2021 and 2020, the reserve was \$619 and \$619, respectively. In 2021, we wrote off \$359 of inventory and reduced the reserve for excess, dated or obsolete inventory by \$359. In 2020, we wrote off \$356 of inventory and increased the reserve for excess, dated or obsolete inventory by \$511.

Property and Equipment

12 Months Ended
Dec. 31, 2021

[Property, Plant and
Equipment \[Abstract\]](#)
[Property and Equipment](#)

Property and Equipment

Property and equipment, net consisted of the following:

	December 31, 20
Production molds, tooling and equipment	\$ 22,
Leasehold improvements	7,
Furniture, fixtures and office equipment	9
Computer equipment and software	1,
Construction and tooling in process	6,
Total property and equipment	39,
Less: Accumulated depreciation	(13,
Total property and equipment, net	\$ 26,

Depreciation expense was \$2,864, \$2,341 and \$2,205 for the years ended December 31, 2021, 2020 and 2019, respectively. In 2021 and 2020, we property and equipment that was fully depreciated and no longer used. We capitalized \$52 and \$231 of interest costs associated with construction during the years ended December 31, 2021 and 2020, respectively.

Leases

[Leases \[Abstract\]](#)
[Leases](#)

12 Months Ended
Dec. 31, 2021

Leases

We are party to non-cancellable operating leases for our corporate headquarters facilities in Ewing, New Jersey, and two facilities in the suburbs of New Jersey used for research and development, manufacturing and administrative functions. We have also entered into a master operating lease arrangement for the use by our sales force and other operating leases for various office and warehouse equipment. Our lease agreements do not contain any material right of first refusal, material bargain purchase options or material restrictive covenants. We have no material sublease arrangements with third parties or lease transactions with related parties.

On November 1, 2021, January 1, 2022 and March 1, 2022, we entered into two-month lease extensions on our operating lease for our corporate headquarters in New Jersey. The three extensions set new lease expiration dates of December 31, 2021, February 28, 2022 and April 30, 2022, respectively, and on the same terms and conditions as the original lease.

On July 1, 2019, we entered into an operating lease for approximately 75,000 square feet of office, laboratory, manufacturing and warehousing space in Minneapolis, Minnesota. The initial lease term is 12.5 years with an option to renew the lease for one additional renewal period of three years. The landlord delivered possession of the premises to us on July 1, 2019 and payment of rent commenced on January 1, 2020. The lease provides for the payment of fixed base rent and additional expenses, insurance premiums and taxes. We are completing the build-out of the premises at our cost with an allowance for tenant improvement to be provided by the landlord up to \$1,200.

The operating leases require payment of all executory costs such as maintenance and property taxes. Operating lease costs were \$2,176, \$2,174 and \$2,174 for the years ended December 31, 2021, 2020 and 2019 respectively. Cash paid for amounts included in the measurement of operating lease liabilities was \$2,000, \$2,000 and \$2,000 for the years ended December 31, 2021, 2020 and 2019 respectively. As of and for the years ended December 31, 2021, 2020 and 2019 the weighted average discount rate was approximately 8.9%, 8.9% and 8.9%, respectively, and the weighted average remaining lease term was 8.3 years, 8.3 years and 8.4 years respectively.

Future lease payments under non-cancelable leases for the next five years and thereafter as of December 31, 2021 are as follows:

2022

2023

2024

2025

2026

Thereafter

Total remaining lease payments

Less: Imputed interest

Present value of lease liabilities

As of December 31, 2021, we have no material additional operating leases that have not yet commenced.

Intangible Assets

12 Months Ended
Dec. 31, 2021

[Goodwill and Intangible Assets Disclosure \[Abstract\]](#) [Intangible Assets](#)

Intangible Assets

Intangible assets are as follows:

	Useful Life (in Years)	December 31, 2021			December 31, 2020	
		Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization
TLANDO® product rights	10	\$ 11,315	\$ —	\$ 11,315	\$ —	\$ —
NOC DURNA® product rights	10	7,500	(937)	6,563	7,500	(937)
Patents ¹	5 - 10	1,048	(1,047)	1	3,995	(3,995)
Total intangibles, net		\$ 19,863	\$ (1,984)	\$ 17,879	\$ 11,495	\$ (4,932)

¹ Patents related to OTREXUP® were sold as part of the Asset Purchase Agreement entered into with Otter in December 2021. See Note 12 for further details regarding the sale of assets.

In October 2021, we entered into an exclusive license agreement (the “TLANDO® License Agreement”) with Lipocine, Inc. (“Lipocine”) for the right to develop, manufacture, and commercialize the product TLANDO® (testosterone undecanoate) in the U.S., a twice-daily oral formulation of testosterone for testosterone replacement therapy and associated with a deficiency or absence of endogenous testosterone, or hypogonadism in adult males. TLANDO® was granted tentative approval in December 2020 and will be eligible for final approval and marketing in the U.S. upon expiration of the exclusivity period previously granted to Clarus for JATENZO® in 2022. Under the terms of the TLANDO® License Agreement, we paid Lipocine an upfront payment of \$11,000 upon execution of agreement. Lipocine is obligated to make additional milestone payments up to \$10,000, minimum tiered royalty payments of \$4,500 over the first three years after commercialization and commercial milestone payments potentially totaling up to \$160,000 based on net sales of TLANDO® in the U.S. We are also obligated to purchase \$2,002 of TLANDO® inventory. \$1,056 was purchased as of December 31, 2021. We accounted for the transaction as an asset purchase. Amortization of the product rights intangible asset, net of transaction costs of \$315, will commence and be included in selling, general and administrative expenses upon commercialization of TLANDO® in the U.S. The exclusivity period obtained from the FDA after the exclusivity period previously granted to Clarus Therapeutics, Inc. (“Clarus”) for JATENZO® expires on March 2, 2022. Milestone and commercial milestone payments associated with TLANDO® are contingent on future events and will be accrued when they are both probable and measurable. Royalty payments will be accrued and included in costs of product sales as incurred.

In connection with the NOCDURNA® license and commercial supply agreement entered into with Ferring International Center S.A. and its affiliates, in December 2020, we paid Ferring an upfront payment of \$5,000 upon execution and an additional \$2,500 in October 2021. Ferring is eligible for tiered royalties and commercial milestone payments potentially totaling up to \$17,500 based on net sales of NOCDURNA® in the U.S. We accounted for the transaction as an asset purchase. Amortization of the product rights intangible asset is included in selling, general and administrative expenses. The royalty payments are accrued as incurred and product sales as incurred. The commercial milestones were determined to be contingent liabilities and will be accrued when they are both probable and measurable.

Amortization expense for the years ended December 31, 2021, 2020 and 2019 was \$1,037, \$286 and \$352, respectively, and is recorded in selling, general and administrative expenses in the Consolidated Statements of Operations. Estimated future aggregate amortization expense is as follows:

2022

2023

2024

2025

2026

Thereafter

Total future amortization expense

Future amortization amounts presented above are estimates. Actual future amortization expense may be different due to future acquisitions, impairment, changes in amortization periods or other factors.

Accrued Expenses and Other
Current Liabilities

12 Months Ended
Dec. 31, 2021

[Payables and Accruals](#)
[\[Abstract\]](#)

[Accrued Expenses and Other Current Liabilities](#)
[Current Liabilities](#)

Accrued Expenses and Other Current Liabilities
Accrued expenses and other liabilities consisted of the following:

	December 31, 20
Product returns and sales allowances	\$ 20,
Accrued employee compensation and benefits	5,
License fees payable	
Other accrued expenses and liabilities	8,
Total accrued expense and other liabilities	\$ 35,

Long-Term Debt

12 Months Ended
Dec. 31, 2021

[Debt Disclosure \[Abstract\]](#)
[Long-Term Debt](#)

Long-Term Debt

Term Loan

On June 6, 2017, we entered into a loan and security agreement (the "Loan Agreement") with Hercules Capital, Inc., for a term loan of up to \$35,000, under which we initially borrowed \$25,000 ("Tranche I"), the proceeds of which are being used for working capital and general corporate purposes, secured by substantially all of our assets, excluding intellectual property and accrued interest at a calculated prime-based variable rate with a maximum of 9.50%. The interest rate in effect as of December 31, 2020 was 8.50%. Payments under the loan were interest-only until the first principal payment.

On June 26, 2019, we entered into a First Amendment (the "Amendment") to the Loan Agreement, which increased the aggregate principal amount of the Term Loan from \$35,000 to \$50,000 and extended the interest-only payment period of the Term Loan to August 1, 2021. The interest only period could be extended to August 1, 2022 if we achieved a certain loan extension milestone, requested such extension, and paid an extension fee equal to one half of one percent of the amount outstanding. Upon signing of the Amendment, an additional \$15,000 ("Tranche II") was funded to us. The Term Loan maturity date remained August 1, 2021; however, the Term Loan maturity date could be extended to July 1, 2024 contingent upon satisfaction of a certain loan extension milestone. We were obligated, to request one or more additional advances of at least \$5,000, not to exceed \$10,000 in the aggregate ("Tranche III"). Our option to request advances expired on October 31, 2020.

We were required to pay an end of term fee ("End of Term Charge") equal to 4.25% of Tranche I and 3.95% of the borrowings under Tranche II, payable on July 1, 2022 or repayment of the Term Loan. The Loan Agreement also imposed a prepayment fee of 1.0% to 3.0% if any or all of the balance was repaid prior to the maturity date.

As of December 31, 2020, the carrying value of the Term Loan was \$40,899, which consisted of the principal balance outstanding and the End of Term Charge, less unamortized debt issuance costs that are being amortized/accrued to interest expense over the term of the Term Loan using the effective interest method. The fair value of our debt was estimated to approximate the carrying value based on our understanding of current market conditions and rates we could obtain for similar debt.

In July 2021, having previously met the loan extension milestone, we requested that the interest-only period be extended to August 1, 2022 and the maturity date be extended to July 1, 2024 in accordance with the terms of the Amendment. The Lender granted the extension of the interest-only period and maturity date, and we paid an extension fee. In 2021, we made principal prepayments of \$20,000 and paid a 1.0% prepayment fee.

On November 1, 2021, we extinguished the Loan Agreement with Hercules Capital, Inc. and repaid the outstanding \$20,000 principal on the Term Loan, the 1.0% prepayment fee of \$200 and the End of Term Charge of \$1,655. All remaining unamortized debt issuance costs associated with the Term Loan were amortized to interest expense.

Credit Facilities

On November 1, 2021, we entered into a Credit Agreement (the "Credit Agreement") with Wells Fargo Bank, National Association, as administrative agent ("Administrative Agent") for credit facilities in an aggregate principal amount of up to \$40,000 with a maturity date of November 1, 2024. The Credit Agreement provides for a \$20,000 term loan facility (the "Term Loan Facility") and a \$20,000 revolving credit facility, \$5,000 of which is available for the issuance of Swingline loans, \$1,000 of which is available for Swingline loans (the "Revolving Credit Facility"), (collectively the "Credit Facilities"), which are secured by substantially all of our assets. The Term Loan Facility was funded upon execution of the Credit Agreement with the proceeds used to repay our \$20,000 Term Loan with Hercules Capital, Inc. and the fees and expenses incurred in connection with the early repayment. The Revolving Credit Facility remains available for future use and can be drawn upon for working capital requirements and other general corporate purposes as needed.

As of December 31, 2021, we had \$20,000 outstanding under our Term Loan Facility with a carrying value of \$19,741 which consisted of the principal balance outstanding, less unamortized debt issuance costs that are being amortized/accrued to interest expense over the term of the Term Loan Facility using the effective interest method. The fair value of our debt is estimated to approximate the carrying value based on our understanding of current market conditions and rates we could obtain for similar loans.

As of December 31, 2021, there were no outstanding borrowings under the Revolving Credit Facility, including no outstanding letters of credit drawn under the Credit Facility or Swingline loans. Commitment fees are payable on the unused portion of the Revolving Credit Facility at rates between 0.30% and 0.50% of the unused portion of the Revolving Credit Facility, as a percentage of the Consolidated Total Leverage Ratio, as defined in the Credit Agreement and below, remeasured quarterly. For the year ended December 31, 2021, commitment fees totaled \$12.

As defined in the Credit Agreement governing the Term Loan Facility, principal payments of the outstanding term loans are due in consecutive quarterly payments on the last business day of each of March, June, September and December, commencing on March 31, 2022. The Credit Agreement also requires prepayment of outstanding loans under the Term Loan Facility, subject to certain exceptions, with (a) 100% of the net cash proceeds of (i) any incurrence or issuance of certain types of debt not permitted under the Credit Agreement; (ii) issuance of equity other than that associated with employee compensation; and (iii) certain asset sales, including condemnation events, subject to reinvestment rights and certain other exceptions. We may voluntarily prepay outstanding loans under the Term Loan Facility with a premium or penalty. All obligations under the Term Facility are secured, subject to certain exceptions, by substantially all of our assets and the assets of our subsidiaries.

Borrowings made under the Credit Agreement bear interest at a rate per annum equal to either the Base Rate or LIBOR plus the Applicable Margin. Swingline loans bear interest at a rate per annum equal to the Base Rate plus the Applicable Margin. The Applicable Margin is based on our Leverage Ratio, as defined in the Credit Agreement and below, remeasured quarterly. Base Rate is defined as the highest of (a) the Prime Rate, (b) plus 0.50% and (c) LIBOR for an interest period of one month plus 1%. In the event of default, we no longer have the option to request LIBOR rate or Letters of Credit and all outstanding financial instruments will bear interest at a rate per annum of 2% in excess of the calculated interest rate.

We have the option to select either the Base Rate or LIBOR as the rate of interest for the Term Loan and Revolving Credit Facilities, along with a 1-month, 3-months or 6-months. Upon cessation of LIBOR on June 30, 2023, an appropriate benchmark replacement will be determined pursuant to the Credit Agreement. We have not yet evaluated the impact the cessation of LIBOR will have on our financial condition and results of operations. As of December 31, 2021, the Applicable Margin was 1.50% for Base Rate loans and 2.50% for LIBOR loans with a 1-month LIBOR selected as the rate of interest for the Term Loan Facility. The weighted average interest rate on the Term Loan Facility outstanding balance during the year ended December 31, 2021 was approximately 2.59%.

Under the Credit Agreement, we are subject to customary affirmative and negative covenants, including, among others, restrictions on our ability to make investments; merge, consolidate or dispose of assets or subsidiaries; enter into transactions with affiliates; modify accounting practices, our organizational documents; pledge assets; revise nature of business; perform sale leasebacks; and enter into any restrictive agreements and customary covenants (including payment defaults, covenant defaults, change of control defaults and bankruptcy defaults). The Credit Agreement also contains financial covenants, including the ratio of consolidated total indebtedness to consolidated earnings before income, taxes, depreciation and amortization (“Consolidated EBITDA”) (“Consolidated Leverage Ratio”), as defined in the Credit Agreement” and the ratio of consolidated senior secured indebtedness to Consolidated EBITDA (“Consolidated Senior Secured Leverage Ratio”), as well as the ratio of Adjusted EBITDA to consolidated fixed charges (“Consolidated Fixed Charge Coverage Ratio”), as defined in the Credit Agreement. These covenants restrict our ability to purchase outstanding shares of our common stock. As of December 31, 2021, we were in compliance with all affirmative, negative and financial covenants.

Future principal payments under the Term Loan Facility are as follows:

2022
2023
2024

Total future principal payments

Stockholders' Equity

**12 Months Ended
Dec. 31, 2021**

[Equity \[Abstract\]](#)
[Stockholders' Equity](#)

Stockholders' Equity

In August 2017, we entered into a sales agreement (the “Sales Agreement”) with Cowen and Company, LLC (“Cowen”) under which we could offer and sell, from time to time and at our sole discretion, shares of our common stock having an aggregate offering price of up to \$30,000 through Cowen as our sales agent and/or as principal. Cowen could sell the common stock by any method permitted by law deemed to be an “at the market offering” as defined in Rule 415 of the Securities Act of 1933, as amended (the “ATM Facility”). The Sales Agreement requires us to pay a commission of 3.0% of the gross sales proceeds of any common stock sold through Cowen.

