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

SCHEDULE 14A

PROXY STATEMENT PURSUANT TO SECTION 14(a) OF THE SECURITIES EXCHANGE ACT OF 1934

Filed by the Registrant ☒
Filed by a Party other than the Registrant ☐

Check the appropriate box:
- ☐ Preliminary Proxy Statement
- ☐ **Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))**
- ☒ Definitive Proxy Statement
- ☐ Definitive Additional Materials
- ☐ Soliciting Material Pursuant to §240.14a-12

AMPHASTAR PHARMACEUTICALS, INC.

(Name of Registrant as Specified In Its Charter)

Payment of Filing Fee (Check all boxes that apply):
- ☒ No fee required.
- ☐ Fee paid previously with preliminary materials.
- ☐ Fee computed in exhibit required by Item 25(b) per Exchange Act Rules 14a-6(i)(1) and 0-11.

AMPHASTAR PHARMACEUTICALS, INC.
11570 6TH STREET
RANCHO CUCAMONGA, CALIFORNIA 91730

NOTICE OF ANNUAL MEETING OF STOCKHOLDERS
To Be Held at 11:00 a.m. Pacific Time on Monday, June 5, 2023

Dear Stockholders of Amphastar Pharmaceuticals, Inc.:

Please be advised that the 2023 annual meeting of stockholders (the "Annual Meeting") of Amphastar Pharmaceuticals, Inc., (or the "Company" or "Amphastar") a Delaware corporation, will be conducted virtually via a live webcast at www.virtualshareholdermeeting.com/AMPH2023 on **Monday, June 5, 2023 at 11:00 a.m. Pacific Time.** The Annual Meeting will be conducted for the following purposes, as more fully described in the accompanying proxy statement:

1. To elect three Class I directors to hold office for a three-year term and until their respective successors are duly elected and qualified or until such director's earlier death, resignation or removal;

2. To ratify the appointment of Ernst & Young LLP as our independent registered public accounting firm for our fiscal year ending December 31, 2023;

3. To approve, on an advisory basis, the compensation of our named executive officers; and

4. To transact such other business as may properly come before the Annual Meeting and any adjournments or postponements thereof.

Our board of directors (the "Board of Directors") has fixed the close of business on April 10, 2023 as the record date for the Annual Meeting. Only stockholders of record on April 10, 2023 are entitled to notice and to vote at the Annual Meeting. Further information regarding voting rights and the matters to be voted upon is presented in the accompanying proxy statement. If you plan on attending this year's virtual Annual Meeting as a stockholder, please go to www.virtualshareholdermeeting.com/AMPH2023. Please have the information that is printed in the box marked by the arrow available and follow the instructions.

On or about April 21, 2023, we expect to mail to our stockholders a Notice of Internet Availability of Proxy Materials (the "Notice") containing instructions on how to access both our proxy statement and our 2023 annual report online. This Notice provides instructions on how to vote via the Internet or by telephone and includes instructions on how to receive a paper copy of our proxy materials by mail. Please note that the proxy statement and our annual report can be accessed directly at the following Internet address http://ir.amphastar.com/financial-information/annual-reports. You can also access our proxy materials by (1) visiting www.ProxyVote.com, (2) calling 1-800-579-1639, or (3) sending an e-mail to sendmaterial@proxyvote.com. All you have to do is enter the control number located on your proxy card.

YOUR VOTE IS IMPORTANT. Whether or not you plan to virtually attend the Annual Meeting, we urge you to submit your vote via the Internet, telephone or mail.

We appreciate your continued support of Amphastar Pharmaceuticals, Inc. and look forward to your attendance at the Annual Meeting and/or receiving your proxy.

By order of the Board of Directors,

Jack Yongfeng Zhang
Chief Executive Officer, President, Chief Scientific Officer and Director

Mary Ziping Luo
Chief Operating Officer, Chief Scientist and Chairman

Rancho Cucamonga, California
April 21, 2023

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AMPHASTAR PHARMACEUTICALS, INC.

PROXY STATEMENT
FOR 2023 ANNUAL MEETING OF STOCKHOLDERS
To Be Held at 11:00 a.m. Pacific Time on Monday, June 5, 2023

This proxy statement and the enclosed form of proxy are furnished in connection with the solicitation of proxies by our board of directors (the "Board of Directors") for use at the 2023 annual meeting of stockholders of Amphastar Pharmaceuticals, Inc., a Delaware corporation, and any postponements, adjournments or continuations thereof (the "Annual Meeting"). The Annual Meeting will be conducted virtually via a live webcast at www.virtualshareholdermeeting.com/AMPH2023 on Monday, June 5, 2023 at 11:00 a.m. Pacific Time. You will be able to vote and submit questions during the meeting at that website. In order to access information and ask questions, please have the information that is printed in the box marked by the arrow available and follow the instructions. The Notice of Internet Availability of Proxy Materials (the "Notice") containing instructions on how to access this proxy statement and our annual report is first being mailed on or about April 21, 2023 to all stockholders entitled to vote at the virtual Annual Meeting.

The information provided in the "question and answer" format below is for your convenience only and is merely a summary of the information contained in this proxy statement. You should read this entire proxy statement carefully. Information contained on, or that can be accessed through, our website is not intended to be incorporated by reference into this proxy statement and references to our website address in this proxy statement are inactive textual references only.

What matters am I voting on?

You will be voting on:

- the election of three Class I directors to hold office for a three-year term and until their respective successors are duly elected and qualified or until such director's earlier death, resignation or removal;
- a proposal to ratify the appointment of Ernst & Young LLP as our independent registered public accounting firm for our fiscal year ending December 31, 2023;
- to approve, on an advisory basis, the compensation of our named executive officers; and
- any other business as may properly come before the Annual Meeting and any adjournments or postponements thereof.

How does the Board of Directors recommend I vote on these proposals?

Our Board of Directors recommends a vote:

1. "FOR" the election of Floyd F. Petersen, Jacob Liawatidewi and William J. Peters as Class I directors;
2. "FOR" the ratification of the appointment of Ernst & Young LLP as our independent registered public accounting firm for our fiscal year ending December 31, 2023; and
3. "FOR" the approval, on an advisory basis, of the compensation of our named executive officers.

Who is entitled to vote?

Holders of our common stock as of the close of business on April 10, 2023, the record date, may vote at the Annual Meeting. As of the record date, there were 48,193,177 shares of our common stock outstanding. In deciding all matters at the Annual Meeting, each stockholder will be entitled to one vote for each share of our common stock held by them on the record date. We do not have cumulative voting rights for the election of directors.

Registered Stockholders. If shares of our common stock are registered directly in your name with our transfer agent, you are considered the stockholder of record with respect to those shares, and the Notice was provided to you directly by us. As the stockholder of record, you have the right to grant your voting proxy directly to the individuals listed on the proxy card or to vote at the Annual Meeting.

Street Name Stockholders. If shares of our common stock are held on your behalf in a stock brokerage account or by a bank or other nominee, you are considered the beneficial owner of those shares held in "street name," and the Notice was forwarded to you by your broker or nominee, who is considered the stockholder of record with respect to those shares. As the beneficial owner, you have the right to direct your broker or nominee as to how to vote your shares. Beneficial owners are also invited to attend the Annual Meeting. However, since a beneficial owner is not the stockholder of record, you may not vote your shares of our common stock at the Annual Meeting unless you follow your broker's procedures for obtaining a legal proxy. If you request a printed copy of our proxy materials by mail, your broker or nominee will provide a voting instruction card for you to use. Throughout this proxy, we refer to stockholders who hold their shares through a broker, bank or other nominee as "street name stockholders."

A complete list of these stockholders will be available at our corporate offices at 11570 6th Street, Rancho Cucamonga, California 91730 during regular business hours or on our website for ten days prior to the Annual Meeting. A stockholder may examine the list for any purpose germane to the Annual Meeting.

How many votes are needed for approval of each proposal?

- *Proposal No. 1*: Each director to be elected by the stockholders of the corporation shall be elected by the affirmative vote of a majority of the votes cast with respect to such director by the shares present or represented by proxy at the Annual Meeting at which a quorum is present and entitled to vote thereon. "Majority of the votes cast" means that the number of votes cast "for" a candidate for director exceeds the number of votes cast "against" that director. Stockholders will be given the choice to cast votes "for" or "against" the election of each director or to "abstain" from such vote. Please note that abstentions are considered votes present and entitled to vote on this proposal, and thus, will have the same effect as a vote "against" the proposal. Broker non-votes will have no effect on the outcome of this proposal.

- *Proposal No. 2:* The ratification of the appointment of Ernst & Young LLP requires the affirmative vote of a majority of the voting power of the shares present or represented by proxy at the Annual Meeting at which a quorum is present and entitled to vote thereon. Please note that abstentions are considered votes present and entitled to vote on this proposal, and thus, will have the same effect as a vote "against" the proposal. Broker non-votes will have no effect on the outcome of this proposal.

- *Proposal No*. 3*:* The approval, on an advisory basis, of the compensation of our named executive officers, requires the affirmative vote of a majority of the voting power of the shares present or represented by proxy at the Annual Meeting at which a quorum is present and entitled to vote

thereon. Please note that abstentions are considered votes present and entitled to vote on this proposal, and thus, will have the same effect as a vote "against" the proposal. Broker non-votes will have no effect on the outcome of this proposal. Although the advisory vote is non-binding, our Board of Directors values stockholders' opinions. The compensation committee will review the results of the vote and, consistent with our record of stockholder responsiveness, consider stockholders' comments and concerns and take into account the outcome of the vote when considering future decisions concerning our executive compensation program.

What is a quorum?

A quorum is the minimum number of shares required to be present at the Annual Meeting for the Annual Meeting to be properly held under our amended and restated bylaws and Delaware law. The presence (including by proxy) of a majority of the voting power of our capital stock entitled to vote at the Annual Meeting will constitute a quorum at the Annual Meeting. Abstentions, withhold votes and broker non-votes will be counted as shares present and entitled to vote for purposes of determining a quorum.

How do I vote?

If you are a stockholder of record, you can vote in one of the following ways:

- by Internet at http://www.proxyvote.com, 24 hours a day, seven days a week, until 11:59 p.m. Eastern Time on June 4, 2023 (have your proxy card in hand when you visit the website);
- by toll-free telephone at 1-800-690-6903 (have your proxy card in hand when you call);
- by completing and mailing your proxy card (if you received printed proxy materials) so that it is received no later than June 4, 2023; or
- by voting at the Annual Meeting by following the instructions at www.virtualshareholdermeeting.com/AMPH2023

If you are a street name stockholder, you will receive voting instructions from your broker, bank or other nominee. You must follow the voting instructions provided by your broker, bank or other nominee in order to instruct your broker, bank or other nominee on how to vote your shares. Street name stockholders should generally be able to vote by returning an instruction card, or by telephone or on the Internet. However, the availability of telephone and Internet voting will depend on the voting process of your broker, bank or other nominee. If you are a street name stockholder, you may not vote your shares at the Annual Meeting unless you obtain a legal proxy from your broker, bank or other nominee.

Can I change my vote?

Yes. If you are a stockholder of record, you can change your vote or revoke your proxy any time before the Annual Meeting by:

- entering a new vote by Internet or by telephone;
- returning a later-dated proxy card;
- notifying the Corporate Secretary of Amphastar Pharmaceuticals, Inc., in writing, at Amphastar Pharmaceuticals, Inc., 11570 6th Street, Rancho Cucamonga, California 91730; or

- following the instructions at www.virtualshareholdermeeting.com/AMPH2023

If you are a street name stockholder, your broker, bank or other nominee can provide you with instructions on how to change your vote.

Do I have to do anything in advance if I plan to attend the Annual Meeting?

The Annual Meeting will be a completely virtual meeting conducted via a live webcast. You are entitled to participate in the annual meeting only if you were a holder of our common stock as of the close of business on April 10, 2023 or if you hold a valid proxy for the Annual Meeting.

You will be able to attend the Annual Meeting online and submit your questions during the meeting www.virtualshareholdermeeting.com/AMPH2023 and entering your control number included in your Notice of Internet Availability Materials, on your proxy card or on the instructions that accompanied your proxy materials.

We encourage you to access the meeting prior to the start time. Online check-in will begin at 10:30 a.m. Pacific Time, and you should allow ample time for the check-in procedures.

How do I ask questions during the Annual Meeting?

You will be able to attend the Annual Meeting online and submit your questions during the meeting at www.virtualshareholdermeeting.com/AMPH2023 and entering your control number included in your Notice of Internet Availability Materials, on your proxy card or on the instructions that accompanied your proxy materials.

Questions pertinent to meeting matters will be answered during the meeting, subject to time constraints. Please be advised that questions regarding personal or other matters are not pertinent to meeting matters will not be answered.

How can I get help if I have trouble checking in or listening to the meeting online?

If you encounter any difficulties accessing the virtual meeting during the check-in or meeting time, please call the technical support number that will be posted on www.virtualshareholdermeeting.com/AMPH2023.

What is the effect of giving a proxy?

Proxies are solicited by and on behalf of our Board of Directors. Jack Yongfeng Zhang, Mary Ziping Luo, and William J. Peters have been designated as proxies by our Board of Directors. When proxies are properly dated, executed and returned, the shares represented by such proxies will be voted at the Annual Meeting in accordance with the instructions of the stockholder. If no specific instructions are given, however, the shares will be voted in accordance with the recommendations of our Board of Directors as described above. If any matters not described in this proxy statement are properly presented at the Annual Meeting, the proxy holders will use their own judgment to determine how to vote the shares. If the Annual Meeting is adjourned, the proxy holders can vote the shares on the new Annual Meeting date as well, unless you have properly revoked your proxy instructions, as described above.

Why did I receive a Notice of Internet Availability of Proxy Materials instead of a full set of proxy materials?

In accordance with the rules of the Securities and Exchange Commission (the "SEC"), we have elected to furnish our proxy materials, including this proxy statement and our annual report, primarily via the Internet. The Notice containing instructions on how to access our proxy materials is first being mailed on or about April 21, 2023 to all stockholders entitled to vote at the Annual Meeting. Stockholders may request to receive all future proxy materials in printed form by mail or electronically by e-mail by following the instructions contained in the Notice. We encourage stockholders to take advantage of the availability of our proxy materials on the Internet to help reduce the environmental impact of our annual meetings of stockholders.

How are proxies solicited for the Annual Meeting?

Our Board of Directors is soliciting proxies for use at the Annual Meeting. All expenses associated with this solicitation will be borne by us. We will reimburse brokers or other nominees for reasonable expenses that they incur in sending our proxy materials to you if a broker or other nominee holds shares of our common stock on your behalf.

Is my vote confidential?

Proxy instructions, ballots and voting tabulations that identify individual stockholders are handled in a manner that protects your voting privacy. Your vote will not be disclosed either within Amphastar Pharmaceuticals, Inc. or to third parties, except as necessary to meet applicable legal requirements, to allow for the tabulation of votes and certification of the vote, or to facilitate a successful proxy solicitation.

How may my brokerage firm or other intermediary vote my shares if I fail to provide timely directions?

Brokerage firms and other intermediaries holding shares of our common stock in street name for customers are generally required to vote such shares in the manner directed by their customers. In the absence of timely directions, your broker will have discretion to vote your shares on our sole "routine" matter: the proposal to ratify the appointment of Ernst & Young LLP. Your broker will not have discretion to vote on any other proposals, which are considered "non-routine" matters, absent directions from you.

Where can I find the voting results of the Annual Meeting?

We will announce preliminary voting results at the Annual Meeting. We will also disclose voting results on a Current Report on Form 8-K that we will file with the SEC within four business days after the Annual Meeting. If final voting results are not available to us in time to file a Current Report on Form 8-K within four business days after the Annual Meeting, we will file a Current Report on Form 8-K to publish preliminary results and will provide the final results in an amendment to such Current Report on Form 8-K as soon as they become available.

I share an address with another stockholder, and we received only one paper copy of the proxy materials. How may I obtain an additional copy of the proxy materials?

We have adopted a procedure called "householding," which the SEC has approved. Under this procedure, we deliver a single copy of the Notice and, if applicable, our proxy materials to multiple stockholders who share the same address unless we have received contrary instructions from one or more of the stockholders. This procedure reduces our printing costs, mailing costs, and fees. Stockholders who participate in householding will continue to be able to access and receive separate proxy cards. Upon written or oral request, we will

deliver promptly a separate copy of the Notice and, if applicable, our proxy materials to any stockholder at a shared address to which we delivered a single copy of any of these materials. To receive a separate copy, or, if a stockholder is receiving multiple copies, to request that we only send a single copy of the Notice and, if applicable, our proxy materials, such stockholder may contact us at the following address:

Amphastar Pharmaceuticals, Inc.
Attention: Investor Relations
11570 6th Street
Rancho Cucamonga, California 91730

Stockholders who beneficially own shares of our common stock held in street name may contact their brokerage firm, bank, broker-dealer or other similar organization to request information about householding.

What is the deadline to propose actions for consideration at next year's annual meeting of stockholders or to nominate individuals to serve as directors?

Stockholder Proposals

Stockholders may present proper proposals for inclusion in our proxy statement and for consideration at the next annual meeting of stockholders pursuant to Rule 14a-8 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") by submitting their proposals in writing to our Corporate Secretary in a timely manner. For a stockholder proposal to be considered for inclusion in our proxy statement for our 2024 annual meeting of stockholders, our Corporate Secretary must receive the written proposal at our principal executive offices not later than December 23, 2023. In addition, stockholder proposals must comply with the requirements of Rule 14a-8 regarding the inclusion of stockholder proposals in company-sponsored proxy materials. Stockholder proposals should be addressed to:

Amphastar Pharmaceuticals, Inc.
Attention: Corporate Secretary
11570 6th Street
Rancho Cucamonga, California 91730

Our amended and restated bylaws also establish an advance notice procedure for stockholders who wish to present a proposal before an annual meeting of stockholders but do not intend for the proposal to be included in our proxy statement. Our amended and restated bylaws provide that the only business that may be conducted at an annual meeting is business that is (i) brought before the meeting by the corporation and specified in the notice of meeting given by or at the direction of our Board of Directors, (ii) brought before the meeting by or at the direction of our Board of Directors, or (iii) otherwise properly brought before the meeting by a stockholder who (A) was a stockholder of record both at the time of giving the notice and at the time of the meeting, (B) is entitled to vote at the meeting, and (C) has complied with all of the notice procedures set forth in our amended and restated bylaws.

To be timely for our 2024 annual meeting of stockholders, our Corporate Secretary must receive the written notice at our principal executive offices:

- not earlier than 8:00 a.m., Pacific time on February 6, 2024; and
- not later than 5:00 p.m., Pacific time on March 7, 2024.

In the event that the date of our 2024 annual meeting of stockholders has been changed by more than 25 days from the one-year anniversary of the Annual Meeting, then to be timely such notice must be received by the Secretary at the principal executive offices of the Company:

- no earlier than 8:00 a.m., Pacific time on the 120th day prior to the day of our 2024 annual meeting;
- no later than 5:00p.m., Pacific time, on the later of the 90th day prior to the day of the annual meeting; or
- if the first public announcement of the date of such annual meeting is less than 100 days prior to the date of such annual meeting, the 10th day following the day on which public announcement of the annual meeting was first made by the Company.

If a stockholder who has notified us of his, her or its intention to present a proposal at an annual meeting does not appear to present his, her or its proposal at such annual meeting, we are not required to present the proposal for a vote at such annual meeting.

In addition to satisfying the foregoing notice requirements under our amended and restated bylaws, to comply with universal proxy rules, under the Exchange Act, stockholders who intend to solicit proxies in support of director nominees other than the Company's nominees must also provide notice that sets forth the information required by Rule 14a-19 of the Exchange Act, no later than April 6, 2024.

Nomination of Director Candidates

You may propose director candidates for consideration by our nominating and corporate governance committee. Any such recommendations should include the nominee's name and qualifications for membership on our Board of Directors and should be directed to our Corporate Secretary at the address set forth above. For additional information regarding stockholder recommendations for director candidates, see "Board of Directors and Corporate Governance-Stockholder Recommendations for Nominations to the Board of Directors."

In addition, our amended and restated bylaws permit stockholders to nominate directors for election at an annual meeting of stockholders. To nominate a director, the stockholder must provide the information required by our amended and restated bylaws. In addition, the stockholder must give timely notice to our Corporate Secretary in accordance with our amended and restated bylaws, which, in general, require that the notice be received by our Corporate Secretary within the time period described above under "Stockholder Proposals" for stockholder proposals that are not intended to be included in a proxy statement.

Availability of Bylaws

A copy of our amended and restated bylaws may be obtained by accessing our filings on the SEC's website at http://www.sec.gov. You may also contact our Corporate Secretary at our principal executive offices for a copy of the relevant bylaw provisions regarding the requirements for making stockholder proposals and nominating director candidates.

BOARD OF DIRECTORS AND CORPORATE GOVERNANCE

Our business affairs are managed under the direction of our Board of Directors, which is currently composed of ten members. Six of our current directors are independent within the meaning of the listing standards of the Nasdaq Stock Market LLC ("Nasdaq"). Our Board of Directors is divided into three staggered classes of directors. At each annual meeting of stockholders, a class of directors will be elected for a three-year term to succeed the same class whose term is then expiring.

The following table sets forth the names, ages as of April 10, 2023, and certain other information for each of the director nominees and the continuing members of our Board of Directors.

	Class	Age	Position	Director Since	Current Term Expires	Expiration of Term For Which Nominated
Nominees						
Floyd F. Petersen (2)	I	79	Director	2004	2023	2026
Jacob Liawatidewi	I	49	Executive Vice President of Sales and Marketing, Executive Vice President of Corporate Administration Center, President of Amphastar France Pharmaceuticals, S.A.S., and Director	2022	2023	2026
William J. Peters	I	55	Chief Financial Officer, Executive Vice President of Finance, Treasurer, President of International Medication Systems, Limited, and Director	2022	2023	2026
Continuing Directors						
Mary Ziping Luo	II	73	Chief Operating Officer, Chief Scientist and Chairman of the Board of Directors	1996	2024	—
Howard Lee (1)(3)	II	61	Director	2008	2024	—
Michael A. Zasloff (2)(3)	II	77	Director	2005	2024	—
Gayle Deflin (1)	II	60	Director	2021	2024	—
Jack Yongfeng Zhang	III	76	Chief Executive Officer, President, Chief Scientific Officer and Director	1996	2025	—
Richard Prins (1)(2)	III	66	Lead Independent Director	2002	2025	—
Diane G. Gerst (3)	III	63	Director	2019	2025	—

(1) Member of the audit committee
(2) Member of the compensation committee
(3) Member of the nominating and corporate governance committee

Nominees for Director

Floyd F. Petersen has served as a member of our Board of Directors since August 2004. From 1986 to until his retirement in August 2014, Mr. Petersen served as an Assistant Professor of Biostatistics at Loma Linda

University Schools of Public Health, Medicine, and Nursing. From 1990 to 2010, Mr. Petersen served as Director of the Loma Linda University Health Research Consulting Group, which consults on health research study design and data analysis. Mr. Petersen was a member of the Loma Linda, California City Council from 1990 to 2010 and served as the Mayor of Loma Linda from 1996 to 2006. Mr. Petersen earned an M.P.H. from Loma Linda University with concentrations in Biostatistics and Health Administration.

We believe that Mr. Petersen's years of experience in scientific academia and consulting qualifies him to serve on our Board of Directors.

Jacob Liawatidewi has served as a member of our Board of Directors since August 2022, Executive Vice President of Sales and Marketing and Executive Vice President of Corporate Administration Center since May 2020, President of Amphastar France Pharmaceuticals, S.A.S. (a wholly-owned subsidiary of Amphastar) since December 2020, and Corporate Secretary since June 2013. Mr. Liawatidewi served as Senior Vice President of Corporate Administration Center and Senior Vice President of Sales and Marketing from March 2014 and December 2013, respectively, until his promotion to Executive Vice President. Mr. Liawatidewi served as Vice President of Sales and Marketing from August 2012 until his promotion to Senior Vice President. From August 2005 to August 2012, Mr. Liawatidewi was our Associate Vice President of Sales and Marketing. From joining us in June 1997 to August 2005, Mr. Liawatidewi held various roles in our business development, sales and marketing department. Mr. Liawatidewi received a B.S. in Biology from California State University of Fresno in 1996, an M.B.A. from National University in 2014, and an E.J.D. from Concord Law School in 2022.

We believe that Mr. Liawatidewi's executive experience extensive knowledge of our business qualifies him to serve on our Board of Directors.

William J. Peters has served as a member of our Board of Directors since August 2022, Chief Financial Officer, Executive Vice President and Treasurer since May 2021 and was Chief Financial Officer, Senior Vice President and Treasurer since April 2014, and as President of International Medication Systems, Limited (a wholly-owned subsidiary of Amphastar) since March 2016. Mr. Peters previously served as Chief Financial Officer of Hi-Tech Pharmacal Co., Inc., or Hi-Tech, from May 2004 to April 2014. From September 2003 to May 2004 he was Vice President of Corporate Development at Hi-Tech. From 2001 to 2003 Mr. Peters was the Director, Financial Evaluations for the Medco Health Solution subsidiary of Merck & Co., Inc., or Merck & Co., and during his seven year career at Merck & Co., he also served in several positions of increasing responsibility. He began his career in General Electric's Financial Management Program, at its Aerospace division, where he later held positions in financial analysis and internal auditing. He earned an M.B.A. from The Wharton School of Business, of the University of Pennsylvania and a B.S. in Business Administration from Bucknell University.

We believe that Mr. Peters' executive experience and expertise as a financial professional at pharmaceutical companies including as our Chief Financial Officer qualifies him to serve on our Board of Directors.

Continuing Directors

Jack Yongfeng Zhang, Ph.D. co-founded our Company in 1996 has served as our Chief Executive Officer and a member of our Board of Directors since our inception and was re-appointed as our President in April 2020, after serving as President from 1996 until June 2013. Dr. Zhang has also served as our Chief Scientific Officer since 2005. Dr. Zhang co-founded APCL, a full service chemical analytical laboratory, in May 1989, where he held the position of President until October 2002. Dr. Zhang is named as the inventor on several U.S. and foreign patents. He received a Ph.D. in chemistry from the State University of New York at Stony Brook and was a Post-Doctoral Research Associate at the California Institute of Technology.

We believe Dr. Zhang's expertise and experience in the pharmaceutical industry and as one of our founders qualifies him to serve on our Board of Directors.

Richard Prins has served as our lead independent director since April 2019 and as a member of our Board of Directors since February 2002. Since 2008, Mr. Prins has been a private investor and involved in various charitable organizations. Mr. Prins also served in various volunteer roles at Advancing Native Missions since 2004 including as a board member, Head of Operations and Stewardship, and as interim CEO. He has also served as a director of India Globalization Capital, Inc., a biopharmaceutical company, since 2007, and as chairman of its board since 2012. Mr. Prins was the Director of Investment Banking for FBW, from 1996 until June 2008 when FBW was acquired by Royal Bank of Canada. Prior to FBW, Mr. Prins was a Managing Director from July 1988 to April 1996 at Crestar Bank (now Truist Bank) in charge of mergers and acquisitions. Mr. Prins began his career in 1983 as the Assistant to the Chairman of the leverage buyout company, Tuscarora Corp., where he held various positions until July 1988. Mr. Prins received a B.A. in liberal arts from Colgate University and an M.B.A. from Oral Roberts University.

We believe that Mr. Prins' experience in corporate finance and investment banking qualifies him to serve on our Board of Directors.

Diane G. Gerst has served as a member of our Board of Directors since June 2019. She previously served as our Executive Vice President of Quality Assurance and Regulatory Affairs from June 2015 until February 2018 and also served as the President of Amphastar Nanjing Pharmaceuticals Inc., one of our subsidiaries, from March 2014 until February 2018. From August 2013 to June 2015, Ms. Gerst served as our Corporate Senior Vice President of Quality Assurance. She served as Corporate Vice President of Quality Assurance from August 2003 until her promotion to Senior Vice President in August 2013 and as Vice President of Regulatory Affairs from June 2001 to July 2002. Prior to joining us, Ms. Gerst held various management level positions in regulatory and quality including eight years at Braun-McGaw and seven years at IMS. Ms. Gerst received a B.A. from the University of California, Berkeley.

We believe that Ms. Gerst is qualified to serve on our Board of Directors because of her perspective, experience and leadership as a former executive of our Company.

Mary Z. Luo, Ph.D. co-founded our Company in 1996 and has served as our Chief Operating Officer and chairman of our Board of Directors since our inception and as Corporate Secretary from 1997 to April 2004. Dr. Luo has also served as our Chief Scientist since 2005. Dr. Luo co-founded Applied Physics & Chemistry Laboratories, Inc., or APCL, a full service chemical analytical laboratory, in May 1989, where she held the position of Chief Operating Officer. Dr. Luo is a professor emeritus of chemistry at California State Polytechnic University, Pomona and is named as the inventor on several U.S. and foreign patents. Dr. Luo received a Ph.D. in chemistry from Princeton University and was a Post-Doctoral Research Associate at the California Institute of Technology.

We believe Dr. Luo's experience in the pharmaceutical industry and as one of our founders qualifies her to serve on our Board of Directors.

Howard Lee, Ph.D. has served as a member of our Board of Directors since August 2007. He previously served as a member of the board of our subsidiary, IMS, from 1998 to 2002 and on our Board of Directors from 2002 to 2004. Dr. Lee has served as the Chairman and Chief Executive Officer of TAHO Pharmaceuticals, Ltd., a drug development company with a transdermal technology platform based in Taiwan since January 2020. Previously, Dr. Lee was the partner at the CID Group, a prominent investment group in the greater China area from March 2012 to January 2020. From 2009 to 2010 he was the Chief Investment Officer at UniMed Venture Management Inc., a biotech venture capital firm. Prior to joining UniMed in July 2009, he was a Managing Director at Silver Biotech Management, Inc. from July 2006 to June 2009. Dr. Lee

served as President and CEO of CDIB Biotech USA Investment Co. Ltd. from 2000 to 2006 and as Vice President of China Development Industrial Bank, an investment bank in Taiwan, from October 1995 to June 2006. Dr. Lee earned his B.Sc. at Fu-Jen University (Taiwan), his M.Sc. and Ph.D. degrees in chemistry from the University of Southern California in Los Angeles and completed his postdoctoral research at the Loker Hydrocarbon Research Institute of the University of Southern California.

We believe Dr. Lee's experience in biotech venture capital consulting qualifies him to serve on our Board of Directors.