During year ended December 31, 2019, we sold 2,307 shares of common stock under the ATM Facility, resulting in net offering proceeds of \$7,781. On June 26, 2019, the Company delivered written notice to Cowen that it was terminating the Sales Agreement effective July 6, 2019, and accordingly the ATM Facility is no longer available for use.

Share Based Compensation

12 Months Ended
Dec. 31, 2021

[Share-based Payment
Arrangement \[Abstract\]
Share Based Compensation](#)

Share-Based Compensation

We have an Equity Compensation Plan (the “Plan”), which allows for grants in the form of incentive stock options, non-qualified stock options, stock appreciation rights, and other stock-based awards. The Plan was amended and restated in June 2021 to increase the total number of shares available under the Plan by 10,000 shares. The cumulative number of shares that have been authorized for issuance under the Plan to date is 50,200 shares and the maximum number of stock that may be granted to any one participant during a calendar year is 4,000 shares. Options to purchase shares of common stock are granted at a price of not less than 100% of fair market value on the date of grant. The term of each option is ten years, and the options typically vest over a three-year period with one-third of the options vesting each year. As of December 31, 2021, the Plan had approximately 366 shares available for grant. Stock option exercises, and the vesting of performance stock awards, are satisfied through the issuance of new shares.

Stock Options

Stock option activity under the Plan is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
Outstanding as of December 31, 2018	14,079	\$ 2.19	
Granted	2,489	3.01	
Exercised	(2,572)	1.76	
Cancelled / Forfeited	(135)	2.81	
Outstanding as of December 31, 2019	13,861	2.41	
Granted	3,335	2.73	
Exercised	(939)	1.93	
Cancelled / Forfeited	(736)	2.83	
Outstanding as of December 31, 2020	15,521	2.49	
Granted	2,660	4.37	
Exercised	(2,307)	2.27	
Cancelled / Forfeited	(297)	3.02	
Outstanding as of December 31, 2021	15,577	2.83	
Exercisable as of December 31, 2021	10,644	\$ 2.46	

The per share weighted average fair value of options granted during 2021, 2020 and 2019 was estimated as \$2.29, \$1.42 and \$1.54, respectively, using the Black-Scholes option pricing model based on the assumptions noted in the table below. Expected volatilities are based on the historical volatility of our common stock. The weighted average expected life is based on both historical and anticipated employee behavior.

	Years Ended December 31	
	2021	2020
Risk-free interest rate	0.8 %	0.4 %
Annualized volatility	59.3 %	59.4 %
Weighted average expected life (in years)	5.4	5.4
Expected dividend yield	0.0 %	0.0 %

Option exercises during 2021, 2020 and 2019 resulted in proceeds of \$5,182, \$1,814 and \$4,405, respectively, and the issuance of shares of common stock of 2,307, 939 and 2,529, respectively. In 2021 and 2019, certain options were net exercised, whereby we withheld 13 and 43 shares, respectively, equivalent to the aggregate exercise price and tax withholding on the date of exercise.

Long Term Incentive Program

Our Board of Directors has approved a long-term incentive program (“LTIP”) for the benefit of our senior executives. Pursuant to the LTIP, our senior executives are awarded stock options, restricted stock units (“RSU”) and performance stock units (“PSU”) with targeted values based on similar award structures of other companies in our group. The stock options have a ten-year term, an exercise price equal to the closing price of our common stock on the date of grant, vest in quarterly installments over three years, were otherwise granted on the same standard terms and conditions as other stock options granted pursuant to the Plan and are included in the Plan.

above. The RSUs generally vest in three equal annual installments, and the PSUs vest and convert into shares of our common stock based on our performance goals over a performance period, which is typically three years.

PSUs and RSUs granted under the LTIP are summarized as follows:

	Performance Stock Units		Restrictive
	Number of Shares	Weighted Average Grant Date Fair Value	Number of Shares
Outstanding as of December 31, 2018	1,842	\$ 2.41	1,842
Granted	593	2.99	593
Incremental shares earned	59	1.25	59
Vested / Settled	(415)	1.18	(415)
Forfeited / Expired	(238)	1.12	(238)
Outstanding as of December 31, 2019	1,841	3.00	1,841
Granted	605	2.00	605
Incremental shares earned	77	3.10	77
Vested / Settled	(388)	3.11	(388)
Forfeited / Expired	(494)	3.02	(494)
Outstanding as of December 31, 2020	1,641	2.61	1,641
Granted	243	5.55	243
Incremental shares earned	210	3.18	210
Vested / Settled	(766)	2.86	(766)
Outstanding as of December 31, 2021	1,328	\$ 3.04	1,328

The outstanding balance of PSUs is stated at the target number of shares to be awarded upon attainment of certain performance goals. Depending on related performance goals, a recipient may ultimately earn a number of shares that is greater or less than the target number of units granted, ranging from 0 to 100% of the target. The outstanding balance of PSUs outstanding as of December 31, 2021 included 308 units granted in 2019 with a performance period ended December 31, 2021 that were deemed to be achieved and approved for settlement in the first quarter of 2022 for a total of 304 shares.

In each of the years in the three-year period ended December 31, 2021, the LTIP awards include PSUs that will be earned based on our total share price performance compared to the Nasdaq Biotechnology Index (“NBI”) at the end of the respective annual performance periods. The fair values of the TSR PSUs were determined using a Monte Carlo simulation and used the following inputs and assumptions:

	2021 Award	2020 Award
Closing stock price on grant date	\$ 4.42	\$ 2.73
Performance period starting price	\$ 3.70	\$ 4.78
Term of award (in years)	2.56	2.55
Volatility	54.4 %	57.5 %
Risk-free interest rate	0.23 %	0.21 %
Expected dividend yield	0.00 %	0.00 %
Fair value per TSR PSU	\$ 5.55	\$ 2.00

The performance period starting price is measured as the average closing price over the last 20 trading days prior to the performance period start. The Monte Carlo simulation model also assumed correlations of returns of the prices of our common stock and the common stocks of the NBI companies and stock prices of the NBI companies. The fair value of the target number of shares that can be earned under the TSR PSUs is being recognized as compensation expense over the performance period. Other PSUs that are not market-based awards are expensed using the grant date fair value of shares expected to vest over the remaining performance period when it becomes probable that the related performance goal will be achieved.

LTIP awards are generally net-share settled such that we withhold shares with value equivalent to the employees’ minimum statutory obligation for federal income and other employment taxes, and remit cash to the appropriate taxing authorities. Total shares withheld for net-settled awards were 626, 425 and 425 in 2021, 2020 and 2019, respectively, and were based on the value of the shares on their vesting date as determined by our closing stock price. Total payment obligations to the taxing authorities were \$2,841, \$1,367 and \$1,131 in 2021, 2020 and 2019, respectively, and are reflected as a financing activity in our Statements of Cash Flows. These net-share settlements reduced the number of shares that would have otherwise been issued as a result of the vesting of the awards.

Members of our Board of Directors also receive grants of RSUs that vest one year from the date of grant. Certain Directors have elected to defer until retirement or separation from the Board of Directors, for which 30, 72 and no shares vested with deferral as of and for the years ended December 31, 2021, 2020 and 2019, respectively.

Share-based Compensation Expense

Compensation costs incurred in connection with share-based awards are as follows:

	Years Ended December 31	
	2021	2020
Stock options	\$ 4,102	\$ 3,000
Restricted stock units	\$ 2,620	\$ 2,000
Performance stock units	\$ 1,293	\$ 2,000
Total share-based compensation expense	\$ 8,015	\$ 7,000

As of December 31, 2021, there was \$6,838 of total unrecognized compensation costs related to non-vested stock option awards that are expected to be recognized over a weighted average period of approximately 1.95 years

**Employee 401(k) Savings
Plan**

**12 Months Ended
Dec. 31, 2021**

Retirement Benefits

[Abstract]

Employee 401(k) Savings Plan Employee 401(k) Savings Plan We sponsor a 401(k) defined contribution retirement savings plan that covers all U.S. employees who have met minimum age and service requirements subject to the provisions of the Employee Retirement Income Security Act. Under the plan, eligible employees may contribute a portion of their annual compensation into the plan up to the IRS annual limits on a pre-tax or after-tax basis. We have elected to make matching contributions to the plan based on a percentage of employee contributions. The total amount contributed by us is determined by plan provisions for matching contributions, as well as at our discretion. Employer matching and discretionary contributions were \$1,151, \$1,097 and \$993 for the years ended December 31, 2021, 2020 and 2019, respectively.

Sale of Assets

**12 Months Ended
Dec. 31, 2021**

[Sale Of Assets \[Abstract\]](#)

[Sale of Assets](#)

Sale of Assets

In December 2021, we entered into an asset purchase agreement (the “Asset Purchase Agreement”) with Otter Pharmaceuticals, LLC (a subsidiary of Assertio Holdings, Inc., together with Assertio Holdings, Inc., as guarantor, individually and collectively referred to as “Otter”) to sell certain worldwide assets used in the operation of the OTREXUP[®] product line for \$44,021 of which we received a \$18,000 at closing and will receive the remaining \$26,021 in installments over a one-year period. As of December 31, 2021, we recorded an increase to the purchase price for estimated changes in closing inventory to be transferred. The Asset Purchase Agreement included the transfer of OTREXUP[®] patents, trademark and intellectual property, product finished goods and sample inventory, and certain other contracts associated with the OTREXUP[®] product line. Subject to the terms of the OTREXUP[®] Asset Purchase Agreement, we generally retained ownership (and related liabilities) of assets not solely related to the OTREXUP[®] product line. We also agreed via the execution of a separate supply agreement to continue to manufacture and supply OTREXUP[®] and sample products to Otter at cost plus mark-up. Further, we entered into a license agreement with Otter pursuant to which we granted Otter a worldwide, exclusive, fully paid-up license to certain patents relating to OTREXUP[®] that may relate to our other products.

We recorded the entire \$38,591 gain on sale of assets in the Consolidated Statements of Operations for the year ended December 31, 2021 as all requirements of the agreement were determined to have been met and it was probable that a significant reversal of the gain would not occur. The gain includes the purchase price of \$44,021 adjusted for estimated changes in closing inventory to be transferred less the net book value of the assets sold and direct transaction costs. The remaining \$26,311 purchase price to be received is classified as other receivables in the Consolidated Balance Sheets as of December 31, 2021, and we recognized \$17,825 of net proceeds from the sale of assets in the Statements of Cash Flows for the year ended December 31, 2021.

Income Taxes

[Income Tax Disclosure](#)

[\[Abstract\]](#)

[Income Taxes](#)

12 Months Ended

Dec. 31, 2021

Income Taxes

We were subject to taxes in both the U.S. and Switzerland in each of the years ended December 31, 2021, 2020 and 2019. Income (loss) before income taxes from the following jurisdictions:

	Years Ended December 31,	
	2021	2020
U.S.	\$ 62,626	\$ 10,500
Switzerland	(355)	(3,500)
Total income (loss) before income taxes	\$ 62,271	\$ 9,999

The income tax provision (benefit) was comprised of:

	Years Ended December 31,	
	2021	2020
Current		
Federal	\$ —	\$ —
State	2,041	1,000
Foreign	2	—
Total current income tax provision (benefit)	2,043	1,000
Deferred		
Federal	11,918	(39,500)
State	2,021	(7,400)
Foreign	—	—
Total deferred income tax provision (benefit)	13,939	(46,900)
Total income tax provision (benefit)	\$ 15,982	\$ (46,400)

Effective tax rates differ from statutory income tax rates as follows:

	Years Ended December 31,	
	2021	2020
Statutory income tax rate	21.0 %	21.0 %
State income taxes	5.5	7.1
Effect of foreign operations	0.1	0.2
Changes in valuation allowance	(0.2)	(516.5)
Change in unused net operating loss and credit carryforwards	—	—
Change in uncertain tax positions	(0.1)	21.4
Research and development credit	(0.7)	(6.0)
Stock-based compensation	(2.0)	3.7
162(m) limitation	2.1	1.9
Nondeductible items	—	1.6
Impact of Tax Cuts and Jobs Act	—	—
Other	—	(0.9)
Effective income tax rate	25.7 %	(466.5 %)

Deferred tax assets (liabilities) consist of the following:

	December 31, 20
Gross deferred tax assets	
Net operating loss carryforward – U.S.	\$ 24,
Net operating loss carryforward – Switzerland	1,
Research and development tax credit carryforward	5,
Deferred revenue	
Stock-based compensation	3,
Inventory reserve	
Compensation accruals	1,
Product reserves	5,
Operating lease liabilities	1,
Amortization	
Other	1,
Total deferred tax assets	42,
Deferred tax liabilities	
Depreciation	(1,
Operating lease right-of-use asset	(1,
Installment sale	(5,
Total deferred tax liabilities	(8,
Net deferred tax asset before valuation allowance	34,
Less: Valuation allowance	(1,
Net deferred tax asset	\$ 33,

In assessing the realizability of deferred tax assets, we consider whether it is more likely than not that some portion or all of the deferred tax assets will be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which temporary differences exist. Management estimates the amount of deferred tax assets that will be realized based on the expected future taxable income in which net operating loss or tax credit carryforwards can be used. As of each reporting date, we consider new evidence, both positive and negative, to assess the realizability of deferred tax assets in light of the future realization of deferred tax assets.

As of December 31, 2021 and 2020, there is sufficient positive evidence to conclude that it is more likely than not that our net U.S. deferred tax assets of \$46,982, respectively, are realizable as a result of generating pretax earnings, utilizing net operating loss carryovers and projecting pre-tax earnings. As of December 31, 2020, we recorded a net valuation allowance release of \$53,383 based on our reassessment of the amount of our deferred tax assets that are not to be realized. The valuation allowances of \$1,154 and \$1,226 as of December 31, 2021 and 2020, respectively, relate to certain state and foreign deferred tax assets for which projected income cannot support utilization.

We have a U.S. federal net operating loss carryforward as of December 31, 2021 of \$99,939, which, subject to limitations of Internal Revenue Code Section 382, is available to reduce income taxes payable in future years. As of December 31, 2021, we have performed a full analysis of IRC Section 382 and concluded that the net operating loss carryforward generated before 2018 will expire in the year 2022 and the net operating loss carryforward generated in 2018 and any future years will carry forward indefinitely. Additionally, we have U.S. Research and Development tax credit carryforward of \$7,328 which will expire in years 2022 through 2041 if unused.

We also have a Swiss net operating loss carryforward as of December 31, 2021, of \$1,130, which is available to reduce income taxes payable in future years. The Swiss net operating loss carryforward will begin to expire in 2023.

A summary of changes to our liability for unrecognized tax benefits is as follows:

	December 31, 20
Beginning liability for unrecognized tax benefits	\$ 2,
Increase (decrease) due to tax positions related to prior years	0,
Increase due to tax positions related to the current year	0,
Ending liability for unrecognized tax benefits	\$ 2,

Included in the balance of unrecognized tax benefits as of December 31, 2021 and 2020, are \$2,057 and \$2,127, respectively, that if recognized will result in a change in our effective tax rate. There is no interest or penalties charged or accrued in relation to unrecognized tax benefits. We will classify any future interest and penalties as a component of income tax expense. We do not anticipate that the total amount of unrecognized tax benefits will change significantly in the next twelve months. We are currently under audit by the IRS and state examinations for the years 2017 and thereafter.

**Revenues, Significant
Customers and
Concentrations of Risk**

**12 Months Ended
Dec. 31, 2021**

**Revenue from Contract with
Customer [Abstract]**

**Revenues, Significant
Customers and Concentrations
of Risk**

Revenues, Significant Customers and Concentrations of Risk

We disaggregate our revenue by type of goods and services and customer location.