Michael A. Zasloff, M.D., Ph.D. has served as a member of our Board of Directors since October 2005 and previously served as our lead independent director from January 2016 to April 2019. Dr. Zasloff has been the Professor of Surgery and Pediatrics at the Georgetown University School of Medicine since 2002, and currently serves as Scientific Director of the MedStart – Georgetown Transplant Institute. In 2016 Dr. Zasloff founded Enterin, Inc., a biopharmaceutical company developing therapeutics for Parkinson's disease and other neurodegenerative disorders, where he serves as Director and Chief Scientific Officer. Dr. Zasloff served as the Dean of Research and Translational Science from 2002 until 2004. Between 2004 and 2007, Dr. Zasloff served as Vice President and Senior Analyst (Life Sciences) at Ferris, Baker Watts, Inc., or FBW. From 1992 to 2001 Dr. Zasloff served as Executive Vice President and Vice Chairman of Magainin Pharmaceuticals Inc., a biopharmaceutical company which he founded. From 1988 until 1992, Dr. Zasloff served as the Charles E.H. Upham Professor in the Department of Pediatrics and Genetics at the University of Pennsylvania School of Medicine, and Chief, Division of Human Genetics and Molecular Biology at The Children's Hospital of Philadelphia. From 1982 until 1988, Dr. Zasloff was Chief of the Human Genetics Branch at the National Institutes of Child Health and Human Development, National Institutes of Health. Dr. Zasloff received a B.A. from Columbia College in biochemistry and holds an M.D., Ph.D. from the New York University School of Medicine.

We believe Dr. Zasloff's expertise and experience in the biopharmaceutical industry qualifies him to serve on our Board of Directors.

Gayle Deflin has been the Chief Financial Officer of LBMB, Inc., since 2014, and its subsidiaries Plasticolor Molded Products, Inc. and Chroma Graphics, Inc., both of which are automotive accessory manufacturers and distributors since 2006. Prior to 2006, Ms. Deflin was at Apria Healthcare, a provider of home respiratory services from 2004 to 2006 as Vice President of Strategic Planning and Budgeting and Vice President of Billing Center Operations. From 2003 to 2004 she served as President and Chief Executive Officer of Ionian Technologies, a diagnostic start-up with biotechnology developed at the Keck Graduate Institute of Applied Life Sciences. Ms. Deflin worked in various positions at International Medication Systems Limited, including as its President, from 1989 until it was sold to Amphastar in 1998, and continued with Celltech Pharmaceuticals, the former owner of International Medication Systems, Limited, as President of MD Pharmaceuticals from 1996 to 2002 and Senior Vice President, Business Support Services of Celltech Pharmaceuticals from 2000 to 2002. Ms. Deflin holds a B.S. in Business Administration (Accounting and MIS) from Bowling Green State University and an M.B.A from the Drucker School of Management at Claremont Graduate University.

We believe that Ms. Deflin's past experience and expertise in the field of pharmaceuticals and retail consumer products, as well as her operational management experience qualifies her to serve on our Board of Directors.

Director Independence

Our common stock is listed on the Nasdaq Global Select Market. Under the listing standards of Nasdaq, independent directors must comprise a majority of a listed company's Board of Directors. In addition, the

listing standards of Nasdaq require that, subject to specified exceptions, each member of a listed company's audit and compensation committees be independent. While the listing standards of Nasdaq do not require a nomination committee, the functions normally undertaken by a nomination committee must, in most cases, be performed by independent directors. Under the listing standards of Nasdaq, a director will only qualify as an "independent director" if, in the opinion of that listed company's Board of Directors, that director does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act, and the listing standards of Nasdaq. In addition, compensation committee members must also satisfy the independence criteria set forth under the listing standards of Nasdaq.

Our Board of Directors has undertaken a review of the independence of each director nominee and director. Based on information provided by each director nominee and director concerning his or her background, employment and affiliations, our Board of Directors has determined that Messrs. Petersen and Prins, Drs. Lee and Zasloff, Mses. Gerst and Deflin do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the listing standards of Nasdaq. In making these determinations, our Board of Directors considered the current and prior relationships that each non-employee director nominee and director has with our Company and all other facts and circumstances our Board of Directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director nominee and director, and the transactions involving them described in the section titled "Related Person Transactions."

Board Leadership Structure

We believe that the current structure of our Board of Directors and its committees is appropriate and provides for strong overall management of our Company. While the Chairman of our Board of Directors and our Chief Executive Officer roles are separate, our current Chairman, Mary Ziping Luo, is not independent under the listing standards of Nasdaq as she is an employee of our Company. Our Board of Directors believes that, given the perspective and experience Dr. Luo brings as one of our founders, Dr. Luo's service as our Chairman is nonetheless appropriate and is in the best interests of our Board of Directors, our Company and our stockholders.

Our Chief Executive Officer and President, Jack Yongfeng Zhang, is responsible for setting the strategic direction of our Company, the general management and operation of the business and the guidance and oversight of senior management. In her capacity as Chief Operating Officer and Chief Scientist, Dr. Luo is responsible for operation of the business and the guidance and oversight of senior management. In her capacity as Chairman of our Board of Directors, Dr. Luo monitors the content, quality and timeliness of information sent to our Board of Directors and is available for consultation with our Board of Directors regarding the oversight of our business affairs.

Family Relationships

Dr. Zhang, our Chief Executive Officer, President, Chief Scientific Officer and a director, and Dr. Luo, our Chief Operating Officer, Chief Scientist and Chairman, are husband and wife. Certain family members of Dr. Zhang and Dr. Luo are employees of the Company as described in the section titled "Related Party Transactions."

Board Diversity Matrix

The following matrix summarizes voluntary disclosure of diversity characteristics of our Board of Directors:

Board Diversity Matrix (As of April 10, 2023)				
Total Number of Directors	10			
	Female	**Male**	**Non-Binary**	**Did Not Disclose Gender**
Part I: Gender Identity				
Directors	3	6	—	1
Part II: Demographic Background				
African American or Black	—	—	—	—
Alaskan Native or Native American	—	—	—	—
Asian	1	3	—	—
Hispanic or Latinx	—	—	—	—
Native Hawaiian or Pacific Islander	—	—	—	—
White	2	2		
Two or More Races or Ethnicities	—	—	—	—
LGBTQ+	—			
Did Not Disclose Demographic Background	2			

ESG Board Oversight Framework

Our Board of Directors assesses and evaluates our overall environmental, social, and governance ("ESG") strategy and how ESG integrates into our long-term strategy. At the committee level, our nominating and corporate governance committee is primarily responsible with respect to board diversity. Our compensation committee oversees the integration of our ESG strategy and policies into our executive compensation plans. Our audit committee oversees the processes and controls that ensure the accuracy and consistency of our ESG disclosures, including information security. Our Board of Directors receives reports from the committees on these ESG matters and considers them in the context of our overall ESG risk management, messaging, and disclosures.

Board Meetings and Committees

During our fiscal year ended December 31, 2022, our Board of Directors held ten (10) meetings (including regularly scheduled and special meetings), and each director attended at least 75% of the aggregate of (i) the total number of meetings of our Board of Directors held during the period for which he or she has been a director and (ii) the total number of meetings held by all committees of our Board of Directors on which he or she served during the periods that he or she served.

Although we do not have a formal policy regarding attendance by members of our Board of Directors at annual meetings of stockholders, we encourage, but do not require, our directors to attend. All ten incumbent directors attended our 2022 annual meeting of stockholders.

Our Board of Directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. The composition and responsibilities of each of the committees of our Board of Directors is described below. Members will serve on these committees until their resignation or until as otherwise determined by our Board of Directors.

Audit Committee

Our audit committee currently consists of Ms. Deflin, who is the chair of the committee, Dr. Lee and Mr. Prins, each of whom is independent in accordance with the Nasdaq and SEC standards. Ms. Deflin is an "audit committee financial expert" as the term is defined under SEC regulations. The audit committee operates under a written charter. The functions of the audit committee include assisting our Board of Directors in oversight of:

- our accounting and financial reporting processes and internal controls;
- the audit and integrity of our financial statements;
- our compliance with applicable law;
- the engagement of, qualifications, independence and performance of our independent auditors; and
- the implementation and performance of our internal audit function.

Both our independent registered accounting firm and internal financial personnel regularly meet with our audit committee and have unrestricted access to the audit committee.

Our audit committee operates under a written charter that satisfies the applicable rules and regulations of the SEC and the listing standards of Nasdaq. A copy of the charter of our audit committee is available on the Corporate Governance portion of our website at http://ir.amphastar.com/corporate-governance/highlights. During 2022, our audit committee held six (6) meetings.

Compensation Committee

Our compensation committee currently consists of Mr. Prins, who is the chair of the committee, Dr. Zasloff and Mr. Petersen, each of whom is independent in accordance with the Nasdaq standards. Each member of our compensation committee is also a non-employee director, as defined pursuant to Rule 16b-3 promulgated under the Exchange Act, and an outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code of 1986, as amended. The compensation committee operates under a written charter. The functions of the compensation committee include:

- oversee our compensation policies, plans, benefits programs, and overall compensation philosophy;
- assisting our Board of Directors in discharging its responsibilities related to overseeing compensation of our CEO and executive officers and evaluating and recommending the executive compensation plans, policies and programs;

- administering our incentive compensation plans, equity compensation plans, and such other plans as designated from time to time by our Board of Directors.

Our compensation committee operates under a written charter that satisfies the applicable rules and regulations of the SEC and the listing standards of Nasdaq. A copy of the charter of our compensation committee is available on the Corporate Governance portion of our website at http://ir.amphastar.com/corporate-governance/highlights. During 2022, our compensation committee held three (3) meetings.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of Dr. Lee, who is the chair of the committee, Ms. Gerst and Dr. Zasloff, each of whom is independent in accordance with the Nasdaq standards. The nomination committee operates under a written charter. The functions of the nomination committee include:

- reviewing the qualifications of, and recommending to the Board of Directors, proposed nominees for election to the Board of Directors and its committees, consistent with criteria approved by the Board of Directors;

- developing, evaluating and recommending to the Board of Directors corporate governance practices applicable to us; and

- facilitating the annual performance review of the Board of Directors and its committees.

Our nomination committee operates under a written charter that satisfies the requirements for directors performing nominating functions under the listing standards of Nasdaq. A copy of the charter of our nomination committee is available on the Corporate Governance portion of our website at http://ir.amphastar.com/corporate-governance/highlights. During 2022, our nominating and corporate governance committee held five (5) meetings.

Compensation Committee Interlocks and Insider Participation

None of the members of the compensation committee is or has ever been one of our officers or employees. None of our executive officers serves, or in the past has served, as a member of the compensation committee or on the Board of Directors of any entity that has one or more executive officers serving on our Board of Directors or compensation committee.

Considerations in Evaluating Director Nominees

Our nominating and corporate governance committee uses a variety of methods for identifying and evaluating director nominees. While our board has not established minimum qualifications for board members, some of the factors that our nominating and corporate governance committee considers in assessing director nominee qualifications include, the existing size and composition of our Board of Directors, the number and qualification of candidates, the benefit of continuity on the Board of Directors and the relevance of the candidate's background and experience to the issues we face. Our nominating and corporate governance committee relies upon various criteria for board membership, which may include, without limitation, that a candidate: be of the highest ethical character; exhibit sound business judgment; preserve the confidentiality of materials given or presented to the board and not use such materials for personal gain; has demonstrated leadership and significant experience in an area of endeavor relevant to our business; comprehend the role of a public company director (particularly the fiduciary obligations to us and our stockholders); understand our business and industry and keep informed on our operations; disclose to other directors any potential conflicts

of interest (and if appropriate, refrain from voting on certain matters); dedicate sufficient time to our business, including attendance at meetings of the Board of Directors or committees on which he or she serves and stockholder meetings (and prepare for such meetings as required and appropriate); be independent of any particular constituency and not engaged in any activity adverse to us or in conflict with our interests (including, without limitation, service on the board or in the management of a competing company) and thus be able to represent all of our stockholders; and demonstrate a willingness toward free and open exchange of ideas and opinions, and exercise balance, fitness, care and due and independent deliberation in the decision-making process.

Qualification and backgrounds of the directors as a whole should provide the proper breadth of knowledge, abilities and experience to appropriate composition of the board. Although our nominating and corporate governance committee does not have specific requirements with respect to board diversity, it believes that our board should be a diverse body, considering such factors as gender, race, ethnicity and experience, area of expertise, potential conflicts of interest and other commitments and other individual qualities and attributes that contribute to the total mix of viewpoints and experience represented on the Board of Directors. Re-nomination of existing directors will not be viewed as automatic, but rather will be based on continuing qualification using the criteria set forth above.

Our nominating and corporate governance committee considers these and other factors as it oversees the annual board of director and committee evaluations. After completing its review and evaluation of director candidates, our nominating and corporate governance committee recommends to our full Board of Directors the director nominees for selection.

Stockholder Recommendations for Nominations to the Board of Directors

Our nominating and corporate governance committee will consider candidates for director recommended by stockholders, provided that (i) any recommending stockholder must have continuously held at least $2,000 in market value, or 1%, of the Company's securities entitled to be voted on the proposal at the meeting for at least one year by the date you submit the proposal, and (ii) such recommendations comply with our amended and restated certificate of incorporation and amended and restated bylaws and applicable laws, rules and regulations, including those promulgated by the SEC. The nominating and corporate governance committee will evaluate such recommendations in accordance with its charter, our amended and restated bylaws, our policies and procedures for director candidates, as well as the regular director nominee criteria described above.

Any nomination should be sent in writing to our Corporate Secretary at Amphastar Pharmaceuticals, Inc., 11570 6th Street, Rancho Cucamonga, California 91730. To be timely for our 2024 annual meeting of stockholders, our Secretary must receive the nomination no earlier than February 5, 2024 and no later than March 7, 2024.

Communications with the Board of Directors

Interested parties wishing to communicate with our Board of Directors or with an individual member or members of our Board of Directors to provide comments, to report concerns, or to ask a question, at the following address:

Amphastar Pharmaceuticals, Inc.
Attention: Corporate Secretary
11570 6th Street
Rancho Cucamonga, California 91730

You may submit your concerns anonymously or confidentially by postal mail. You may also indicate whether you are a stockholder, customer, supplier, or other interested party.

Communications are distributed to the Board of Directors, or to any individual directors as appropriate, depending on the facts and circumstances outlined in the communication. In that regard, the Amphastar Pharmaceuticals, Inc. Board of Directors has requested that certain items which are unrelated to the duties and responsibilities of the Board of Directors should be excluded, such as:

- Product complaints
- Product inquiries
- New product suggestions
- Resumes and other forms of job inquiries
- Surveys
- Business solicitations or advertisements

In addition, material that is unduly hostile, threatening, illegal or similarly unsuitable will be excluded, with the provision that any communication that is filtered out must be made available to any non-management director upon request.

You may also communicate online with our Board of Directors as a group on our website at http://ir.amphastar.com/corporate-governance/contact-the-board.

Code of Conduct

We have adopted a code of conduct that applies to our officers, directors and employees, including our Chief Executive Officer, Chief Financial Officer, and other executive and senior financial officers. Our code of conduct is available on our website at http://ir.amphastar.com/corporate-governance/highlights. We intend to disclose any amendments of our code of conduct, or waivers of its requirements for directors or executive officers, on our website.

Annual Board and Committee Self-Assessments

Our Board of Directors and each committee conduct an annual self-assessment designed to determine whether the board and the committees are functioning effectively and to provide them with an opportunity to improve their effectiveness. The self-assessments enables directors to provide confidential feedback on a variety of topics ranging from Board and committee structure and composition, culture, responsibility and accountability of directors and individual directors. A summary of the results is presented to the board and each committee, which each consider ways in which effectiveness may be enhanced. While the formal board and committee self-evaluation is conducted on an annual basis, the directors share perspectives, feedback and suggestions year-round.

Board Leadership Structure and Role in Risk Oversight

Our Board of Directors has responsibility for the oversight of our risk management processes and, either as a whole or through our committees, regularly discusses with management our major risk exposures, their potential impact on our business and the steps we take to mitigate or manage them. The risk oversight process includes receiving reports from committees of our Board of Directors and members of senior management to enable our Board of Directors to understand our risk identification, risk management and risk mitigation strategies with respect to areas of potential material risk, including operations, finance, legal, regulatory, strategic, cybersecurity and reputational risk.

The audit committee oversees our management of financial risks. Periodically, the audit committee reviews our policies with respect to risk assessment and risk management. Oversight by the audit committee includes direct communication with our external auditors, and discussions with management regarding significant risk exposures and the actions management has taken to limit, monitor or control such exposures. The compensation committee is responsible for assessing whether any of our compensation policies or programs has the potential to encourage excessive risk-taking. The nominating and corporate governance committee manages risks associated with the independence of the Board of Directors, corporate disclosure practices and potential conflicts of interest. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, the entire board or directors is regularly informed through committee reports about such risks. Matters of significant strategic risk are considered by our Board of Directors as a whole.

Lead Independent Director

Recognizing the importance of strong independent oversight, effective April 2019, our Board of Directors appointed Richard Prins to serve as our lead independent director. As lead independent director, Mr. Prins presides over regularly scheduled executive sessions of our independent directors without management participation, serves as a liaison between our Chairman and CEO and the independent directors, disseminates information to the rest of the Board of Directors in a timely manner, and raises issues with management on behalf of the outside directors when appropriate. In addition, the lead independent director's responsibilities include the following:

- Building a productive relationship between the Board of Directors and the Chairman and CEO; and

- Performing such other duties as the Board of Directors may from time to time designate

Non-Employee Director Compensation

Cash and Equity Compensation

We compensate non-employee members of the Board of Directors. Directors who are also employees do not receive cash or equity compensation for service on the Board of Directors in addition to compensation payable for their service as our employees. The non-employee members of our Board of Directors are reimbursed for travel, lodging and other reasonable expenses incurred in attending Board of Directors or committee meetings. Our directors receive equity grants annually at the fair market value of our common stock at the time of grant under our Amended and Restated 2015 Equity Incentive Plan (the "2015 Plan").

The cash and equity components of our compensation policy for non-employee directors are set forth below:

Position	Annual Cash Retainer	Equity Grant
Base Fee	$ 55,000	$ 250,000
Lead Independent Director	25,000	
Chairperson Fee		
Audit Committee	25,000	
Compensation Committee	20,000	
Nominating and Corporate Governance Committee	12,500	
Committee Member Fee		
Audit Committee	12,000	
Compensation Committee	10,000	
Nominating and Corporate Governance Committee	6,000	

Under our director compensation program, on the date of each annual meeting of our stockholders each outside director will receive an equity award with a grant date fair value of $250,000 comprised of 50% restricted stock units and 50% stock options which vest on the first anniversary of the date of grant, subject to continued service through the vesting date until the annual meeting the following year.

Compensation for 2022

The following table sets forth summary information concerning the compensation awarded to, paid to, or earned by the non-employee members of our Board of Directors for the fiscal year ended December 31, 2022:

Director	Fees Earned or Paid in Cash($)	Stock Awards ($)(1)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)
Howard Lee	79,500	124,973	125,030	—	329,503
Floyd F. Petersen	67,670	124,973	125,030	—	317,673
Richard Prins	109,775	124,973	125,030	—	359,778
Michael A. Zasloff	71,000	124,973	125,030	—	321,003
Diane Gerst	46,091	124,973	125,030	—	296,094
Gayle Deflin	80,000	124,973	125,030	—	330,003

(1) This amount reflects the aggregate grant fair value computed in accordance with ASC Topic 718. The assumptions that we used to calculate these amounts are discussed in Note 16 to our consolidated financial statements included in our Annual Report on Form 10-K, as filed with the SEC on March 1, 2023.

The following table lists all outstanding equity awards held by our non-employee directors as of December 31, 2022.

Name	Aggregate Number of Stock Options Outstanding as of December 31, 2022	Aggregate Number of Stock Awards Outstanding as of December 31, 2022
Howard Lee	74,764 (1)	4,163 (2)
Floyd F. Petersen	74,764 (1)	4,163 (2)
Richard Prins	74,764 (1)	4,163 (2)
Michael A. Zasloff	74,764 (1)	4,163 (2)
Diane Gerst	24,538 (3)	4,163 (2)
Gayle Deflin	28,166 (4)	4,163 (2)

(1) Includes (i) 63,780 shares subject to options which are fully vested and immediately exercisable and (ii) 10,984 shares subject to an option all of which vest on June 10, 2023.

(2) The shares are represented by RSUs consisting of 4,163 shares which vest on June 10, 2023.

(3) Includes (i) 13,554 shares subject to options which are fully vested and immediately exercisable and (ii) 10,984 shares subject to an option all of which vest on June 10, 2023.

(4) Includes (i) 17,182 shares subject to options which are fully vested and immediately exercisable and (ii) 10,984 shares subject to an option all of which vest on June 10, 2023.

PROPOSAL NO. 1
ELECTION OF DIRECTORS

Our Board of Directors is currently composed of ten members. In accordance with our amended and restated certificate of incorporation, our Board of Directors is divided into three staggered classes of directors. At the Annual Meeting, three Class I directors will be elected for a three-year term to succeed the same class whose term is then expiring.

Each director's term continues until the election and qualification of his or her successor, or such director's earlier death, resignation, or removal. Any increase or decrease in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of our directors. This classification of our Board of Directors may have the effect of delaying or preventing changes in control of our Company.

Nominees

Our nominating and corporate governance committee has recommended, and our Board of Directors has approved, Floyd F. Petersen, Jacob Liawatidewi, and William J. Peters as nominees for election as Class I directors at the Annual Meeting. If elected, each of Messrs. Petersen, Liawatidewi and Peters will serve as Class I directors until the 2026 annual meeting of stockholders and until their successors are duly elected and qualified and our board will be composed of ten directors. Messrs. Petersen, Liawatidewi and Peters each currently serve as a director of our Company. For information concerning the nominees, please see the section titled "Board of Directors and Corporate Governance."

If you are a stockholder of record and you sign your proxy card or vote by telephone or over the Internet but do not give instructions with respect to the voting of directors, your shares will be voted "FOR" the election of Messrs. Petersen, Liawatidewi and Peters. We expect that Messrs. Petersen, Liawatidewi and Peters will accept such nomination; however, in the event that a director nominee is unable or declines to serve as a director at the time of the Annual Meeting, the proxies will be voted for any nominee who shall be designated by our Board of Directors to fill such vacancy. If you are a street name stockholder and you do not give voting instructions to your broker or nominee, your broker will leave your shares unvoted on this matter.

Vote Required

Each director to be elected by the stockholders of the corporation shall be elected by the affirmative vote of a majority of the votes cast with respect to such director by the shares present or represented by proxy at the Annual Meeting at which a quorum is present and entitled to vote thereon. Abstentions and broker non-votes will have no effect on the outcome of this proposal.

THE BOARD OF DIRECTORS RECOMMENDS A VOTE "FOR"
EACH OF THE NOMINEES NAMED ABOVE.

PROPOSAL NO. 2
RATIFICATION OF APPOINTMENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Our audit committee has appointed Ernst & Young LLP ("EY"), an independent registered public accounting firm, to audit our consolidated financial statements for our fiscal year ending December 31, 2023. During our fiscal year ended December 31, 2022, EY served as our independent registered public accounting firm.

Notwithstanding the appointment of EY and even if our stockholders ratify the appointment, our audit committee, in its discretion, may appoint another independent registered public accounting firm at any time during our fiscal year if our audit committee believes that such a change would be in the best interests of Amphastar Pharmaceuticals, Inc. and its stockholders. At the Annual Meeting, our stockholders are being asked to ratify the appointment of EY as our independent registered public accounting firm for our fiscal year ending December 31, 2023. Our audit committee is submitting the appointment of EY to our stockholders because we value our stockholders' views on our independent registered public accounting firm and as a matter of good corporate governance. Representatives of EY will be present at the Annual Meeting, and they will have an opportunity to make a statement and will be available to respond to appropriate questions from our stockholders.

If our stockholders do not ratify the appointment of EY, our Board of Directors may reconsider the appointment.

Fees Paid to the Independent Registered Public Accounting Firm

The following table presents fees for professional audit services and other services rendered to our Company by EY for our fiscal years ended December 31, 2021 and 2022.

	2022	2021
	(In Thousands)	
Audit Fees (1)	$ 3,516	$ 3,037
Audit-Related Fees (2)	—	—
Tax Fees (3)	—	—
All Other Fees (4)	4	3
Total Fees	$ 3,520	$ 3,040

(1) Audit Fees consist of professional services rendered in connection with the integrated audit of our annual consolidated financial statements and of our internal control over financial reporting services that are normally provided by the independent registered public accountants in connection with statutory and regulatory filings or engagements for those fiscal years and timely review of our quarterly consolidated financial statements. This category also includes advice on accounting matters that arose during the audit or the review of consolidated financial statements.

(2) Audit-Related Fees consist of fees for professional services for assurance and related services that are reasonably related to the performance of the audit or review of our consolidated financial statements and are not reported under "Audit Fees." These services include accounting, consultations and audits in connection with acquisitions, internal control reviews, attest services related to financial reporting that are not required by statute or regulation and consultation concerning financial accounting and reporting standards not classified as audit fees.

(3) Tax Fees consist of fees for professional services for tax compliance, tax advice and tax planning.

(4) All Other Fees consist of fees related to accessing Ernst & Young LLP's online research database.

Auditor Independence

In our fiscal year ended December 31, 2022, there were no other professional services provided by EY, other than those listed above, that would have required our audit committee to consider their compatibility with maintaining the independence of EY.

Audit Committee Policy on Pre-Approval of Audit and Permissible Non-Audit Services of Independent Registered Public Accounting Firm

Our audit committee has established a policy governing our use of the services of our independent registered public accounting firm. Under the policy, our audit committee is required to pre-approve all audit and non-audit services performed by our independent registered public accounting firm in order to ensure that the provision of such services does not impair the public accountants' independence. All fees paid to EY for our fiscal years ended December 31, 2021 and 2022 were pre-approved by our audit committee.

Vote Required

The ratification of the appointment of EY requires the affirmative vote of a majority of the voting power of the shares present or represented by proxy at the Annual Meeting at which a quorum is present and entitled to vote thereon. Abstentions will have the effect of a vote AGAINST the proposal and broker non-votes will have no effect on the outcome of this proposal.

THE BOARD OF DIRECTORS RECOMMENDS A VOTE "FOR" THE RATIFICATION OF THE APPOINTMENT OF ERNST & YOUNG LLP.

PROPOSAL NO. 3
ADVISORY VOTE ON THE COMPENSATION OF OUR NAMED EXECUTIVE OFFICERS

The Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (the "Dodd-Frank Act"), enables our stockholders to approve, on an advisory or non-binding basis, the compensation of our named executive officers as disclosed pursuant to Section 14A of the Exchange Act. This proposal, commonly known as a "Say-on-Pay" proposal, gives our stockholders the opportunity to express their views on our named executive officers' compensation as a whole. This vote is not intended to address any specific item of compensation or any specific named executive officer, but rather the overall compensation of all of our named executive officers and the philosophy, policies and practices described in this proxy statement.

The Say-on-Pay vote is advisory, and therefore is not binding on us, our compensation committee or our Board of Directors. The Say-on-Pay vote will, however, provide information to us regarding investor sentiment about our executive compensation philosophy, policies and practices, which our compensation committee will be able to consider when determining executive compensation for the remainder of the current fiscal year and beyond. Our Board of Directors and our compensation committee value the opinions of our stockholders. To the extent there is any significant vote against the compensation of our named executive officers as disclosed in this proxy statement, we will endeavor to communicate with stockholders to better understand the concerns that influenced the vote and consider our stockholders' concerns, and our compensation committee will evaluate whether any actions are necessary to address those concerns.

We believe that the information provided in the section titled "Executive Compensation" and in particular the information discussed in the section titled "Executive Compensation-Objectives and Philosophy of Our Executive Compensation Program" demonstrates that our executive compensation program was designed appropriately and is working to ensure management's interests are aligned with our stockholders' interests to support long-term value creation. Accordingly, we ask our stockholders to vote "FOR" the following resolution at the Annual Meeting:

"RESOLVED, that the stockholders approve, on an advisory basis, the compensation paid to our named executive officers, as disclosed in the proxy statement for the Annual Meeting pursuant to the compensation disclosure rules of the SEC, including the compensation discussion and analysis, compensation tables and narrative discussion and other related disclosure."

Vote Required

The approval, on an advisory basis, of the compensation of our named executive officers requires the affirmative vote of a majority of the voting power of the shares of our common stock present virtually or by proxy at the Annual Meeting and entitled to vote thereon to be approved. Abstentions will have the effect of a vote against this proposal, and broker non-votes will have no effect.

As an advisory vote, the result of this proposal is non-binding. Although the vote is non-binding, our Board of Directors and our compensation committee value the opinions of our stockholders and will consider the outcome of the vote when making future compensation decisions for our named executive officers.

THE BOARD OF DIRECTORS RECOMMENDS A VOTE "FOR" THE APPROVAL, ON AN ADVISORY BASIS, OF THE COMPENSATION OF OUR NAMED EXECUTIVE OFFICERS.

REPORT OF THE AUDIT COMMITTEE

The audit committee is a committee of the Board of Directors comprised solely of independent directors as required by the listing standards of Nasdaq and rules and regulations of the SEC. The audit committee operates under a written charter approved by the Board of Directors, which is available on the Corporate Governance portion of our website at http://ir.amphastar.com/corporate-governance/highlights. The composition of the audit committee, the attributes of its members and the responsibilities of the audit committee, as reflected in its charter, are intended to be in accordance with applicable requirements for corporate audit committees. The audit committee reviews and assesses the adequacy of its charter and the audit committee's performance on an annual basis.

With respect to our financial reporting process, our management is responsible for (1) establishing and maintaining internal controls and (2) preparing our consolidated financial statements. Our independent registered public accounting firm, Ernst & Young LLP ("EY"), is responsible for auditing these financial statements. It is the responsibility of the audit committee to oversee these activities. It is not the responsibility of the audit committee to prepare our financial statements. These are the fundamental responsibilities of management. In the performance of its oversight function, the audit committee has:

- reviewed and discussed the audited financial statements with management and EY;
- discussed with EY the matters required to be discussed by the applicable requirements of Public Company Accounting Oversight Board ("PCAOB") Auditing Standard No. 1301, Communications with Audit Committees, and the SEC;
- received the written disclosures and the letter from EY required by applicable requirements of the PCAOB regarding the independent accountant's communications with the audit committee concerning independence, and has discussed with EY its independence; and
- discussed with EY critical audit matters included in their audit opinion.

In addition, the audit committee has regularly met separately with management and with EY, and further to the matters specified above, had discussed with EY the overall scope, plans, and estimated costs of its audits. The audit committee met with EY periodically to discuss the results of their examinations, the overall quality of our financial reporting, and their reviews of the quarterly financial statements.