	Years Ended December	
	2021	2020
Types of Goods and Services		
Proprietary product sales, net	\$ 80,016	\$ 62,016
Partnered product sales	46,651	50,982
Total product revenue, net	126,667	113,000
Licensing and development revenue	19,623	14,623
Royalties	37,692	21,692
Total revenue, net	\$ 183,982	\$ 149,315
Customer Location		
U.S.	\$ 178,290	\$ 145,315
Europe	5,692	3,692
Other	—	—
Total revenue, net	\$ 183,982	\$ 149,315

Customers from which we derive 10% or more of our total revenue are as follows:

	Years Ended December	
	2021	2020
Teva	42%	40%
McKesson ¹	13%	12%
AmerisourceBergens Corporation ¹	12%	12%
Cardinal Health ¹	11%	11%
Covis	<10%	<10%

¹ Revenue from sales to distributors, net of estimated sales returns and allowances based on shipments.

Earnings (Loss) per Share

12 Months Ended
Dec. 31, 2021

[Earnings Per Share](#)

[\[Abstract\]](#)

[Earnings \(Loss\) per Share](#)

Earnings (Loss) per Share

Basic earnings (loss) per common share is computed by dividing net income applicable to common stockholders by the daily weighted-average number of common shares outstanding for the applicable period. Diluted earnings (loss) per common share is computed in a similar manner, except that the weighted average number of common shares outstanding is increased to reflect the potential dilution from the exercise or conversion of securities into common stock. Diluted earnings (loss) per common share is computed assuming the complete conversion to common shares of all convertible instruments only if such instruments are dilutive in nature with respect to earnings per common share. The following table sets forth the computation for basic and diluted earnings (loss) per common share:

	Years Ended December 31,	
	2021	2020
Net income (loss)	\$ 46,289	\$ 56,289
Weighted average common shares outstanding	169,226	166,226
Dilutive effects of stock options and share-based awards issuable under equity compensation plans	5,507	4,507
Weighted average dilutive common shares outstanding	174,733	170,733
Earnings (loss) per common share		
Basic	\$ 0.27	\$ 0.34
Diluted	\$ 0.26	\$ 0.32
Anti-dilutive common stock equivalents ¹	2,224	7,224

¹ These common stock equivalents were outstanding for the period but were not included in the computation of diluted earnings (loss) per common share as their inclusion would have had an anti-dilutive effect.

Commitments and Contingencies

**12 Months Ended
Dec. 31, 2021**

Commitments and Contingencies Disclosure

[Abstract]

Commitments and Contingencies

Commitments and Contingencies

Contingent Considerations

In connection with the TLANDO[®] exclusive license agreement and asset purchase entered into with Lipocine in October 2021, we paid Lipocine an upfront payment of \$11,000 upon execution of agreement. Lipocine is eligible for additional milestone payments up to \$10,000, minimum tiered royalty payments of \$4,500 over the first three years after commercialization has occurred and commercial milestones up to \$160,000 based on net sales of TLANDO[®] in the U.S. The additional milestone and commercial milestone payments are contingent on future events and will be accrued when they are both probable and estimable. We also have the option to license and develop LPCN 1111 (TLANDO XR) for an additional \$4,000 in license fees to be paid in two installments upon exercise of the option, if exercised. The option to license and develop LPCN 111 (TLANDO XR) will be accrued and expensed to research and development when and only if we decide to exercise our option. No decision had been made as of December 31, 2021 to exercise the option; therefore, no accrual was recorded.

In connection with the NOCDURNA[®] license agreement and asset purchase entered into with Ferring in October 2020, we paid Ferring an upfront payment of \$5,000 upon execution and paid an additional \$2,500 in October 2021. Ferring is eligible for additional commercial milestone payments potentially totaling up to \$17,500 based on our net sales of NOCDURNA[®] in the U.S.

Pending Litigation

From time to time, we may be involved in various legal matters generally incidental to our business. Although the results of litigation and claims cannot be predicted with certainty, after discussion with legal counsel, we are not aware of any matters for which the likelihood of a loss is probable and reasonably estimable and which could have a material impact on our consolidated financial condition, liquidity, or results of operations.

On October 23, 2017, Randy Smith filed a complaint in the District of New Jersey, captioned *Randy Smith, Individually and on Behalf of All Others Similarly Situated v. Antares Pharma, Inc., Robert F. Apple and Fred M. Powell* (“*Smith*”), Case No. 3:17-cv-8945-MAS-DEA, on behalf of a putative class of persons who purchased or otherwise acquired Antares securities between December 21, 2016 and October 12, 2017, inclusive, asserting claims for purported violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, against Antares, Robert F. Apple and Fred M. Powell. The Smith complaint contends that defendants made false and/or misleading statements and/or failed to disclose that: (i) Antares had provided insufficient data to the FDA in connection with the NDA for XYOSTED[®]; and (ii) accordingly, Antares had overstated the approval prospects for XYOSTED[®]. On July 27, 2018, the court entered an order appointing Serghei Lungu as lead plaintiff, Pomerantz LLP as lead counsel, and Lite DePalma Greenberg, LLC as liaison counsel for plaintiff. On August 3, 2018, the parties submitted a stipulation and proposed order, setting forth an agreed-upon schedule for responding to the complaint, which the court granted. Pursuant to that order, plaintiff filed a Consolidated Amended Class Action Complaint on October 9, 2018. On November 26, 2018,

defendants filed a motion to dismiss. Plaintiff filed an opposition to the motion on January 10, 2019 and defendants filed a reply in support of their motion on February 25, 2019. On July 2, 2019, the court dismissed the complaint in its entirety without prejudice. On July 29, 2019, plaintiff filed a Consolidated Second Amended Class Action Complaint against the same parties alleging substantially similar claims. On September 12, 2019, defendants filed a motion to dismiss the Consolidated Second Amended Class Action Complaint. Plaintiffs' opposition was filed on October 28, 2019 and defendants' reply in support of their motion was filed on November 27, 2019. On April 28, 2020, the court dismissed the Consolidated Second Amended Class Action Complaint in its entirety. The court further ordered that plaintiff may file an amended complaint by May 29, 2020 and provide the court with a form of the amended complaint that indicates in what respect(s) it differs from the complaint which it proposes to amend. On May 29, 2020, plaintiff filed a Consolidated Third Amended Class Action Complaint and defendants filed a motion to dismiss on July 10, 2020. Briefing on defendants' motion was complete on August 25, 2020. On February 26, 2021, the court granted defendants' motion to dismiss with prejudice, and on March 29, 2021 the plaintiff filed a notice of appeal. On June 21, 2021, plaintiff-appellant filed his opening brief. Defendants-appellees' response brief was filed on August 4, 2021 and plaintiff-appellant's reply was filed on September 8, 2021. On January 25, 2022, the Third Circuit ruled in defendants' favor affirming dismissal. If plaintiffs choose to appeal, they have ninety days to file a petition for writ of certiorari to the U.S. Supreme Court. We believe the claims in the *Smith* action lack merit and intend to continue to defend them vigorously.

On January 12, 2018, a stockholder of the Company filed a derivative civil action, captioned *Chiru Mackert, derivatively on behalf of Antares Pharma, Inc., v. Robert F. Apple, et al.*, in the Superior Court of New Jersey Chancery Division, Mercer County (Case No. C-11-18). On January 17, 2018, another stockholder filed a derivative action in the same court, captioned *Vikram Rao, Derivatively on Behalf of Antares Pharma, Inc. v. Robert F. Apple, et al.* (Case No. C-4-18). Both complaints name Robert F. Apple, Fred M. Powell, Thomas J. Garrity, Jacques Gonella, Anton Gueth, Leonard S. Jacob, Marvin Samson and Robert P. Roche, Jr. as defendants, and the Company as nominal defendant, and they assert claims for breach of fiduciary duties, unjust enrichment, abuse of control, gross mismanagement, and waste of corporate assets arising from the same facts underlying the *Smith* securities class action. The plaintiffs seek damages, corporate governance and internal procedure reforms and improvements, restitution, reasonable attorneys' fees, experts' fees, costs, and expenses. The parties have filed a stipulation and order consolidating the two actions and staying the proceedings pending the court's decision on defendants' motion to dismiss the *Smith* action; the motion to dismiss in *Smith* was granted on February 26, 2021 and notice of appeal was filed on March 29, 2021. On January 25, 2022, the Third Circuit ruled in defendants' favor affirming dismissal of the securities fraud class action. If plaintiffs in the securities action choose to appeal, they have ninety days to file a petition for writ of certiorari to the U.S. Supreme Court.

On January 17, 2018, a stockholder of the Company filed a derivative civil action, captioned *Robert Clark, Derivatively on Behalf of Antares Pharma, Inc. v. Robert F. Apple, et al.* ("*Clark*") (Case No. 3:18-cv-703-MAS-DEA), against Robert F. Apple, Thomas J. Garrity, Jacques Gonella, Leonard S. Jacob, Marvin Samson, Anton G. Gueth and Robert P. Roche, Jr. as defendants, and Company as a nominal defendant. The action was filed in the U.S. District Court for the District of New Jersey and asserts claims for breach of fiduciary duties, unjust enrichment, abuse of control, waste of corporate assets, and a violation of Section 14(a) of the Securities Exchange Act of 1934. This complaint relates to the same facts underlying the *Smith* securities

class action and the other derivative actions. The plaintiff in *Clark* seeks damages, corporate governance and internal procedure reforms and improvements, reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses. The parties have filed a stipulation and order staying the action pending the court's decision on defendants' motion to dismiss the *Smith* action; the motion to dismiss in *Smith* was granted on February 26, 2021 and notice of appeal was filed on March 29, 2021. After the expiration of all appeals related to the *Smith* dismissal, the parties shall submit a proposed order regarding the derivative action. On January 25, 2022, the Third Circuit ruled in defendants' favor affirming dismissal of the securities fraud class action. If plaintiffs in the securities action choose to appeal, they have ninety days to file a petition for writ of certiorari to the U.S. Supreme Court.

Summary of Significant Accounting Policies (Policies)

12 Months Ended
Dec. 31, 2021

[Accounting Policies](#)

[\[Abstract\]](#)

[Basis of Presentation](#)

Basis of Presentation

The accompanying consolidated financial statements include the accounts of Antares Pharma, Inc. and its two wholly-owned foreign subsidiaries. All accounts and transactions have been eliminated in consolidation.

[Use of Estimates](#)

Use of Estimates

The preparation of financial statements in accordance with U.S. generally accepted accounting principles ("GAAP") requires us to make estimates that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the date of the financial statements and revenues and expenses during the reporting period. Our most significant accounting estimates relate to revenue recognition and variable consideration, inventory carrying value of deferred tax assets and the valuation of equity instruments used in the computation of share-based compensation. Actual results may differ from estimates, and significant variances could materially impact our financial condition and results of operations.

[Reclassifications](#)

Reclassifications

Certain reclassifications have been made to prior year amounts to conform with the current year presentation. As of and for the year ended December 31, 2021, product sales and the cost of development revenue were classified under the heading *Operating expenses* in the Consolidated Statements of Operations. The corresponding prior period amount was reclassified to conform to this presentation. The reclassifications had no impact on our operating income or cash flows as previously reported.

[Accounting Pronouncements Recently Adopted and Recently Issued Accounting Pronouncements Not Yet Adopted](#)

Accounting Pronouncements Recently Adopted

We adopted FASB ASU No. 2018-15, *Customers' Accounting for Implementation Costs Incurred in Cloud Computing Arrangement that is a Service Contract*, effective January 1, 2020, which provides new guidance on a customer's accounting for implementation, set-up, and other upfront costs incurred in a cloud computing arrangement that is hosted by the vendor (i.e., a service contract). Under the new guidance, entities apply the same criteria for capitalizing implementation costs incurred in a cloud computing arrangement that has a software license. Adoption of this standard did not have a material impact on our financial condition, results of operations or disclosures.

We adopted FASB ASU No. 2018-18, *Clarifying the Interaction Between Topic 808 and 606*, effective January 1, 2020, which clarifies that certain collaborative arrangement participants should be accounted for under the revenue guidance, adds unit of account guidance to the collaborative arrangement standard, aligns with the revenue standard, and clarifies presentation guidance for transactions with a collaborative arrangement participant that is not accounted for under the revenue standard. Adoption of this standard did not have a material impact on our financial condition, results of operations or disclosures.

Recently Issued Accounting Pronouncements Not Yet Adopted as December 31, 2021

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which includes related amendments, which changes the accounting for credit losses on instruments measured at amortized cost by adding an impairment model that recognizes credit losses rather than incurred losses. Any entity will recognize as an allowance its estimate of expected credit losses, which is believed to result in more consistent measurement of such losses as the standard eliminates the probable initial recognition threshold. The new guidance is required to be adopted using a modified retrospective cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period of adoption. Adoption of the new guidance was effective for our annual periods beginning after December 15, 2019, including interim periods within the annual period.

In October 2019, the FASB issued ASU 2019-10, *Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates*, which deferred the effective date of ASU 2016-13 for certain entities, including those that are eligible for smaller reporting company status. Determination of eligibility for deferral was a one-time assessment as of November 15, 2019 based on the entity's most recent smaller reporting company determination as of the last business day of its most recently completed second quarter. Based on this determination, we qualified as a smaller reporting company and therefore eligible for the adoption deferral resulting in a new effective date of January 1, 2023. The impact on our financial condition, results of operations or disclosures is being evaluated but is not expected to be significant as we have historically had minimal credit losses on financial instruments.

In April 2020, the FASB issued ASU No. 2020-04, *Facilitation of the Effects of Reference Rate Reform on Financial Reporting*, which provides relief for entities preparing for discontinuation of interest rates such as LIBOR. The standard can be applied immediately through December 31, 2022. We have not yet determined the adoption of this guidance may have on our financial condition, results of operations or disclosures.

[Foreign Currency Translation](#)

Foreign Currency Translation

The majority of our foreign subsidiaries' revenues are denominated in U.S. dollars, and any required funding of the subsidiaries is provided by the subsidiaries. The operating expenses of our foreign subsidiaries are denominated in Swiss Francs. Additionally, bank accounts held by foreign subsidiaries are denominated in Swiss Francs. As there is a low volume of intercompany transactions and there is not an extensive interrelationship between the operations of the subsidiaries and the parent, we have determined that the Swiss Franc is the functional currency for our foreign subsidiaries. Our reporting currency is the United States dollar. The financial statements of our foreign subsidiaries are translated into USD for consolidation purposes. All assets and liabilities are translated using period-end exchange rates. Statements of operations items are translated using average exchange rates for the period. The resulting translation adjustments are recorded as a component of stockholders' equity, comprising all of the accumulated other comprehensive income (loss). Sales to certain customers and purchases from certain

parent are in currencies other than USD and are subject to foreign currency exchange rate fluctuations. Foreign currency transaction gains and loss (income) (expense) in the Consolidated Statements of Operations.

Cash and Cash Equivalents

Cash and Cash Equivalents

Cash and cash equivalents represent demand deposits at commercial banks and highly liquid investments with an original maturity of three months or less. Cash and cash equivalents, consisting of investments in money market funds and bank certificate of deposits, are remeasured and reported at fair value each reporting period. Cash and cash equivalents, which is a Level 1 input within the three-level valuation hierarchy for disclosure of fair value measurements, and totaled \$26,889 and \$36,201 as of December 31, 2021 and 2020, respectively.

Investments

Investments

From time to time, we also invest in bank certificates of deposit that are classified as held-to-maturity because of our intent and ability to hold securities to maturity. Investments with original maturities greater than three months but less than one year are classified as short-term investments on the Consolidated Balance Sheet. Investment securities are carried at their amortized cost and fair value is determined by quoted market prices for identical or similar securities. The carrying amount of short-term investments as of December 31, 2021 approximate fair value.

Fair Value Measurements

Fair Value Measurements

Financial assets and liabilities are required to be measured and reported at fair value each reporting period. Fair value is defined 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. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. When considering market participant assumptions in fair value measurement, the following fair value hierarchy distinguishes between the three levels of unobservable inputs, which are categorized in one of the following levels.

- **Level 1:** Unadjusted quoted prices which are available in active markets for identical assets or liabilities accessible to us at the measurement date.
- **Level 2:** Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities in active markets; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the asset or liability.
- **Level 3:** Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The hierarchy gives the highest priority to Level 1, as this level provides the most reliable measure of fair value, while given the lowest priority to Level 3.

Financial assets and liabilities that are not measured at fair value on a recurring basis include held-to-maturity investments and long-term debt as of December 31, 2021 and 2020, which approximate fair value. The estimated fair value of debt is based on Level 2 inputs, including our understanding of current market rates and terms of the loans. The fair value of our cash and cash equivalents, accounts receivable, other receivables, contract assets, accounts payable and accrued liabilities are measured at fair value due to their short-term nature.

We measure certain financial instruments at fair value on a nonrecurring basis. These assets primarily include goodwill and intangible assets, as well as property, plant and equipment and right-of-use lease assets. These assets were initially measured and recognized at amounts equal to the fair value determined as of the date of acquisition. Periodically, these assets are tested for impairment, by comparing their respective carrying values to the estimated fair value of the reporting unit in which they reside. In the event any of these assets were to become impaired, we would recognize an impairment loss equal to the amount by which the carrying value of the reporting unit, impaired asset or asset group exceeds its estimated fair value. Fair value measurement of the reporting unit associated with our goodwill is performed at least annually in the fourth quarter of each calendar year for purposes of impairment testing if a quantitative analysis is performed. Fair value measurements for our intangible assets, other long-lived assets and property and equipment are estimated when events or changes in circumstances such as market conditions, physical change, legal factors or other matters indicate that the carrying value may not be recoverable.

Accounts Receivable

Accounts Receivable

Trade accounts receivable represents amounts billed to customers and are stated at the amount we expect to collect. Customer creditworthiness, payment history and the customer and changes in customer payment terms are factors considered when determining collectability of specific customer accounts. As of December 31, 2021, the trade accounts receivable balance was due primarily from Teva and major wholesale distributors. Each of these customers have historically paid in a timely manner and demonstrated creditworthiness. Accordingly, we believe the risk of accounts being uncollectible is minimal and no significant allowances for doubtful accounts are established as of December 31, 2021 or 2020. If the financial condition of our customers were to deteriorate, adversely affecting their ability to make payments, additional allowances may be required. We had no material write-offs to bad debt expense in the years ended December 31, 2021, 2020 or 2019.

Royalties receivable from partners are included in accounts receivable and are typically payable to us within 45 to 60 days after the end of each quarter. Royalties earned.

Inventories

Inventories

Inventories are stated at the lower of cost or net realizable value with cost determined on a first-in, first-out basis. Certain components of our production are sourced from a limited number of vendors, and our production, assembly, warehousing and distribution operations are outsourced to third-party suppliers where such components of inventory is located. Disruption of supply from key vendors or third-party suppliers may have a material adverse impact on our operations and financial results.

We record reserves for potentially excess, dated or obsolete inventories based on forecasted product demand estimates and the likelihood of consumptions in the near course of business, considering the expiration dates of the inventories on hand, planned production volumes and lead times required for restocking. Although every effort is made to ensure that forecasts and assessments are reasonable, changes to these assumptions are possible. In such cases, estimates may be inaccurate and result in an understatement or overstatement of the reserves required to fairly state such inventories.

[Contract Assets](#)

Contract Assets

Contract assets are recognized when control of goods or services has transferred to the customer, and corresponding revenue is recognized on an accrual basis, but is not yet billable to the customer in accordance with the terms of the contract. Costs that have been incurred in connection with development services performed under contracts, which the associated revenue has not yet been recognized are also recorded as contract assets and totaled \$564 and \$1,685 as of December 31, 2022 and 2021, respectively.

[Property and Equipment](#)

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation is computed using the straight-line method over an asset's estimated useful life as follows:

	Useful Life
Computer equipment and software	3-5 years
Furniture, fixtures and office equipment	5-7 years
Production molds, tooling and equipment	3-10 years
Leasehold improvements	Lesser of useful life or lease term

Expenditures, including interest costs, for assets under construction and internal-use software that are not yet ready for their intended use are capitalized. Assets are depreciated based on the above guidelines when placed in service. Costs associated with repairs and maintenance activities are expensed as incurred.

[Leases](#)

Leases

We recognize right-of-use ("ROU") assets and lease liabilities when we obtain the right to control the asset under a leasing arrangement with an initial term of more than twelve months. We evaluate the nature of each lease at the inception of an arrangement to determine whether it is an operating or financing lease. For operating leases, an asset and lease liability based on the present value of future minimum lease payments over the expected lease term. Our leases do not generally contain variable lease payments; therefore, we use the incremental borrowing rate we would expect to pay to borrow on a similar collateralized basis over a similar term in our market to determine the present value of our lease payments. The incremental borrowing rate is used in determining the present value of lease payments, unless an implicit rate is readily determinable. Lease arrangements contain renewal options that have not been included in the determination of the lease term, as they are not reasonably certain to be exercised. If a lease contains both lease and non-lease components, we account for both components as a single lease component. Variable lease payments are expensed as incurred.

[Intangible Assets](#)

Intangible Assets

We capitalize and include the costs of acquired product licenses and trademark rights as intangible assets. These intangible assets with finite useful lives are amortized over their estimated useful lives less accumulated amortization. Amortization is computed on a straight-line basis over the shorter of the contractual or estimated economic life of the intangible asset. The useful life generally ranges from five to ten years.

[Impairment of Long-Lived Assets and Intangible Assets](#)

Impairment of Long-Lived Assets and Intangible Assets

Long-lived assets and intangible assets are reviewed for impairment whenever events or changes in circumstances such as market value, asset utilization, legal factors or other matters indicate that the carrying value of an asset or asset group may not be recoverable. The impairment test is based on a comparison of the carrying value of the asset or asset group with its undiscounted cash flows expected to be generated from the use of the asset or asset group and its eventual disposition to the carrying value of the asset or asset group. If indicated, the asset is written down by the amount by which the carrying value of the asset exceeds the related fair value of the asset with the related impairment recognized within the Consolidated Statement of Operations. The determination of an asset's fair value requires management to make certain estimates.

[Goodwill](#)

Goodwill

Goodwill is evaluated for impairment annually as of December 31, or more frequently if an event occurs or circumstances change such as market conditions, legal factors or other matters that indicate the carrying value may not be recoverable. Evaluating goodwill for impairment involves the determination of the fair value of each reporting unit in which goodwill is recorded using a qualitative or quantitative analysis. A reporting unit is an operating segment or a component of an operating segment for which discrete financial information is available and reviewed by management on a regular basis.

[Revenue Recognition](#)

Revenue Recognition

We generate revenue from proprietary and partnered product sales, license and development activities and royalty arrangements. Revenue is recognized when we transfer control of the promised goods or services to the customer at the transaction price, which is the amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services.

At inception of each contract, we identify the goods and services that have been promised to the customer and each of those that represent a distinct performance obligation. We determine the transaction price including any variable consideration, allocate the transaction price to the distinct performance obligations and determine the amount of revenue to recognize when control transfers to the customer at a point in time or over time. Variable consideration is included in the transaction price to the extent that it is probable that we will receive the consideration.

in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. We maintain reserves for variable consideration at each reporting date and make adjustments, if necessary, which may affect revenue and earnings in periods in which the actual amounts become known.

We have elected to recognize the cost for freight and shipping activities as a fulfillment cost. Amounts billed to customers for shipping and handling are included in the transaction price and recognized as revenue when control of underlying goods are transferred to the customer. The related shipping and freight costs are included in cost of product sales in the Consolidated Statements of Operations.

Proprietary Product Sales

We sell our proprietary commercial products primarily to wholesale and specialty distributors. Revenue is recognized when control has transferred to the customer, typically upon delivery, at the net selling price, which reflects the variable consideration for which reserves and sales allowances are established for discounts, wholesale distribution fees, prompt payment discounts, government rebates and chargebacks, plan rebate arrangements and patient discount and sales commissions.

The determination of certain reserves and sales allowances requires us to make a number of judgements and estimates to reflect our best estimate of the amount of consideration to which we believe we would be ultimately entitled to receive. The expected value is determined based on unit sales volume, contracts with customers and third-party payers, historical and estimated future percentage of rebates incurred on sales, historical and future insurance plan participation rates, anticipated changes in programs or regulations that would impact the amount of the actual rebates, customer purchasing patterns, product expiration dates and inventory in the distribution channel. Reserves for prompt payment discounts are recorded as a reduction in accounts receivable in the Consolidated Balance Sheet. Reserves for returns, distributor fees, rebates and customer co-pay support programs are included within current liabilities in the Consolidated Balance Sheet.

Wholesaler Distribution Fees – Distribution fees are paid to certain wholesalers based on contractually determined rates and units purchased. Since the fee is not for a distinct good or service, the consideration is recognized as a reduction of the transaction price of the goods delivered. We accrue the fee at the time of sale based on the contracted price and adjust the accrual at each reporting period, if necessary, to reflect actual experience.

Prompt Pay Discounts – We offer cash discounts to our customers, generally 2% of the sales price, as an incentive for prompt payment. Based on historical experience, customers take advantage of this discount and accordingly we accrue 100% of the cash discounts offered by reducing accounts receivable and recognizing a reduction of revenue in the same period the related sales are made. The accrual is reviewed at each reporting period and adjusted if actual experience differs from the estimate.

Chargebacks – We provide discounts primarily to authorized users of the Federal Supply Schedule (“FSS”) of the General Services Administration. These entities purchase products from distributors at a discounted price, and the wholesale distributors then charge us back the difference between the current wholesale acquisition cost and the price paid for the product. We estimate and accrue chargebacks based on estimated wholesaler inventory levels, current contract prices and historical chargeback rates. Chargebacks are recognized as a reduction of revenue in the same period the related revenue is recognized.

Rebates – We participate in certain government and insurance plan rebate programs, which provide discounted prescriptions to qualified insured persons. In these programs, we pay a rebate to the third-party administrators of the programs. The rebate payments are generally made in periods subsequent to the period the prescriptions subject to the rebate are filled, generally on a two- to three-month lag for insurance plan rebates and three- to six-month lag for government programs. We estimate and accrue for these rebates based on unit sales data, contractual terms with third-party payers, historical and estimated future percentage of prescriptions filled, sales, historical and future insurance plan billings, any new or anticipated changes in programs or regulations that would impact the amount of the rebates and levels of inventory in the distribution channel. Rebates are recognized as a reduction of revenue in the same period the related revenue is recognized.

Patient Discount Programs – We offer discount cards, co-pay coupons and free trial programs to off-set the cost of prescriptions to patients. We estimate the amount of discounts that will be redeemed or used based on historical redemption experience and on levels of inventory in the distribution and retail channels, and recognize a reduction of revenue in the same period the related revenue is recognized.

Product Returns – Consistent with industry practice, we generally offer wholesalers and specialty distributors a limited right to return products, generally within 30 days prior to and 12 months following the product’s expiration date. Our proprietary products generally have expiration dates ranging from 24 to 33 months. We estimate and record at the time of sale based on historical return patterns. Actual returns are tracked by individual production lots and charged back to the customer. Reserves may be adjusted, if necessary, if actual returns differ from historical estimates. We also monitor and take into consideration the amount of inventory in the distribution channel, product dating and any known or expected changes in the marketplace when establishing the estimated rate of returns.

Partnered Product Sales

We are party to several license, development, supply and distribution arrangements with pharmaceutical partners, under which we produce and distribute certain products, devices and/or components. Revenue is recognized when or as control of the goods transfers to the customer as discussed below.

We are the exclusive supplier of the Makena[®] subcutaneous auto injector product to Covis and beginning in December 2021, OTREXUP[®] to Otis. These products are custom manufactured for each customer with no alternative use and we have a contractual right to payment for performance completed to date. Control is transferred to the customer as the product is produced pursuant to firm purchase orders. Revenue is recognized over time using the output method, which is the selling price and number of units produced. The amount of revenue recognized in excess of the amount shipped/billed to the customer, if any, is recorded as a liability in the Consolidated Balance Sheets due to the short-term nature in which the amount is ultimately expected to be billed and collected from the customer.

All other partnered product sales are recognized at the point in time in which control is transferred to the customer, which is typically upon shipment. Return and pricing are governed by the respective supply and distribution agreements, and there is generally no right of return. Revenue is recognized at the time of sale.

includes the contractual per unit selling price and estimated variable consideration, such as volume-based pricing arrangements or profit-sharing arrangements, to recognize revenue, including the estimated variable consideration we expect to receive for contract margin on future commercial sales, upon shipment to the partner. The estimated variable consideration is recognized at an amount we believe is not subject to significant reversal based on historical experience in each reporting period if the most likely amount of expected consideration changes or becomes fixed.

Licensing and Development Revenue

We have entered into several license, development and supply arrangements with pharmaceutical partners under which we grant a license to our drug know-how and provide research and development services that often involve multiple performance obligations and highly customized deliverables. We identify each of the promised goods and services within the contract and the distinct performance obligations at inception and allocate consideration to each obligation based on relative standalone selling price, which is generally determined based on the expected cost plus mark-up.

If the contract includes an enforceable right to payment for performance completed to date and performance obligations are satisfied over time, we recognize revenue over the development period using either the input or output method depending on which is most appropriate given the nature of the distinct deliverables. If the contract does not contain an enforceable right to payment for performance completed to date, revenue is recognized when control is transferred to the customer. Indicators that the transfer of control has occurred include the transfer of legal title, transfer of physical possession, the customer has obtained the significant benefits of ownership of the assets and we have a present right to payment.

Our typical payment terms for development contracts may include an upfront payment equal to a percentage of the total contract value with the remainder billed upon completion and transfer of the individual deliverables or satisfaction of the individual performance obligations. We record a liability for the upfront payment in advance of performance, which is presented within deferred revenue in the Consolidated Balance Sheets and recognized as revenue when the associated performance obligations have been satisfied. We recognized \$3,889 in licensing and development revenue in connection with contract liabilities that were outstanding as of December 31, 2020 and satisfied during the year ended December 31, 2021.

License fees and milestones received in exchange for the grant of a license to our functional intellectual property ("IP") such as patented technology, in connection with a partnered development arrangement are generally recognized at inception of the arrangement, or over the development period depending on the circumstances, as the license is generally not distinct from the non-licensed goods or services to be provided under the contract. Milestone payments are recognized upon the occurrence of future events, are evaluated and recorded at the most likely amount, and to the extent that it is probable that a significant reversal of the associated uncertainty is resolved.

Royalties

We earn royalties in connection with licenses granted under license and development arrangements with partners. Royalties are based upon a percentage of net sales of partnered products with rates ranging from mid-single digits to low double digits and are tiered based on levels of net sales. These sales-based royalties are generally reported and payable to us within 45 to 60 days of the end of the period in which the commercial sales are made. We base our royalties on actual sales information from our partners when available or estimated prescription sales from external sources and estimated net selling price. If actual sales received are different than amounts estimated, we would adjust the royalty revenue in the period in which the adjustment becomes known.

Remaining Performance Obligations

Remaining performance obligations represent the transaction price of firm orders and development contract deliverables for which work has not been fully fulfilled, and excludes potential purchase orders under ordering-type supply contracts with indefinite delivery or quantity. As of December 31, 2020, the remaining performance obligations, excluding contracts with an original expected length of one year or less, was \$14,879. We expect to recognize the remaining performance obligations over the next three years, with the majority being recognized in the next twelve months.

Share-Based Compensation

Share-Based Compensation

We use share-based compensation in the form of stock options, restricted stock units ("RSUs") and performance-based restricted stock units ("PSUs"). The Black-Scholes model is used to determine the fair value of stock options. The fair values of RSU and PSU grants containing service or performance conditions are based on the fair value of our common stock on the date of grant. The fair value of PSUs containing a market condition are estimated using a Monte Carlo simulation. The portion of the award that is ultimately expected to vest is expensed ratably over the requisite service period as compensation expense in the Consolidated Statement of Operations. Forfeitures are recorded as incurred. Assumptions concerning our stock price volatility and projected employee exercise behavior over the term of the award impact the estimated fair value of the stock option awards.