Based on the audit committee's review and discussions with management and EY, the audit committee recommended to the Board of Directors that the audited financial statements be included in the Annual Report on Form 10-K for the fiscal year ended December 31, 2022 for filing with the Securities and Exchange Commission.

Respectfully submitted by the members of the audit committee of the Board of Directors:

Gayle M. Deflin (Chairperson)
Howard Lee
Richard Prins

This report of the audit committee is required by the SEC and, in accordance with the SEC's rules, will not be deemed to be part of or incorporated by reference by any general statement incorporating by reference this proxy statement into any filing under the Securities Act or under the Exchange Act, except to the extent that we specifically incorporate this information by reference, and will not otherwise be deemed "soliciting material" or "filed" under either the Securities Act or the Exchange Act.

EXECUTIVE OFFICERS

The following table identifies certain information about our executive officers as of April 10, 2023. Officers are elected by our Board of Directors to hold office until their successors are elected and qualified.

Name	Age	Position
Jack Yongfeng Zhang, Ph.D	76	Chief Executive Officer, President, Chief Scientific Officer and Director
William J. Peters	55	Chief Financial Officer, Executive Vice President of Finance, and Treasurer; President of International Medication Systems, Limited, and Director
Mary Ziping Luo, Ph.D	73	Chief Operating Officer, Chief Scientist and Chairman of the Board of Directors
Rong Zhou	64	Senior Executive Vice President of Production Center; Executive Vice President of Scientific Affairs and President of Amphastar Nanjing Pharmaceuticals, Co., Ltd.
Jacob Liawatidewi	49	Executive Vice President of Sales and Marketing and Corporate Administration Center, President of Amphastar France Pharmaceuticals, S.A.S., Corporate Secretary, and Director

For biographies of Drs. Zhang and Luo, Messrs. Peters and Liawatidewi, please see "Board of Directors and Corporate Governance."

Rong Zhou has served in various executive roles since joining us in October 1998, most recently as Senior Executive Vice President of Production Center since February 2023, Executive Vice President of Scientific Affairs since February 2023, and President of Amphastar Nanjing Pharmaceuticals, Co., Ltd. (a wholly-owned subsidiary of Amphastar) since February 2021. Mr. Zhou served as our Executive Vice President of Production Center from June 2015 until his promotion to Senior Executive Vice President, President of Armstrong Pharmaceuticals, Inc. (a wholly-owned subsidiary of Amphastar) from March 2014 to February 2023 and as our Senior Vice President of Scientific Affairs from August 2012 until his promotion to Executive Vice President. Mr. Zhou served as Corporate Vice President of Scientific Affairs from October 2001 until his promotion to Senior Vice President. Mr. Zhou received a B.S. in Chemical Engineering from the Fuzhou University and an M.S. from Youngstown State University.

EXECUTIVE COMPENSATION

Compensation Discussion and Analysis

This Compensation Discussion and Analysis provides information related to our 2022 compensation program and related decisions for our named executive officers. For 2022, our named executive officers were:

- Jack Yongfeng Zhang, Ph.D, our Chief Executive Officer, President, Chief Scientific Officer and Director;
- William J. Peters, our Chief Financial Officer, Executive Vice President of Finance, and Treasurer;
- Mary Ziping Luo, Ph.D, our Chief Operating Officer, Chief Scientist and Chairman of the Board of Directors;
- Rong Zhou, our Senior Executive Vice President of Production Center; and
- Jacob Liawatidewi, our Executive Vice President of Sales and Marketing and Corporate Administration Center.

Mr. Zhou was promoted from Executive President of Production Center to Senior Executive Vice President of Production Center in February 2023.

Executive Summary

2022 Business Summary

We are a bio-pharmaceutical company that focuses primarily on developing, manufacturing, marketing and selling technically challenging generic and proprietary injectable, inhalation, and intranasal products, and insulin active pharmaceutical ingredient, or insulin API, products. We currently manufacture and sell over 20 products. We are currently developing a portfolio of generic products, biosimilar products, and proprietary products, which are in various stages of development and targets a variety of indications. We currently have three Abbreviated New Drug Applications ("ANDAs") on file with the FDA. Our primary strategic focus is to develop and commercialize products with high technical barriers to market entry. We are specifically focused on products that:

- leverage our proprietary research and development capabilities;
- require raw materials or active pharmaceutical ingredients, or API, for which we believe we have a competitive advantage in sourcing, synthesizing or manufacturing; and/or
- improve upon an existing drug's formulation with respect to drug delivery, safety and/or efficacy.

For 2022, we achieved strong sales growth and significantly improved business results on an adjusted non-GAAP earnings basis which provides context for stockholders reviewing our executive compensation disclosures, including:

- *Net Income*: Our net income in 2022 was $91.4 million, compared to a net income of $62.1 million in 2021. Our non-GAAP adjusted net income increased to $103.2 million in 2022 from $68.0 million in 2021. For a reconciliation of the non-GAAP adjusted net income to GAAP net income for 2022 and 2021, see Annex A.
- *Sales*: Our sales in 2022 were $499.0 million, which represented an increase of 14.0% from 2021.

Sales and net income were elements of our short-term incentive compensation plan for 2022. Please see the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K filed with the SEC on March 1, 2023, for a more detailed discussion of our 2022 financial results.

Objectives and Philosophy of Our Executive Compensation Program

The objectives of our executive compensation program are to encourage high performance, promote accountability, align employee interests with the interests of the Company's stockholders, and attract, develop, and retain talented leadership to serve the long-term best interest of the Company.

The following table identifies the components of our executive compensation program and the reasons for each:

Element	Reasons for Providing Element
Base Salary	Provides compensation for our named executive officers' services based on their knowledge, skills, experience, duties, and responsibilities
Short-Term Incentive Compensation	Incentivizes and rewards the achievement of our annual financial and operational objectives and progress towards our long-term strategic goals
Long-Term Incentive Compensation	Aligns the interests of our named executive officers and stockholders and incentivizes and rewards long-term performance of the Company
Employee Benefits	Provide for our named executive officers' health and well-being
Change-in-Control and Severance Benefits	Minimize any distractions to our named executive officers concerning termination of employment and/or a change in control and allow them to focus on their duties and responsibilities

At the 2022 annual meeting of our stockholders, we held a non-binding, stockholder advisory vote on the compensation of our named executive officers, commonly referred to as a say-on-pay vote. Our stockholders approved the compensation of our named executive officers, with over 96.7% of the votes cast in favor of our say-on-pay resolution. As our compensation committee, with the assistance of Dr. Zhang, evaluated our executive compensation program for 2022, it was mindful of the strong support our stockholders expressed for our executive compensation program. Accordingly, for 2022, our compensation committee decided to retain our general approach to executive compensation.

Compensation-Setting Process

Role of Board, Compensation Committee and Chief Executive Officer

The compensation committee discharges the responsibilities of the Board of Directors relating to compensation of the Company's executives, including by designing (in consultation with management or the board), recommending to the board for approval, and evaluating the compensation plans, policies and programs of the Company.

The compensation committee is responsible for overseeing the design of compensation programs that achieve the compensation objectives and philosophy described above. In each year, the compensation committee (i) reviews our compensation philosophy and (ii) reviews and approves the compensation of our officers. The compensation committee also reviews and approves employment agreements and severance arrangements for our executive officers. The compensation committee also periodically reviews and oversees the administration of executive compensation and equity plans of the Company and makes recommendations to the Board of Directors as to administration and amendments to such plans. The compensation committee also establishes and periodically reviews policies concerning change of control payments and perquisites. The compensation committee alternatively may recommend for approval by the Board of Directors any component of executive compensation. For example, in 2022, our Board of Directors approved the grant of equity awards to our named executive officers, as discussed further below.

As part of the compensation committee's annual review and approval of executive compensation, Dr. Zhang makes recommendations to the compensation committee regarding compensation for all executive officers based on individual and Company performance and prevailing market conditions. Based on its review of Dr. Zhang's recommendations and the input and data provided by the compensation committee's independent compensation consultant, the compensation committee approves each component of each executive officer's compensation. No executive officer participates in portions of any meetings during which decisions are made regarding the executive officer's own compensation.

Role of Compensation Consultant

The compensation committee has the authority to retain any compensation and benefits consultants that the Committee believes to be necessary or appropriate. For 2022, the compensation committee retained Willis Towers Watson ("WTW") to provide it with information, recommendations, and other advice relating to the compensation of our executive officers. WTW reports directly to the compensation committee. The compensation committee annually reviews the independence of its compensation consultant based on consideration of the factors specified in the SEC rules and Nasdaq listing standards, and during 2022, the compensation committee determined that its engagement of WTW did not present any conflicts of interest.

Peer Group Compensation Data

In making compensation decisions for our executive officers, the compensation committee reviews and analyzes competitive market practices using data drawn from a group of peer companies. In late 2021, our compensation committee requested the assistance of WTW in reviewing the appropriate peer group and related market data for evaluating our executive compensation program.

For the compensation decisions made by the compensation committee in 2022, our compensation peer group was made up of publicly-traded companies in the biotechnology and/or pharmaceuticals industries with annual revenue between $0.2 and $1.7 billion, earnings before interest, taxes, depreciation, and amortization between -$260 million and $604 million, net income between -$557 million and $509 million, a one-year total stockholder return between -74% and 68%, a three-year total stockholder return between -49% and 20%, and market capitalization between $144 million and $5.6 billion. To minimize disruption of the peer group, companies which are no longer in that range generally are replaced only when they have been outside that range for more than one year and there is a more appropriate replacement.

Based on these criteria, the peer group for the compensation decisions made by the compensation committee in 2022 was approved by the compensation committee in November 2021 and consisted of the following 17 companies:

Amarin Corporation plc.	Emergent BioSolutions Inc.	Pacira Pharmaceuticals, Inc.
ANI Pharmaceuticals, Inc.	FibroGen Inc.	PTC Therapeutics, Inc.
Coherus BioSciences, Inc.	Intercept Pharmaceuticals, Inc.	Supernus Pharmaceuticals, Inc.
Collegium Pharmaceuticals, Inc.	Ionis Pharmaceuticals, Inc.	Travere Therapeutics, Inc.
Corcept Therapeutics Inc.	Ironwood Pharmaceuticals, Inc.	Vanda Pharmaceuticals, Inc.
Eagle Pharmaceuticals, Inc.	Lannett Company, Inc.	

The above peer group reflects the following changes to the peer group from the peer group approved by the compensation committee in 2021: (a) the removal of the following companies that no longer fit within the

sales parameters used for determining our peer companies: Acorda Therapeutics, Inc., Akorn, Inc., Alnylam Pharmaceuticals, Inc., AMAG Pharmaceuticals, Inc., Assertio Therapeutics, Inc., Nektar Therapeutics, Seattle Genetics, Inc., and Spectrum Pharmaceuticals, Inc., and (b) the addition of Amarin Corporation plc., Coherus BioSciences, Inc., Corcept Therapeutics, Inc., Intercept Pharmaceuticals, Inc., Ironwood Pharmaceuticals, Inc., PTC Therapeutics, Inc., Travere Therapeutics, Inc., and Vanda Pharmaceuticals, Inc., as the compensation committee determined that these companies better fit within the sales parameters used for determining our peer companies and were better benchmarks to our business.

In March 2022, Dr. Zhang presented to the compensation committee a proposal with respect to the compensation of our executive officers for 2022.

Dr. Zhang's proposal considered the compensation provided to similarly situated executive officers of our peer group companies and/or market compensation data in WTW's 2021 Pharmaceutical and Health Sciences Executive Compensation Survey as reviewed by WTW. Based on how the Company compared to the companies in its peer group with respect to (i) revenue, (ii) earnings before interest, taxes, depreciation, and amortization, (iii) operating income, (iv) net income, (v) total shareholder return for the previous one, three, and five years, (vi) market capitalization, (vii) number of employees; (viii) whether the company manufactures a majority of its products sold; and (ix) the number of units manufactured and sold by the company, the proposal considered the compensation provided to similarly situated executives in relation to the 75th percentile. In the cases of Dr. Zhang and Mr. Peters, such compensation was determined by averaging (i) the compensation provided to similarly situated executives of our peer group at the 75th percentile and (ii) the compensation provided to similarly situated executives of the companies in the WTW survey in relation to the 75th percentile. In the case of Dr. Luo, because the WTW survey's sample size for similarly situated executive officers was too low, Dr. Zhang's proposal considered only the compensation by our peer group companies. In the cases of Messrs. Zhou and Liawatidewi, because many of our peer group members were not manufacturers and the job titles of the top five most highly compensated employees at many of our peer companies did not match to their titles, Dr. Zhang's proposal considered the market compensation data from the WTW survey combined with the data from the executive officers who were presented as the fourth and fifth most highly compensated executive officers for companies in the peer group.

In the discussion below, references to "relevant market data" refer to the relevant compensation provided to similarly situated executive officers of our peer group companies and/or market compensation data from the WTW survey, as described above.

Components of Our Executive Compensation Program

The following sections provide a description of each component of our 2022 executive compensation program, discuss the rationale for each such component, and explain how the compensation committee determined the amounts of compensation and awards.

Base Salary

Dr. Zhang's proposal recommended a modest increase to the base salary of each of Messrs. Peters, Zhou, and Liawatidewi (retroactively effective to the beginning of 2022), which was an increase of approximately 2.0% to 4.0% from the named executive officer's base salary for 2021, as indicated below. Since their base salaries were already above the 75th percentile of the relevant market data, no base salary increases were proposed in the cases of Drs. Zhang and Luo. Our named executive officers' recommended base salaries ranged from -19.0% to 31.0% of the relevant base salaries under the relevant market data, as indicated below.

Named Executive Officer	2022 Base Salary	Difference from 2021 Base Salary	Difference from Relevant Market Data (75th Percentile)
Dr. Zhang	$ 898,000	0.0%	4.0%
Mr. Peters	$ 584,058	2.0%	5.0%
Dr. Luo	$ 732,002	0.0%	31.0%
Mr. Zhou	$ 463,116	4.0%	(19.0%)
Mr. Liawatidewi	$ 440,348	4.0%	(1.0%)

In March 2022, the compensation committee reviewed Dr. Zhang's proposal, and upon consideration of the proposed terms of our executive officers' 2022 compensation, the relevant market data, and management's performance in 2021, the compensation committee approved the base salaries for our named executive officers as recommended in Dr. Zhang's proposal.

Short-Term Incentive Compensation

We maintain an annual incentive compensation program pursuant to which our named executive officers are eligible to earn cash bonuses based on achievement of performance criteria established by the compensation committee at the beginning of the year. Dr. Zhang proposed to our compensation committee a short-term incentive compensation program for 2022 consisting of the following three components: (i) performance-based bonus ("PBB") opportunity, with the target PBB opportunities effective from March 2022 through March 2023, (ii) a general annual bonus opportunity for 2022, and (iii) a discretionary bonus opportunity, each as discussed further below.

In March 2022, the compensation committee reviewed Dr. Zhang's proposal, and upon consideration of the proposed terms of our executive officers' 2022 compensation, the relevant market data, and management's performance in 2021, the compensation committee approved the short-term incentive compensation opportunities for our named executive officers as recommended in Dr. Zhang's proposal.

General Annual Bonuses

For each of our named executive officers, the 2022 general annual bonus opportunity was based on progress towards our strategic goals and individual goals for the named executive officer. The maximum amount of the 2022 general annual bonus that each named executive officer could receive and the actual amount of the general annual bonus paid to each named executive officer are listed in the table below. General annual bonuses are paid upon approval by the compensation committee, after taking into account Dr. Zhang's evaluation (or in the case of Dr. Zhang's general annual bonus, the compensation committee's evaluation) of progress that we had made on strategic goals and that the individual has made on personal goals.

Named Executive Officer	Maximum General Annual Bonus	Actual General Annual Bonus
Dr. Zhang	$ 311,000	$ 293,578
Mr. Peters	$ 179,847	$ 179,847
Dr. Luo	$ 225,232	$ 225,232
Mr. Zhou	$ 115,951	$ 115,951
Mr. Liawatidewi	$ 110,251	$ 110,251

Performance-Based Bonuses

Dr. Zhang proposed, and the compensation committee approved, PBB opportunities for each named executive officer based on the achievement of various goals with respect to five performance metrics related to the Company's sales, adjusted net income, filing ANDAs, New Drug Applications ("NDAs") or biologics license applications ("BLAs"), approval of ANDAs or NDAs, and general corporate goals for the period from March 2022 through February 2023. These metrics were selected as the achievement of the goals would significantly contribute towards accomplishment of our financial and operational objectives for 2022 and our long-term strategic goals. Bonuses would be paid only if minimum thresholds were met, and bonuses would increase in size if performance hit target, stretch and super-stretch levels, as outlined in the tables below.

For each named executive officer's minimum PBB, target PBB, stretch PBB, and super stretch PBB opportunities, the specific performance criteria and the amount payable upon the achievement of such criteria are listed on the following tables.

PBBs Performance Criteria				
Performance Criteria	**Minimum**	**Target**	**Stretch**	**Super Stretch**
Sales Growth on Budget vs. 2021	1.0% - 5.0%	5.1% - 10.0%	10.1% - 15.0%	> 15%
Adjusted Net Income	$45 - 55 million	$55.1 - $65 million	$65.1 - $75 million	> $75 million
Filing of an ANDA, NDA, or BLA	1	2	3	> 3
Approval of ANDA or NDA	1	2	3	> 3
General Corporate Goals[(1)]	1	2	3	>3

(1) The general corporate goals were (i) successful completion of pivotal clinical trials for intranasal epinephrine with good data to support an NDA filing, (ii) successful completion of phase III/pivotal clinical trials for any one of the Company's diabetes product pipeline with good data to support ANDA/NDA/BLA filing, (iii) successful completion of Phase III/pivotal clinical trials for second diabetes product pipeline with good data to support ANDA/NDA/BLA filing, (iv) launch first IMS UK product, (v) add four new products to pipeline.

PBB Opportunity for Achievement of Sales Growth on Budget vs. 2021					
	Dr. Zhang	**Mr. Peters**	**Dr. Luo**	**Mr. Zhou**	**Mr. Liawatidewi**
Minimum PBB	$101,000	$47,000	$41,000	$19,000	$25,000
Target PBB	$126,000	$58,000	$51,000	$23,000	$31,000
Stretch PBB	$157,000	$73,000	$64,000	$29,000	$39,000
Super Stretch PBB	$189,000	$88,000	$77,000	$35,000	$46,000

PBB Opportunity for Achievement of Adjusted Net Income					
	Dr. Zhang	**Mr. Peters**	**Dr. Luo**	**Mr. Zhou**	**Mr. Liawatidewi**
Minimum PBB	$101,000	$47,000	$41,000	$15,000	$25,000
Target PBB	$126,000	$58,000	$51,000	$19,000	$31,000
Stretch PBB	$157,000	$73,000	$64,000	$23,000	$39,000
Super Stretch PBB	$189,000	$88,000	$77,000	$28,000	$46,000

PBB Opportunity for Achievement of Filing of a qualifying ANDA, NDA, or BLA[2]					
	Dr. Zhang	Mr. Peters	Dr. Luo	Mr. Zhou	Mr. Liawatidewi
Minimum PBB	$108,000	$19,000	$41,000	$26,000	$11,000
Target PBB	$135,000	$23,000	$51,000	$32,000	$13,000
Stretch PBB	$168,000	$29,000	$64,000	$41,000	$17,000
Super Stretch PBB	$202,000	$35,000	$77,000	$49,000	$20,000

(2) A "qualifying ANDA, NDA or BLA" means any ANDA, NDA, or BLA (i) for which the U.S. sales is more than $20 million and is not on the U.S. market for the Company and (ii) is filed and accepted by the U.S. FDA.

PBB Opportunity for Approval of ANDA or NDA[3]					
	Dr. Zhang	Mr. Peters	Dr. Luo	Mr. Zhou	Mr. Liawatidewi
Minimum PBB	$115,000	$19,000	$41,000	$26,000	$11,000
Target PBB	$144,000	$23,000	$51,000	$32,000	$13,000
Stretch PBB	$180,000	$29,000	$64,000	$41,000	$17,000
Super Stretch PBB	$216,000	$35,000	$77,000	$49,000	$20,000

(3) Includes ANDAs or NDAs that were not being marketed.

PBB Opportunity for Achievement of General Corporate Goals					
	Dr. Zhang	Mr. Peters	Dr. Luo	Mr. Zhou	Mr. Liawatidewi
Minimum PBB	$72,000	$19,000	$23,000	$19,000	$14,000
Target PBB	$90,000	$23,000	$29,000	$23,000	$18,000
Stretch PBB	$112,000	$29,000	$37,000	$29,000	$22,000
Super Stretch PBB	$135,000	$35,000	$44,000	$35,000	$26,000

In 2022, we achieved the following performance:

Performance Criteria	Achievement	Level of Achievement
Sales Growth on Budget vs. 2021	14.0%	Stretch
Adjusted Net Income	$103.2 million	Super Stretch
Filing of an ANDA, NDA or BLA	One Filing	Minimum
Approval of ANDA or NDA	Two Approval	Target
General Corporate Goals:	1	Minimum
(i) successful completion of pivotal clinical trials for intranasal epinephrine with good data to support an NDA filing,	Not achieved	
(ii) successful completion of phase III/pivotal clinical trials for any one of the Company's diabetes product pipeline with good data to support a ANDA/NDA/BLA filing,	Not achieved	
(iii) successful completion of phase III/pivotal clinical trials for a second diabetes product pipeline with good data to support ANDA/NDA/BLA filing,	Not achieved	
(iv) launch first IMS UK product, and	Not achieved	
(v) Add four new products to pipeline	Achieved	

As a result of the performance achievement set forth above, the following amounts of PBB became payable to our named executive officers:

PBBs achieved in 2022					
Performance Criteria	**Dr. Zhang**	**Mr. Peters**	**Dr. Luo**	**Mr. Zhou**	**Mr. Liawatidewi**
Sales Growth on Budget vs. 2021	$157,000	$73,000	$64,000	$29,000	$39,000
Adjusted Net Income	$189,000	$88,000	$77,000	$28,000	$46,000
Filing of a qualifying ANDA, NDA, or BLA	$108,000	$19,000	$41,000	$26,000	$11,000
Approval of ANDA or NDA	$144,000	$23,000	$51,000	$32,000	$13,000
General Corporate Goals	$72,000	$19,000	$23,000	$19,000	$14,000
Total	**$670,000**	**$222,000**	**$256,000**	**$134,000**	**$123,000**

Special Bonuses

The compensation committee also established a special discretionary bonus pool of $500,000 under the short-term incentive compensation program for our named executive officers other than Dr. Zhang. The special bonuses could be awarded to such named executive officers for significant achievements not anticipated at the time the target and stretch PBB opportunities were set. Dr. Zhang was excluded because the compensation committee believed, that as the senior most executive of the Company with responsibility to lead the entire Company, Dr. Zhang should have an overall compensation package more heavily weighted toward compensation subject to pre-established performance criteria. For the other named executive officers, the compensation committee believed that the special bonuses were appropriate in order for the Company to recognize demonstrated leadership by such executive officers during the year beyond the parameters of any specific performance objective.

Based on Dr. Zhang's recommendations, the compensation committee approved the following discretionary bonuses to the following named executive officers for 2022: (i) $28,100 for Mr. Peters, $35,200 for Dr. Luo, $22,300 for Mr. Zhou, and $21,200 for Mr. Liawatidewi, for their contribution towards the response to the COVID-19 pandemic; and (ii) $56,200 for Mr. Peters, $49,300 for Dr. Luo, $58,000 for Mr. Zhou, and $59,400 for Mr. Liawatidewi for the continuous improvement of our training systems, advancement on our pipeline candidates, business development projects during the year, improving production efficiencies and exceeding Primatene MIST® and glucagon sales goals for the year. The total amount of special bonuses paid to each named executive officer is as follows:

Named Executive Officer	**Special Bonus Amount**
Mr. Peters	$84,300
Dr. Luo	$84,500
Mr. Zhou	$80,300
Mr. Liawatidewi	$80,600
Total:	**$329,700**

Summary of Target Total Cash Compensation

For 2022, the total amount of short-term incentive compensation received by each named executive officer, each named executive officer's total cash compensation and the target total cash compensation's deviation from the relevant market data are as follows:

Named Executive Officer	Target Total Cash Compensation	Difference from Relevant Market Data (75th Percentile)
Dr. Zhang	$1,703,000	(5%)
Mr. Peters	980,000	10%
Dr. Luo	$1,206,000	21%
Mr. Zhou	751,000	(16%)
Mr. Liawatidewi	705,000	6%

For each of the named executive officers, target total cash compensation included base salary and 70% of the target amount of the named executive officer's PBB compensation to account for a potential to miss certain targets. Additionally, in the case of the named executive officers other than Dr. Zhang, the target total cash compensation included (a) special bonus amounts of $40,000 for each of Mr. Peters and Dr. Luo and $50,000 for each of Messrs. Zhou and Liawatidewi; and (b) other cash compensation of $60,000 for Dr. Zhang, $45,000 for each of Mr. Peters and Dr. Luo, and $30,000 for each of Messrs. Zhou and Liawatidewi.

Long-Term Incentive Compensation

Under his proposal, Dr. Zhang recommended that our named executive officers be granted an equal mix of stock options, which incentivize our named executive officers to create additional stockholder value since the stock options deliver value to them only if our stock price increases after the options are granted, and restricted stock units ("RSUs"), which help us retain our named executive officers by providing them with the certainty of receiving some value from their equity awards since the RSUs will never be out of the money. For the equity awards granted to our named executive officers, each equity award would vest annually in equal installments over a 4-year period from the date of grant, and each option would have a 10-year term and an exercise price per share equal to 100% of the fair market value of the Company's common stock as of the date of the grant.

The amounts recommended by Dr. Zhang were based on approximately 110% to 120% of the value of the equity awards granted to the named executive officers for 2021. The 10% - 20% increase was recommended due to the Company's strong operating performance the prior year and to bring the executives closer to the 75th percentile. The compensation committee considered the mix and the intended value of the equity awards recommended by Dr. Zhang, and agreed with Dr. Zhang's proposal. The compensation committee approved the following equity awards for our named executive officers for 2022:

Named Executive Officer	Intended Value of Options[(1)]	Intended Value of Restricted Stock Units[(1)]	Total Intended Value of Equity Awards[(1)]	Difference from Relevant Market Data (75th percentile)
Dr. Zhang	$ 2,672,017	$ 2,671,992	$5,344,009	(20%)
Mr. Peters	$ 764,034	$ 763,967	$1,528,001	(31%)
Dr. Luo	$ 1,126,017	$ 1,125,993	$2,252,010	(1%)
Mr. Zhou	$ 474,534	$ 474,479	$949,013	(59%)
Mr. Liawatidewi	$ 400,017	$ 399,996	$800,013	(34%)

(1) Values shown are as set forth in the Summary Compensation Table further below

The intended value of the equity awards for each named executive officer (other than Dr. Luo) was significantly below the 75th percentile of the relevant market data because Dr. Zhang and the Compensation Committee believed that a 10% - 20% increase was sufficient to reward these executives for their current performance.

In March 2022, the compensation committee reviewed Dr. Zhang's proposal, and upon consideration of the proposed terms of our executive officers' 2022 compensation, the relevant market data, and management's performance in 2021, the compensation committee recommended to our Board of Directors that our named executive officers be granted the equity awards described in Dr. Zhang's proposal.

Accordingly, our Board of Directors approved the grant of the following equity awards in March 2022.

Named Executive Officer	Number of Shares Subject to Options	Number of Shares Subject to Restricted Stock Units
Dr. Zhang	177,461	76,914
Mr. Peters	50,743	21,991
Dr. Luo	74,784	32,412
Mr. Zhou	31,516	13,658
Mr. Liawatidewi	26,567	11,514

In determining the number of shares covered by the equity awards granted in 2022, the intended value of each equity award was translated into a number of shares by: (i) with respect to restricted stock units, dividing the dollar amount by the closing price of our common stock the date of grant; and (ii) with respect to stock options, dividing the dollar amount by the Black-Scholes value of the option.

Employee Benefits

Our named executive officers are only eligible to receive the same benefits as our other employees, which include medical, and dental insurance, a tax-qualified retirement plan under Section 401(k) of the Internal Revenue Code, and other plans and programs, including the 2014 Employee Stock Purchase Plan, made available to other eligible employees. We provide a matching contribution under the Section 401(k) plan that is applicable to all eligible participants, including our named executive officers.

In December 2019, we established a non-qualified deferred compensation plan. The deferred compensation plan allows certain eligible participants, including each of our named executive officers, to defer a portion of their cash compensation and provides a matching contribution at the discretion of the Company. The plan

obligations are payable upon retirement, termination of employment and/or certain other times in a lump-sum distribution or in installments, as elected by the participant in accordance with the plan. Participants can allocate their deferred compensation amongst various investment options with earnings accruing to the participant. The Company has established a Rabbi Trust to fund the plan obligation and to hold the plan assets. Eligible participants began contributing to the plan in January 2020. Our compensation committee believes that the deferred compensation plan is appropriate as part of the overall compensation package for senior members of management.

In March 2022, Dr. Zhang recommended, and the compensation committee approved the reimbursement of automobile related expenses, life and disability insurance, tax preparation expenses, health insurance, dental insurance, and medical expenses of up to the following amounts: (i) $60,000 for Dr. Zhang; (ii) $45,000 for Mr. Peters; (iii) $45,000 for Dr. Luo; (iv) $30,000 for Mr. Zhou, and (v) $30,000 for Mr. Liawatidewi. The compensation committee believed that these benefits were appropriate and were included as part of an executive's total cash compensation.

Change-of-Control and Severance Benefits

We have entered into an employment agreement with each of Dr. Zhang, Dr. Luo, and Mr. Peters that provides for severance benefits upon certain terminations of the executive officer's employment, but have not entered into such agreements with Mr. Zhou or Mr. Liawatidewi. We believe that these severance benefits provide retention value by encouraging these named executive officers to continue service with us and increase stockholder value by reducing any potential distractions caused by the possibility of an involuntary termination of employment (including in connection with a change in control), allowing the named executive officers to focus on their duties and responsibilities. A summary of the material terms and conditions of these employment agreements is provided below in the section of this proxy statement titled "Potential Payments upon Termination or Change of Control."

Stock Trading Practices; Hedging Policy

We have an Insider Trading Policy, which, among other things, prohibits our officers, directors and employees from short sales, engaging in transactions in publicly-traded options (such as puts and calls) and other derivative securities relating to our common stock. This prohibition extends to any hedging or similar transaction designed to decrease the risks associated with holding our securities. Our Insider Trading Policy also prohibits our executive officers and directors from entering into transactions to pledge, hypothecate or otherwise encumber more than 20% of shares of our common stock held by such individual or more than 5% of our total outstanding shares, whichever is lower, as collateral for indebtedness. In addition, previously-existing pledges made by our executive officers and directors shall be reduced to no more than 20% of shares of our common stock held by such individual within three years of December 31, 2022.

Other Compensation Policies

We have adopted a code of business conduct and ethics that applies to our officers, directors and employees, including our Chief Executive Officer, Chief Financial Officer, and other executive and senior financial officers. Our code of business conduct and ethics is available on our website at http://ir.amphastar.com/corporate-governance/highlights. We intend to disclose any amendments of our code of business conduct and ethics, or waivers of its requirements for directors or executive officers, on our website.

Stock Ownership Guidelines

We have adopted Stock Ownership Guidelines that set requirements relating to the ownership of the Company's common stock by executive officers and non-employee directors. The stock ownership requirements provide that the Company's Chief Executive Officer will be required to hold shares valued at three times his or her annual base salary, other executive officers will be required to hold shares valued at one times their annual base salary, and non-employee directors are expected to hold shares valued at three times their annual base cash retainer for board service. The applicable levels of ownership are required to be achieved by current executive officers, and expected to be achieved by non-employee directors, within five years of the date of the adoption of the Stock Ownership Guidelines. All named executive officers and all non-employee directors who have served for more than one year currently meet these guidelines.

Clawback Policy

We have adopted a Clawback Policy that allows the Company to recover erroneously awarded cash-based or equity incentive compensation from an executive officer in the case a restatement of the Company's financial statements that was determined by the Compensation Committee of the board to be caused by gross negligence, intentional misconduct or fraud of such executive officer.

Minimum Vesting

Our amended and restated 2015 Equity Incentive Plan provides that at least 95% of the shares awarded under the Plan will be subject to a minimum vesting requirement of at least one year.

Accounting Treatment of Compensation

We account for the equity compensation awarded to our executive officers and other employees under ASC 718, which requires us to estimate and record an expense for each award of equity compensation over the service period of the award. Accounting rules also require us to record cash compensation as an expense at the time the obligation is incurred.

Risk Considerations

The compensation committee (i) reviews the risks associated with our compensation programs to determine whether they encourage excessive risk-taking, (ii) discusses, at least annually, the relationship between risk management policies and practices and compensation, and (iii) evaluates compensation policies and practices that could mitigate any such risk. We do not believe that our executive compensation program creates risks that are reasonably likely to have a material adverse effect on us.

Compensation Committee Report

The compensation committee has reviewed and discussed the section titled "Compensation Discussion and Analysis" with management. Based on such review and discussion, the compensation committee has recommended to the Board of Directors that the section titled "Compensation Discussion and Analysis" be included in this proxy statement.

Respectfully submitted by the members of the compensation committee of the Board of Directors:

Richard Prins (Chairman)
Floyd F. Petersen
Michael A. Zasloff

Fiscal 2022 Summary Compensation Table

The following table sets forth total compensation paid to our named executive officers for the fiscal years 2022, 2021, and 2020.

Name and Principal Position	Year	Salary($)	Bonus($)	Non-Equity Incentive Plan Compensation($)	Stock Awards ($)(1)	Option Awards ($)(1)	All Other Compensation ($)	Total($)
Jack Yongfeng Zhang	2022(2)	1,113,866	293,578	670,000	2,671,992	2,672,017	56,498 (3)	7,477,951
Chief Executive Officer,	2021	898,000	310,847	673,000	2,288,490	2,288,518	50,565 (4)	6,509,420
President, Chief Scientific Officer and Director	2020	898,000	394,000	657,520	1,989,994	1,990,009	33,426 (5)	5,962,949
William J. Peters	2022	584,058	264,147	222,000	763,967	764,034	48,972 (6)	2,647,178
Chief Financial Officer,	2021	572,135	261,408	226,000	664,388	664,427	52,290 (7)	2,440,648
Executive Vice President of Finance, Treasurer, President of International Medication Systems, Limited, and Director	2020	547,489	297,231	189,992	524,992	525,014	53,967 (8)	2,138,685
Mary Ziping Luo	2022(9)	907,964	309,732	256,000	1,125,993	1,126,017	56,355 (10)	3,782,061
Chief Operating Officer, Chief	2021	732,002	305,632	259,000	1,023,487	1,023,515	47,777 (11)	3,391,413
Scientist and Chairman	2020	732,002	230,000	239,880	889,988	890,014	24,910 (12)	3,006,794
Rong Zhou	2022	463,116	196,251	134,000	474,479	474,534	41,686 (13)	1,784,066
Senior Executive Vice President of Production and President of.	2021(14)	478,775	194,401	128,000	395,492	395,515	41,594 (15)	1,633,777
Amphastar Nanjing Pharmaceuticals, Co., Ltd	2020	426,409	197,269	112,890	343,992	344,011	32,097 (16)	1,456,668
Jacob Liawatidewi	2022	440,348	190,851	123,000	399,996	400,017	39,956 (17)	1,594,168
Executive Vice President of Sales and Marketing, Executive Vice President of Corporate Administration Center and	2021	423,379	186,801	124,000	347,999	348,003	39,510 (18)	1,469,692
President of Amphastar France Pharmaceuticals, S.A.S.	2020	405,463	204,462	102,736	302,491	302,517	36,909 (19)	1,354,578

(1) This amount reflects the aggregate grant fair value computed in accordance with ASC Topic 718. The assumptions that we used to calculate these amounts are discussed in Note 16 to our consolidated financial statements included in our Annual Report on Form 10-K, as filed with the SEC on March 1, 2023.

(2) The amount includes $215,866 in accrued paid vacation, which was elected to be taken in the form of cash.

(3) The amount includes a $9,150 Company contribution made under our 401(k) plan, a $34,239 vehicle allowance, a $4,944 group life insurance benefit in excess of the standard threshold granted to all other employees; and a $8,165 for additional medical expenses.

(4) The amount includes a $8,700 Company contribution made under our 401(k) plan, a $34,230 vehicle allowance, a $4,944 group life insurance benefit in excess of the standard threshold granted to all other employees; and a $2,691 for additional medical expenses.

(5) The amount includes a $8,550 Company contribution made under our 401(k) plan, a $18,429 vehicle allowance, a $4,944 group life insurance benefit in excess of the standard threshold granted to all other employees; and a $1,503 for additional medical expenses.

(6) The amount includes a $9,150 Company contribution made under our 401(k) plan; employee health and dental insurance premiums of $10,652; $8,296 life and disability insurance premium payments; $6,049 for additional medical expenses; $12,503 for vehicle allowance; and a $2,322 group life insurance benefit in excess of the standard threshold to all other employees.

(7) The amount includes a $8,700 Company contribution made under our 401(k) plan; employee health and dental insurance premiums of $10,614; $9,186 life and disability insurance premium payments; $8,452 for additional medical expenses; $14,096 for vehicle allowance; and a $1,242 group life insurance benefit in excess of the standard threshold to all other employees.

(8) The amount includes a $8,550 Company contribution made under our 401(k) plan; employee health and dental insurance premiums of $10,403; $14,338 life and disability insurance premium payments; $19,434 for vehicle allowance; and a $1,242 group life insurance benefit in excess of the standard threshold to all other employees.

(9) The amount includes $175,962 in accrued paid vacation, which was elected to be taken in the form of cash.

(10) The amount includes a $9,150 Company contribution made under our 401(k) plan, a $34,096 vehicle allowance; a $4,944 group life insurance benefit in excess of the standard threshold granted to all other employees; and a $8,165 for additional medical expenses.

(11) The amount includes a $8,700 Company contribution made under our 401(k) plan, a $34,133 vehicle allowance; and a $4,944 group life insurance benefit in excess of the standard threshold granted to all other employees.

(12) The amount includes a $8,550 Company contribution made under our 401(k) plan, a $11,416 vehicle allowance; and a $4,944 group life insurance benefit in excess of the standard threshold granted to all other employees.

(13) The amount includes a $8,145 Company contribution made under our 401(k) plan; employee health and dental insurance premiums of $6,710; additional medical expenses of $5,878; $17,255 for vehicle allowance; $134 for tax preparation fees; and a $3,564 group life insurance benefit in excess of the standard threshold to all other employees.

(14) The amount includes $33,431 in accrued paid vacation, which was elected to be taken in the form of cash.

(15) The amount includes a $8,314 Company contribution made under our 401(k) plan; employee health and dental insurance premiums of $6,397; additional medical expenses of $8,113; $15,071 for vehicle allowance; $135 for tax preparation fees; and a $3,564 group life insurance benefit in excess of the standard threshold to all other employees.

(16) The amount includes a $7,800 Company contribution made under our 401(k) plan; employee health and dental insurance premiums of $6,020; additional medical expenses of $958; $13,620 for vehicle allowance; $135 for tax preparation fees; and a $3,564 group life insurance benefit in excess of the standard threshold to all other employees.

(17) The amount includes a $9,150 Company contribution made under our 401(k) plan; $4,230 for additional life insurance; $275 for tax preparation fees; $25,491 for vehicle allowance; and a $810 group life insurance benefit in excess of the standard threshold to all of our employees.

(18) The amount includes a $8,700 Company contribution made under our 401(k) plan; employee health and dental insurance premiums of $4,475; $2,950 for additional life insurance; $275 for tax preparation fees; $22,300 for vehicle allowance; and a $810 group life insurance benefit in excess of the standard threshold to all of our employees.

(19) The amount includes a $8,550 Company contribution made under our 401(k) plan; employee health and dental insurance premiums of $4,546; additional medical expenses of $1,596; $4,230 for additional life insurance; $16,902 for vehicle allowance; $275 for tax preparation fees; and a $810 group life insurance benefit in excess of the standard threshold to all of our employees.

Outstanding Equity Awards at 2022 Year-End

The following table sets forth summary information regarding the outstanding equity awards for each of the named executive officers as of December 31, 2022:

		Option Awards(1)				Stock Awards	
Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($) (2)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($) (3)
Jack Y. Zhang	3/17/16	722,046(4)	—	12.46	3/17/24	—	—
	3/16/17	490,477(4)	—	14.69	3/16/25	—	—
	3/15/18	273,692(4)	—	21.77	3/15/26	—	—
	3/15/19	262,182(4)	—	22.25	3/15/27	—	—
	3/16/20	270,002(5)	135,001	13.03	3/16/28	—	—
	3/16/20	—	—	—	—	50,908(6)	1,426,442
	3/17/21	74,672(7)	224,016	17.99	3/17/31	—	—
	3/17/21	—	—	—	—	95,406(8)	2,673,276
	3/15/22	—(7)	177,461	34.74	3/15/32	—	—
	3/15/22	—	—	—	—	76,914(9)	2,155,130
William J. Peters	3/26/15	6,688(4)	—	14.95	3/26/25	—	—
	3/17/16	19,800(4)	—	11.33	3/17/26	—	—
	3/16/17	49,522(4)	—	13.35	3/16/27	—	—
	3/15/18	51,921(4)	—	19.79	3/15/28	—	—
	3/15/19	43,294(7)	14,431	20.23	3/15/29	—	—
	3/15/19	—	—	—	—	6,487(10)	181,766
	3/16/20	47,175(7)	47,175	13.03	3/16/30	—	—
	3/16/20	—	—	—	—	20,145(11)	564,463
	3/17/21	19,709(7)	59,124	17.99	3/17/31	—	—
	3/17/21	—	—	—	—	25,180(12)	705,544
	5/19/21	1,803(7)	5,406	19.82	5/19/31	—	—
	5/19/21	—	—	—	—	2,285(14)	64,026
	3/15/22	—(7)	50,743	34.74	3/15/32	—	—
	3/15/22	—	—	—	—	21,991(9)	616,188
Mary Z. Luo	3/17/16	310,930(4)	—	12.46	3/17/24	—	—
	3/16/17	211,213(4)	—	14.69	3/16/25	—	—
	3/15/18	116,392(4)	—	21.77	3/15/26	—	—
	3/15/19	110,671(4)	—	22.25	3/15/27	—	—
	3/16/20	120,756(5)	60,378	13.03	3/16/28	—	—
	3/16/20	—	—	—	—	22,767(6)	637,931
	3/17/21	33,397(7)	100,188	17.99	3/17/31	—	—
	3/17/21	—	—	—	—	42,669(8)	1,195,585
	3/15/22	—(7)	74,784	34.74	3/15/32	—	—
	3/15/22	—	—	—	—	32,412(9)	908,184
Rong Zhou	4/14/14	32,891(4)	—	14.40	4/14/24	—	—
	3/26/15	18,524(4)	—	14.95	3/26/25	—	—
	6/15/15	4,685(4)	—	16.19	6/15/25	—	—
	3/17/16	34,438(4)	—	11.33	3/17/26	—	—
	3/16/17	29,424(4)	—	13.35	3/16/27	—	—
	3/15/18	20,827(4)	—	19.79	3/15/28	—	—
	3/15/19	16,906(7)	5,635	20.23	3/15/29	—	—
	3/15/19	—	—	—	—	2,533(10)	70,975
	3/16/20	30,911(7)	30,911	13.03	3/16/30	—	—
	3/16/20	—	—	—	—	13,200(11)	369,864
	3/17/21	12,906(7)	38,715	17.99	3/17/31	—	—
	3/17/21	—	—	—	—	16,488(12)	461,994
	3/15/22	—(7)	31,516	34.74	3/15/32	—	—
	3/15/22	—	—	—	—	13,658(9)	382,697
Jacob Liawatidewi	6/14/18	3,319(4)	—	16.96	6/14/28	—	—
	3/15/19	16,494(7)	5,497	20.23	3/15/29	—	—
	3/15/19	—	—	—	—	2,471(10)	69,237
	3/16/20	14,251(7)	21,925	13.03	3/16/30	—	—
	3/16/20	—	—	—	—	9,363(11)	262,351
	6/4/20	3,546(7)	3,545	19.19	6/4/30	—	—
	6/4/20	—	—	—	—	1,524(13)	42,702
	3/17/21	11,355(7)	34,065	17.99	3/17/31	—	—
	3/17/21	—	—	—	—	14,508(12)	406,514
	3/15/22	—(7)	26,567	34.74	3/15/32	—	—
	3/15/22	—	—	—	—	11,514(9)	322,622

(1) Information for this table is depicted on an award-by-award basis unless the exercise price and expiration date are identical.

(2) This column represents the fair value of a share of our common stock on the date of grant, as determined by our Board of Directors.
(3) This column represents the market value of the shares of our common stock underlying the RSUs as of December 31, 2022, based on the closing price of our common stock, as reported on the Nasdaq Global Select Market, of $28.02 per share on December 31, 2022.
(4) Shares subject to the option are fully vested and immediately exercisable.
(5) Shares subject to the option vest in three equal annual installments beginning on the first anniversary of the grant date, subject to continued service.
(6) The RSUs set forth above, which represent the remaining portion of the applicable RSU award, vest on March 16, 2023, subject to continued service.
(7) Shares subject to the option vest in four equal annual installments beginning on the first anniversary of the grant date, subject to continued service.
(8) The RSUs set forth above, which represent the remaining portion of the applicable RSU award, vest in three equal annual installments beginning on March 17, 2023, subject to continued service.
(9) The RSUs set forth above, vest in four equal annual installments beginning on March 15, 2023, subject to continued service.
(10) The RSUs set forth above, which represent the remaining portion of the applicable RSU award, vest on March 15, 2023, subject to continued service.
(11) The RSUs set forth above, which represent the remaining portion of the applicable RSU award, vest in two equal annual installments beginning on March 16, 2023, subject to continued service.
(12) The RSUs set forth above, which represent the remaining portion of the applicable RSU award, vest in three equal annual installments beginning on March 17, 2023, subject to continued service.
(13) The RSUs set forth above, which represent the remaining portion of the applicable RSU award, vest in two equal annual installments beginning on June 4, 2023, subject to continued service.
(14) The RSUs set forth above vest in three equal annual installments beginning on May 19, 2023, subject to continued service.

2022 Grants of Plan-Based Awards

The following table sets forth grants of plan-based awards for each of the named executive officers for the fiscal year ended December 31, 2022:

		Estimated Future Payouts under Non-Equity Incentive Plan(1)						
Name	**Grant Date**	**Threshold ($)**	**Target ($)**	**Maximum ($)**	**All Other Stock Awards: Number of Securities Underlying Stock or Units**	**All Other Option Awards: Number of Securities Underlying Options**	**Exercise or Base Price of Option Awards ($/Sh)(2)**	**Grant Date Fair Value of Stock and Option Awards($)(3)**
Jack Y. Zhang		497,000	621,000	931,000				
	3/15/2022				76,914	—	—	2,671,992
	3/15/2022				—	177,461	34.74	2,672,017
William J. Peters		151,000	185,000	281,000				
	3/15/2022				21,991	—	—	763,967
	3/15/2022				—	50,743	34.74	764,034
Mary Z. Luo		187,000	233,000	352,000				
	3/15/2022				32,412	—	—	1,125,993
	3/15/2022				—	74,784	34.74	1,126,017
Rong Zhou		105,000	129,000	196,000				
	3/15/2022				13,658	—	—	474,479
	3/15/2022				—	31,516	34.74	474,534
Jacob Liawatidewi		86,000	106,000	158,000				
	3/15/2022				11,514	—	—	399,996
	3/15/2022				—	26,567	34.74	400,017

(1) The amounts in the threshold, target and maximum columns reflect the minimum, target, and super stretch PBB amounts payable, respectively, which is described above in the "Compensation Discussion and Analysis under the heading "Performance-Based Bonus." The actual amounts paid to each named executive officer can be found in the Summary Compensation Table under the column entitled Non-Equity Incentive Plan Compensation.

(2) For each of the named executive officers the exercise price represents the per share fair market value of our common stock on the grant date as determined by our Board of Directors.

(3) This amount reflects the aggregate grant fair value computed in accordance with ASC Topic 718. The assumptions that we used to calculate these amounts are discussed in Note 16 to our consolidated financial statements included in our Annual Report on Form 10-K, as filed with the SEC on March 1, 2023.

2022 Options Exercised and Stock Vested

The following table summarizes the option exercises and vesting of stock awards for each of the named executive officers for the fiscal year ended December 31, 2022.

	Option Awards		Stock Awards	
Name	Number of Shares Acquired on Exercise	Value Realized on Exercise ($)(1)	Number of Shares Acquired on Vesting	Value Realized on Vesting ($)(2)
Jack Y. Zhang	—	$ —	115,500	$ 3,968,188
William J. Peters	172,965	2,745,024	31,306	1,076,839
Mary Z. Luo	—	—	50,831	1,746,065
Rong Zhou	28,000	437,263	16,871	579,589
Jacob Liawatidewi	18,892	332,355	15,152	522,178

(1) The value realized on exercise is the difference between the market price of the shares of our common stock underlying the option when exercised and the applicable exercise price.

(2) The value realized upon vesting of RSUs is calculated by multiplying the number of shares vested by the closing price of our common stock on the vesting date (or, in the event the vesting date occurs on a holiday or weekend, the closing price of our common stock on the immediately preceding trading day).

Equity Compensation Plan Information

The following table summarizes our equity compensation plan information as of December 31, 2022. Information is included for equity compensation plans approved by our stockholders and equity compensation plans not approved by our stockholders. We will not grant equity awards in the future under any of the equity compensation plans not approved by our stockholders included in the table below.

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	(b) Weighted Average Exercise Price of Outstanding Options, Warrants and Rights (1)	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
Equity compensation plans approved by stockholders(2)	8,936,202	$ 17.66	7,410,409
Equity compensation plans not approved by stockholders	—	—	—
Total	8,936,202	$ 17.66	7,410,409

(1) The weighted average exercise price is calculated based solely on outstanding stock options. It does not take into account the shares of our common stock underlying RSUs, which have no exercise price.

(2) Includes the following plans: Amended and Restated 2015 Plan, Amended and Restated 2005 Equity Incentive Award Plan, and 2014 Employee Stock Purchase Plan. The 2015 Plan also contains an "evergreen provision" that allows for an annual increase in the number of shares available for issuance on January 1 of each year, beginning January 1, 2016. The annual increase in the number of shares shall be an amount equal to the least of (i) 3,000,000 shares, (ii)) two and one-half percent (2.5%) of the outstanding shares of common stock on the last day of the immediately preceding fiscal year or (iii) such number of shares of common stock determined by our Board of Directors. On January 1, 2023, the number of shares of our common stock available for issuance under our Amended and Restated 2015 Plan increased by 1,202,802 shares pursuant to this provision. This increase is not reflected in the table above.

2022 Nonqualified Deferred Compensation Plan

In order to enhance our ability to attract and retain qualified employees, in December 2019 our Board approved our Deferred Compensation Plan, which is intended to comply with the requirements of Section 409A of the Internal Revenue Code. The Deferred Compensation Plan is intended to be an unfunded plan which is maintained primarily to permit deferral of eligible compensation by a select group of management or highly compensated employees or independent contractors who have been notified during an applicable enrollment of their status as eligible participants, including our named executive officers. Under the Deferred Compensation Plan, participants will have the opportunity to make elections to defer up to a specified amount or percentage of their eligible cash compensation, as established by the administrator, and we have the option, but not the obligation, to make discretionary or matching cash contributions.

Unless otherwise specified by the administrator of the Deferred Compensation Plan and subject to applicable tax laws, the Deferred Compensation Plan provides eligible participants the opportunity to defer up to 75% of their base salary and up to 100% of certain of their bonuses, commissions, and other cash or equity-based compensation approved by the administrator of the Deferred Compensation Plan. Participants will be 100% vested at all times in their cash deferrals, and participants' deferrals of vesting awards will become vested according to the provisions of the underlying award. Each participant may allocate his or her deferrals to accounts under the Deferred Compensation Plan that provide for payment of deferred amounts upon specified events, such as the participant's retirement, other separation from service, and/or other predetermined times. Participants may elect to receive payment of their account balances in a single lump-sum distribution or in annual installments (as elected by the participant in accordance with the Deferred Compensation Plan), except in certain limited circumstances and provided that payments upon a participant's death will be provided in a single lump sum.

In addition, the Company may, in its sole discretion, provide matching, profit sharing, and/or other contributions to the Deferred Compensation Plan, including make-up matching contributions with respect to deferrals that reduce 401(k) plan compensation below the compensation limit in Section 401(a)(17) of the Internal Revenue Code and supplemental matching contributions with respect to compensation deferred above such compensation limit. These contributions, if any, may be subject to a vesting schedule as provided by the administrator of the Deferred Compensation Plan. Make-up and supplemental matching contributions vest at the same rate as matching contributions under the Company's 401(k) plan. Deferrals of equity-based compensation will vest as provided under the terms of the applicable award. All of a participant's Company contributions become 100% vested, if while employed by the Company, the participant dies, becomes disabled, or attains the age of 65 or the Company experiences a change in control. Company contributions will be credited to the applicable participant's account under the Deferred Compensation Plan that becomes payable upon the participant's retirement.

Participants can allocate their account balances amongst various investment choices established by the administrator under the Deferred Compensation Plan, with earnings accruing to the participant's account. The value of the accounts may increase or decrease depending upon the performance of the selected investments. The administrator of the Deferred Compensation Plan may add or remove investment choices from time to time, provided that such changes will not be effective for any period before the effective date of such change. Participant investment allocations become effective on the same business day or, if an investment allocation is received after a specified period of time designated by the administrator of the Deferred Compensation Plan, the next business day. Participants may change investment allocations, which will become effective on the same business day or, if an investment allocation is received after a specified period of time designated by the administrator of the Deferred Compensation Plan, the next business day. If a participant does not make an investment allocation with respect to an account under the Deferred Compensation Plan, then the account balances will be invested in an investment choice selected by the administrator of the Deferred Compensation

Plan for which its primary objective is preservation of capital. Valuations of accounts are performed in accordance with such procedures as are established by the administrator of the Deferred Compensation Plan.

Upon a participant's death or separation from service with the Company, the balances under any of the participant's accounts that are payable in connection with retirement or separation from service will be paid in a single lump sum in the calendar year following the calendar year in which the separation from service occurs (or if the participant has attained 55 years of age and 10 years of service at the time of such separation, in any later calendar year that had been elected by the participant). If the separation from service occurs before the participant attains 55 years of age and 10 years of service, balances under any of the participant's accounts payable on specified dates also will be paid in a single lump sum in the calendar year following the calendar year in which the separation from service occurs, notwithstanding the specified dates applicable to such accounts. The Deferred Compensation Plan provides its plan administrator with the authority to accelerate or delay the payment timing of account balances, provided such changes are permitted under applicable tax rules and requirements.

Compensation deferred under the Deferred Compensation Plan represents an unsecured obligation of the Company. Amounts deferred under the Deferred Compensation Plan are held in a separate rabbi trust established to pay Deferred Compensation Plan benefits.

The following table summarizes activity under the Deferred Compensation Plan in 2022:

Name	Executive Contribution in last FY ($)[1]	Registrant Contributions in last FY ($)	Aggregate Earnings (loss) in last FY ($)	Aggregate Withdrawals/ Distributions ($)	Aggregate Balance at last FYE ($)[2]
Jack Y. Zhang	—	—	(8,358)	—	84,225
William J. Peters	121,754	—	(28,221)	—	251,598
Mary Z. Luo	—	—	(5,417)	—	54,591
Rong Zhou	391,365	—	(77,067)	(4,216)	793,597
Jacob Liawatidewi	44,035	—	(12,653)	—	102,317

(1) These amounts represent each named executive officer's deferrals of salary and/or bonus amounts earned for 2022 and were also reported in the columns entitled "Salary" and/or "Bonus" in the Summary Compensation Table.

(2) These amounts include each named executive officer's deferrals of salary and/or bonus amounts earned in aggregate for 2020, 2021 and 2022, are reported in the columns entitled "Salary" and/or "Bonus" in the Summary Compensation Table for 2020, 2021 and 2022: $84,225 for Dr. Zhang, $251,598 for Mr. Peters, $54,951 for Dr. Luo, $793,597 for Mr. Zhou, and $102,317 for Mr. Liawatidewi.

Potential Payments upon Termination or Change of Control

We entered into an employment agreement with Jack Y. Zhang, Mary Z. Luo and William J. Peters that govern the terms of each such named executive officer's employment. Each employment agreement provided for an initial term of three years and is automatically extended for successive one-year periods, unless one of the parties provides the other 90 days' prior notice before the expiration of the annual renewal term that the term will not be extended. Each employment agreement is terminable (i) by the applicable named executive officer at any time, provided the named executive officer gives at least four weeks' prior notice of resignation; (ii) by us at any time; or (iii) due to the disability or death of the named executive officer.

Pursuant to each employment agreement, unless the applicable named executive officer resigns without "good reason" (as defined in the employment agreement) or the named executive officer's employment is terminated for "cause" (as defined in the employment agreement), the named executive officer is entitled to any applicable prorated bonus, based on actual performance for the year of termination, as determined by the

Board of Directors in its discretion when making bonus determinations for other senior executives and payable at such time as annual bonuses are otherwise determined for such other senior executives.

If we do not renew an employment agreement at the end of any renewal term, the applicable named executive officer's employment is terminated by us without "cause" (as defined in the employment agreement), or the named executive officer resigns with "good reason" (as defined in the employment agreement), then such named executive officer, conditioned upon execution of a release in form and substance satisfactory to us, is entitled to:

- an amount equal to three, or two in the case of Mr. Peters, times the sum of (i) the highest base annual salary in effect during the 12 months immediately prior to the date of termination, plus (ii) the average annual bonus earned by the named executive officer for the most recent three, or two in the case of Mr. Peters, fiscal years ending prior to the date of termination or the base salary for the remainder of the agreement, whichever is greater, such amount to be paid in cash or immediately-available funds in a lump sum thirty days following the date of termination;

- continued payment of his or her health insurance premiums as may be necessary to allow the named executive officer and his or her spouse and dependents to continue to receive health insurance coverage substantially similar to the coverage they received prior to the date of termination of the named executive officer's employment, for a period of 12 months or the remainder of the term of the agreement, which is greater commencing on the date of termination; and

- vesting of any restricted stock, stock option or other equity compensation awards granted by us, except to the extent that the provisions of the applicable restricted stock, stock option or other equity award are more favorable.

Under each employment agreement, if, on or within one year after a "change of control" (as defined in the employment agreement), the applicable named executive officer's employment is terminated by us without "cause" (as defined in the employment agreements), or the named executive officer resigns with "good reason" (as defined in the employment agreements), then such named executive officer, conditioned upon execution of a release in form and substance satisfactory to us, is also entitled to receive the following severance benefits, in addition to the severance benefits described above:

- payment in an amount equal to three, or two in the case of Mr. Peters, times the sum of (i) the highest base salary in effect during the 12 months immediately prior to the date of termination, plus (ii) the average annual bonus earned by the named executive officer for the most recent three, or two in the case of Mr. Peters, fiscal years ending prior to the date of termination, such amount to be paid in cash or immediately-available funds in a lump sum sixty days following the date of termination;

- extension of the period that we will provide the health insurance premium payments described above by 12 months; and

- full vesting of all restricted stock, stock options or other equity compensation awards granted by us that were unvested immediately prior to the change in control, except to the extent that the provisions of the applicable restricted stock, stock option or other equity award are more favorable.

In addition, each of these employment agreements provides that in the event any payments and benefits (including the severance benefits under the employment agreement) provided to the applicable named executive officer would constitute "parachute payments" within the meaning of Section 280G of the Internal

Revenue Code and could be subject to the related excise tax, the named executive officer would be entitled to receive either the full amount of such payments and benefits or such lesser amount which would result in no portion of the benefits being subject to the excise tax, whichever results in the greater after-tax amount of payments and benefits to the named executive officer.

As defined in the employment agreements, "cause" generally means (i) the continued willful failure by the applicable named executive officer to substantially perform his or her duties with the Company, (ii) the willful engaging by named executive officer in misconduct materially and demonstrably injurious to the Company or (iii) the named executive officer's material breach of the employment agreement; provided, that with respect to any breach that is curable by the named executive officer, as determined by our Board of Directors in good faith, the Company has provided the named executive officer written notice of the material breach and the named executive officer has not cured such breach, as determined by our Board of Directors in good faith, within 15 days following the date the Company provides such notice.

As defined in the employment agreements, "good reason" generally means: (i) a material reduction (without the applicable named executive officer's express written consent) in the named executive officer's duties or responsibilities; (ii) the requirement that the named executive officer relocate to an employment location that is more than 50 miles from his or her employment location on the effective date of the employment agreement; or (iii) the Company's material breach (without the named executive officer's express written consent) of the employment agreement; provided, that the named executive officer has provided the Company written notice of the material breach and the Company has not cured such breach within 15 days following the date the named executive officer provides such notice.