Research and Development

Research and Development

Research and development expenses include costs directly attributable to the conduct of research and development programs including personnel salaries, supplies associated with design work and prototype development, FDA filing fees and the cost of services provided by outside contractors such as clinical trials. All costs associated with research and development activities are expensed as incurred.

Income Taxes

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to tax

which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that includes the enactment date. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

We account for uncertain tax positions in accordance with ASC 740, *Income Taxes* (“ASC 740”), which applies to all tax positions related to income taxes. A tax position is recognized when it is more-likely-than-not that a tax position will be sustained upon examination by the authorities. Interest and penalties accrued on unrecognized tax positions are recognized as a component of income tax expense in the Consolidated Statements of Operations.

Earnings (Loss) Per Common Share

Earnings (Loss) Per Common Share

Basic earnings (loss) per common share is computed by dividing the net income (loss) applicable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted earnings (loss) per common share is computed in a similar manner, except that the weighted average number of common shares is increased to reflect the potential dilution from the exercise or conversion of securities into common stock. Diluted earnings (loss) per common share is computed assuming the complete conversion to common shares of all convertible instruments only if such instruments are dilutive in nature with respect to earnings (loss).

Segments

Segments

Operating segments are components of an enterprise for which separate financial information is available and is evaluated regularly by the Chief Financial Officer (“CODM”), our Chief Executive Officer, in deciding how to allocate resources and assess performance. Our CODM currently evaluates our operations from a number of different operational perspectives, including but not limited to, on a product-by-product, customer and partner basis. We derive all significant revenue from pharmaceutical products and development services, and have a single reportable, operating segment of business.

Going Concern

Going Concern

We are responsible for evaluating, and providing disclosure of uncertainties about, our ability to continue as a going concern. As of December 31, 2021, we had cash equivalents of \$65,913. Based on our evaluation, we concluded there is no substantial doubt or uncertainty about our ability to meet our obligations for the next 12 months from the date the Consolidated Financial Statements were issued.

**Summary of Significant
Accounting Policies (Tables)**

[Accounting Policies](#)

[\[Abstract\]](#)

[Summary of Property and
Equipment, Net](#)

**12 Months Ended
Dec. 31, 2021**

Property and equipment are stated at cost less accumulated depreciation. Depreciation is computed using the straight-line method over an asset's useful life as follows:

	Useful Life
Computer equipment and software	3-5 years
Furniture, fixtures and office equipment	5-7 years
Production molds, tooling and equipment	3-10 years
Leasehold improvements	Lesser of useful life or

Property and equipment, net consisted of the following:

	December 31, 2021
Production molds, tooling and equipment	\$ 22,000
Leasehold improvements	7,500
Furniture, fixtures and office equipment	9,000
Computer equipment and software	1,500
Construction and tooling in process	6,500
Total property and equipment	39,500
Less: Accumulated depreciation	(13,500)
Total property and equipment, net	\$ 26,000

[Summary of Changes in
Reserves for Product Returns
and Sales Allowances](#)

Changes in reserves for product returns and sales allowances are as follows:

	Rebates and Chargebacks	Patient Discount Programs	Returns	Wholesale Distribution Fees
Balance as of December 31, 2019	\$ 6,308	\$ 845	\$ 370	\$ 1,000
Accruals and adjustments	34,947	12,422	2,657	11,000
Payments and other reserve reductions	(34,068)	(11,975)	(2,569)	(10,000)
Balance as of December 31, 2020	7,187	1,292	458	2,000
Accruals and adjustments	52,243	15,629	4,163	15,000
Payments and other reserve reductions	(46,129)	(13,971)	(3,992)	(14,000)
Balance as of December 31, 2021	\$ 13,301	\$ 2,950	\$ 629	\$ 3,000

Inventories (Tables)

12 Months Ended
Dec. 31, 2021

[Inventory Disclosure](#)
[\[Abstract\]](#)
[Summary of Inventories](#)

Inventories consisted of the following:

	December 31, 20
Raw materials	\$
Work in process	6,
Finished goods	4,
Total inventories, net	\$ 11,

**Property and Equipment
(Tables)**

**12 Months Ended
Dec. 31, 2021**

[Property, Plant and
Equipment \[Abstract\]](#)
[Summary of Property and
Equipment, Net](#)

Property and equipment are stated at cost less accumulated depreciation. Depreciation is computed using the straight-line method over an asset's useful life. Depreciation expense is recorded as follows:

	Useful Life
Computer equipment and software	3-5 years
Furniture, fixtures and office equipment	5-7 years
Production molds, tooling and equipment	3-10 years
Leasehold improvements	Lesser of useful life or

Property and equipment, net consisted of the following:

	December 31, 2021
Production molds, tooling and equipment	\$ 22,000
Leasehold improvements	7,500
Furniture, fixtures and office equipment	9,000
Computer equipment and software	1,500
Construction and tooling in process	6,000
Total property and equipment	39,000
Less: Accumulated depreciation	(13,000)
Total property and equipment, net	\$ 26,000

Leases (Tables)

12 Months Ended
Dec. 31, 2021

[Leases \[Abstract\]](#)
[Summary of Operating Lease](#)
[Maturities](#)

Future lease payments under non-cancelable leases for the next five years and thereafter as of December 31, 2021 are as follows:

2022
2023
2024
2025
2026
Thereafter
Total remaining lease payments
Less: Imputed interest
Present value of lease liabilities

Intangible Assets (Tables)

12 Months Ended
Dec. 31, 2021

[Goodwill and Intangible
Assets Disclosure \[Abstract\]
Schedule of Intangible Assets](#)

Intangible assets are as follows:

	Useful Life (in Years)	December 31, 2021			December 31, 2020	
		Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization
TLANDO® product rights	10	\$ 11,315	\$ —	\$ 11,315	\$ —	\$ —
NOC DURNA® product rights	10	7,500	(937)	6,563	7,500	(937)
Patents ¹	5 - 10	1,048	(1,047)	1	3,995	(3,995)
Total intangibles, net		\$ 19,863	\$ (1,984)	\$ 17,879	\$ 11,495	\$ (4,932)

¹ Patents related to OTREXUP® were sold as part of the Asset Purchase Agreement entered into with Otter in December 2021. See Note 12 for further details regarding the sale of assets.

[Schedule of Estimated Future
Aggregate Amortization
Expense](#)

Estimated future aggregate amortization expense is as follows:

2022	
2023	
2024	
2025	
2026	
Thereafter	
Total future amortization expense	

Accrued Expenses and Other
Current Liabilities (Tables)

12 Months Ended
Dec. 31, 2021

[Payables and Accruals](#)
[\[Abstract\]](#)

[Schedule of Accrued Expenses
and Other Liabilities](#)

Accrued expenses and other liabilities consisted of the following:

	December 31, 20
Product returns and sales allowances	\$ 20,
Accrued employee compensation and benefits	5,
License fees payable	
Other accrued expenses and liabilities	8,
Total accrued expense and other liabilities	\$ 35,

Long-Term Debt (Tables)

12 Months Ended
Dec. 31, 2021

[Debt Disclosure \[Abstract\]](#)
[Schedule of Future Principal](#)
[Payments under Term Loan,](#)
[Excluding End of Term](#)
[Charge](#)

Future principal payments under the Term Loan Facility are as follows:

2022

2023

2024

Total future principal payments

**Share Based Compensation
(Tables)**

**12 Months Ended
Dec. 31, 2021**

[Share-based Compensation
Arrangement by Share-
based Payment Award \[Line
Items\]](#)

[Summary of Stock Option
Activity](#)

Stock option activity under the Plan is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
Outstanding as of December 31, 2018	14,079	\$ 2.19	
Granted	2,489	3.01	
Exercised	(2,572)	1.76	
Cancelled / Forfeited	(135)	2.81	
Outstanding as of December 31, 2019	13,861	2.41	
Granted	3,335	2.73	
Exercised	(939)	1.93	
Cancelled / Forfeited	(736)	2.83	
Outstanding as of December 31, 2020	15,521	2.49	
Granted	2,660	4.37	
Exercised	(2,307)	2.27	
Cancelled / Forfeited	(297)	3.02	
Outstanding as of December 31, 2021	15,577	2.83	
Exercisable as of December 31, 2021	10,644	\$ 2.46	

[Assumptions Used in Fair
Value Measurement of Options
Granted](#)

	Years Ended December	
	2021	2020
Risk-free interest rate	0.8 %	0.4
Annualized volatility	59.3 %	59.4
Weighted average expected life (in years)	5.4	5.0
Expected dividend yield	0.0 %	0.0

[Schedule of Performance
Stock Unit Awards and
Restricted Stock Granted
Under Long-Term Incentive
Program](#)

PSUs and RSUs granted under the LTIP are summarized as follows:

	Performance Stock Units		Restricti
	Number of Shares	Weighted Average Grant Date Fair Value	Number of Shares
Outstanding as of December 31, 2018	1,842	\$ 2.41	1,842
Granted	593	2.99	593
Incremental shares earned	59	1.25	59
Vested / Settled	(415)	1.18	(415)
Forfeited / Expired	(238)	1.12	(238)
Outstanding as of December 31, 2019	1,841	3.00	1,841
Granted	605	2.00	605
Incremental shares earned	77	3.10	77
Vested / Settled	(388)	3.11	(388)
Forfeited / Expired	(494)	3.02	(494)
Outstanding as of December 31, 2020	1,641	2.61	1,641
Granted	243	5.55	243
Incremental shares earned	210	3.18	210
Vested / Settled	(766)	2.86	(766)
Outstanding as of December 31, 2021	1,328	\$ 3.04	1,328

[Summary of Share Based
Compensation Allocation
Expense](#)

Compensation costs incurred in connection with share-based awards are as follows:

	Years Ended December 31	
	2021	2020
Stock options	\$ 4,102	\$ 3,102
Restricted stock units	\$ 2,620	\$ 2,620
Performance stock units	\$ 1,293	\$ 1,293
Total share-based compensation expense	\$ 8,015	\$ 7,015

[Performance Stock Units
Share-based Compensation
Arrangement by Share-
based Payment Award \[Line
Items\]
Assumptions Used in Fair
Value Measurement of Options
Granted](#)

The fair values of the TSR PSUs granted were determined using a Monte Carlo simulation and used the following inputs

	2021 Award	2020 Award
Closing stock price on grant date	\$ 4.42	\$ 2.73
Performance period starting price	\$ 3.70	\$ 4.78
Term of award (in years)	2.56	2.55
Volatility	54.4 %	57.5 %
Risk-free interest rate	0.23 %	0.21 %
Expected dividend yield	0.00 %	0.00 %
Fair value per TSR PSU	\$ 5.55	\$ 2.00

Income Taxes (Tables)

12 Months Ended
Dec. 31, 2021

[Income Tax Disclosure](#)

[\[Abstract\]](#)

[Schedule of Income \(Loss\)](#)

[before Income Tax Domestic](#)

[and Foreign](#)

We were subject to taxes in both the U.S. and Switzerland in each of the years ended December 31, 2021, 2020 and 2019. Income (loss) before income taxes from the following jurisdictions:

	Years Ended December 31,	
	2021	2020
U.S.	\$ 62,626	\$ 10,355
Switzerland	(355)	(3,000)
Total income (loss) before income taxes	\$ 62,271	\$ 9,355

[Schedule of Income Tax](#)

[Expense \(Benefit\)](#)

The income tax provision (benefit) was comprised of:

	Years Ended December 31,	
	2021	2020
Current		
Federal	\$ —	\$ —
State	2,041	1,000
Foreign	2	—
Total current income tax provision (benefit)	2,043	1,000
Deferred		
Federal	11,918	(39,500)
State	2,021	(7,400)
Foreign	—	—
Total deferred income tax provision (benefit)	13,939	(46,900)
Total income tax provision (benefit)	\$ 15,982	\$ (46,200)

[Summary of Effective Tax](#)

[Rates Differ from Statutory](#)

[Income Tax Rates](#)

Effective tax rates differ from statutory income tax rates as follows:

	Years Ended December 31,	
	2021	2020
Statutory income tax rate	21.0 %	21.0 %
State income taxes	5.5	7.1
Effect of foreign operations	0.1	0.2
Changes in valuation allowance	(0.2)	(516.5)
Change in unused net operating loss and credit carryforwards	—	—
Change in uncertain tax positions	(0.1)	21.4
Research and development credit	(0.7)	(6.0)
Stock-based compensation	(2.0)	3.7
162(m) limitation	2.1	1.9
Nondeductible items	—	1.6
Impact of Tax Cuts and Jobs Act	—	—
Other	—	(0.9)
Effective income tax rate	25.7 %	(466.5)

[Summary of Deferred Tax](#)

[Assets \(Liabilities\)](#)

Deferred tax assets (liabilities) consist of the following:

	December 31, 20
Gross deferred tax assets	
Net operating loss carryforward – U.S.	\$ 24,
Net operating loss carryforward – Switzerland	
Research and development tax credit carryforward	5,
Deferred revenue	
Stock-based compensation	3,
Inventory reserve	
Compensation accruals	1,
Product reserves	5,
Operating lease liabilities	1,
Amortization	
Other	
Total deferred tax assets	42,
Deferred tax liabilities	
Depreciation	(1,7
Operating lease right-of-use asset	(1,0
Installment sale	(5,5
Total deferred tax liabilities	(8,
Net deferred tax asset before valuation allowance	34,
Less: Valuation allowance	(1,
Net deferred tax asset	\$ 33,

[Schedule of Unrecognized Tax Benefits](#)

A summary of changes to our liability for unrecognized tax benefits is as follows:

	December 31, 20
Beginning liability for unrecognized tax benefits	\$ 2,
Increase (decrease) due to tax positions related to prior years	0
Increase due to tax positions related to the current year	
Ending liability for unrecognized tax benefits	\$ 2,

**Revenues, Significant
Customers and
Concentrations of Risk
(Tables)**

12 Months Ended

Dec. 31, 2021

**[Revenue from Contract with
Customer \[Abstract\]](#)**

**[Summary of Revenues
Disaggregated by Major Types
and Sources and Customer
Geographic Location](#)**

We disaggregate our revenue by type of goods and services and customer location.

	Years Ended December	
	2021	2020
Types of Goods and Services		
Proprietary product sales, net	\$ 80,016	\$ 62,016
Partnered product sales	46,651	50,900
Total product revenue, net	126,667	113,916
Licensing and development revenue	19,623	14,623
Royalties	37,692	21,692
Total revenue, net	\$ 183,982	\$ 149,231
Customer Location		
U.S.	\$ 178,290	\$ 145,290
Europe	5,692	3,692
Other	—	—
Total revenue, net	\$ 183,982	\$ 149,231

**[Summary of Significant
Customers from which the
Company Derived 10% or
More of Total Revenue](#)**

Customers from which we derive 10% or more of our total revenue are as follows:

	Years Ended December	
	2021	2020
Teva	42%	40%
McKesson ¹	13%	12%
AmerisourceBergen Corporation ¹	12%	12%
Cardinal Health ¹	11%	11%
Covis	<10%	<10%

¹ Revenue from sales to distributors, net of estimated sales returns and allowances based on shipments.

**Earnings (Loss) per Share
(Tables)**

**12 Months Ended
Dec. 31, 2021**

[Earnings Per Share](#)

[\[Abstract\]](#)

[Summary of Computation for](#)

[Basic and Diluted Earnings](#)

[\(Loss\) per Common Share](#)

The following table sets forth the computation for basic and diluted earnings (loss) per common share:

	Years Ended December	
	2021	2020
Net income (loss)	\$ 46,289	\$ 56,289
Weighted average common shares outstanding	169,226	166,226
Dilutive effects of stock options and share-based awards issuable under equity compensation plans	5,507	4,507
Weighted average dilutive common shares outstanding	174,733	170,733
Earnings (loss) per common share		
Basic	\$ 0.27	\$ 0.34
Diluted	\$ 0.26	\$ 0.33
Anti-dilutive common stock equivalents ¹	2,224	7,224

¹ These common stock equivalents were outstanding for the period but were not included in the computation of diluted earnings (loss) per common share as their inclusion would have had an anti-dilutive effect.