The following table provides an estimate of the severance benefits that would be provided to Dr. Zhang, Dr. Luo, and Mr. Peters in the circumstances described above pursuant to their employment agreements, assuming the triggering event took place on December 30, 2022 (the last business day of 2022) and based on the $28.02 closing price for a share of our common stock on the Nasdaq Stock Market on that date. Due to the number of factors that affect the nature and amount of the severance benefits, the amount of the severance benefits actually provided (if any) may be different. For example, a triggering event may occur on a different date, the price per share of our common stock on the date of the triggering event may not be $28.02, or the assumptions relied upon in the estimate of potential severance benefits below may not reflect the actual circumstances of the triggering event. As a result, there is no guarantee that a qualifying termination would produce the same or similar results as those estimated below.

Name	Severance Benefit	Termination Apart from a Change of Control ($)	Termination in Connection with a Change of Control ($)
Jack Y. Zhang	Cash Severance[1]	5,692,945	11,385,890
	Equity Acceleration[2]	10,525,394	10,525,394
	Health Coverage[3]	5,048	10,096
	Total	**16,223,387**	**21,921,380**
William J. Peters	Cash Severance[1]	2,142,555	4,285,110
	Equity Acceleration[2]	3,588,899	3,588,899
	Health Coverage[3]	10,652	21,305
	Total	**5,742,106**	**7,895,314**
Mary Z. Luo	Cash Severance[1]	3,796,244	7,592,488
	Equity Acceleration[2]	4,651,653	4,651,653
	Health Coverage[3]	6,552	13,104
	Total	**8,454,449**	**12,257,245**

(1) This amount represents (i) the prorated bonus based on actual performance for the year of termination and (ii) the lump sum cash

severance payment(s) calculated based on the named executive officer's base salary and average annual bonus, in each case as described above.

(2) This amount represents the value of the named executive officer's vesting acceleration benefit described above, which is calculated for each equity award by multiplying (i) the number of shares covered by the equity award that accelerate multiplied by (ii) the excess, if any, of the closing sales price per share of our common stock on December 30, 2022 ($28.02) over the equity award's exercise price, if any.

(3) This amount represents the continued payment of health insurance premiums described above.

CEO Pay Ratio

We calculated our President and CEO pay ratio described below in compliance with the requirements set forth in Item 402(u) of Regulation S-K.

We identified the median employee using our employee population, excluding the CEO, as of December 31, 2022, which included 1,615 global full-time and part-time employees employed on that date, and used our consistently applied compensation measure of base salary or wages paid for the year through December 31, 2022. Nearly all of our employees receive an annual base salary (paid on an hourly, weekly, biweekly or monthly basis), which reasonably reflects the annual compensation of our employees. For employees outside the United States, we converted the annual base salary into United States dollars using the applicable exchange rates on December 31, 2022.

Once we identified our median employee, we then calculated the median employee's annual total compensation in the same manner as the named executive officers found in the Summary Compensation Table on page 39. Our median employee's annual total compensation was $54,127. Our President and Chief Executive Officer's annual total compensation disclosed in the Total column of the Summary Compensation Table was $7,477,951. Accordingly, our estimated President and Chief Executive Officer to median employee pay ratio for 2022 was 138:1. Approximately 26% of the employees who earned below the median were employed in China, where wages are systematically lower than in the U.S.

PAY VERSUS PERFORMANCE

As required by Section 953(a) of the Dodd-Frank Wall Street Reform and Consumer Protection Act, and Item 402(v) of Regulation S-K, we are providing the following information about the relationship between executive compensation actually paid and certain financial performance of the Company. For further information concerning the Company's variable pay-for-performance philosophy and how the Company's aligns executive compensation with the Company's performance, refer to "Executive Compensation – Compensation Discussion and Analysis."

Year	Summary Compensation Table Total for PEO (1)	Compensation Actually Paid to PEO (1)(3)	Average Summary Compensation Table for Non-PEO NEOs (2)	Average Compensation Actually Paid to Non-PEO NEOs (2)(3)	Value of Initial Fixed $100 Investment Based On: Total Shareholder Return (4)	Value of Initial Fixed $100 Investment Based On: Peer Group Total Shareholder Return (5)	Net Income (in '000) (6)	Sales Growth on Budget vs. 2021 (7)
2022	$ 7,477,951	$ 12,892,333	$ 2,451,868	$ 3,860,080	$ 145.26	$ 113.65	$ 91,386	14.0%
2021	6,509,420	8,829,336	2,233,883	2,890,154	120.74	126.45	62,116	25.1%
2020	5,962,949	6,951,075	2,948,576	1,958,840	104.25	126.42	1,403	8.5%

(1) Jack Y. Zhang served as our principal executive officer (PEO) for each of the years 2022, 2021, and 2020.

(2) Our non-PEO named executive officers (NEOs) for each of the years 2022, 2021, and 2020 were: (i) William J. Peters, Mary Ziping Luo, Rong Zhou, and Jacob Liawatidewi for 2022 and 2021, and (ii) William J. Peters, Mary Ziping Luo, Jason B. Shandell, Rong Zhou, and Jacob Liawatidewi for 2020.

(3) The Compensation Actually Paid Schedule shown below sets forth the adjustment made during each year represented in the Pay Versus Performance Table to arrive at the "compensation actually paid" to our PEO and average "compensation actually paid" to our non-PEO NEOs.

Compensation Actually Paid Schedule

	2022		2021		2020	
	CEO	Average Non-PEO NEOs	CEO	Average Non-PEO NEOs	CEO	Average Non-PEO NEOs
Summary Compensation table total for applicable year.	$ 7,477,951	$ 2,451,868	$ 6,509,420	$ 2,233,883	$ 5,962,949	$ 2,948,576
Deduction for amounts reported under the "Stock Awards" and "Option Awards" columns in the Summary Compensation table for applicable year.	(5,344,009)	(1,382,259)	(4,577,008)	(1,215,707)	(3,980,003)	(1,624,237)
Increase based on ASC Topic 718 fair value of Awards granted during applicable year that remain unvested as of applicable year end, determined as of applicable year end	4,179,167	1,080,965	6,373,743	1,688,333	7,152,085	1,441,852
Increase/deduction for Awards granted in prior years that were outstanding and unvested as of applicable year end, determined based on change in ASC Topic 718 fair value from the prior year end to the applicable year end.	2,338,630	701,571	1,010,138	291,068	(231,663)	(31,974)
Increase/deduction for Awards granted in prior years that vested during the applicable year, determined based on change in ASC Topic 718 fair value from the prior year end to the vesting date	4,240,594	1,007,935	(486,957)	(107,423)	(1,952,293)	(674,251)
Deduction of Awards granted in prior year that were forfeited in the applicable year, determined based on ASC Topic 718 fair value as of prior year end	-	-	-	-	-	(101,127)
Compensation Actually Paid for applicable year	$ 12,892,333	$ 3,860,080	$ 8,829,336	$ 2,890,154	$ 6,951,075	$ 1,958,840

(4) Represents the cumulative total shareholder return of the Company's common stock, based on an initial fixed investment of $100 made on the market close on the last trading day before the earliest fiscal year in the table, assuming the reinvestment of any dividends

(5) Represents the cumulative total shareholder return of the NASDAQ Biotechnology index (which is the peer group we used for the stock performance graph required by Item 201(e) of Regulation S-K included in our Annual Report for the year ended December 31, 2022) based on an initial fixed investment of $100 made on the market close on the last trading day before the earliest fiscal year in the table, assuming the reinvestment of any dividends.

(6) Represents the Company's net income, calculated in accordance with U.S. GAAP, as reported in our Annual Report on Form 10-K, as filed with the SEC on March 1, 2023.
(7) Represents the Company's sales growth on budget vs. 2021.

Financial Performance Measures

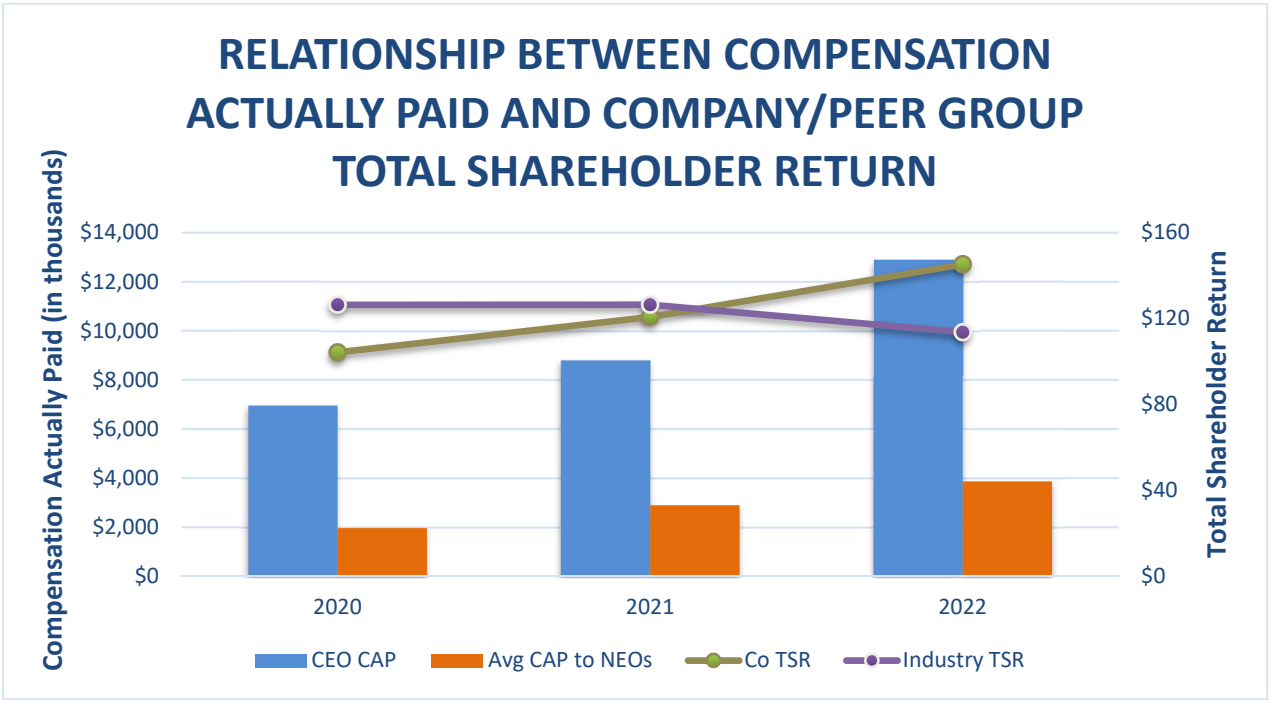
The following lists the financial performance measures that we believe represents the most important financial performance measures used to link compensation actually paid to our NEOs for 2022 to Company performance.

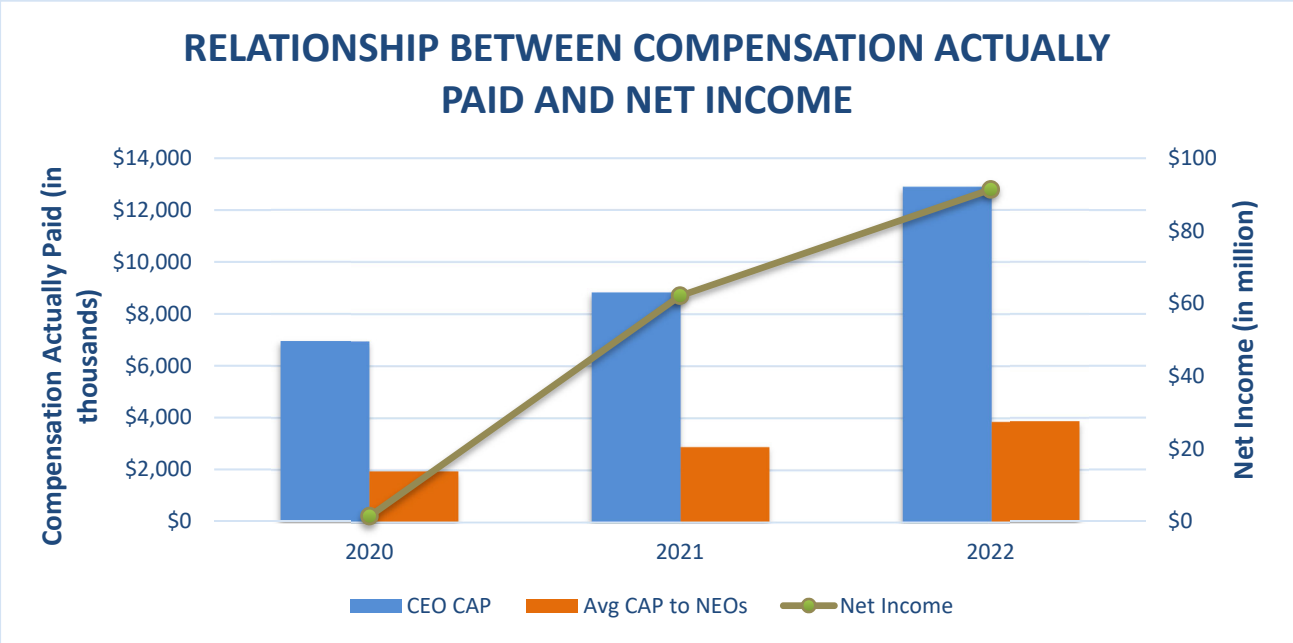
Financial Performance Measures
Company's sales growth on budget vs. 2021
Adjusted Net Income
Relative Total Shareholder Return (TSR) (The Company's TSR as compared to the NASDAQ Biotechnology Index)

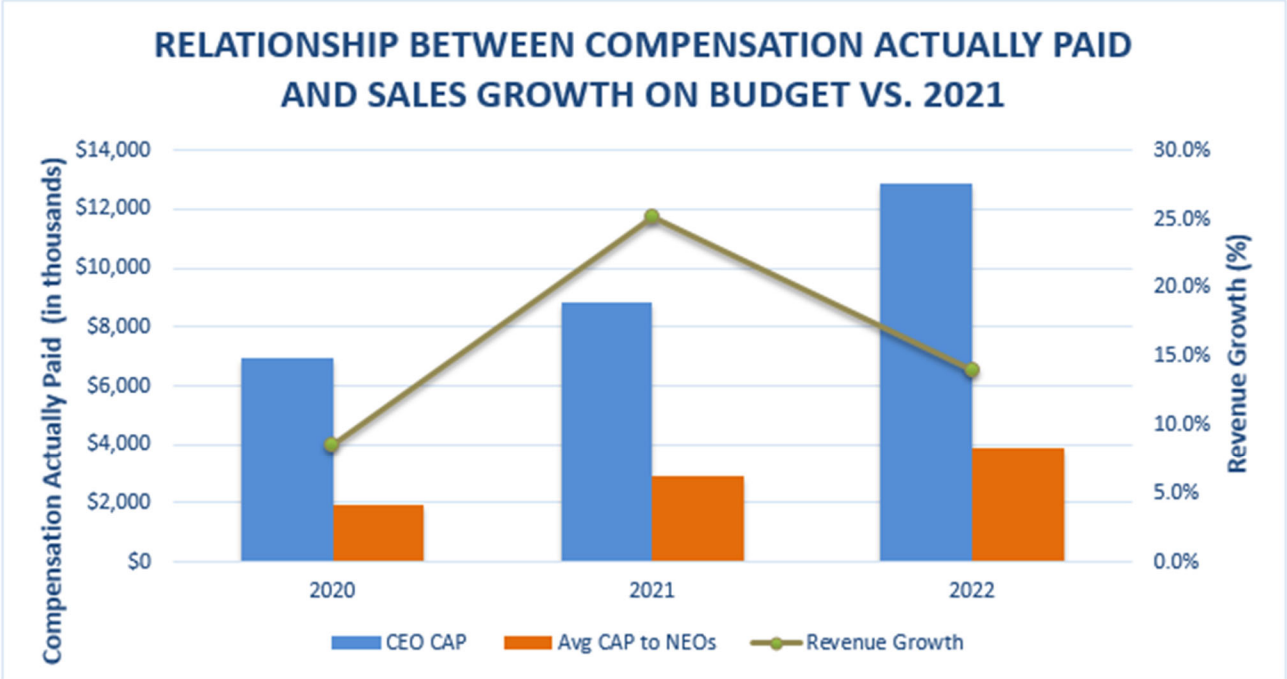
Pay Versus Performance Relationship Descriptions

We believe the Company's pay-for-performance philosophy is well reflected in the tables above because the Compensation Actually Paid tracks well to the performance measures disclosed in such tables. The graphs below describe, in a manner compliant with the relevant rules, the relationship between Compensation Actually Paid and the individual performance measures shown.

The following graphical comparisons describe the relationship between certain figures included in the Pay versus Performance Table for the years 2022, 2021, and 2020, including: (a) comparison between the Company's total shareholder return and the total shareholder return for the NASDAQ Biotechnology index and (b) comparisons between (i) the compensation actually paid to the NEO and the average compensation actually paid to our Non-PEO NEOs and (ii) the Company's net income and percentage of revenue growth set forth in the pay versus performance table above.




RELATIONSHIP BETWEEN COMPENSATION ACTUALLY PAID AND NET INCOME
Compensation Actually Paid (in thousands)
$14,000
$12,000
$10,000
$8,000
$6,000
$4,000
$2,000
$0
$100
$80
$60
$40
$20
$0
Net Income (in million)
2020
2021
2022
CEO CAP
Avg CAP to NEOs
Net Income


RELATIONSHIP BETWEEN COMPENSATION ACTUALLY PAID AND SALES GROWTH ON BUDGET VS. 2021
Compensation Actually Paid (in thousands)
$14,000
$12,000
$10,000
$8,000
$6,000
$4,000
$2,000
$0
30.0%
25.0%
20.0%
15.0%
10.0%
5.0%
0.0%
Revenue Growth (%)
2020
2021
2022
CEO CAP
Avg CAP to NEOs
Revenue Growth

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information with respect to the beneficial ownership of our common stock as of March 31, 2023 for:

- each of our named executive officers;
- each of our directors and nominees for director;
- all of our then-current executive officers and directors as a group; and
- each person known by us to own beneficially more than 5% of our common stock;

Applicable percentage ownership is based on 48,179,238 shares of common stock outstanding as of March 31, 2023. Beneficial ownership is determined according to the rules of the SEC and generally means that a person has beneficial ownership of a security if he or she possesses sole or shared voting or investment power of that security, including options that are currently exercisable within 60 days of March 31, 2023 or shares issuable upon the vesting of RSUs within 60 days of March 31, 2023, and subject to community property laws where applicable.

Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Amphastar Pharmaceuticals, Inc., 11570 6th Street, Rancho Cucamonga, California 91730. The information provided in the table is based on our records, information filed with the SEC and information provided to us, except where otherwise noted.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
Named Executive Officers, Directors and Director Nominees:		
Jack Y. Zhang (1)(2)	13,440,210	26.1
Mary Z. Luo (1)(2)	13,440,210	26.1
William J. Peters (3)	330,813	*
Rong Zhou (4)	392,689	*
Jacob Liawatidewi (5)	117,832	*
Howard Lee (6)	202,556	*
Floyd F. Petersen (7)	145,225	*
Michael A. Zasloff (8)	110,986	*
Richard Prins (9)	106,959	*
Diane G. Gerst (10)	22,233	*
Gayle Deflin (11)	23,201	*
All executive officers and directors as a group (11 persons) (12)	14,892,704	28.4
5% Stockholders:		
BlackRock Inc.(13)	7,038,769	14.6
Applied Physics & Chemistry Laboratories, Inc. (14)	6,827,679	14.2
Federated Hermes, Inc.(15)	3,284,217	6.8
The Vanguard Group (16)	2,621,807	5.4

* Represents beneficial ownership of less than one percent (1%) of the outstanding shares of our common stock.

(1) Dr. Zhang and Dr. Luo are spouses and the number and percentage of beneficial ownership of each represents their aggregate combined ownership of 26.1% as described in footnotes (2) and (13) below.

(2) Includes (i) 6,827,679 shares held of record by Applied Physics & Chemistry Laboratories, Inc. ("APCL"), for which Drs. Zhang and Luo, and The Bill Luobei Zhang 2004 Irrevocable Trust (the "BLZ Trust") are the sole owners; (ii) 1,876,046

shares held of record by Dr. Zhang; (iii) 1,368,546 shares held of record by Dr. Luo; (iv) 5,000 shares held in an account for the benefit of the son of Drs. Zhang and Luo; (v) 2,347,110 shares exercisable by Dr. Zhang within 60 days of March 31, 2023; and (vi) 1,015,829 shares exercisable by Dr. Luo within 60 days of March 31, 2023. Of the reported shares, 1,750,000 shares held of record by APCL and 600,000 shares held of record by Dr. Zhang are pledged as collateral to secure certain personal indebtedness, including various lines of credit.

(3) Includes (i) 35,586 shares held of record by Mr. Peters; (ii) 294,465 shares exercisable within 60 days of March 31, 2023; and (iii) 762 shares issuable within 60 days of March 31, 2023.

(4) Includes (i) 44,634 shares held of record by Mr. Zhou; (ii) 99,668 shares held of record by the Zhou Family Trust for which Mr. Zhou serves as a trustee; (iii) 5,000 shares held of record by Mr. Zhou's spouse; and (iv) 243,387 shares exercisable within 60 days of March 31, 2023.

(5) Includes (i) 31,951 shares held of record by Mr. Liawatidewi; (ii) 2,459 shares held of record by the Yakob and Sunmoon Family Trust for which Mr. Liawatidewi serves as a trustee; and (iii) 83,422 shares exercisable within 60 days of March 31, 2023.

(6) Includes (i) 138,776 shares held of record by Dr. Lee and (ii) 63,780 shares exercisable within 60 days of March 31, 2023.

(7) Includes (i) 81,445 shares held of record by Mr. Petersen and (ii) 63,780 shares exercisable within 60 days of March 31, 2023.

(8) Includes (i) 47,206 shares held of record by Dr. Zasloff and (ii) 63,780 shares exercisable within 60 days of March 31, 2023.

(9) Includes (i) 43,179 shares held of record by Mr. Prins and (ii) 63,780 shares exercisable within 60 days of March 31, 2023.

(10) Includes (i) 8,679 shares held of record by Ms. Gerst and (ii) 13,554 shares exercisable within 60 days of March 31, 2023.

(11) Includes (i) 6,019 shares held of record by Ms. Deflin and (ii) 17,182 shares exercisable within 60 days of March 31, 2023.

(12) Includes (i) 10,621,873 shares beneficially owned by our executive officers and directors as a group; (ii) 4,270,069 shares exercisable within 60 days of March 31, 2023; and (iii) 762 shares issuable within 60 days of March 31, 2023.

(13) Based on a Schedule 13G/A filed with the SEC on January 26, 2023, BlackRock, Inc. ("BlackRock") holds sole voting power with respect to 6,830,951 shares and sole dispositive power with respect to 7,038,769 shares. The address for BlackRock is 55 East 52nd Street, New York, New York 10055.

(14) Drs. Zhang and Luo and the BLZ Trust are the sole owners of APCL. Of the reported shares, 2,350,000 shares are pledged as collateral to secure certain personal indebtedness, including various lines of credit. The address for this entity is 13760 Magnolia Avenue, Chino, California 91710.

(15) Based on a Schedule 13G/A filed with the SEC on February 1, 2023, Federated Hermes, Inc. ("Federated Hermes") holds sole voting and dispositive power with respect to 3,284,217 shares. The address for Federated Hermes is 1001 Liberty Avenue, Pittsburgh, Pennsylvania 15222

(16) Based on a Schedule 13G/A filed with the SEC on February 9, 2023, The Vanguard Group ("Vanguard") holds shared voting power with respect to 65,941 shares, sole dispositive power with respect to 2,524,028 shares and shared dispositive power with respect to 97,779 shares. The address for Vanguard is 100 Vanguard Blvd., Malvern, Pennsylvania 19355.

RELATED PERSON TRANSACTIONS

Policies and Procedures for Related Party Transactions

As set forth in our audit committee charter, our audit committee or our board is responsible for reviewing and approving all related-party transactions, which consist of all transactions and series of similar transactions to which we were a party or will be a party and in which any of our directors, executive officers and holders of more than 5% of our voting securities and their respective affiliates has a direct or indirect material interest. As used in this section, the terms "related person" and "transaction" have the meanings set forth in Item 404(a) of Regulation S-K under the Securities Act. In the course of its review and approval of transactions with related persons, the audit committee or the board considers:

- the nature of the related person's interest in the transaction;
- the material terms of the transaction, including the amount involved and the type of the transaction;
- the importance of the transaction to the related person and to Amphastar;
- whether the transaction would impair the judgment of a director or executive officer to act in our best interest and the best interest of our stockholders; and
- any other matters the audit committee deems appropriate.

Any member of the board who is a related person with respect to a transaction under review will not be able to participate in the discussions or vote on the approval or ratification of the transaction, other than to provide all material information regarding the transaction, including information regarding the extent of the member's interest in the transaction. Any material changes to the terms of, or any renewal of, any of these transactions will also require the same approval. If a related party transaction will be ongoing, the audit committee or the board may establish guidelines or other parameters or conditions relating to our participation in the transaction. The audit committee or the board may from time to time pre-approve types or categories of transactions by related persons but we have no such pre-approved types or categories of transactions at this time.

Related Person Transactions

We describe below transactions and series of similar transactions, since the beginning of our last fiscal year, to which we were a party or will be a party, in which:

- the amounts involved exceeded or will exceed $120,000; and
- any of our directors, nominees for director, executive officers or holders of more than 5% of our outstanding capital stock, or any immediate family member of, or person sharing the household with, any of these individuals or entities, had or will have a direct or indirect material interest.

Other than as described below, there has not been, nor is there any currently proposed, transactions or series of similar transactions to which we have been or will be a party.

Contract manufacturing agreement with Hanxin

In April 2022, Amphastar Nanjing Pharmaceuticals, Inc., or ANP, a wholly-owned subsidiary of the Company, entered into a contract manufacturing agreement with Nanjing Hanxin Pharmaceutical Technology Co., Ltd., or Hanxin. Dr. Jack Zhang, our Chief Executive Officer, President, and Director and Dr. Mary Luo, our Chairman, Chief Operating Officer, and Director and certain members of their family beneficially own a majority of the equity interest in Hanxin, whereby Hanxin will develop several active pharmaceutical ingredients and finished products for the Chinese market and will engage ANP to manufacture the products on a cost-plus basis. Hanxin will purchase certain quantities from ANP subject to the terms and conditions set forth in the agreement, including Hanxin filing for and obtaining any required marketing authorizations.

Since April 2022, the Company has recognized approximately $370,000 from manufacturing services provided to Hanxin.

Contract Research Agreement with Hanxin

In July 2022, the Company entered into a three-year contract research agreement with Hanxin, pursuant to which Hanxin will develop Recombinant Human Insulin Research Cell Banks, or RCBs, for the Company and license the RCBs to the Company subject to a fully paid, exclusive, perpetual, transferable, sub-licensable worldwide license. The RCBs will be used by the Company to make Master Cell Banks for one of its product candidates. Per the terms of the agreement with Hanxin, all title to the RCBs developed, prepared and produced by Hanxin in conducting research and development will belong to the Company. The Company will also own any confidential and proprietary information, technology regarding development and manufacturing of the RCBs, which shall include engineering, scientific and practical information and formula, research data, design, and procedures and others to develop and manufacture the RCBs, in use or developed by Hanxin. Dr. Jack Zhang , our Chief Executive Officer, President, and Director and Dr. Mary Luo, our Chairman, Chief Operating Officer, and Director and certain members of their family beneficially own a majority of the equity interest in Hanxin. The total cost of the agreement to the Company shall not exceed approximately $2.2 million, with payments adjusted based on the then current exchange rates.

In March 2023, the Company amended the agreement with Hanxin, whereby Hanxin will perform scale-up manufacturing process development using the RCBs for the Company. Per the terms of the agreement the Company will own any confidential and proprietary information and technology produced during the scale-up manufacturing, which shall include engineering, scientific and practical information and formula, research data design and procedures and others to develop and manufacture the RCBs. The amendment will remain in full force and effect for the same period as contract research agreement, currently July 5, 2025. The total cost of the amendment to the Company shall not exceed approximately $0.5 million, with payments adjusted based on actual currency exchange rates. Any additional work or changes to the scope of work requested by the Company will be charged by Hanxin to the Company on a cost-plus basis, plus any applicable taxes.

Since July 2022, the Company has paid approximately $579,000 to Hanxin under the contract research agreement and amendment.

Supply Agreement with Letop

In November 2022, ANP, entered into a supply agreement with Nanjing Letop Biotechnology Co., Ltd., or Letop, whereby Letop would manufacture and deliver chemical intermediates for ANP on a cost-plus basis. Henry Zhang (Haoning Zhang), the son of Dr. Jack Zhang, our Chief Executive Officer, President, and Director and Dr. Mary Luo, our Chairman, Chief Operating Officer, and Director, beneficially owns a majority of the equity interest in Letop. The agreement is effective for three years and the total cost of the

agreement shall not exceed approximately $1.5 million, with payments adjusted based on the then current exchange rates.

Since November 2022, ANP has paid approximately $194,000 under this agreement.

Other Transactions

We have granted stock options and RSUs to our executive officers and certain of our directors. See the sections titled “Executive Compensation—Outstanding Equity Awards at 2022 Year-End” and “Non-Employee Director Compensation – Compensation for 2022.” for a description of these stock options and RSUs.

We have entered into employment agreements with certain of our executive officers that, among other things, provides for certain severance and change in control benefits. See the section titled “Executive Compensation—Potential Payments upon Termination or Change of Control.”

Indemnification Agreements

We have entered into indemnification agreements with each of our directors and executive officers. The indemnification agreements, our amended and restated certificate of incorporation and our amended and restated bylaws require us to indemnify our directors to the fullest extent permitted by Delaware law.

OTHER MATTERS

Fiscal Year 2022 Annual Report and SEC Filings

Our financial statements for our fiscal year ended December 31, 2022 are included in our Annual Report on Form 10-K, which we will make available to stockholders at the same time as this proxy statement. This proxy statement and our annual report are posted on the Financials & Filings portion of our website at http://ir.amphastar.com/ and are available from the SEC at its website at http://www.sec.gov. You may also obtain a copy of our annual report without charge by sending a written request to Amphastar Pharmaceuticals, Inc., Attention: Investor Relations, 11570 6th Street, Rancho Cucamonga, California 91730.

* * *

The Board of Directors does not know of any other matters to be presented at the Annual Meeting. If any additional matters are properly presented at the Annual Meeting, the persons named in the enclosed proxy card will have discretion to vote the shares of our common stock they represent in accordance with their own judgment on such matters.

It is important that your shares of our common stock be represented at the Annual Meeting, regardless of the number of shares that you hold. You are, therefore, urged to vote by telephone or by using the Internet as instructed on the enclosed proxy card or execute and return, at your earliest convenience, the enclosed proxy card in the envelope that has also been provided.

THE BOARD OF DIRECTORS

Rancho Cucamonga, California
April 21, 2023

ANNEX A – Reconciliation of GAAP to Non-GAAP Financial Measures

	Year Ended December 31,	
	2022	2021
GAAP net income	$ 91,386	$ 63,301
Adjusted for:		
Intangible amortization	1,420	1,290
Share-based compensation	17,860	18,687
Impairment of long-lived assets	—	348
Gain on ANP Restructuring	—	(13,587)
Reserves for litigation and settlements	(4,929)	274
Income tax benefit provision on pre-tax adjustments	(2,550)	(2,043)
Non-GAAP net income	$ 103,187	$ 68,270
Non-GAAP net income attributable to non-controlling interests	$ —	$ 271
Non-GAAP net income attributable to Amphastar	$ 103,186	$ 67,999
Non-GAAP net income per share attributable to Amphastar stockholders:		
Basic	$ 2.13	$ 1.42
Diluted	$ 1.97	$ 1.37
Weighted-average shares used to compute non-GAAP net income per share attributable to Amphastar stockholders:		
Basic	48,551	47,777
Diluted	52,427	49,784

	Year Ended December 31, 2022						
	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Non-operating income (expense), net	Income tax provision (benefit)	Non-controlling interest adjustment
GAAP	$ 250,127	$ 21,531	$ 45,061	$ 74,771	$ 8,543	$ 23,477	$ —
Intangible amortization	(866)	—	(554)	—	—	—	—
Share-based compensation	(4,179)	(726)	(11,180)	(1,775)	—	—	—
Reserves for litigation and settlements	—	—	(800)	—	(5,729)	—	—
Income tax provision on pre-tax adjustments	—	—	—	—	—	2,550	—
Non-GAAP	$ 245,082	$ 20,805	$ 32,527	$ 72,996	$ 2,814	$ 26,027	$ —

	Year Ended December 31, 2021						
	Cost of revenue	Selling, distribution and marketing	General and administrative	Research and development	Non-operating income (expense), net	Income tax provision (benefit)	Non-controlling interest adjustment
GAAP	$ 238,029	$ 17,486	$ 51,434	$ 60,932	$ 14,252	$ 20,630	$ 1,185
Intangible amortization	(963)	—	(327)	—	—	—	26
Share-based compensation	(3,778)	(596)	(12,622)	(1,691)	—	—	870
Impairment of long-lived assets	(93)	—	(33)	(222)	—	—	7
Gain on ANP Restructuring	—	—	—	—	(13,587)	—	(2,062)
Reserves for litigation and settlements	—	—	(1,295)	—	(1,021)	—	—
Income tax provision on pre-tax adjustments	—	—	—	—	—	2,043	245
Non-GAAP	$ 233,195	$ 16,890	$ 37,157	$ 59,019	$ (356)	$ 22,673	$ 271

SCAN TO
VIEW MATERIALS & VOTE

AMPHASTAR PHARMACEUTICALS, INC.
C/O BROADRIDGE CORPORATE ISSUER SOLUTIONS, INC.
P.O. BOX 1342
BRENTWOOD, NY 11717

VOTE BY INTERNET
Before The Meeting – Go to **www.proxyvote.com or scan the QR Barcode above**

Use the Internet to transmit your voting instructions and for electronic delivery of information. Vote by 11:59 P.M. ET on June 4, 2023. Have your proxy card in hand when you access the web site and follow the instructions to obtain your records and to create an electronic voting instruction form.

During The Meeting – Go to **www.virtualshareholdermeeting.com/AMPH2023**

You may attend the meeting via the Internet and vote during the meeting. Have the information that is printed in the box marked by the arrow available and follow the instructions.

VOTE BY PHONE - 1-800-690-6903
Use any touch-tone telephone to transmit your voting instructions. Vote by 11:59 P.M. ET on June 4, 2023. Have your proxy card in hand when you call and then follow the instructions.

VOTE BY MAIL
Mark, sign and date your proxy card and return it in the postage-paid envelope we have provided or return it to Vote Processing, c/o Broadridge, 51 Mercedes Way, Edgewood, NY 11717.

TO VOTE, MARK BLOCKS BELOW IN BLUE OR BLACK INK AS FOLLOWS:

V05470-P91485 KEEP THIS PORTION FOR YOUR RECORDS

THIS PROXY CARD IS VALID ONLY WHEN SIGNED AND DATED. DETACH AND RETURN THIS PORTION ONLY

AMPHASTAR PHARMACEUTICALS, INC.

The Board of Directors recommends you vote FOR the following proposal:

1. To elect three Class I directors to serve until the Company's 2026 Annual Meeting of Stockholders and until each such director's successor is elected and qualified or until such director's earlier death, resignation or removal;

Nominees:	For	Against	Abstain
1a. Floyd F. Petersen	☐	☐	☐
1b. Jacob Liawatidewi	☐	☐	☐
1c. William J. Peters	☐	☐	☐

The Board of Directors recommends you vote FOR the following proposal:

	For	Against	Abstain
2. To ratify the appointment of Ernst & Young LLP as the Company's independent registered public accounting firm for its fiscal year ending December 31, 2023; and	☐	☐	☐
3. To approve, on an advisory basis, the compensation of the Company's named executive officers.	☐	☐	☐

Note: The proxy holders will vote, in their discretion, on any other business as may properly come before the Annual Meeting and any adjournment or postponement thereof.

Please sign exactly as your name(s) appear(s) hereon. When signing as attorney, executor, administrator, or other fiduciary, please give full title as such. Joint owners should each sign personally. All holders must sign. If a corporation or partnership, please sign in full corporate or partnership name by authorized officer.

Signature [PLEASE SIGN WITHIN BOX] Date

Signature (Joint Owners) Date

Important Notice Regarding the Availability of Proxy Materials for the Annual Meeting:
The Notice and Proxy Statement and Annual Report are available at www.proxyvote.com.

V05471-P91485

AMPHASTAR PHARMACEUTICALS, INC.
Annual Meeting of Stockholders
June 5, 2023 11:00 AM, Pacific Time
This proxy is solicited by the Board of Directors

The stockholder(s) hereby appoint(s) Jack Yongfeng Zhang, Mary Ziping Luo, William J. Peters, or any of them, as proxies, each with the power to appoint his or her substitute, and hereby authorize(s) them to represent and to vote, as designated on the reverse side of this ballot, all of the shares of Common Stock of AMPHASTAR PHARMACEUTICALS, INC. that the stockholder(s) is/are entitled to vote at the Annual Meeting of Stockholders to be held at 11:00 AM, Pacific Time on June 5, 2023 at www.virtualshareholdermeeting.com/AMPH2023, and any adjournment or postponement thereof.

This proxy, when properly executed, will be voted in the manner directed herein. If no such direction is made, this proxy will be voted in accordance with the Board of Directors' recommendations.

Continued and to be signed on reverse side

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

FORM 10-K

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

For the fiscal year ended December 31, 2022

OR

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

For the transition period from ____ to _____

Commission File Number 001-36509

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

Delaware	**33-0702205**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
11570 6th Street Rancho Cucamonga, CA	**91730**
(Address of principal executive offices)	**(zip code)**

(909) 980-9484
(Registrant's telephone number, including area code)

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 $0.0001 per share	AMPH	The NASDAQ Stock Market LLC

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

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

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

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

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

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☒ No ☐

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

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

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant on June 30, 2022 (the last business day of the registrant's most recently completed second fiscal quarter), based upon the closing price of Common Stock on such date as reported by Nasdaq Global Select Market, was approximately $885,261,017. Shares of common stock known to be held by directors, executive officers and holders of 5% or more of the outstanding common stock of the registrant are not included in the computation. No determination has been made that such persons are "affiliates" of the registrant for any other purpose.

At February 22, 2023, there were 47,896,820 shares of the registrant's common stock outstanding.

Documents Incorporated by Reference

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after the end of its fiscal year to which this report relates in connection with its 2023 Annual Meeting of Stockholders are incorporated by reference into Part III hereof.

AMPHASTAR PHARMACEUTICALS, INC.
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SPECIAL NOTE ABOUT FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or Annual Report, contains "forward-looking statements" that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by the following words: "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these identifying words. Forward-looking statements relate to future events or future financial performance or condition and involve known and unknown risks, uncertainties and other factors that could cause actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by the forward-looking statements. These forward-looking statements include, but are not limited to, statements about:

- our expectations regarding the sales and marketing of our products;
- our expectations regarding our manufacturing and production and the integrity of our supply chain for our products, including the risks associated with our single source suppliers;
- our business and operations in general, including: uncertainty regarding the magnitude, duration and geographic reach of the ongoing COVID-19 pandemic, adverse impacts of the Russia-Ukraine conflict and related macroeconomic conditions on our business, financial condition, operations, cash flows and liquidity;
- our ability to successfully execute and maintain the activities and efforts related to the measures we have taken or may take in response to the COVID-19 pandemic and associated costs therewith;
- our ability to attract, hire, and retain highly skilled personnel;
- interruptions to our manufacturing and production as a result of natural catastrophic events or other causes beyond our control such as power disruptions or widespread disease outbreaks, such as the ongoing COVID-19 pandemic and the Russia-Ukraine conflict;
- global, national and local economic and market conditions, specifically with respect to geopolitical uncertainty, including the Russia-Ukraine conflict, the ongoing COVID-19 pandemic, inflation and rising interest rates;
- the timing and likelihood of U.S. Food and Drug Administration, or FDA, approvals and regulatory actions on our product candidates, manufacturing activities and product marketing activities;
- our ability to advance product candidates in our platforms into successful and completed clinical trials and our subsequent ability to successfully commercialize our product candidates;
- cost and delays resulting from the extensive pharmaceutical regulations to which we are subject or delays in governmental processing time due to travel and work restrictions caused by the COVID-19 pandemic;
- our ability to compete in the development and marketing of our products and product candidates;
- our expectations regarding the business of our Chinese subsidiary, Amphastar Nanjing Pharmaceuticals, Ltd., or ANP;
- the potential for adverse application of environmental, health and safety and other laws and regulations on our operations;
- our expectations for market acceptance of our new products and proprietary drug delivery technologies, as well as those of our active pharmaceutical ingredient, or API, customers;
- the effects of reforms in healthcare regulations and reductions in pharmaceutical pricing, reimbursement and coverage;
- our expectations in obtaining insurance coverage and adequate reimbursement for our products from third-party payers;
- the amount of price concessions or exclusion of suppliers adversely affecting our business;
- variations in intellectual property laws, our ability to establish and maintain intellectual property protection for our products and our ability to successfully defend our intellectual property in cases of alleged infringement;
- the implementation of our business strategies, product development strategies and technology utilization;
- the potential for exposure to product liability claims;
- our ability to successfully bid for suitable acquisition targets or licensing opportunities, or to consummate and

integrate acquisitions, divestitures or investments, including the anticipated benefits of such acquisitions, divestitures or investments;

- our ability to expand internationally;
- economic and industry trends and trend analysis;
- our ability to remain in compliance with laws and regulations that currently apply or become applicable to our business both in the United States and internationally;
- the impact of trade tariffs, export or import restrictions, or other trade barriers;
- the impact of Patient Protection and Affordable Care Act (as amended) and other legislative and regulatory healthcare reforms in the countries in which we operate including the potential for drug price controls;
- the impact of global and domestic tax reforms, including the Tax Cuts and Jobs Acts of 2017, or the Tax Act, as amended by the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act;
- the timing for completion and the validation of the new construction at our ANP and Amphastar facilities;
- the timing and extent of share buybacks; and
- our financial performance expectations, including our expectations regarding our backlog, revenue, cost of revenue, gross profit or gross margin, operating expenses, including changes in research and development, sales and marketing and general and administrative expenses, and our ability to achieve and maintain future profitability.

You should read this Annual Report and the documents that we reference elsewhere in this Annual Report completely and with the understanding that our actual results may differ materially from what we expect as expressed or implied by our forward-looking statements. In light of the significant risks and uncertainties to which our forward-looking statements are subject, you should not place undue reliance on or regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all. In particular, the extent of COVID-19's ongoing impact on our business and the impacts of the ongoing Russia-Ukraine conflict, will depend on several factors, including the severity, duration and extent of the pandemic and the conflict, all of which continue to evolve and remain uncertain at this time. We discuss many of these risks and uncertainties in greater detail in this Annual Report, particularly in Item 1A. "Risk Factors." These forward-looking statements represent our estimates and assumptions only as of the date of this Annual Report regardless of the time of delivery of this Annual Report, and such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this Annual Report.

Unless expressly indicated or the context requires otherwise, references in this Annual Report to "Amphastar," "the Company," "we," "our," and "us" refer to Amphastar Pharmaceuticals, Inc. and our subsidiaries.

Item 1. Business.

Overview

We are a bio-pharmaceutical company that focuses primarily on developing, manufacturing, marketing, and selling technically challenging generic and proprietary injectable, inhalation, and intranasal products, and insulin active pharmaceutical ingredient, or insulin API products. We currently manufacture and sell over 20 products, the overwhelming majority of which are prescription pharmaceuticals. Since December 2018, we have sold our patented Primatene MIST® using a new hydrofluoroalkanes, or HFA, formulation as our sole over-the-counter product.

Our largest products by net revenues currently include Primatene MIST®, epinephrine, glucagon, phytonadione, lidocaine, and enoxaparin sodium. In April 2022, the FDA approved our ganirelix acetate injection 250mg/0.5mL prefilled syringe, which we launched in June 2022. In July 2022, the FDA approved our vasopressin injection, USP 20 Units/mL, 1 mL single-dose vial, which we launched in August 2022. In May 2022, the FDA approved our regadenoson injection, 0.08mg/mL, 5mL, single-dose prefilled syringe. The timing of the launch of this product is subject to a confidential settlement agreement with the product's innovator.

For the years ended December 31, 2022, 2021, and 2020, we recorded net revenues of $499.0 million, $437.8 million, and $349.8 million, respectively. We recorded net income of $91.4 million, $62.1 million, and $1.4 million for the years ended December 31, 2022, 2021, and 2020, respectively.

We are currently developing a portfolio of generic abbreviated new drug applications, or ANDAs, biosimilar insulin product candidates and proprietary product candidates, which are in various stages of development and target a variety of indications. Three of the ANDAs and one new drug application, or NDA, are currently on file with the FDA.

Our multiple technological capabilities enable the development of technically challenging products with limited competition. These capabilities include characterizing complex molecules, analyzing and synthesizing peptides and proteins, conducting immunogenicity studies, engineering particles, and improving drug delivery through sustained-release technology. These technological capabilities have enabled us to produce bioequivalent versions of complex drugs and support the development and manufacture of a broad range of dosage formulations, including solutions, emulsions, suspensions, and lyophilized products, as well as products administered via pre-filled syringes, vials, nasal sprays, metered-dose inhalers, or MDIs, and dry powder inhalers, or DPIs.

Our primary strategic focus is developing and commercializing products with high technical barriers to market entry. We are specifically focused on products that:

- leverage our proprietary research and development capabilities;
- require raw materials or APIs for which we believe we have a competitive advantage in sourcing, synthesizing, or manufacturing; and/or
- improve upon an existing drug's formulation with respect to drug delivery, safety, and/or efficacy.

Not all of our products will include all of these characteristics. Moreover, we may opportunistically develop and commercialize product candidates with lower technical barriers to market entry if, for example, our existing supply chain and manufacturing infrastructure allow us to pursue a specific product candidate competitively and cost-effectively.

To complement our internal growth and expertise, we have made several strategic acquisitions of companies, products and technologies. These acquisitions collectively have strengthened our core injectable and inhalation product technology infrastructure by providing additional manufacturing, marketing, and research and development capabilities, including the ability to manufacture raw materials, API, and other components for our products.

In 2021, we completed the restructuring of our Chinese subsidiary, ANP, resulting in the reduction of ANP's ownership of Hanxin Pharmaceutical Technology Co., Ltd, or Hanxin to 14%. See Note 3 in the accompanying "Notes to Consolidated Financial Statements" in this Annual Report on Form 10-K. As a result of the restructuring, we determined that we have significant influence over Hanxin and as such the retained non-controlling investment in Hanxin is accounted for as an equity method investment. Hanxin continues to be a related party subsequent to the restructuring.

Our Markets

We primarily target products with high technical barriers to market entry, with a particular focus on the injectable and inhalation markets. We also manufacture and sell certain APIs.

- *Injectable market.* Based on a December 2022 IQVIA National Sales Perspective Report, the U.S. injectable drug market in 2022 was over $285 billion. Our generic development portfolio is targeting opportunities in over $16 billion of this market. The injectable market requires highly technical manufacturing capabilities and compliance with strict current Good Manufacturing Practice, or cGMP, requirements, which create high barriers to market entry. Due to these high barriers to market entry, there are a limited number of companies with the technology and experience needed to manufacture injectable products. There have also been a number of quality issues over the past several years that have disrupted the ability of certain injectable manufacturers to produce sufficient product quantity to meet market demand. As such, the supply of injectables has been constrained, even as demand for injectable products has continued to increase.

- *Inhalation market.* Based on a December 2022 IQVIA National Sales Perspective Report, the U.S. inhalation drug market in 2022 was approximately $29 billion. Our generic development portfolio is targeting opportunities in over $6 billion of this market. Inhalation drug therapy is used extensively to treat respiratory conditions such as asthma and chronic obstructive pulmonary disease. The MDI is the most widely used device to deliver inhalation therapies. It uses pressurized gas, historically chlorofluorocarbons, or CFCs, and more recently HFAs, to release its dose when the patient activates the device. The DPI, which does not rely on a propellant, is also widely used. As in the case of injectables, there are significant technical barriers to manufacturing inhalation products. The evolution of inhalation delivery technologies from nebulizers and CFCs to HFAs and DPIs has required manufacturers of inhalation products to re-formulate their products, which in many cases may require technical engineering capabilities, additional regulatory approvals and modified delivery devices. Additionally, the development of generic HFA and DPI products requires bioequivalence studies for FDA approval.

Our Strengths

We have built our company by integrating the following capabilities and strengths that we believe enable us to compete effectively in the pharmaceutical industry:

- *Robust portfolio of products and product candidates.* We have over 20 commercial products and over 20 product candidates at different stages of development. We also continue to develop our product candidates, which represent our longer-term growth opportunities.

- *Advanced technical capabilities and multiple delivery technologies.* We have developed multiple advanced technical capabilities that we incorporate into the development of our products and product candidates, including characterization of complex molecules, peptide and protein analysis and synthesis, immunogenicity studies, particle engineering, and sustained-release technology. In addition, we apply these capabilities across our injectable, inhalation, and intranasal delivery technologies. Our injectable delivery technologies enable us to develop and manufacture generic and proprietary injectables in normal solution, lyophilized, suspension, jelly, and emulsion forms, as well as in pre-filled syringes. Our inhalation technologies cover a variety of delivery methods, including DPIs and HFA formulations of MDIs. These technical capabilities form the foundation of our strategy to develop products with high barriers to market entry targeting a wide range of indications.

- *Vertically integrated infrastructure.* We are a vertically integrated company with the demonstrated ability to advance a product candidate from the research and development stage through commercialization. Our capabilities include strong research and development expertise, sophisticated pharmaceutical engineering capabilities, comprehensive manufacturing capabilities (including the ability to synthesize and manufacture API), a strict quality assurance system, extensive regulatory and clinical experience, and established marketing and distribution relationships. We believe our vertical integration allows us to achieve better operating efficiencies, accelerated product development, and internal control over product quality.

- *Experienced management team with deep scientific expertise.* Our management team has a successful track record in product development, project management, quality assurance, acquisitions, and sales and marketing, as well as established relationships with our key customers, partners, and suppliers. Our research and development leadership has deep expertise in areas including pharmaceutical formulation, process development, *in vivo* and *in vitro* studies, analytical chemistry, physical chemistry, drug delivery, and clinical research. We believe that our scientific and technical expertise, coupled with our management team's business, legal, regulatory, and business development experience, will enable us to successfully expand our position with respect to our current products and establish a meaningful market position for our product candidates.

Our Strategy

Our goal is to be an industry leader in developing, manufacturing, and marketing technically challenging injectable and inhalation pharmaceutical products. To achieve this goal, we are pursuing the following key strategies:

- *Diversify our revenues by commercializing our product candidates.* Assuming we successfully develop and obtain regulatory approvals, we plan to commercialize our product candidates and diversify our revenue sources. We have over 20 product candidates in various stages of development, including generic ANDAs or NDAs, biosimilar product candidates, and proprietary product candidates. We also expect to expand our internal sales and marketing capabilities and, in some cases, enter into strategic alliances with other pharmaceutical companies to drive market penetration for our product candidates.

- *Focus on high-margin generic product opportunities.* We believe that we have significant opportunities for growth driven by our technical expertise in developing generic product candidates with high technical barriers to market entry. We believe that if these product candidates are commercialized, they are likely to face less competition than less technically challenging generic products, which may enable us to earn higher margins for a longer period of time. We believe that generic competition for these products will likely be limited because of challenges in product development, manufacturing, or sourcing raw materials or APIs.

- *Develop proprietary products.* We currently have four proprietary product candidates at various stages of development, targeting a broad range of indications. We believe that proprietary products tend to face less competition than generic products due to market exclusivity, intellectual property protection, and other barriers to entry. For these reasons, we believe that our proprietary products will provide us with the opportunity for higher margins and long-term revenue growth.

- *Leverage our vertically integrated infrastructure to drive operational efficiencies.* We believe our vertically integrated infrastructure provides significant benefits, including better operating efficiencies, accelerated product development, and internal control over product quality. Our ability to manufacture APIs allows us to develop products that other companies may not focus on due to the uncertainty of API supply. In addition, our vertically integrated infrastructure, including our research and development capabilities, allows us to conduct technically challenging studies in-house. We believe this vertically integrated infrastructure has led and will continue to lead to a competitive portfolio of products and product candidates.

- *Target and integrate acquisitions of pharmaceutical companies, products, and technologies.* We have a demonstrated ability to identify, acquire and integrate pharmaceutical companies, products, and technologies to complement our internal product development capabilities. Companies we have acquired include (1) International Medication Systems, Limited or IMS, (2) Armstrong Pharmaceuticals, Inc. or Armstrong, (3) Nanjing Puyan Pharmaceutical Technology Co., Ltd. (which we renamed Amphastar Nanjing Pharmaceuticals Co., Ltd.), or ANP, (4) Merck's API Manufacturing Business in Éragny-sur-Epte, France, in connection with which, we established our French subsidiary, Amphastar France Pharmaceuticals, S.A.S., or AFP, and (5) International Medication Systems (UK) Limited, or IMS UK. Products we have acquired include Cortrosyn® and Epinephrine Mist, as well as trade names such as Primatene®. We believe that our scientific and managerial expertise and our integration experience have improved the quality of the product lines and companies that we have acquired, which has had, and we believe will continue to have, a positive effect on our results of operations. For example, in 2018, we

received approval from the FDA to manufacture semi-purified heparin at our Chinese subsidiary, ANP. We plan to have ANP manufacture API for certain other products and product candidates.

Our Technical Capabilities

We develop, manufacture, market, and sell generic and proprietary products that utilize injectable, inhalation, and intranasal delivery systems. We also manufacture and sell insulin API.

- *Injectable.* Our injectable product technologies enable us to develop and manufacture generic and proprietary injectables in liquid, lyophilized, suspension, and emulsion forms, as well as the use of pre-filled syringes to facilitate the safety and convenience to users. We have multiple injectable manufacturing facilities that include aseptic filling lines dedicated to the sterile production of injectable products. Additionally, we maintain compliance with cGMP regulations, which has enabled us to obtain regulatory approvals and support commercial supply.

- *Inhalation and Intranasal.* We are focused on developing a broad range of generic and proprietary inhalation and intranasal products utilizing various delivery technologies. We have expertise in formulating HFA-based MDIs and DPIs, as well as packaging our inhalation drugs in blister packs and other forms which can be used for loading our products into a variety of inhalation devices. As with our injectable products, we maintain compliance with cGMP regulations, which we believe will enable us to obtain regulatory approvals and support commercial supply. Additionally, we have extensive formulation and clinical experience in developing complex formulations that can be administered by intranasal delivery.

We have advanced capabilities that enable us to develop technically challenging products.

- *Characterization of complex molecules.* Complex molecule characterization includes determining physicochemical properties, biological activity, immunochemical properties, and purity. Such characterization is important in developing a generic product that is considered the same as a reference drug product, which in turn allows the generic drug developer to demonstrate such "sameness" to the FDA, which ultimately allows for interchangeability with the reference drug product. Complex drugs typically have large molecules composed of a mixture of molecules that differ very slightly from one another. These slight variances make such complex molecules difficult to characterize. We have developed analytical tools that have enabled us to characterize complex molecules in our products and product candidates. We believe that we have the technology to develop a variety of additional analytical tools that will enable us to characterize other complex molecules, including peptide and protein-based products.

- *Immunogenicity.* The ability of an antigen to elicit immune responses is called immunogenicity. Unwanted immunogenicity, which is strongly linked with peptide and protein drug products, occurs when a patient mounts an undesired immune response against drug therapy. As a result, the FDA has signaled that they may require immunogenicity studies as part of the new pathway for biosimilars and biogenerics. In the past, the FDA has required these studies to approve products with complex molecules. We have gained expertise in immunogenicity by performing immunogenicity studies in connection with the FDA approval process for our enoxaparin product. We believe that our experience conducting these complex immunogenicity studies will be of primary importance in our future efforts to develop complex molecules, biosimilar, and biogeneric product candidates.

- *Peptide and protein product development and production.* The development of peptide and protein drug products utilizes our characterization technology and immunogenicity studies, synthetic capabilities, recombinant DNA, or rDNA, and API manufacturing technology. We have experience using rDNA manufacturing technology, including the genetic engineering of host cells, fermentation to promote cell culture growth, and isolation and purification of the desired protein from the cell culture. Testing is required to ensure that only the desired protein is included in the finished product through each step. We believe that this technology will allow us to develop protein and peptide drug products. In December 2020, we received the first-ever FDA approval for a generic version of Glucagon for Injection Emergency Kit. The FDA determined our approved peptide product to be bioequivalent and therapeutically equivalent to the reference listed drug, which has rDNA origin.

- *Particle engineering.* Particle engineering is important in the field of pulmonary drug delivery as there is a direct relationship between the properties of a particle and its absorption by the lungs. We believe our expertise and technology, which applies to particle engineering and physical chemistry, allow us to engineer particles' size, shape, surface smoothness and distribution to develop inhalation products that are more easily dispersed through targeted areas. We believe this expertise will allow us to formulate difficult-to-disperse inhalation products and demonstrate the sameness of the reference-listed drugs to the FDA.

- *Sustained-release.* We have developed technology to improve drug delivery through sustained-release injectable products. Our sustained-release technology aims to create products that require less dosing frequency, which we believe can lead to diminishing fluctuations of drug concentrations in a patient's bloodstream that would otherwise require more frequent dosing. We plan to use our sustained-release technology to develop both generic and proprietary products.

- *Novel formulation.* We have the capability to develop novel formulations to enhance drug delivery. For certain intranasal medications, novel formulations might be required to increase the drug's absorption rate to deliver the medication safely and efficiently. We plan to use our novel formulation with our intranasal epinephrine product.

Finished Pharmaceutical Products

Our Marketed Products

We currently manufacture and sell over 20 products in our finished pharmaceutical product segment. The following is a description of products in our existing portfolio.

Primatene MIST®

Primatene MIST®, an over-the-counter epinephrine inhalation product, is indicated for the temporary relief of mild symptoms of intermittent asthma. We developed an HFA version of Primatene MIST® to replace the over-the-counter CFC formulation of our Primatene MIST® product which was withdrawn for environmental reasons under the Montreal Protocol.

Glucagon for Injection Emergency Kit

Glucagon for injection is a difficult to manufacture injectable product. We received the first-ever FDA approval of a generic version of rDNA Glucagon in the fourth quarter of 2020. Using a dedicated process and sophisticated characterization technology, we demonstrated to the FDA that our highly purified synthetic peptide product is bioequivalent and therapeutically equivalent to the reference listed drug, or RLD, which is an rDNA product. Glucagon for injection emergency kit is indicated for the treatment of severe hypoglycemia and for use as a diagnostic aid.

Enoxaparin

Enoxaparin is a difficult to manufacture injectable form of low molecular weight heparin which is used as an anticoagulant, and has multiple indications, including the prevention and treatment of deep vein thrombosis. Enoxaparin is difficult to produce in part because the API is not easily obtained or manufactured. We manufacture the API for our enoxaparin product and perform all subsequent manufacturing of the finished product in-house.

Naloxone

We sell two versions of naloxone injections indicated for the emergency treatment of known or suspected opioid overdose.

Other Marketed Products

Other finished pharmaceutical products that we currently market include the following:

- Cortrosyn® (cosyntropin for injection), a lyophilized powder that is indicated for use as a diagnostic agent in the screening of patients with adrenocortical insufficiency;

- Amphadase®, a bovine-sourced hyaluronidase injection that is used as an adjuvant in subcutaneous fluid administration for achieving hydration, to increase absorption and dispersion of other injected drugs, and in subcutaneous urography for improving absorption of radiopaque agents;

- Epinephrine injection, indicated for emergency treatment of allergic reactions, including anaphylaxis, and to increase mean arterial blood pressure in adult patients with hypotension associated with septic shock;

- Lidocaine jelly, a local anesthetic product used primarily for urological procedures;

- Lidocaine topical solution, a local anesthetic used for a variety of procedures;

- Phytonadione injection, an injection of Vitamin K1 that is used for newborn babies;

- Our portfolio of emergency syringe products, including critical care drugs such as atropine, calcium chloride, dextrose, epinephrine, lidocaine, and sodium bicarbonate, are provided in pre-filled syringes and are designed for emergency use in hospital settings;

- Morphine injection in prefilled syringe, pain management product indicated for use with Patient Controlled Analgesia (PCA) pumps;

- Lorazepam injection, a sedative used prior to surgery and medical procedures;

- Neostigmine methylsulfate injection, a cholinesterase inhibitor used in the treatment of myasthenia gravis and to reverse the effects of muscle relaxants such as gallamine and tubocurarine;

- Isoproterenol hydrochloride injection, indicated for multiple uses, including mild or transient episodes of heart block that do not require electric shock or pacemaker therapy;

- Ganirelix Acetate Injection, indicated for the inhibition of premature luteinizing hormone surges in women undergoing controlled ovarian hyperstimulation; and

- Vasopressin is indicated to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines.