**Summary of Significant
Accounting Policies -
Additional Information
(Detail)**

Summary of Significant Accounting Policies [Line Items]

Wholly-owned subsidiaries of Antares Pharma | subsidiary

Allowance for doubtful accounts balance

Write-offs to bad debt expense

Revenue not yet recognized recorded in contract assets

Finite-lived intangible assets, amortization method

Goodwill

Goodwill impairment loss

Cash discount to incentive for prompt payment

Cash discounts offered by reducing accounts receivable

Limited rights for product return, period before product expiration

Product Return Policy, Limited Rights, Period After Product
Expiration

Remaining performance obligations

Cash, cash equivalents and investments

Licensing and development revenue

Summary of Significant Accounting Policies [Line Items]

Revenue recognized

Minimum

Summary of Significant Accounting Policies [Line Items]

Royalty payment period

Useful Life (in Years)

Product expiration period

Minimum | Insurance plans

Summary of Significant Accounting Policies [Line Items]

Rebate payment period

Minimum | Government

Summary of Significant Accounting Policies [Line Items]

Rebate payment period

Maximum

Summary of Significant Accounting Policies [Line Items]

Royalty payment period

Useful Life (in Years)

Product expiration period

Maximum | Insurance plans

Summary of Significant Accounting Policies [Line Items]

Rebate payment period

Maximum | Government

Summary of Significant Accounting Policies [Line Items]

12 Months Ended		
Dec. 31, 2021	Dec. 31,	Dec. 31,
USD (\$)	2020	2019
subsidiary	USD (\$)	USD (\$)

2		
\$ 0	\$ 0	
0	0	\$ 0
\$ 564,000	1,685,000	
straight-line		
basis		
\$ 1,095,000	1,095,000	
\$ 0	0	\$ 0
2.00%		
100.00%		
6 months		
12 months		
\$ 14,879,000		
65,913,000		
\$ 3,889,000		
45 days		
5 years		
24 months		
2 months		
3 months		
60 days		
10 years		
33 months		
3 months		

[Rebate payment period](#)

6 months

[Level 1 Input](#)

[Summary of Significant Accounting Policies \[Line Items\]](#)

[Cash and cash equivalents, remeasured and reported at fair value](#)

\$ 26,889,000

\$ 36,133,000

**Summary of Significant
Accounting Policies -
Remaining Performance
Obligations (Detail)**

**Dec. 31,
2021**

Revenue, Remaining Performance Obligation, Expected Timing of Satisfaction, Start Date:
2022-01-01

Summary of Significant Accounting Policies [Line Items]

Remaining performance obligation, expected to recognize, period

3 years

**Summary of Significant
Accounting Policies -
Summary of Estimated
Useful Lives of Property and
Equipment (Details)**

12 Months Ended

Dec. 31, 2021

<u>Computer equipment and software Minimum Property, Plant and Equipment [Line Items]</u>	
<u>Property, plant and equipment, useful life</u>	3 years
<u>Computer equipment and software Maximum Property, Plant and Equipment [Line Items]</u>	
<u>Property, plant and equipment, useful life</u>	5 years
<u>Furniture, fixtures and office equipment Minimum Property, Plant and Equipment [Line Items]</u>	
<u>Property, plant and equipment, useful life</u>	5 years
<u>Furniture, fixtures and office equipment Maximum Property, Plant and Equipment [Line Items]</u>	
<u>Property, plant and equipment, useful life</u>	7 years
<u>Production molds, tooling and equipment Minimum Property, Plant and Equipment [Line Items]</u>	
<u>Property, plant and equipment, useful life</u>	3 years
<u>Production molds, tooling and equipment Maximum Property, Plant and Equipment [Line Items]</u>	
<u>Property, plant and equipment, useful life</u>	10 years
<u>Leasehold improvements</u>	
<u>Property, Plant and Equipment [Line Items]</u>	
<u>Property, plant and equipment, estimated useful lives</u>	Lesser of useful life or lease term

**Summary of Significant
Accounting Policies -
Summary of Changes in
Reserves for Product
Returns and Sales
Allowances (Detail) - USD
(\$)
\$ in Thousands**

12 Months Ended

Dec. 31, 2021 Dec. 31, 2020

Rebates and Chargebacks

Revenue From Contract With Customer Contractual Adjustments [Line Items]

<u>Balance at beginning of year</u>	\$ 7,187	\$ 6,308
<u>Accruals and adjustments</u>	52,243	34,947
<u>Payments and other reserve reductions</u>	(46,129)	(34,068)
<u>Balance at end of year</u>	13,301	7,187

Patient Discount Programs

Revenue From Contract With Customer Contractual Adjustments [Line Items]

<u>Balance at beginning of year</u>	1,292	845
<u>Accruals and adjustments</u>	15,629	12,422
<u>Payments and other reserve reductions</u>	(13,971)	(11,975)
<u>Balance at end of year</u>	2,950	1,292

Returns

Revenue From Contract With Customer Contractual Adjustments [Line Items]

<u>Balance at beginning of year</u>	458	370
<u>Accruals and adjustments</u>	4,163	2,657
<u>Payments and other reserve reductions</u>	(3,992)	(2,569)
<u>Balance at end of year</u>	629	458

Wholesaler Distribution Fees

Revenue From Contract With Customer Contractual Adjustments [Line Items]

<u>Balance at beginning of year</u>	2,498	1,683
<u>Accruals and adjustments</u>	15,683	11,619
<u>Payments and other reserve reductions</u>	(14,498)	(10,804)
<u>Balance at end of year</u>	3,683	2,498

Prompt Payment Discounts

Revenue From Contract With Customer Contractual Adjustments [Line Items]

<u>Balance at beginning of year</u>	436	320
<u>Accruals and adjustments</u>	3,423	2,494
<u>Payments and other reserve reductions</u>	(3,222)	(2,378)
<u>Balance at end of year</u>	\$ 637	\$ 436

**Inventories - Summary of
Inventories (Detail) - USD
(\\$)**

Dec. 31, 2021 Dec. 31, 2020

\$ in Thousands

[Inventory Disclosure \[Abstract\]](#)

<u>Raw materials</u>	\$ 325	\$ 325
<u>Work in process</u>	6,784	7,120
<u>Finished goods</u>	4,435	10,771
<u>Total inventories, net</u>	\$ 11,544	\$ 18,216

**Inventories - Additional
Information (Detail) - USD**

(\$)

\$ in Thousands

12 Months Ended

Dec. 31, 2021 Dec. 31, 2020

[Inventory Disclosure \[Abstract\]](#)

<u>Inventory reserve</u>	\$ 214	\$ 619
<u>Inventory written-off</u>	359	356
<u>Increase in inventory reserve</u>	\$ (46)	\$ 511

**Property and Equipment -
Summary of Property and
Equipment (Detail) - USD (\$)
\$ in Thousands**

Dec. 31, 2021 Dec. 31, 2020

Property, Plant and Equipment [Line Items]

<u>Total property and equipment</u>	\$ 39,194	\$ 34,393
<u>Less: Accumulated depreciation</u>	(13,179)	(10,373)
<u>Total property and equipment, net</u>	26,015	24,020

Production molds, tooling and equipment

Property, Plant and Equipment [Line Items]

<u>Total property and equipment</u>	22,069	20,260
-------------------------------------	--------	--------

Leasehold improvements

Property, Plant and Equipment [Line Items]

<u>Total property and equipment</u>	7,559	6,298
-------------------------------------	-------	-------

Furniture, fixtures and office equipment

Property, Plant and Equipment [Line Items]

<u>Total property and equipment</u>	907	865
-------------------------------------	-----	-----

Computer equipment and software

Property, Plant and Equipment [Line Items]

<u>Total property and equipment</u>	1,717	756
-------------------------------------	-------	-----

Construction and tooling in process

Property, Plant and Equipment [Line Items]

<u>Total property and equipment</u>	\$ 6,942	\$ 6,214
-------------------------------------	----------	----------

**Property and Equipment -
Additional Information
(Detail) - USD (\$)
\$ in Thousands**

12 Months Ended

Dec. 31, 2021 Dec. 31, 2020 Dec. 31, 2019

Property, Plant and Equipment [Abstract]

<u>Depreciation expense</u>	\$ 2,864	\$ 2,341	\$ 2,205
<u>Interest costs capitalized</u>	\$ 52	\$ 231	

Leases - Additional Information (Detail) ft² in Thousands	Jul. 01, 2019 USD (\$) ft² renewal_option	4 Months Ended	12 Months Ended			
		Mar. 01, 2022	Dec. 31, 2021 USD (\$) extension renewal_option	Dec. 31, 2020 USD (\$)	Dec. 31, 2019 USD (\$)	Mar. 01, 2021
Regulatory Assets [Line Items]						
Lease renewal term	3 years					2 months
Leased area ft²	75					
Lease term	12 years 6 months					
Number of renewal options renewal_option	1					
Operating lease, allowance (up to)	\$ 1,200,000					
Operating lease costs			\$ 2,176,000	\$ 2,174,000	\$ 1,391,000	
Cash paid for operating lease liabilities			2,005,000	1,884,000	1,401,000	
Non-cash operating lease ROU assets obtained in exchange for operating lease obligations			\$ 850,000	\$ 778,000	\$ 6,511,000	
Weighted average discount rate			8.90%	8.60%	8.30%	
Weighted average remaining lease term			8 years 3 months 18 days	8 years 3 months 18 days	8 years 4 months 24 days	
Subsequent Event						
Regulatory Assets [Line Items]						
Number of extensions extension		3				
Suburbs of Minneapolis						
Regulatory Assets [Line Items]						
Leased facilities renewal_option			2			

**Leases - Summary of
Operating Lease Maturities Dec. 31, 2021
(Detail) USD (\$)
\$ in Thousands**

Future Lease Payments

<u>2022</u>	\$ 1,334
<u>2023</u>	969
<u>2024</u>	762
<u>2025</u>	676
<u>2026</u>	678
<u>Thereafter</u>	3,593
<u>Total remaining lease payments</u>	8,012
<u>Less: Imputed interest</u>	(2,532)
<u>Lease liability</u>	\$ 5,480

**Intangible Assets - Schedule
of Intangible Assets (Detail) -**

12 Months Ended

USD (\$)

Dec. 31, 2021

Dec. 31, 2020

\$ in Thousands

Finite-Lived Intangible Assets [Line Items]

<u>Gross Carrying Amount</u>	\$ 19,863	\$ 11,495
<u>Accumulated Amortization</u>	(1,984)	(3,802)
<u>Net Book Value</u>	\$ 17,879	7,693

Minimum

Finite-Lived Intangible Assets [Line Items]

<u>Useful Life (in Years)</u>	5 years
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Maximum

Finite-Lived Intangible Assets [Line Items]

<u>Useful Life (in Years)</u>	10 years
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TLANDO® product rights

Finite-Lived Intangible Assets [Line Items]

<u>Useful Life (in Years)</u>	10 years	
<u>Gross Carrying Amount</u>	\$ 11,315	0
<u>Accumulated Amortization</u>	0	0
<u>Net Book Value</u>	\$ 11,315	0

NOCDURNA® product rights

Finite-Lived Intangible Assets [Line Items]

<u>Useful Life (in Years)</u>	10 years	
<u>Gross Carrying Amount</u>	\$ 7,500	7,500
<u>Accumulated Amortization</u>	(937)	(188)
<u>Net Book Value</u>	6,563	7,312

Patents

Finite-Lived Intangible Assets [Line Items]

<u>Gross Carrying Amount</u>	1,048	3,995
<u>Accumulated Amortization</u>	(1,047)	(3,614)
<u>Net Book Value</u>	\$ 1	\$ 381

Patents | Minimum

Finite-Lived Intangible Assets [Line Items]

<u>Useful Life (in Years)</u>	5 years
-------------------------------	---------

Patents | Maximum

Finite-Lived Intangible Assets [Line Items]

<u>Useful Life (in Years)</u>	10 years
-------------------------------	----------

Intangible Assets - Additional Information (Detail) - USD (\$)	1 Months Ended		3 Months Ended	12 Months Ended		
	Oct. 31, 2021	Oct. 31, 2020	Dec. 31, 2021	Dec. 31, 2021	Dec. 31, 2020	Dec. 31, 2019
Selling, General and Administrative Expenses						
Finite-Lived Intangible Assets [Line Items]						
Amortization expense				\$	\$	\$
				1,037,000	286,000	352,000
Lipocine Inc. License Agreement						
Finite-Lived Intangible Assets [Line Items]						
Upfront payment paid	\$					
	11,000,000					
Additional milestone payment	10,000,000					
Minimum royalty payments	\$ 4,500,000					
Royalty payment period	3 years					
Tiered royalties and additional commercial milestone payments	\$					
	160,000,000					
Purchase obligation			\$			
			2,002,000	2,002,000		
Purchases under license agreement			\$			
			1,056,000			
Amortization expense					\$ 315,000	
Ferring International Center S.A. and its Affiliates License Agreement						
Finite-Lived Intangible Assets [Line Items]						
Upfront payment paid	5,000,000	\$				
		5,000,000				
Tiered royalties and additional commercial milestone payments		\$				
		17,500,000				
Additional upfront payment made at one year from execution	\$ 2,500,000					

**Intangible Assets - Schedule
of Estimated Future**

Aggregate Amortization Dec. 31, 2021 Dec. 31, 2020
Expense (Detail) - USD (\$)
\$ in Thousands

Estimated Amortization Expense

<u>2022</u>	\$ 1,600	
<u>2023</u>	1,882	
<u>2024</u>	1,882	
<u>2025</u>	1,882	
<u>2026</u>	1,882	
<u>Thereafter</u>	8,751	
<u>Net Book Value</u>	\$ 17,879	\$ 7,693

**Accrued Expenses and Other
Current Liabilities -
Schedule of Accrued
Expenses and Other
Liabilities (Detail) - USD (\$)
\$ in Thousands**

Dec. 31, 2021 Dec. 31, 2020

Payables and Accruals [Abstract]

<u>Product returns and sales allowances</u>	\$ 20,563	\$ 11,435
<u>Accrued employee compensation and benefits</u>	5,648	4,555
<u>License fees payable</u>	0	2,500
<u>Other accrued expenses and liabilities</u>	8,832	7,145
<u>Total accrued expense and other liabilities</u>	\$ 35,043	\$ 25,635

Long-Term Debt - Additional Information (Detail) - USD (\$)	12 Months Ended							
	Nov. 01, 2021	Jun. 26, 2019	Jun. 16, 2017	Dec. 31, 2021	Dec. 31, 2020	Dec. 31, 2019	Jun. 25, 2019	Jun. 06, 2017
Debt Instrument [Line Items]								
Carrying value of long term debt				\$ 18,241,000	\$ 24,669,000			
Repayments of long-term debt				40,000,000	\$ 0	\$ 0		
Carrying value of debt excluding unamortized issuance costs				20,000,000				
Credit Agreement								
Debt Instrument [Line Items]								
Maximum borrowing capacity	\$ 40,000,000							
Commitment fees incurred amount				\$ 12				
Debt, weighted average interest rate				2.59%				
Credit Agreement Revolving Credit Facility								
Debt Instrument [Line Items]								
Debt instrument subject to certain exceptions percentage				100.00%				
Credit Agreement Secured Debt								
Debt Instrument [Line Items]								
Maximum borrowing capacity	20,000,000							
Credit Agreement Line of Credit Revolving Credit Facility								
Debt Instrument [Line Items]								
Maximum borrowing capacity	20,000,000							
Outstanding debt				\$ 20,000,000				
Carrying value of debt excluding unamortized issuance costs				19,741				
Amount outstanding				0				

[Credit Agreement | Line of
Credit | Letters of credit
Debt Instrument \[Line
Items\]](#)

[Maximum borrowing capacity](#) 5,000,000

[Amount outstanding](#) 0

[Credit Agreement | Line of
Credit | Swingline Loan
Debt Instrument \[Line
Items\]](#)

[Maximum borrowing capacity](#) \$
1,000,000

[Amount outstanding](#) \$ 0

[Credit Agreement | London
Interbank Offered Rate
\(LIBOR\)](#)

[Debt Instrument \[Line
Items\]](#)

[Debt Instrument, variable
interest rate](#) 2.50%

[Credit Agreement | Base Rate](#)

[Debt Instrument \[Line
Items\]](#)

[Debt Instrument, variable
interest rate](#) 1.50%

[Credit Agreement | Minimum |
Revolving Credit Facility](#)

[Debt Instrument \[Line
Items\]](#)

[Commitment fee on unused
capacity \(percent\)](#) 0.30%

[Credit Agreement | Minimum |
Federal funds rate | Letters of
credit](#)

[Debt Instrument \[Line
Items\]](#)

[Debt Instrument, variable
interest rate](#) 0.50%

[Credit Agreement | Minimum |
London Interbank Offered
Rate \(LIBOR\)](#)

[Debt Instrument \[Line
Items\]](#)

[Debt Instrument, variable
interest rate](#) 1.00%

[Credit Agreement | Minimum |
London Interbank Offered
Rate \(LIBOR\) | Letters of
credit](#)

**[Debt Instrument \[Line
Items\]](#)**

[Debt instrument, interest rate,
spread on effective percentage](#) 2.00%

[Credit Agreement | Maximum
| Revolving Credit Facility](#)

**[Debt Instrument \[Line
Items\]](#)**

[Commitment fee on unused
capacity \(percent\)](#) 0.45%

[Hercules Capital, Inc | Term
Loan](#)

**[Debt Instrument \[Line
Items\]](#)**

[Debt instrument, effective
interest rate](#) 8.50%

[Debt instrument, payment
terms](#) Payments
under the
loan were
interest-
only until
the first
principal
payment
was due.