Our Product Candidates

We seek to develop product candidates with high technical barriers to competitive market entry that leverage our technical capabilities and other competitive advantages. We are focused on both generic and proprietary product candidates in the injectable, inhalable and intranasal markets. Our pipeline products are in various stages of development, with a number of these candidates still in the early stages of development. We currently have over 20 product candidates in our pipeline, including generic ANDAs, biosimilar product candidates and proprietary product candidates.

The following table summarizes our technical capabilities needed for the generic ANDAs, biosimilar product candidates and proprietary products in development.

Delivery Technology	*Characterization*	*Immunogenicity*	*Particle Engineering*	*Sustained-Release*	*Peptide and Protein Technology*
Injectable	✓	✓		✓	✓
Inhalation	✓		✓		

The development, regulatory approval for and commercialization of our product candidates are subject to numerous risks. See Item 1A, "Risk Factors" for additional information.

Generic Product Candidates

We generally employ a strategy of developing generic product candidates that possess a combination of factors that present technical barriers to competition, including difficult formulations, which require complex characterizations, difficult manufacturing requirements and/or limited availability of raw materials. We believe that such factors will make these product candidates less susceptible to competition and pricing pressure. We currently have generic ANDAs and biosimilar product candidates at various development stages that leverage our various technical capabilities, including:

- injectable technologies, which include various delivery methods and sizes of pre-filled syringes, vials in solution, suspension and lyophilized forms;
- inhalation technologies, which include MDIs and DPIs; and
- sophisticated analytical technologies, including characterization and immunogenicity studies for complex molecules, particle engineering, sustained-release technology, peptide, protein and DNA analysis and synthesis.

Proprietary Product Candidates

Our integrated technical skills and expertise provide a strong basis for the development of proprietary drug candidates. These skills include new chemical entity assessment, peptide and protein synthesis technology, complex formulation development, characterization analysis and immunogenicity studies, among others.

With respect to our proprietary pipeline strategy, we currently have proprietary drug candidates at various development stages that leverage our various technical capabilities. The following paragraph summarizes our proprietary product candidates for which NDAs have been filed with the FDA.

Intranasal naloxone

Intranasal naloxone, a prescription naloxone nasal spray product candidate, is intended to be used for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.

We filed an NDA for Naloxone Hydrochloride Nasal Spray in April 2016. In February 2017, we received a Complete Response Letter, or CRL, from the FDA, which identified four primary issues that need to be addressed prior to approval of our NDA. The four issues are comprised of (1) improving on our human factor validation study, (2) modifying the delivery accuracy verification method, (3) improving our standards of device reliability, and (4) adjusting the volume per actuation to account for pediatric use down to birth. We have worked with the FDA to resolve these issues, most recently in 2020 with a Face-to-Face Meeting in which a clear pathway for addressing these issues was created. In September 2022, we responded to the CRL. We intend to continue to work with the FDA to address their concerns described in the CRL. However, there can be no guarantee that our response to the CRL will result in timely approval of intranasal naloxone or approval at all.

Intranasal epinephrine

Intranasal epinephrine, a prescription epinephrine nasal spray product candidate, is intended to be used for emergency treatment of allergic reactions, including anaphylaxis to stinging insects, allergen immunotherapy, foods, drugs and other

allergens.

Other Proprietary Product Candidates

In addition to intranasal naloxone and intranasal epinephrine, we have two other proprietary product candidates in development. These product candidates incorporate multiple indications utilizing a wide variety of our technical capabilities.

APIs

We began to manufacture and sell two API products, Recombinant Human Insulin, or RHI API, and porcine insulin API, as a result of our acquisition of Merck Sharpe & Dohme's, or Merck's, API manufacturing business in Éragny-sur-Epte, France, or the Merck API Transaction, in April 2014. The purpose of the acquisition was to enhance our vertical integration strategy as we target certain finished products for the injectable insulin market. However, we continue to sell RHI API and porcine insulin API to third parties, which helps fund our vertical integration strategy.

Supply Agreement with MannKind Corporation

On July 31, 2014, we entered into a supply agreement with MannKind Corporation, or MannKind, or the Supply Agreement, pursuant to which we agreed to manufacture for and supply to MannKind certain quantities of RHI API for use in MannKind's product Afrezza®. Under the Supply Agreement, MannKind agreed to purchase annual minimum quantities of RHI API in an aggregate amount of approximately $146.0 million, over five years from calendar years 2015 through 2019.

The MannKind agreement was amended several times between 2014 and 2021. In August 2019, we amended the Supply Agreement with MannKind whereby MannKind's aggregate total commitment of RHI API under the Supply Agreement was modified and extended for an additional two years through 2026, which timeframe would have previously lapsed after calendar year 2024. As a result of this amendment, MannKind paid us an amendment fee of $2.75 million, which we recognized in net revenues in our consolidated statement of operations for the year ended December 31, 2019.

In May 2021, we amended the Supply Agreement with MannKind whereby MannKind's aggregate total commitment of RHI API under the Supply Agreement was modified and extended for an additional year through 2027, which timeframe would have previously lapsed after calendar year 2026. MannKind agreed to pay us an amendment fee of $2.0 million. We received the first payment of the amendment fee of $1.0 million in June 2021, which we recognized in net revenues during the year ended December 31, 2021. The remaining $1.0 million of the amendment fee was received in January 2022, which we recognized in net revenues during the year ended December 31, 2022, and relates to the amendments to the 2022 supply level and will be recognized ratably to net revenues in 2022.

For the years ended December 31, 2022, 2021 and 2020, sales of RHI API to MannKind totaled $5.0 million, $6.2 million and $4.9 million, which fulfilled the 2022, 2021 and 2020 commitment of RHI API under the amended Supply Agreement, respectively.

Research and Development

As of December 31, 2022, we had 249 employees dedicated to research and development with expertise in areas such as pharmaceutical formulation, process development, toxicity studies, analytical, synthetic, and physical chemistry, drug delivery, device development, equipment and engineering, clinical research statistical analysis, etc. Our focus on developing products with high barriers to market entry requires a significant investment in research and development, including clinical development. In particular, developing proprietary products that are reformulations of existing proprietary compounds often requires clinical trials to gain regulatory approval, and we have a team dedicated to designing and managing clinical trials. We have successfully completed several clinical trials for some of our product candidates and are in the process of planning clinical trials for other product candidates under development.

Backlog

A significant portion of our customer shipments in any fiscal year relates to orders received and shipped in that fiscal year, generally resulting in a low product backlog relative to total shipments at any time. However, as of December 31,

2022, we experienced a backlog of approximately $7.0 million for various products, partially as a result of competitor shortages, supplier constraints and labor shortages at our facility in California. We are currently working on resolving backlog related issues and believe that we will be able to reduce the backlog in the near future. Historically, our backlog has not been a meaningful indicator of our ability to achieve any particular level of overall revenue or financial performance.

Manufacturing and Facilities

Our manufacturing facilities are located in Rancho Cucamonga and South El Monte, California; Canton, Massachusetts; Éragny-sur-Epte, France; and Nanjing, China. We own or lease a total of 56 buildings at six locations in the United States, France and China, that comprise 1.8 million square feet of manufacturing, research and development, distribution, packaging, laboratory, office and warehouse space. Our facilities are regularly inspected by the FDA in connection with our product approvals, and we believe that all of our facilities are being operated in material compliance with the FDA's cGMP regulations.

We continue to expand our facility in Nanjing, China, and expect further significant investment in this facility.

Our API manufacturing business in Éragny-sur-Epte, France, which we acquired in April 2014, manufactures porcine insulin API and RHI API, and we expect to continue the current site activities. We have completed a project to modify our current facility in France to increase our internal manufacturing capabilities so that we can take over the manufacture of inclusion bodies, which are our RHI API's starting material. The project was completed in 2020 with a cost of $40.1 million.

We believe that our current manufacturing capacity is adequate for the near term. In 2019 we completed a project to increase production and modernize the facilities at our South El Monte, California plant. The project cost was $14.9 million. In February 2020, the FDA approved our supplemental ANDA to transfer production of Sodium Bicarbonate into this facility and we have begun manufacturing operations there.

Raw Material and Other Suppliers

We depend on suppliers for raw materials, APIs and other components that are subject to stringent FDA requirements. In some cases, we obtain raw materials, components or APIs used in certain of our products from single sources. Currently, we obtain API for certain of our other marketed products from single sources. If we experience difficulties acquiring sufficient quantities of required materials or products from our existing suppliers, or if our suppliers are found to be non-compliant with the FDA's quality system regulation, or QSR, cGMPs or other applicable laws or regulations, we would be required to find alternative suppliers. Obtaining the required regulatory approvals to use alternative suppliers may be a lengthy and uncertain process during which we could lose sales. If our primary suppliers become unable or unwilling to perform, we could experience protracted delays or interruptions in the supply of materials that would ultimately delay our manufacture of products for commercial sale, which could materially and adversely affect our development programs, commercial activities, operating results and financial condition.

If our suppliers encounter problems during manufacturing, establishing additional or replacement suppliers for these materials may take a substantial period of time, as suppliers must be approved by the FDA. Further, a significant portion of our raw materials may be available only from foreign sources, which are subject to the risks of doing business abroad. For example, heparin USP is the starting material for the production of the API in our enoxaparin product. We have established a supply chain for heparin that originates in China and have implemented validated technology processes designed to screen and test incoming starting material, which include methods currently required by the FDA. However, the FDA has required companies importing heparin to test imported heparin using specific screening methods to detect certain contaminants and it has increased its scrutiny of Chinese facilities that produce heparin for the U.S. market. For example, in August 2008, the FDA inspected two facilities in China belonging to suppliers in our heparin supply chain and issued warning letters, one of which needed to be resolved as a precondition to approving the ANDA for our enoxaparin product candidate in September 2011. In 2018, we received approval from the FDA for the manufacture of semi-purified heparin at ANP.

The U.S. Department of Agriculture, or USDA, the Animal and Plant Health Inspection Service, or APHIS, and the Veterinary Services regulates the importation of animals and animal-derived materials into the U.S. A USDA veterinary permit is required for importation of materials derived from animals or exposed to animal-source materials. Some of our

raw materials sourced from foreign sources are subject to import regulations and permit requirements, including from the USDA. Recently, USDA enhanced its African swine fever, or ASF, surveillance efforts, including placing restrictions on the importation of pork products from affected countries, such as China, where the first cases of ASF were reported in August 2018. While ASF does not affect human health, it is a highly contagious and deadly disease to pig populations. We anticipate that our current supply of heparin USP in the United States is useable and sufficient for our manufacturing needs for the foreseeable future, and we are evaluating the use of heparin USP produced at our ANP facility. If we are unable to import raw materials, rely upon existing supplies of raw materials or manufacture raw materials in sufficient amounts for our manufacturing needs, we may be required to find alternative suppliers or sources of such materials, which would require prior FDA approval for such alternative suppliers or sources of such materials, which would disrupt or delay the manufacturing of our products.

Similarly, on December 27, 2020, the American Innovation in Manufacturing Act of 2020, or AIM Act, was enacted. The AIM Act directs the United States Environmental Protection Agency to address usage of hydrofluorocarbons, or HFC, by reducing production and consumption of certain HFCs. One of our products, Primatene MIST®, utilizes HFCs subject to the AIM Act's reduction mandate. Moreover, many of our inhalation pipeline assets use HFCs subject to the AIM Act's reduction mandate. There can be no assurance that we will be able to acquire adequate supplies of HFCs for current and future commercialization of our products as a result of the AIM Act or other similar statutes and regulations. Moreover, changes to the ingredients of our proprietary and generic products requires FDA approval and there can be no assurance that we will be able to obtain such approval or the timing of such approval.

ANP currently manufactures heparin sodium for our enoxaparin product, isoproterenol and hyaluronidase for Amphastar's current products, and we plan to have ANP manufacture APIs and starting materials for APIs for certain other products and product candidates.

Sales and Marketing

Our products are primarily marketed and sold to institutions such as hospitals, long-term care facilities, alternate care sites, clinics, and doctors' offices. Additionally, we also sell to retail pharmacies. Most institutional customers are members of one or more group purchasing organizations, which negotiate collective purchasing agreements on behalf of their members. These facilities purchase products through specialty distributors and wholesalers. We have relationships with the major group purchasing organizations in the United States. We also have relationships with major specialty distributors, wholesalers and retailers who distribute pharmaceutical products nationwide.

The following table provides information regarding the percentage of our net revenues that is derived from each of our major customers and partners:

	% of Net Revenues Year Ended December 31,		
	2022	2021	2020
AmerisourceBergen Corporation	23 %	24 %	23 %
McKesson Corporation	22 %	21 %	22 %
Cardinal Health, Inc.	17 %	16 %	17 %

Our marketing department is responsible for establishing and maintaining contracts and relationships with the group purchasing organizations, distributors, retailers, wholesalers and, occasionally, directly with hospitals or long-term care facilities. One or more of our proprietary product candidates may require deployment of a sales force either directly or through a strategic partner.

Competition

The majority of our marketed products are generic products. We face and will face significant competition for our products and product candidates from pharmaceutical companies that focus on the generic injectable and inhalation markets such as Pfizer, Inc., Eli Lilly and Co., Sagent Pharmaceuticals, Inc., Akorn, Inc., Sandoz Inc., Viatris Inc., Fresenius Kabi USA, Nexus Pharmaceuticals, Apotex Corp, Amneal Biosciences, American Regent Inc., Hikma Pharmaceuticals USA, Inc., Par Pharmaceuticals, Cipla USA Inc., Meitheal Pharmaceuticals, Dr. Reddy's Laboratories, Inc., Sun Pharmaceuticals, Inc., Accord Healthcare Ltd., Amring Pharmaceuticals, Bausch Health, Zydus

Pharmaceuticals USA Inc., AuroMedics Pharma LLC, and Teva Pharmaceutical Industries Ltd. Competition in the generic pharmaceutical industry has increased as producers of branded products have entered the business by creating generic drug subsidiaries, purchasing generic drug companies, or licensing their products to generic manufacturers prior to patent expiration and/or as their patents expire. Therefore, our competitors also include the innovator companies of our generic drug products. For example, enoxaparin is currently marketed by Sanofi S.A., or Sanofi, under the brand name Lovenox®. Sanofi also markets its authorized generic enoxaparin product through its subsidiary, Winthrop. Fresenius Kabi USA, Apotex Corp., Zydus Pharmaceuticals USA Inc., Sandoz, and Meithael Pharmaceuticals, Inc. also market a generic version of enoxaparin. Other companies may have filed an ANDA with the FDA for its generic version of enoxaparin. The presence of these current and prospective competitive products may have an adverse effect on our market share, revenue and gross profit from our enoxaparin product.

Similarly, we will face significant competition for our proprietary product candidates. Our competitors vary depending upon product categories, and within each product category, upon dosage strengths and drug-delivery systems. Based on total assets, annual revenues and market capitalization, we are smaller than many of our national and international competitors with respect to both our generic and proprietary products and product candidates. Many of our competitors have been in business for a longer period of time, have a greater number of products on the market and have greater financial and other resources than we do. It is also possible that developments by our competitors will make our generic or proprietary products and product candidates noncompetitive or obsolete.

For pharmaceutical companies, the most important competitive factors are scope of product line, ability to timely develop new products and relationships with group purchasing organizations, retailers, wholesalers and customers. Sales of generic pharmaceutical products tend to follow a pattern based on regulatory and competitive factors. As patents for brand-name products and related exclusivity periods expire, the first generic pharmaceutical manufacturer to receive regulatory approval for generic versions of products is typically able to achieve significant market penetration and higher margins. As competing generic manufacturers receive regulatory approval on the same products, market size, revenue and gross profit typically decline. The level of market share and price will be affected, which will in turn affect the revenue and gross profit attributable to a particular generic pharmaceutical product. This impact is normally related to the number of competitors in that product's market and the timing of that product's regulatory approval. We must develop and introduce new products in a timely and cost-effective manner and identify products with significant barriers to market entry in order to grow our business.

Government Regulation

In the United States

General

Our operations and many of the products manufactured or sold by the company are subject to extensive regulation by a number of government agencies, both within and outside the United States. In the United States, the federal agencies that regulate the company's facilities, operations, employees, products (including their manufacture, sale, import and export) and services include: the U.S. Food and Drug Administration, the Drug Enforcement Agency, the Environmental Protection Agency, the Occupational Health & Safety Administration, the Department of Agriculture, the Department of Labor, the Department of Defense, Customs and Border Protection, the Department of Commerce, the Department of Treasury and others. International government agencies also regulate public health, product registration, manufacturing, environmental conditions, exports, imports, and other aspects of the company's global operations and products.

Pharmaceutical companies and their prescription brand and generic pharmaceutical products are subject to extensive pre- and post-market regulation by the FDA under the Federal Food, Drug, and Cosmetic Act, or FFDCA, the Public Health Service Act of 1944, or PHSA, and regulations implementing those statutes, with regard to the testing, manufacturing, safety, efficacy, labeling, storage, record-keeping, advertising and promotion of such products, and by comparable agencies and laws in foreign countries. For many drugs (drugs falling within the definition of "new drug" in the FFDCA), FDA approval is required before the product can be marketed in the United States. All applications for FDA approval must contain, among other things, comprehensive and scientifically reliable information relating to pharmaceutical formulation, stability, manufacturing, processing, packaging, labeling and quality control. These applications must also contain data and information related to safety, effectiveness, bioavailability and/or bioequivalence.

Many of our activities are subject to the jurisdiction of other federal regulatory and enforcement departments and agencies, such as the Department of Health and Human Services, or HHS, Office of the Inspector General, or OIG, the Federal Trade Commission (which also has the authority to regulate the advertising of consumer healthcare products, including over-the-counter drugs), the Department of Justice, the Drug Enforcement Administration, or DEA, the Veterans Administration, the Centers for Medicare and Medicaid Services and the Securities and Exchange Commission, or SEC. Individual states, acting through their attorneys general, have become active as well, seeking to regulate the marketing of prescription drugs under state consumer protection and false advertising laws.

FDA Approval and Regulatory Considerations

Prescription generic and branded pharmaceutical products are subject to extensive regulation by the FDA under the FFDCA and PHSA and regulations implementing those statutes, with regard to the testing, manufacturing, safety, efficacy, labeling, storage, record-keeping, advertising and promotion of such products, and regulation by other state, federal and foreign agencies under the laws that they enforce. For many drugs (drugs falling within the definition of "new drug" in the FFDCA), including the drugs in our current drug portfolio, FDA approval is required before marketing in the U.S. Applications for FDA drug approval must generally contain, among other things, information relating to pharmaceutical formulation, stability, manufacturing, processing, packaging, labeling, quality control and either safety and effectiveness or bioequivalence. There are two drug approval processes under the FFDCA — an ANDA approval process for generic drugs and an NDA approval process for new drugs that cannot be approved in ANDAs. For drugs that are "biological products" within the meaning of the PHSA, there are two different approval processes — a biological license application, or BLA, approval process for original biological products and a biosimilar application approval process for biosimilar products that are approved based on their similarity to biologicals that were previously approved in BLAs.

The ANDA Approval Process

Our pipeline generic drug product candidates cannot be lawfully marketed unless we obtain FDA approval. The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as "the Hatch-Waxman Act," established abbreviated FDA approval procedures for drugs that are shown to be bioequivalent to drugs previously approved by the FDA through its NDA process, which are commonly referred to as the "innovator" or "reference" drugs. Approval to market and to distribute these bioequivalent drugs is obtained by filing an ANDA with the FDA. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the API, drug product formulation, specifications, stability, analytical methods, manufacturing process validation data, quality control procedures and bioequivalence. Rather than demonstrating safety and effectiveness, an ANDA applicant must demonstrate that its product is bioequivalent to an approved reference drug. In certain situations, an applicant may submit an ANDA for a product with a strength or dosage form that differs from a reference drug based upon FDA approval of an ANDA Suitability Petition. The FDA will approve an ANDA Suitability Petition if it finds that the product does not raise questions of safety and efficacy requiring new clinical data. ANDAs generally cannot be submitted for products that are not bioequivalent to the referenced drug or that are labeled for a use that is not approved for the reference drug. Applicants seeking to market such products can submit an NDA under Section 505(b)(2) of the FFDCA with supportive data from clinical trials.

The Generic Drug User Fee Act, or GDUFA, was enacted by Congress in 2012 and was reauthorized as GDUFA II in 2017 and GDUFA III in 2022. GDUFA is designed to provide funding to the FDA to expedite timelines for the FDA's review of ANDA applications. GDUFA funding is intended to increase the ability of the FDA to perform critical program functions and to reduce costs. Under the GDUFA, the FDA has specific goals for reviewing ANDA applications. For example, as part of GDUFA II, the goal of the FDA is to complete the review of 90% of original ANDA applications within 10 months from filing of the ANDA. Under previous GDUFA authorizations, the average time for sponsors to obtain FDA approval of ANDAs was 32-34 months post-filing. As newer GDUFA reauthorizations occur in 5 year increments, it is expected that these ANDA timelines will also change.

Upon approval of an NDA or ANDA, the FDA lists the product in a publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," which is commonly known as the "Orange Book." In the case of an NDA, the FDA also lists patents identified by the NDA applicant as claiming the drug or an approved method of using the drug. Any applicant who files an ANDA must certify to the FDA with regard to each relevant patent that (1) no patent information has been submitted to the FDA; (2) the patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the patent is invalid or will not be

infringed upon by the manufacture, use or sale of the drug product for which the ANDA is submitted. This last certification is known as a Paragraph IV certification. 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 refers. If the NDA holder submits the patent information to the FDA prior to submission of the ANDA and the NDA holder or patent owner(s) sues the ANDA applicant for infringement within 45 days of its receipt of the certification notice, the FDA is prevented from approving that ANDA until the earlier of 30 months from the receipt of the notice of the Paragraph IV certification, the expiration of the patent or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. An ANDA applicant that is sued for infringement may file a counterclaim to challenge the listing of the patent or information submitted to the FDA about the patent.

Generally, the ANDA applicant that (1) files a substantially complete ANDA using a Paragraph IV certification on the first day prior to any other ANDA applicant filing an application with such a certification, based on the same reference drug and (2) provides appropriate notice to the NDA holder, and all patent owner(s) for a particular generic product, the applicant may be awarded a delay in the approval of other subsequently filed ANDAs with Paragraph IV certifications based on the same reference drug. This statutory delay is commonly referred to as 180-day exclusivity. A substantially complete ANDA is one that contains all the information required by the statute and the FDA's regulations, including the results of any required bioequivalence studies. The FDA may refuse to accept the filing of an ANDA that is not substantially complete or may determine during substantive review of the ANDA that additional information, such as an additional bioequivalence study, is required to support approval. Such a determination may affect an applicant's first to file status and eligibility for 180-day exclusivity. The Medicare Prescription Drug Improvement and Modernization Act of 2003, or the MMA, provides that the 180-day exclusivity delay ends 180 days after the first commercial marketing of the ANDA product. This exclusivity may be forfeited under a number of different circumstances, including: (1) failure to market within certain prescribed periods of time following certain events related to submission of the application, approval of the application, court decisions and settlements and patent withdrawals from the Orange Book; (2) an amendment or withdrawal of the Paragraph IV certification or certifications upon which the exclusivity was based; (3) failure to obtain tentative approval within certain prescribed time periods (30, 36, or 40 months after submission of the ANDA); (4) an agreement with the NDA holder, patent owner or another ANDA applicant that is determined by a court or the FTC to violate provisions of antitrust laws; (5) withdrawal of the ANDA; or (6) expiration of patent or patents upon which exclusivity is based. The 180-day exclusivity provisions described above were passed in the MMA, and do not apply where the first ANDA with a Paragraph IV certification submitted for the reference drug was filed before December 8, 2003.

ANDA approvals can be delayed by exclusivities awarded to the holder of the NDA for the reference drug. The FFDCA provides five-year exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, or NCE, meaning that the FDA has not previously approved any other drug containing the same active moiety. This exclusivity generally prohibits the submission of an ANDA for any drug product containing the same active moiety during the five-year exclusivity period. However, submission of an ANDA with a Paragraph IV certification is permitted after four years, and if a patent infringement lawsuit is brought within 45 days after such certification, FDA approval of the ANDA is delayed until 7.5 years after the NCE approval date. The FFDCA also provides three-year exclusivity for the approval of new and supplemental NDAs for product changes that require new clinical investigations (other than bioavailability studies) that were conducted or sponsored by the applicant. These changes include, among other things, new indications, dosage forms, routes of administration or strengths of an existing drug and new uses.

ANDA approvals can also be delayed by orphan drug exclusivity, pediatric exclusivity and exclusivity for certain new antibiotic drugs. The FDA may grant orphan drug designation to a drug 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 more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug for this type of disease or condition will be recovered from sales in the U.S. for that drug. Seven-year orphan drug exclusivity is available to a product that has orphan drug designation and that receives the first FDA approval for the indication for which the drug has such designation. Orphan drug exclusivity prevents approval of another application for the same drug, for the same orphan indication, for a period of seven years, regardless of whether the application is a full NDA or an ANDA, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Pediatric exclusivity, if granted, provides an additional six months to an existing exclusivity or statutory delay in approval resulting from a patent certification. This six-month exclusivity, which runs from the end of other exclusivity protection or patent delay, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued written request for such a study. The FFDCA also provides exclusivity

for certain antibiotic drugs for serious or life-threatening infections that FDA designates as "qualified infectious disease products." This exclusivity extends other exclusivities for the same drug by five years, but does not extend patent-related delays in approval.

In 2017, the FDA Reauthorization Act of 2017, or FDARA, was passed, which created a new pathway to allow the FDA to expedite the development and review of an ANDA for a drug that is designated as a Competitive Generic Therapy, or CGT. To qualify for the designation, the FDA must confirm that the ANDA is for a generic drug in which there is inadequate generic competition. Inadequate generic competition is defined to mean, that there is not more than one approved drug in the active section of the Orange Book.

Once assigned CGT designation by the FDA, the FDA may take various actions to help expedite the development and review process. This includes priority granting and expediting review during Product Development and Pre-Submission Meetings, Mid-Review Cycle Meetings and provide for a more coordinated review of ANDA's with CGT.

As part of the FDARA, a new type of 180-day marketing exclusivity period for ANDA applicants with CGT designation has been created. Broadly, this exclusivity applies when the ANDA applicant is considered as the first approved applicant, and there is no other exclusivity period eligibility.

Many of our ANDAs on file and many of the products that we are developing qualify for CGT. Having a generic product designated as CGT provides for certain actions which the FDA may take in order to expedite the development and review of an ANDA.

The NDA Approval Process

The NDA approval process is generally far more demanding than the ANDA process, depending on whether the applicant is submitting a "full NDA" containing all of the data and information required for approval of a new drug or a "Section 505(b)(2) NDA" which is a more limited submission that is generally utilized for modifications to previously approved products.

The Prescription Drug User Fee Act, or PDUFA, was enacted by Congress in 1992. It authorizes the FDA to collect fees from companies that produce certain new human drug and biological products. The fees collected are designed to play an important role in expediting the new drug approval process. Like GDUFA, PDUFA must be reauthorized every 5 years. It is currently authorized as PDUFA VII through September of 2027. As part of the PDUFA, the FDA has specific goals for reviewing NDA/BLA applications. For example, as part of PDUFA VII, the goal of the FDA is to complete the review of 90% of original NDAs that are not new molecular entities within 10 months of the date of filing the NDA.

The Full NDA

The approval process for a full NDA generally involves:

- completion of preclinical laboratory and animal testing to demonstrate safety, in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an investigational new drug application, or IND, for human clinical testing that must satisfy the FDA and become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials to establish the efficacy of the proposed drug product for each intended use;
- satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is produced to assess compliance with the FDA's cGMP regulations; and
- submission to and approval by the FDA of an NDA.

Before human clinical trials can begin on a new drug, the results of preclinical tests, together with manufacturing information and analytical data, must be submitted to the FDA as part of an IND and the FDA must permit the IND to become effective. Each clinical trial under an IND must be reviewed and approved by an independent Institutional

Review Board, or IRB. Human clinical trials are typically conducted in three sequential phases that may overlap. These phases generally include:

- Phase 1, during which the drug is introduced into healthy human subjects, or on occasion, patients and is tested for safety, stability, dose tolerance and metabolism;
- Phase 2, during which the drug is introduced into a limited patient population to determine the efficacy of the product in specific targeted indications, to determine dosage tolerance and optimal dosage and to identify possible adverse effects and safety risks; and
- Phase 3, during which the clinical trial is expanded to a larger and more diverse patient group at geographically dispersed clinical trial sites to further evaluate the drug and ultimately to demonstrate effectiveness.

The IND sponsor, the FDA or the IRB may suspend a clinical trial at any time for various reasons, including failure to follow appropriate ethical trial protocols, failure to provide adequate protections for trial participants or a belief that the subjects are being exposed to an unacceptable health risk.

The results of preclinical animal studies and human clinical studies, together with other detailed information (e.g., relating to pharmaceutical formulation, stability, manufacturing, processing, packaging, labeling, quality control) are submitted to the FDA in the NDA.

The Section 505(b)(2) NDA

For modifications to products previously approved by the FDA, an applicant may file an NDA under Section 505(b)(2) of the FFDCA. This section permits the filing of an NDA where some or all of the data 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. Under this section, an applicant may rely on the approval of another NDA or on studies published in the scientific literature. The applicant may be required to conduct additional studies or provide additional information to fully demonstrate the safety and effectiveness of its modification to the approved product.

Where a Section 505(b)(2) applicant relies on the FDA's approval of another NDA, the applicant is required to submit the same types of patent certifications as are required for an ANDA. As in the case of an ANDA, a Paragraph IV certification challenging one or more of the patents listed for the reference drug will require notice to the patent owner(s) and NDA holder and will permit a patent infringement suit that may result in a 30-month stay in the approval of the Section 505(b)(2) NDA. The approval of a Section 505(b)(2) NDA may also be delayed by the NCE, three-year, orphan drug, pediatric and new antibiotic exclusivities that are applicable to ANDAs as discussed above.

The Biosimilar Application Approval Process

The BPCIA, passed by Congress in 2010, amended the PHSA to create an abbreviated approval pathway for follow-on biologics. This approval pathway is available for "biosimilar" products, which are products that are highly similar to biologics that have been approved in BLAs under the PHSA notwithstanding minor differences in clinically inactive components. A biosimilar application must contain information demonstrating (1) biosimilarity to the reference product, (2) sameness of strength, dosage form, route of administration and mechanism(s) of action with the reference product (where known), (3) approval of the reference product for the indication(s) proposed for the biosimilar product and (4) appropriate manufacturing facilities. FDA will approve the application based on a finding of biosimilarity or interchangeability with the reference product. A finding of biosimilarity must be based on (1) a demonstration that the products are "highly similar" notwithstanding minor differences in clinically inactive components, (2) animal studies, including an assessment of toxicity, and (3) a clinical study or studies (including an assessment of immunogenicity and pharmacokinetics or pharmacodynamics) sufficient to show the safety, purity and potency of the proposed product for one or more "appropriate" conditions of use for which licensure is sought and for which the reference product is licensed, unless FDA waives a specific requirement. The definition of "biosimilar" requires that there be no clinically meaningful differences between the biosimilar and reference product with regard to safety, purity and potency.