[Prepayment fee percentage on
principal loan prepaid](#) 1.00% 1.00%

[Carrying value of long term
debt](#) \$ 20,000,000 \$ 40,899,000

[Prepayment of principal](#) \$ 20,000,000

[Debt prepayment fee](#) 200,000

[Debt instrument, end of term
fee](#) 1,655,000

[Hercules Capital, Inc | Term
Loan | Secured Debt](#)

**[Debt Instrument \[Line
Items\]](#)**

[Repayments of long-term debt](#) \$ 20,000,000

[Hercules Capital, Inc | Term
Loan | First Amendment](#)

**Debt Instrument [Line
Items]**

<u>Long-term debt, face amount</u>	\$	\$
	50,000,000	35,000,000

<u>Interest only period extension fee as a percentage of principal (percent)</u>	1.00%
--	-------

Hercules Capital, Inc | Term
Loan | Prime Based Variable
Rate

**Debt Instrument [Line
Items]**

<u>Debt Instrument, variable interest rate</u>	9.50%
--	-------

Hercules Capital, Inc | Term
Loan | Minimum

**Debt Instrument [Line
Items]**

<u>Prepayment fee percentage on principal loan prepaid</u>	1.00%
--	-------

Hercules Capital, Inc | Term
Loan | Maximum

**Debt Instrument [Line
Items]**

<u>Long-term debt, face amount</u>		\$
		35,000,000

<u>Prepayment fee percentage on principal loan prepaid</u>	3.00%
--	-------

Hercules Capital, Inc | Tranche
I Loan

**Debt Instrument [Line
Items]**

<u>Long-term debt, borrowed amount</u>		\$
		25,000,000

<u>Percentage of loan fee on original principal amount</u>	4.25%
--	-------

Hercules Capital, Inc | Tranche
II

**Debt Instrument [Line
Items]**

<u>Percentage of loan fee on original principal amount</u>	3.95%
--	-------

Hercules Capital, Inc | Tranche
II | First Amendment

**Debt Instrument [Line
Items]**

Long-term debt, increase in \$
face amount 15,000,000

Hercules Capital, Inc | Tranche
III | Minimum | First
Amendment

Debt Instrument [Line
Items]

Debt instrument, available
option to request additional 5,000,000
advance amount

Hercules Capital, Inc | Tranche
III | Maximum | First
Amendment

Debt Instrument [Line
Items]

Debt instrument, available \$
option to request additional 10,000,000
advance amount

**Long-Term Debt - Schedule
of Future Principal
Payments under Term Loan, Dec. 31, 2021
Excluding End of Term USD (\$)
Charge (Detail)
\$ in Thousands**

Future Principal Payments

<u>2022</u>	\$ 1,500
<u>2023</u>	1,500
<u>2024</u>	17,000
<u>Total future principal payments</u>	\$ 20,000

Stockholders' Equity - Additional Information (Detail) - USD (\$)	1 Months Ended	12 Months Ended		
	Aug. 31, 2017	Dec. 31, 2021	Dec. 31, 2020	Dec. 31, 2019
<u>Share-based Compensation Arrangement by Share-based Payment Award [Line Items]</u>				
<u>Aggregate offering price of common stock</u>				\$ 7,781,000
<u>Proceeds from sale of common stock</u>		\$ 0	\$ 0	\$ 7,781,000
<u>Sales Agreement Cowen and Company, LLC</u>				
<u>Share-based Compensation Arrangement by Share-based Payment Award [Line Items]</u>				
<u>Percentage of commission on proceeds from gross sales of common stock</u>	3.00%			
<u>Sales Agreement Cowen and Company, LLC Maximum</u>				
<u>Share-based Compensation Arrangement by Share-based Payment Award [Line Items]</u>				
<u>Aggregate offering price of common stock</u>	\$ 30,000,000			
<u>ATM Facility</u>				
<u>Share-based Compensation Arrangement by Share-based Payment Award [Line Items]</u>				
<u>Issuance of common stock (in shares)</u>				2,307,000
<u>Proceeds from sale of common stock</u>				\$ 7,781,000

Share Based Compensation - Additional Information (Detail) \$ / shares in Units, \$ in Thousands	1 Months Ended	3 Months Ended	12 Months Ended			
	Jun. 30, 2021 shares	Mar. 31, 2022 shares	Dec. 31, 2021 USD (\$) installment \$ / shares shares	Dec. 31, 2020 USD (\$) \$ / shares shares	Dec. 31, 2019 USD (\$) \$ / shares shares	Dec. 31, 2018 shares
Share-based Compensation Arrangement by Share-based Payment Award [Line Items]						
Increase in shares authorized for issuance (shares)	10,000,000					
Proceeds from the issuance of stock options \$			\$ 5,182	\$ 1,814	\$ 4,405	
Shares withheld to meet employees' minimum statutory income tax obligation (in shares)			626	425	409	
Payments for the employees' minimum statutory income tax obligation \$			\$ 2,841	\$ 1,367	\$ 1,131	
Board of Directors						
Share-based Compensation Arrangement by Share-based Payment Award [Line Items]						
Number of shares vested with deferral (in shares)			30	72	0	
Employees Tax Obligations						
Share-based Compensation Arrangement by Share-based Payment Award [Line Items]						
Payments for the employees' minimum statutory income tax obligation \$			\$ 2,841	\$ 1,367	\$ 1,131	
Amended and Restated Equity Compensation Plan						
Share-based Compensation Arrangement by Share-based Payment Award [Line Items]						
Share-based compensation arrangement by share- based payment award, number of shares authorized (in shares)			50,200,000			
Maximum number of shares of stock granted to one participant (in shares)			4,000,000			
Minimum percentage of exercise price			100.00%			
Stock options						
Share-based Compensation Arrangement by Share-based Payment Award [Line Items]						
Weighted average fair value of options granted (in dollars per share) \$ / shares			\$ 2.29	\$ 1.42	\$ 1.54	
Proceeds from the issuance of stock options \$			\$ 5,182	\$ 1,814	\$ 4,405	
Exercise of options (in shares)			2,294,000	939	2,529	

Shares withheld to meet employees' minimum statutory income tax obligation (in shares)	13,000	43,000		
Unrecognized compensation cost related to non-vested outstanding stock awards \$	\$ 6,838			
Weighted average period expected to be recognized	1 year 11 months 12 days			
Stock options Long Term Incentive Program				
Share-based Compensation Arrangement by Share-based Payment Award [Line Items]				
Contractual term of options granted	10 years			
Vesting period	3 years			
Stock options Amended and Restated Equity Compensation Plan				
Share-based Compensation Arrangement by Share-based Payment Award [Line Items]				
Contractual term of options granted	10 years			
Vesting period	3 years			
Shares available for grant under the plan (in shares)	366,000			
Stock options Minimum Amended and Restated Equity Compensation Plan				
Share-based Compensation Arrangement by Share-based Payment Award [Line Items]				
Vesting period	1 year			
Performance Stock Units				
Share-based Compensation Arrangement by Share-based Payment Award [Line Items]				
Number of shares granted in 2019 (in shares)	1,328,000	1,641,000	1,841,000	1,842,000
Number of trading days prior to performance start	20 days			
Number of shares vested with deferral (in shares)	766,000	388,000	415,000	
Performance Stock Units Long Term Incentive Program				
Share-based Compensation Arrangement by Share-based Payment Award [Line Items]				
Vesting period	3 years			
Annual vesting installments installment	3			
Performance Stock Units Long Term Incentive Program Subsequent Event				
Share-based Compensation Arrangement by Share-based Payment Award [Line Items]				
Number of shares approved for settlement (in shares)	304			
Performance Stock Units Minimum Long Term Incentive Program				

**Share-based Compensation Arrangement by
Share-based Payment Award [Line Items]**

Share based compensation award percentage 0.00%
Performance Stock Units | Maximum | Long
Term Incentive Program

**Share-based Compensation Arrangement by
Share-based Payment Award [Line Items]**

Share based compensation award percentage 150.00%
Performance Stock Units | 2019 | Long Term
Incentive Program

**Share-based Compensation Arrangement by
Share-based Payment Award [Line Items]**

Number of shares granted in 2019 (in shares) 308
Restricted Stock Units

**Share-based Compensation Arrangement by
Share-based Payment Award [Line Items]**

Number of shares granted in 2019 (in shares) 1,504,000 1,567,000 1,401,000 1,226,000
Number of shares vested with deferral (in shares) 832,000 785,000 614,000
Restricted Stock Units | Board of Directors

**Share-based Compensation Arrangement by
Share-based Payment Award [Line Items]**

Vesting period 1 year
Restricted Stock Units | Long Term Incentive
Program

**Share-based Compensation Arrangement by
Share-based Payment Award [Line Items]**

Vesting period 3 years

**Share Based Compensation -
Summary of Stock Option
Activity (Detail) - USD (\$)
\$ / shares in Units, shares in
Thousands, \$ in Thousands**

12 Months Ended

**Dec. 31, Dec. 31, Dec. 31,
2021 2020 2019**

**Share-based Compensation Arrangement by Share-based Payment
Award, Options, Outstanding [Roll Forward]**

<u>Number of Shares Outstanding, Beginning Balance (in shares)</u>	15,521	13,861	14,079
<u>Number of Shares Granted (in shares)</u>	2,660	3,335	2,489
<u>Number of Shares Exercised (in shares)</u>	(2,307)	(939)	(2,572)
<u>Number of Shares Cancelled / Forfeited (in shares)</u>	(297)	(736)	(135)
<u>Number of Shares Outstanding, Ending Balance (in shares)</u>	15,577	15,521	13,861
<u>Number of Shares Exercisable, Ending Balance</u>	10,644		

**Share-based Compensation Arrangement by Share-based Payment
Award, Options, Outstanding, Weighted Average Exercise Price
[Abstract]**

<u>Weighted Average Exercise Price Outstanding, Beginning Balance (in dollars per share)</u>	\$ 2.49	\$ 2.41	\$ 2.19
<u>Weighted Average Exercise Price Granted (in dollars per share)</u>	4.37	2.73	3.01
<u>Weighted Average Exercise Price Exercised (in dollars per share)</u>	2.27	1.93	1.76
<u>Weighted Average Exercise Price Cancelled/Forfeited (in dollars per share)</u>	3.02	2.83	2.81
<u>Weighted Average Exercise Price Outstanding, Ending Balance (in dollars per share)</u>	2.83	\$ 2.49	\$ 2.41
<u>Weighted Average Exercise Price Exercisable, Ending Balance (in dollars per share)</u>	\$ 2.46		

**Share-Based Compensation Arrangement by Share-Based Payment
Award, Options, Weighted Average Remaining Contractual Term
[Abstract]**

<u>Weighted Average Remaining Contractual Term (Years) Outstanding, Ending Balance</u>	6 years 6 months	6 years 7 months 6 days	6 years 8 months 12 days
<u>Weighted Average Remaining Contractual Term (Years) Exercisable, Ending Balance</u>	5 years 4 months 24 days		
<u>Aggregate Intrinsic Value, Exercised</u>	\$ 5,052	\$ 1,072	\$ 6,477
<u>Aggregate Intrinsic Value Outstanding, Ending Balance</u>	13,839	\$ 23,407	\$ 31,713
<u>Aggregate Intrinsic Value Exercisable, Ending Balance</u>	\$ 12,028		

**Share Based Compensation -
Assumptions Used in Fair
Value Measurement of
Options Granted (Detail)**

12 Months Ended

Dec. 31, 2021 Dec. 31, 2020 Dec. 31, 2019

Share-based Payment Arrangement [Abstract]

<u>Risk-free interest rate</u>	0.80%	0.40%	1.90%
<u>Annualized volatility</u>	59.30%	59.40%	55.70%
<u>Weighted average expected life (in years)</u>	5 years 4 months 24 days	5 years 6 months	5 years 6 months
<u>Expected dividend yield</u>	0.00%	0.00%	0.00%

**Share Based Compensation -
Schedule of Performance
Stock Unit Awards and
Restricted Stock Granted
Under Long-Term Incentive
Program (Detail) - \$ / shares
shares in Thousands**

12 Months Ended

**Dec. 31,
2021 Dec. 31,
2020 Dec. 31,
2019**

Performance Stock Units

Share-based Compensation Arrangement by Share-based Payment Award, Equity Instruments Other than Options, Nonvested, Number of Shares [Roll Forward]

<u>Number of Shares, Beginning Balance (in shares)</u>	1,641	1,841	1,842
<u>Number of Shares, Granted (in shares)</u>	243	605	593
<u>Number of Shares, Incremental shares earned (in shares)</u>	210	77	59
<u>Number of Shares, Vested / Settled (in shares)</u>	(766)	(388)	(415)
<u>Number of Shares, Forfeited / Expired (in shares)</u>		(494)	(238)
<u>Number of Shares, Ending Balance (in shares)</u>	1,328	1,641	1,841

Share-based Compensation Arrangement by Share-based Payment Award, Equity Instruments Other than Options, Nonvested, Weighted Average Grant Date Fair Value [Abstract]

<u>Weighted Average Grant Date Fair Value, Beginning Balance (in dollars per share)</u>	\$ 2.61	\$ 3.00	\$ 2.41
<u>Weighted Average Grant Date Fair Value, Granted (in dollars per share)</u>	5.55	2.00	2.99
<u>Weighted Average Grant Date Fair Value, Incremental shares earned (in dollars per share)</u>	3.18	3.10	1.25
<u>Weighted Average Grant Date Fair Value, Vested / Settled (in dollars per share)</u>	2.86	3.11	1.18
<u>Weighted Average Grant Date Fair Value, Forfeited / Expired (in dollars per share)</u>		3.02	1.12
<u>Weighted Average Grant Date Fair Value, Ending Balance (in dollars per share)</u>	\$ 3.04	\$ 2.61	\$ 3.00

Restricted Stock Units

Share-based Compensation Arrangement by Share-based Payment Award, Equity Instruments Other than Options, Nonvested, Number of Shares [Roll Forward]

<u>Number of Shares, Beginning Balance (in shares)</u>	1,567	1,401	1,226
<u>Number of Shares, Granted (in shares)</u>	769	1,078	789
<u>Number of Shares, Incremental shares earned (in shares)</u>	0	0	0
<u>Number of Shares, Vested / Settled (in shares)</u>	(832)	(785)	(614)
<u>Number of Shares, Forfeited / Expired (in shares)</u>		(127)	0
<u>Number of Shares, Ending Balance (in shares)</u>	1,504	1,567	1,401

Share-based Compensation Arrangement by Share-based Payment Award, Equity Instruments Other than Options, Nonvested, Weighted Average Grant Date Fair Value [Abstract]

<u>Weighted Average Grant Date Fair Value, Beginning Balance (in dollars per share)</u>	\$ 2.77	\$ 2.82	\$ 2.44
<u>Weighted Average Grant Date Fair Value, Granted (in dollars per share)</u>	4.42	2.73	2.92
<u>Weighted Average Grant Date Fair Value, Incremental shares earned (in dollars per share)</u>	0	0	0
<u>Weighted Average Grant Date Fair Value, Vested / Settled (in dollars per share)</u>	2.76	2.80	2.19
<u>Weighted Average Grant Date Fair Value, Forfeited / Expired (in dollars per share)</u>		2.83	0
<u>Weighted Average Grant Date Fair Value, Ending Balance (in dollars per share)</u>	\$ 3.62	\$ 2.77	\$ 2.82

**Share Based Compensation -
Fair Value of PSUs Granted
Determined Using Monte
Carlo Simulation (Detail) - \$
/ shares**

12 Months Ended

Dec. 31, 2021 Dec. 31, 2020 Dec. 31, 2019

**Share-based Compensation Arrangement by Share-based
Payment Award [Line Items]**

<u>Term of award (in years)</u>	5 years 4 months 24 days	5 years 6 months	5 years 6 months
<u>Volatility</u>	59.30%	59.40%	55.70%
<u>Risk-free interest rate</u>	0.80%	0.40%	1.90%
<u>Expected dividend yield</u>	0.00%	0.00%	0.00%

Performance Stock Units

**Share-based Compensation Arrangement by Share-based
Payment Award [Line Items]**

<u>Closing stock price on grant date (in dollars per share)</u>	\$ 4.42	\$ 2.73	\$ 2.92
<u>Performance period starting price (in dollars per share)</u>	\$ 3.70	\$ 4.78	\$ 3.01
<u>Term of award (in years)</u>	2 years 6 months 21 days	2 years 6 months 18 days	2 years 6 months 18 days
<u>Volatility</u>	54.40%	57.50%	63.70%
<u>Risk-free interest rate</u>	0.23%	0.21%	1.79%
<u>Expected dividend yield</u>	0.00%	0.00%	0.00%
<u>Fair value per TSR PSU (in dollars per share)</u>	\$ 5.55	\$ 2.00	\$ 3.18

**Share Based Compensation -
Summary of Share Based
Compensation Allocation
Expense (Detail) - USD (\$)
\$ in Thousands**

12 Months Ended

**Dec. 31, Dec. 31, Dec. 31,
2021 2020 2019**

**Share-based Compensation Arrangement by Share-based Payment
Award [Line Items]**

<u>Total share-based compensation expense</u>	\$ 8,015	\$ 7,948	\$ 6,470
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Stock options

**Share-based Compensation Arrangement by Share-based Payment
Award [Line Items]**

<u>Total share-based compensation expense</u>	4,102	3,709	3,436
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Restricted Stock Units

**Share-based Compensation Arrangement by Share-based Payment
Award [Line Items]**

<u>Total share-based compensation expense</u>	2,620	2,239	1,830
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Performance Stock Units

**Share-based Compensation Arrangement by Share-based Payment
Award [Line Items]**

<u>Total share-based compensation expense</u>	\$ 1,293	\$ 2,000	\$ 1,204
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Employee 401(k) Savings Plan - Additional Information (Detail) - USD (\$) \$ in Thousands	12 Months Ended		
	Dec. 31, 2021	Dec. 31, 2020	Dec. 31, 2019
Retirement Benefits [Abstract]			
Contributions to plan amount	\$ 1,151	\$ 1,097	\$ 993

Sale of Assets - Additional Information (Detail) - USD (\$)	1 Months Ended	12 Months Ended		
	Dec. 31, 2021	Dec. 31, 2021	Dec. 31, 2020	Dec. 31, 2019
Sale of Assets [Line Items]				
Gain on sale of assets		\$ 38,591,000	\$ 0	\$ 0
Proceeds from sale of assets, net of transaction costs		17,825,000	\$ 282,000	\$ 5,000,000
OTREXUP Assets Disposal Group, Disposed of by Sale, Not Discontinued Operations				
Sale of Assets [Line Items]				
Product line	\$ 44,021	44,021		
Proceeds from divestiture of businesses	18,000			
Asset sale of remaining	\$ 26,021	26,021		
Period over which remaining installments will be received	1 year			
Remaining purchase price	\$ 26,311	\$ 26,311		

**Income Taxes - Schedule of
Income (Loss) before Income
Tax Domestic and Foreign
(Detail) - USD (\$)
\$ in Thousands**

12 Months Ended

**Dec. Dec. Dec.
31, 31, 31,
2021 2020 2019**

**Income (Loss) from Continuing Operations before Equity Method Investments,
Income Taxes, Extraordinary Items, Noncontrolling Interest [Abstract]**

<u>U.S.</u>	\$	\$	\$
	62,626	10,284	(1,734)
<u>Switzerland</u>	(355)	(363)	(293)
<u>Income (loss) before income taxes</u>	\$	\$ 9,921	\$
	62,271		(2,027)

**Income Taxes - Schedule of
Income Tax Expense
(Benefit) (Detail) - USD (\$)
\$ in Thousands**

12 Months Ended

Dec. 31, 2021 Dec. 31, 2020 Dec. 31, 2019

Current

<u>Federal</u>	\$ 0	\$ 0	\$ 0
<u>State</u>	2,041	700	0
<u>Foreign</u>	2	2	0
<u>Total current income tax provision (benefit)</u>	2,043	702	0

Deferred

<u>Federal</u>	11,918	(39,542)	0
<u>State</u>	2,021	(7,440)	0
<u>Foreign</u>	0	0	0
<u>Total deferred income tax provision (benefit)</u>	13,939	(46,982)	0
<u>Total income tax provision (benefit)</u>	\$ 15,982	\$ (46,280)	\$ 0

**Income Taxes - Summary of
Effective Tax Rates Differ
from Statutory Income Tax
Rates (Detail)**

12 Months Ended

Dec. 31, 2021 Dec. 31, 2020 Dec. 31, 2019

Effective Income Tax Rate Reconciliation, Percent [Abstract]

<u>Statutory income tax rate</u>	21.00%	21.00%	21.00%
<u>State income taxes</u>	5.50%	7.10%	14.40%
<u>Effect of foreign operations</u>	0.10%	0.20%	(1.00%)
<u>Changes in valuation allowance</u>	(0.20%)	(516.50%)	(59.90%)
<u>Change in unused net operating loss and credit carryforwards</u>	0.00%	0.00%	24.70%
<u>Change in uncertain tax positions</u>	(0.10%)	21.40%	0.00%
<u>Research and development credit</u>	(0.70%)	(6.00%)	0.00%
<u>Stock-based compensation</u>	(2.00%)	3.70%	22.30%
<u>162(m) limitation</u>	2.10%	1.90%	(18.20%)
<u>Nondeductible items</u>	0.00%	1.60%	(1.80%)
<u>Impact of Tax Cuts and Jobs Act</u>	0.00%	0.00%	(1.50%)
<u>Other</u>	0.00%	(0.90%)	0.00%
<u>Effective income tax rate</u>	25.70%	(466.50%)	0.00%

**Income Taxes - Summary of
Deferred Tax Assets
(Liabilities) (Detail) - USD
(\$)**

Dec. 31, 2021 Dec. 31, 2020

\$ in Thousands

Gross deferred tax assets

<u>Net operating loss carryforward – U.S.</u>	\$ 24,738	\$ 36,071
<u>Net operating loss carryforward – Switzerland</u>	162	106
<u>Research and development tax credit carryforward</u>	5,836	5,418
<u>Deferred revenue</u>	14	219
<u>Stock-based compensation</u>	3,423	2,954
<u>Inventory reserve</u>	56	159
<u>Compensation accruals</u>	1,426	1,304
<u>Product reserves</u>	5,235	2,820
<u>Operating lease liabilities</u>	1,436	1,546
<u>Amortization</u>	64	607
<u>Other</u>	188	145
<u>Total deferred tax assets</u>	42,578	51,349

Deferred tax liabilities

<u>Depreciation</u>	(1,753)	(1,838)
<u>Operating lease right-of-use asset</u>	(1,048)	(1,303)
<u>Installment sale</u>	(5,580)	0
<u>Total deferred tax liabilities</u>	(8,381)	(3,141)
<u>Net deferred tax asset before valuation allowance</u>	34,197	48,208
<u>Less: Valuation allowance</u>	(1,154)	(1,226)
<u>Net deferred tax asset</u>	\$ 33,043	\$ 46,982

**Income Taxes - Additional
Information (Detail) - USD
(\$)**

**12 Months Ended
Dec. 31, 2021 Dec. 31, 2020 Dec. 31, 2019**

Operating Loss Carryforwards [Line Items]

<u>Deferred tax assets</u>	\$ 33,043,000	\$ 46,982,000	
<u>Net valuation allowance releases</u>		53,383,000	
<u>Valuation allowance for deferred tax assets</u>	1,154,000	1,226,000	
<u>Unrecognized tax benefits</u>	2,057,000	\$ 2,127,000	\$ 0
<u>Unrecognized tax benefits, income tax penalties and interest accrued</u>	\$ 0		
<u>Total unrecognized tax benefits changing period</u>	12 months		
<u>U.S Federal Tax</u>			

Operating Loss Carryforwards [Line Items]

<u>Net operating loss carry forward</u>	\$ 99,939,000
<u>Research credit carryforward</u>	7,328,000

Foreign Tax Authority

Operating Loss Carryforwards [Line Items]

<u>Net operating loss carry forward</u>	\$ 1,130,000
<u>Tax credit carryforward expiration year</u>	2023

Minimum | U.S Federal Tax

Operating Loss Carryforwards [Line Items]

<u>Tax credit carryforward expiration year</u>	2018
<u>Net operating loss carryforward expiration year</u>	2033

Maximum | U.S Federal Tax

Operating Loss Carryforwards [Line Items]

<u>Net operating loss carryforward expiration year</u>	2037
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**Income Taxes -
Unrecognized Tax Benefits
(Detail) - USD (\$)
\$ in Thousands**

**12 Months Ended
Dec. 31, 2021 Dec. 31, 2020**

**Reconciliation of Unrecognized Tax Benefits, Excluding Amounts Pertaining to
Examined Tax Returns [Roll Forward]**

<u>Beginning liability for unrecognized tax benefits</u>	\$ 2,127	\$ 0
<u>Increase (decrease) due to tax positions related to prior years</u>		2,067
<u>Increase (decrease) due to tax positions related to prior years</u>	(70)	
<u>Increase due to tax positions related to the current year</u>	0	60
<u>Ending liability for unrecognized tax benefits</u>	\$ 2,057	\$ 2,127

**Revenues, Significant
Customers and
Concentrations of Risk -
Summary of Revenue
Disaggregated by Major
Types and Sources (Detail) -
USD (\$)
\$ in Thousands**

12 Months Ended

Dec. 31, 2021 Dec. 31, 2020 Dec. 31, 2019

Disaggregation of Revenue [Line Items]

Total revenue, net \$ 183,982 \$ 149,599 \$ 123,864

U.S.

Disaggregation of Revenue [Line Items]

Total revenue, net 178,290 145,789 120,231

Europe

Disaggregation of Revenue [Line Items]

Total revenue, net 5,692 3,810 3,463

Other

Disaggregation of Revenue [Line Items]

Total revenue, net 0 0 170

Total product revenue, net

Disaggregation of Revenue [Line Items]

Total revenue, net 126,667 113,834 92,103

Licensing and development revenue

Disaggregation of Revenue [Line Items]

Total revenue, net 19,623 14,466 7,529

Royalties

Disaggregation of Revenue [Line Items]

Total revenue, net 37,692 21,299 24,232

Proprietary product sales, net | Total product revenue, net

Disaggregation of Revenue [Line Items]

Total revenue, net 80,016 62,878 39,215

Partnered product sales | Total product revenue, net

Disaggregation of Revenue [Line Items]

Total revenue, net \$ 46,651 \$ 50,956 \$ 52,888

**Revenues, Significant
Customers and
Concentrations of Risk -
Summary of Significant
Customers from which the
Company Derived 10% or
More of Total Revenue
(Detail) - Customer
Concentration Risk -
Revenue from Contract with
Customer Benchmark**

12 Months Ended

Dec. 31, 2021 Dec. 31, 2020 Dec. 31, 2019

Teva

Concentration Risk [Line Items]

Total revenue by customer, percentage 42.00% 40.00% 41.00%

McKesson

Concentration Risk [Line Items]

Total revenue by customer, percentage 13.00% 12.00% 10.00%

AmerisourceBergen Corporation

Concentration Risk [Line Items]

Total revenue by customer, percentage 12.00% 12.00%

Cardinal Health

Concentration Risk [Line Items]

Total revenue by customer, percentage 11.00% 11.00%

Covis

Concentration Risk [Line Items]

Total revenue by customer, percentage 20.00%

**Earnings (Loss) per Share -
Summary of Computation
for Basic and Diluted Net
Earnings (Loss) per Share
(Detail) - USD (\$)
\$ / shares in Units, shares in
Thousands, \$ in Thousands**

12 Months Ended

	Dec. 31, 2021	Dec. 31, 2020	Dec. 31, 2019
<u>Earnings Per Share [Abstract]</u>			
<u>Net income (loss)</u>	\$ 46,289	\$ 56,201	\$ (2,027)
<u>Weighted average common shares outstanding (in shares)</u>	169,226	166,066	162,574
<u>Dilutive effects of stock options and share-based awards issuable under equity compensation plans (in shares)</u>	5,507	4,089	0
<u>Weighted average dilutive common shares outstanding (in shares)</u>	174,733	170,155	162,574
<u>Earnings (loss) per common share</u>			
<u>Basic (in dollars per share)</u>	\$ 0.27	\$ 0.34	\$ (0.01)
<u>Diluted (in dollars per share)</u>	\$ 0.26	\$ 0.33	\$ (0.01)
<u>Anti-dilutive common stock equivalents (in shares)</u>	2,224	7,092	17,103

**Commitments and
Contingencies - Additional
Information (Detail)**

1 Months Ended
Oct. 31, 2021 **Oct. 31, 2020**
USD (\$) **USD (\$)**
installment

[Lipocine Inc.](#)

[**Loss Contingencies \[Line Items\]**](#)

[License fee](#) \$ 4,000,000

[Number of installments | installment](#) 2

[License Agreement | Lipocine Inc.](#)

[**Loss Contingencies \[Line Items\]**](#)

[Upfront payment paid](#) \$ 11,000,000

[Additional milestone payment](#) 10,000,000

[Minimum royalty payments](#) \$ 4,500,000

[Minimum royalty payment period](#) 3 years

[Tiered royalties and additional commercial milestone payments](#) \$ 160,000,000

[License Agreement | Ferring International Center S.A. and its Affiliates](#)

[**Loss Contingencies \[Line Items\]**](#)

[Upfront payment paid](#) 5,000,000 \$ 5,000,000

[Tiered royalties and additional commercial milestone payments](#) \$ 17,500,000

[Additional upfront payment made at one year from execution](#) \$ 2,500,000

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