An applicant with a pending or approved biosimilar application may seek an FDA determination that its product is interchangeable with the reference drug. In addition to demonstrating biosimilarity to the reference product, the

biosimilar applicant must demonstrate that its product can be expected to yield the same clinical result as the reference product in any given patient. If the biosimilar product may be administered more than once to a patient, the applicant must demonstrate that the risk in terms of safety or diminished efficacy of alternating or switching between the biosimilar and reference products is not greater than the risk of continued administration of the reference product. The PHSA provides that a determination of interchangeability means that the biosimilar product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product. The first biosimilar determined to be interchangeable with a particular reference product for any condition of use is protected by an exclusivity that delays an FDA determination of interchangeability with regard to any other biosimilar application. The exclusivity delays the subsequent interchangeability determination until the earlier of: (1) one year after the first commercial marketing of the first interchangeable product; (2) 18 months after resolution of a patent infringement suit based on a final court decision regarding all of the patents in the litigation or dismissal of the litigation with or without prejudice; (3) 42 months after approval of the first interchangeable biosimilar biological product, if an expedited patent action was commenced against the applicant under section 351(l)(6) and the litigation is still pending; or (4) 18 months after approval of the first interchangeable product if the reference product sponsor did not sue the biosimilar applicant for infringement under the patent resolution provisions of the PHSA.

The PHSA provides a number of exclusivity protections for reference products that may delay submission and approval of biosimilar applications. The PHSA delays submission of a biosimilar application until four years after the date on which the reference product was first licensed and delays final approval of a biosimilar application until 12 years after the first licensure of the reference product. The first-licensure requirement precludes an additional period of exclusivity for a supplement to the original application for the reference product. It also precludes exclusivity for an entirely new BLA in certain circumstances. A new BLA submitted by a sponsor or manufacturer of a previously approved biologic would not be protected by exclusivity for (1) a non-structural change that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength or (2) a structural change that does not result in a change in safety, purity or potency. As in the case of NDAs approved under the FFDCA, BLAs may be entitled to orphan exclusivity and to pediatric exclusivity.

The BPCIA amended the definition of biological product to include proteins (other than synthetic polypeptides). Applications for biological products, including proteins, must now be approved under the PHSA rather than under the FFDCA. The BPCIA provides a grandfather exception for biologics falling within a product class for which FDA has approved an application under the FFDCA. Applications for approval of these types of proteins may be submitted under the FFDCA until March 23, 2020, unless there is a biological product licensed under the PHSA that could serve as a reference product for a biosimilar application.

Under the PHSA, patents are not listed in the Orange Book and companies submitting biosimilar applications are not required to submit patent certifications. Patent disputes are resolved outside of the FDA regulatory process. The biosimilar applicant must share the contents of its biosimilar application and information on its manufacturing processes with counsel for the company holding the BLA for the reference drug. The biosimilar applicant and BLA holder must exchange information about relevant patents and seek agreement on patents to be litigated under an expedited litigation procedure.

The BLA Approval Process

The BLA approval process is similar to the Full NDA approval process and generally involves:

- completion of preclinical laboratory and animal testing in compliance with the FDA's GLP regulations;
- submission to the FDA of an IND for human clinical testing, which must satisfy FDA and become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials to establish the efficacy of the proposed drug product for each intended use;
- satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is produced to assess compliance with the FDA's cGMP regulations; and
- submission to and approval by the FDA of a BLA.

Combination Products

- A combination product is a product comprising of two or more regulated components (e.g., a drug and device) that are combined into a single product, co-packaged, or sold separately but intended for co-administration, as evidenced by the labeling for the products. A drug that is administered using an inhaler is an example of a combination drug/device product.

- The FDA is divided into various Centers, which each have authority over a specific type of product. NDAs are reviewed by personnel within the Center for Drug Evaluation and Research, or CDER, while device applications and premarket notifications are reviewed by the Center for Devices and Radiological Health, or CDRH. For biologic products, the BLAs are generally reviewed by personnel within the Center for the Biologic Evaluation and Research, or CBER. When reviewing a drug (biologic)/device combination product, the FDA must assign a lead Center to review the product, based on the combination product's primary mode of action, or PMOA, which is the single mode of a combination product that provides the most important therapeutic action of the combination product. The Center that regulates that portion of the product that generates the PMOA becomes the lead evaluator. If there are two independent modes of action, neither of which is subordinate to the other, the FDA makes a determination as to which Center to assign the product based on consistency with other combination products raising similar types of safety and effectiveness questions or to the Center with the most expertise in evaluating the most significant safety and effectiveness questions raised by the combination product.

- When evaluating an application, a lead Center may consult other Centers and apply the standards that would be applicable but still retain complete reviewing authority, or it may collaborate with another Center, by which the Center assigns review of a specific section of the application to another Center, delegating its review authority for that section. Typically, the FDA requires a single marketing application submitted to the Center selected to be the lead evaluator, although the agency has the discretion to require separate applications to more than one Center. One reason to submit multiple applications is if the applicant wishes to receive some benefit that accrues only from approval under a particular type of application, like new drug product exclusivity. If multiple applications are submitted, each may be evaluated by a different lead Center.

- Our inhalers and prefilled syringes, which deliver a specific drug or biologic, are regulated by the FDA as combination products. We believe the combination products will be regulated by the FDA as a drug or biologic (and not a device) because the primary mode of action of the combination will be a drug (or biological) action. As such, we will need to submit a marketing application to the CDER (or CBER) for our inhalers or prefilled syringes that deliver a specific drug. CDRH will provide input to CDER (or CBER) on the device aspects of the combination. We can provide no assurance that any of our combination products will be approved by FDA in a timely fashion, if at all.

- Like their constituent products—e.g., drugs/biologics and devices—combination products are highly regulated and subject to a broad range of post marketing requirements including cGMPs, adverse event reporting, periodic reports, labeling and advertising and promotion requirements and restrictions, market withdrawal and recall.

FDA Action on an Application for Approval

If applicable statutory or regulatory requirements are not satisfied, the FDA may deny approval of an NDA, ANDA, BLA, or biosimilar application, or the FDA may require additional data or information. After approval of the application (or license), the FDA may suspend or withdraw the approval based on various criteria, including new information related to safety or effectiveness or failure to comply with post-approval requirements. In addition, the FDA may in some instances require post-marketing studies on approved products and may take actions to limit marketing of the product based on the results of those studies.

The new drug and biological product approval processes may take years, and the time may vary substantially based upon the type of application and the type, complexity and novelty of the product or disease. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures upon a manufacturer’s activities. Success in early stage clinical trials does not assure success in later stage clinical trials. Data

obtained from clinical activities are not always conclusive and may be subject to varying interpretations that could delay, limit or prevent regulatory approval. Even if a product receives regulatory approval, later discovery of previously unknown problems with a product may result in restrictions on the product or complete withdrawal of the product from the market.

Manufacturing (cGMP) Requirements

We and our suppliers are required to comply with applicable FDA manufacturing requirements contained in the FDA's cGMP regulations. These cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. The manufacturing facilities for our products must meet cGMP requirements to the satisfaction of the FDA before the FDA will approve our products and we must continue to meet these requirements after our products are approved. We and our suppliers are subject to periodic inspections of facilities by the FDA and other authorities to assess our compliance with applicable regulations.

Other Regulatory Requirements

Maintaining substantial compliance with appropriate federal, state and local statutes and regulations requires the expenditure of substantial time and financial resources. Drug and biologic manufacturers are required to register their establishments with the FDA and certain state agencies. After approval, the FDA and these state agencies conduct periodic unannounced inspections to ensure continued compliance with ongoing regulatory requirements.

In addition, after approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. The FDA may require post-approval testing and surveillance programs to monitor safety and effectiveness of approved products that have been commercialized. Any drug or biologic products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including:

- record-keeping requirements;
- reporting of adverse experiences with the drug;
- providing the FDA with updated safety and efficacy information;
- reporting on advertisements and promotional labeling;
- drug sampling and distribution requirements; and
- complying with electronic record and signature requirements.

In addition, the FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. There are numerous regulations and policies that govern various means for disseminating information to health-care professionals, as well as consumers, including industry sponsored scientific and educational activities, information provided to the media and information provided over the Internet. Drugs or biologics may be promoted only for the approved indications and in accordance with the provisions of the approved label.

FDA Enforcement Authority

The FDA has very broad enforcement authority and the failure to comply with applicable regulatory requirements can result in administrative or judicial sanctions being imposed on us or on the manufacturers and distributors of our approved products, including warning letters, refusals of government contracts, clinical holds, civil penalties, injunctions (which may in some circumstances involve restitution, disgorgement or profits, recalls and/or total or partial suspension of production or distribution), seizure of products, withdrawal of approvals, refusal to approve pending applications and criminal prosecution of the company and company officials that may result in fines and incarceration. The FDA has authority to inspect manufacturing facilities as well as other facilities in which drug products are held, packaged or stored, to determine compliance with cGMP and other requirements under the FDCA. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to

have improperly promoted off-label uses may be subject to significant liability. In addition, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

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 has broad regulatory and enforcement powers, including 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 materially adverse effect on us.

Foreign Regulatory Requirements

Outside the United States, our ability to market a product is contingent upon receiving marketing authorization from the appropriate regulatory authorities. The requirements governing marketing authorization, pricing and reimbursement vary widely from country to country. At present, foreign marketing authorizations are applied for at a national level, although within the European Union registration procedures are available to companies wishing to market a product in more than one European Union member state. The regulatory authority generally will grant marketing authorization if it is satisfied that we have presented it with adequate evidence of safety, quality and efficacy.

Prescription Drug Wrap-Up

When Congress passed the FFDCA in 1938, it required that "new drugs" be approved based on their safety. In 1962, Congress amended the FFDCA to require that sponsors demonstrate that new drugs are effective, as well as safe, in order to receive FDA approval. We refer to these provisions as the "1962 Amendments." The 1962 Amendments also required the FDA to conduct a retrospective evaluation of the efficacy of the drug products that the FDA approved between 1938 and 1962 on the basis of safety alone. The FDA contracted with the National Academy of Science/National Research Council, or the NAS/NRC, to make an initial evaluation of the efficacy of many of these drug products. The FDA's administrative implementation of the NAS/NRC reports was called the Drug Efficacy Study Implementation, or DESI.

Drugs that were not subject to applications approved between 1938 and 1962 were not subject to DESI review. For a period of time, the FDA did not challenge the marketing of these drugs without approval. In 1984, however, spurred by serious adverse reactions to one of these products and concerns expressed by Congress, FDA undertook an assessment of the products under an initiative known as the "Prescription Drug Wrap-Up." Most of these drugs contain active ingredients that were first marketed prior to the enactment of the FFDCA. One of our marketed pharmaceutical products falls within this category.

The FDA has asserted that all drugs subject to the Prescription Drug Wrap-Up are on the market illegally unless they fall within two "grandfather" exceptions to the new drug definition. The first is a provision in the new drug definition exempting drugs that were on the market prior to the passage of the FFDCA and that contain the same representations concerning the conditions of use as they did prior to passage of the FFDCA. The 1962 Amendments also exempt drugs that were not new drugs prior to the passage of the 1962 Amendments and that have the same composition and labeling as they had prior to the passage of the 1962 Amendments. The FDA and the courts have interpreted these two exceptions very narrowly. Therefore, the FDA could commence enforcement action at any time regarding our unapproved prescription product. The FDA requested us to discontinue the manufacturing and distribution of our epinephrine injection, USP vial product, which has been marketed under the "grandfather" exception to the FDA's "Prescription Drug Wrap-Up" program. We discontinued selling this product in the second quarter of 2017. In April 2020, the FDA granted approval of our Epinephrine Injection USP 30mg/30mL Multiple Dose Vial.

Additionally, the FDA granted approval of our ANDAs for atropine sulfate injection, dextrose injection, morphine sulfate injection, and epinephrine injection single dose prefilled syringe in October 2020, March 2021, April 2021, and August 2022, respectively.

The FDA has adopted a risk-based enforcement policy that prioritizes enforcement of new drug requirements for these and other unapproved drugs that pose safety concerns, lack evidence of efficacy, prevent patients from pursuing effective therapies, are marketed fraudulently, violate other provisions of the FFDCA, such as cGMP requirements, or directly compete with approved drugs. The FDA has indicated that approval of an NDA for one drug within a class of drugs marketed without FDA approval may trigger agency enforcement of the new drug requirements. Once the FDA issues an

approved NDA for one of the drug products at issue or completes the efficacy review for that drug product, it may require other manufacturers to also obtain approval for that same drug in order to continue marketing it in the United States. While the FDA generally provides sponsors a one-year grace period, the agency is not statutorily required to do so.

USDA Animal and Plant Health Inspection Service

USDA-APHIS regulates the importation of certain animals and animal-derived materials into the U.S. In particular, a USDA veterinary permit is required for importation of materials derived from animals or exposed to animal-source materials. Recently, USDA enhanced its ASF surveillance efforts, including restrictions on importation of pig-derived products from affected countries and testing for the ASF virus. While ASF does not affect human health, it is a highly contagious and deadly disease to local pig populations. ASF is currently widespread and endemic in various parts of Africa and Sardinia. In recent years, ASF has been reported in parts of the European Union and in China, where the first cases of ASF were reported in August 2018. Complying with additional requirements, such as additional analytical data and documentation of processing flow, may be required for obtaining an import permit for certain materials from affected countries. Changes made to suppliers or sources of raw materials for drug products will require prior FDA approval, which would disrupt or delay the manufacturing of our products.

Fraud and Abuse Laws

Because of the significant federal funding involved in Medicare and Medicaid, Congress and the states have enacted, and actively enforce, a number of laws to eliminate fraud and abuse in federal health care programs. Our business is subject to compliance with these laws.

Federal False Claims Act

The False Claims Act, or FCA, imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal health care program. The *qui tam* provisions of the FCA allow a private individual to bring actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government and to share in any monetary recovery. In recent years, the number of suits brought against health care providers by private individuals has increased dramatically. In addition, various states have enacted false claims laws analogous to the FCA, and many of these state laws apply where a claim is submitted to any third-party payer and not merely a federal or other governmental health care program.

When an entity is determined to have violated the FCA, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of between $12,537 and $25,076 for each separate instance of a false claim, subject to adjustment for inflation. There are many potential bases for liability under the FCA. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. The federal government has used the FCA to assert liability on the basis of inadequate care, kickbacks and other improper referrals, and improper use of Medicare numbers when detailing the provider of services, in addition to the more predictable allegations of misrepresentations with respect to the services rendered. In addition, the federal government has prosecuted companies under the FCA in connection with off-label promotion of products. Our current and future activities relating to the reporting of wholesale or estimated retail prices of our products, the reporting of discount and rebate information and other information affecting federal, state and third-party reimbursement of our products, and the sale and marketing of our products may be subject to scrutiny under these laws. While we are unaware of any current matters, we are unable to predict whether we will be subject to actions under the False Claims Act or a similar state law, or the impact of such actions. However, the costs of defending such claims, as well as any sanctions imposed, could significantly affect our financial performance.

The Open Payment Act

The Physician Payment Sunshine Act, or the Open Payment Act, which was enacted as part of the Affordable Care Act, requires all pharmaceutical manufacturers that participate in Medicare, Medicaid or the Children's Health Insurance Program to report annually to the Secretary of the Department of Health and Human Services payments or other transfers of value made in the previous year by that entity, or by a third party as directed by that entity, to covered recipients, including physicians (defined to include doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and licensed chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others), and teaching hospitals, as defined by law, or to third parties on behalf of such covered

recipients, as well as ownership and investment interests held by physicians and their immediate family members. The payments and transfer of value required to be reported include the cost of meals provided to a physician, travel reimbursements and other transfers of value provided as part of contracted services, including speaker programs, advisory boards, consultation services and clinical trial services. The statute requires the federal government to make reported information available to the public. Failure to comply with the reporting requirements can result in significant civil monetary penalties ranging from $1,264 to $12,646 for each payment or other transfer of value that is not reported (up to a maximum per annual report of $189,692) and from $12,646 to $126,463 for each knowing failure to report (up to a maximum per annual report of $1,264,622). Additionally, there are criminal penalties if an entity intentionally makes false statements in such reports. We are subject to the Open Payment Act and the information we disclose may lead to greater scrutiny, which may result in modifications to established practices and additional costs. Additionally, similar reporting requirements have also been enacted on the state level domestically, and an increasing number of countries worldwide either have adopted or are considering adopting similar laws requiring transparency of interactions with health care professionals.

The Anti-kickback Statute

As a life sciences company, we are subject to the federal anti-kickback statute, or AKS. The AKS prohibits payments or providing anything of "value" (remuneration) for the purpose of inducing or rewarding the referral or generation of healthcare business. The intent is to protect the independence and clinical judgment of providers. There are numerous exceptions, or safe harbors, the most notable of which are that it is permissible to provide a discount or rebate to a healthcare provider based upon volume, and that manufacturers can pay administrative fees to GPOs or buying groups.

As a result of the AKS, the company pays particular attention to interactions with healthcare providers and how it structures sales. Any and all discounts that are offered are appropriately disclosed and documented to promote compliance with the AKS. At present, we employ our own salespeople and do not utilize a third-party sales force.

Both consulting relationships with healthcare providers and educational and research activities with healthcare providers and teaching hospitals receive considerable enforcement scrutiny. As a result, the company also pays particular attention to these relationships.

The Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act, or FCPA, prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA arguably includes interactions with certain healthcare professionals in many countries. Other countries have enacted similar anticorruption laws and/or regulations. Failure by our employees, agents, contractors, vendors, licensees, partners or collaborators to comply with the FCPA and other anticorruption laws and/or regulations could result in significant civil or criminal penalties.

Environmental Considerations

We are subject to federal, state and local environmental laws and regulations, both U.S. and foreign, including those promulgated by the Occupational Safety and Health Administration, the Environmental Protection Agency, the Department of Health and Human Services and the Air Quality Management District, which govern activities and operations that may have adverse environmental effects such as discharges to air, soil and water, as well as handling and disposal practices for solid and hazardous wastes. Because we own and operate real property, these laws impose strict liability for the costs of cleaning up, and for damages resulting from, sites of past spills, disposals or other releases of hazardous substances and materials. These laws and regulations may also require us to pay for the investigation and remediation of environmental contamination at properties operated by us and at off-site locations where we have arranged for the disposal of hazardous substances. If it is determined that our operations or facilities are not in compliance with current environmental laws, we could be subject to fines and penalties, the amount of which could be material.

The costs of complying with various applicable environmental requirements, as they now exist or as may be altered in the future, could adversely affect our financial condition and results of operations. For example, as a result of environmental concerns about the use of CFCs, the FDA issued a final rule on January 16, 2009 that required the phase-out of the CFC version of our Primatene MIST® product by December 31, 2011. This phase out caused us to halt sales of

the CFC version of our Primatene MIST® product subsequent to December 31, 2011 and write off our inventory for the product, which had an adverse effect on our financial results.

Similarly, on December 27, 2020, the American Innovation in Manufacturing Act of 2020, or AIM Act, was enacted. The AIM Act directs the United States Environmental Protection Agency to address usage of hydrofluorocarbons, or HFC, by reducing production and consumption of certain HFCs. One of our products, Primatene MIST®, utilizes HFCs subject to the AIM Act's reduction mandate. Moreover, many of our inhalation pipeline assets use HFCs subject to the AIM Act's reduction mandate. There can be no assurance that we will be able to acquire adequate supplies of HFCs for current and future commercialization of our products as a result of the AIM Act or other similar statutes and regulations. Moreover, changes to the ingredients of our proprietary and generic products requires FDA approval and there can be no assurance that we will be able to obtain such approval or the timing of such approval.

We have made and will continue to make expenditures to comply with current and future U.S. and foreign environmental laws and regulations. We anticipate that we will incur additional capital and operating costs in the future to comply with existing environmental laws and new requirements arising from new or amended statutes and regulations. We cannot accurately predict the impact and costs that future regulations will impose on our business.

Other Regulations

We are subject to various national, regional and local laws of general applicability, such as laws regulating working conditions. We are also subject to country specific data protection laws and regulations relating to the collection and processing of personal data around the world. In addition, we are subject to various national, regional and local environmental protection laws and regulations, including those governing the emission of material into the environment. We are also subject to various national, regional and local laws regulating how we interact with healthcare professionals and representatives of government that impact our promotional and other commercial activities.

We also must comply with data protection and data privacy requirements such as HIPAA, GDPR, CCPA, and the upcoming CPRA. Compliance with these laws, rules and regulations regarding privacy, security and protection of employee data could result in higher compliance and technology costs for us, as well as significant fines, penalties and damage to our global reputation and our brand as a result of non-compliance.

In November 2013, the federal Drug Supply Chain Security Act, or the DSCSA, became effective in the United States, mandating an industry-wide, national serialization system for pharmaceutical packaging with a ten-year phase-in process. By November 2018, all manufacturers and re-packagers were required to mark each prescription drug package with a unique serialized code. Each of Amphastar and our U.S.-based subsidiaries subject to or covered by DSCSA comply with the new requirements. In addition, under the DSCSA, we are required by November 2023, to provide to downstream trading partners, serial number specific transaction details. This may require additional modification to Amphastar and our U.S.-based subsidiaries' manufacturing sites. Additionally, should any subsidiary that is not subject to or covered by the DSCSA become subject to or covered by the DSCSA, we may be required to modify our manufacturing sites to comply with the rules and regulations.

Intellectual Property

Our success depends on our ability to operate without infringing the patents and proprietary rights of third parties. However, we cannot determine with certainty whether patents or patent applications of other parties will have a materially adverse effect on our ability to make, use, or sell any products. A number of pharmaceutical companies, biotechnology companies, universities and research institutions may have filed patent applications or may have been granted patents that cover aspects of our, or our licensors' products, product candidates, or other technologies.

With respect to our existing generic products and generic product candidates, we primarily rely on trade secrets, unpatented proprietary know-how and continuing technological innovation to protect our products and technologies, especially where we do not believe patent protection is appropriate or obtainable. Although in some cases, we seek patent protection to preserve our competitive position, our current patent portfolio does not cover the majority of our existing products and product candidates. We own several U.S. and foreign patents covering processes and equipment used in the manufacture of a few of our products. The expiration dates of these patents range from 2024 to 2039. We also own several trademarks registered with the USPTO.

We own a U.S. patent covering the HFA version of Primatene MIST®: U.S. Patent Number 8,367,734, which was issued on February 5, 2013, and expires in January 2026. We have several patent applications that are currently pending. For our product candidates that are not intended to be generic products, we may seek to obtain patent rights or rely on trade secret protection. We may not be able to obtain patent or other forms of protection for inventions or other intellectual property developed by our officers, employees, or consultants because we might not have been the first to file or to invent the patentable technology or others may have independently developed similar or alternative technology.

The majority of our products and product candidates are not currently covered by any U.S. or foreign patents owned by us. Indeed, many of our products and product candidates are generic products, and therefore may not be eligible for patent protection. For example, our enoxaparin product is a generic product, and as such, our enoxaparin product is not covered by any U.S. or foreign patents. Other of our products, including Amphadase®, are based on compounds for which any applicable patents have expired, or which were not patented by Amphastar in the first instance because they are older compounds.

Despite our efforts to protect our proprietary information through the use of confidentiality and non-disclosure agreements, unauthorized parties may copy aspects of our products or obtain and use information that we regard as proprietary. Other parties may also independently develop know-how or obtain unauthorized access to our technologies.

Intellectual property protection is highly uncertain and involves complex legal and factual questions. Our patents and those for which we have or will license rights may be challenged, invalidated, infringed or circumvented, and the rights granted in those patents may not provide proprietary protection or competitive advantages to us. We and our licensors may not be able to develop patentable products. Even if a patent application is filed, some or all of the patent claims may not be allowed, the patent itself may not issue, or in the event of issuance, the issued claims may not be sufficient to protect the technology owned by or licensed to us.

Third-party patent applications and patents could reduce the coverage of the patents licensed, or that may be licensed to, or owned by us. If patents containing competitive or conflicting claims are issued to third parties, we may be enjoined from the commercialization of products or be required to obtain licenses to these patents or to develop or obtain alternative technology. In addition, other parties may duplicate, design around or independently develop similar or alternative technologies to ours or those of our licensors.

Litigation may be necessary to enforce patents issued or licensed to us or to determine the scope or validity of another party's proprietary rights. USPTO interference proceedings may be necessary if we and another party both claim to have invented the same subject matter. Even if we ultimately prevail, we could incur substantial costs and our management's attention would be diverted if:

- litigation is required to defend against patent suits brought by third parties;
- we participate in patent suits brought against or initiated by our licensors;
- we initiate suits against third parties who are infringing on our patents; or
- we participate in an interference or other similar USPTO proceeding.

However, even if we pursue litigation or other action to protect our intellectual property rights, we may not prevail in any of these actions or proceedings.

Human Capital

As of December 31, 2022, we had 1,615 full-time employees in the United States, China, and France. Of these employees, 21 hold Ph.D.'s, and an additional 116 employees hold a master's degree or other post-graduate degrees. We consider our employees' intellectual capital an essential driver of our business and key to our future prospects. None of our U.S. employees are subject to a collective bargaining agreement or represented by a trade or labor union.

The following table summarizes our employees by category and location:

	United States	China	France	Total
Manufacturing	774	83	81	938
QA/QC and Regulatory Affairs	166	62	32	260
Sales and Marketing	17	—	—	17
General and administrative	102	29	20	151
Research and Development	247	0	2	249
Total employees	1,306	174	135	1,615

Talent Acquisition and Retention

We recognize that our employees largely contribute to our success. To this end, we support business growth by attracting and retaining best-in-class talent. Our talent acquisition team uses internal and external resources to recruit highly skilled candidates globally.

Total Rewards

Our total rewards philosophy recognizes the contributions of our workforce by offering competitive compensation and benefits packages. We provide employees with compensation packages that include base salary, annual incentive bonuses, and long-term equity awards. We also provide comprehensive employee benefits, which vary by country and region, such as life and health insurance, health savings accounts, paid time off, an Employee Stock Purchase Program, and a 401(k) plan.

Health, Safety, and Wellness

Our employees' health, safety, and wellness are a priority in which we have always invested and will continue to do so. We provide our employees and their families with access to various innovative, flexible, and convenient health and wellness programs. Program benefits are intended to provide protection and security, so employees can have peace of mind concerning events that may require time away from work or impact their financial well-being. These programs are highlighted regularly in our monthly human resources newsletters.

These investments and the prioritization of employee health, safety, and wellness were particularly significant in 2021 and 2022 in light of the ongoing COVID-19 pandemic. To protect and support our essential team members, we implemented and/or trained employees on health and safety measures that included maximizing personal workspaces, changing shift schedules, providing personal protective equipment, or PPE, implementing heightened cleaning of high contact surfaces, and instituting mandatory screening before accessing buildings. We notify employees of exposure and close contacts and offer COVID-19 testing after potential exposure. We will continue to monitor this evolving situation and will continue to seek programs to educate and assist employees whenever possible.

Diversity, Equity, and Inclusion

We believe a diverse workforce is critical to our success. Our mission is to value differences in races, ethnicities, religions, nationalities, genders, ages, sexual orientations, education, skill sets, and experience. We are focused on inclusive hiring practices, fair and equitable treatment, organizational flexibility, and training and resources.

Corporate Information

We incorporated in California under the name Amphastar Pharmaceuticals, Inc. in 1996 and merged our California corporation into Amphastar Pharmaceuticals, Inc., a newly formed Delaware corporation, in 2004. Our corporate offices are located at 11570 6th Street, Rancho Cucamonga, CA 91730. Our telephone number is (909) 980-9484. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge as soon as reasonably practicable after we electronically file them with, or furnish them to, the SEC. You can access our filings with the SEC by visiting http://www.amphastar.com. The SEC also maintains an Internet website that contains reports, proxy statements and other information about issuers, like us, that file electronically with the SEC. The address of that website is http://www.sec.gov.

We use our website as a channel of distribution for important company information. Important information, including press releases, analyst presentations and financial information regarding us, as well as corporate governance information, is routinely posted and accessible on the "Investors" section of the website, which is accessible by clicking on the tab labeled "Investors" on our website home page. The contents of the websites provided above are not intended to be incorporated by reference into this Annual Report on Form 10-K or in any other report or document we file with the SEC. Further, our reference to the URLs for these websites are intended to be inactive textual references only.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes thereto. Our future operating results may vary substantially from anticipated results due to a number of risks and uncertainties, many of which are beyond our control. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. The following discussion highlights some of these risks and uncertainties and the possible impact of these risks on future results of operations. If any of the following risks occur, our business, financial condition or results of operations could be materially and adversely affected. In that case, the market value of our common stock could decline substantially and you could lose part or all of your investment.

Summary of Risk Factors

Our business is subject to numerous risks and uncertainties that you should consider before investing in our company, as more fully described below. The principal factors and uncertainties that make investing in our company risky include, among others:

- our success depends on our ability to develop and/or acquire and commercialize additional pharmaceutical products;
- our Primatene MIST®, glucagon, epinephrine, lidocaine, phytonadione, and enoxaparin products collectively represent a significant portion of our net revenues; if the sales volume or pricing of our Primatene MIST®, glucagon, epinephrine, lidocaine, phytonadione, and enoxaparin products decline, or if we are unable to satisfy market demand for these products, they could have a material adverse effect on our business, financial position and results of operations;
- our success depends on the integrity of our supply chain, including multiple single source suppliers, the disruption of which could negatively impact our business;
- our ability to develop new products and additional revenue streams depends upon a variety of factors including being able to invest ongoing revenue and borrow funds or raise additional capital when needed;
- we face significant competition in the pharmaceutical industry with respect to both our proprietary and generic drugs, which may result in others developing or commercializing products before or more successfully than we do, which could significantly limit our growth and materially and adversely affect our financial results;
- health care providers may not be receptive to our products, particularly those that incorporate our proprietary drug delivery platforms;
- sales of our products may be adversely affected by the continuing consolidation of our customer base;
- we depend upon our key personnel, the loss of whom could adversely affect our operations. If we fail to attract and retain the talent required for our business, our business could be materially harmed;
- our business may be adversely affected by the ongoing COVID-19 pandemic and the related challenging macroeconomic conditions globally;
- because a portion of our manufacturing takes place in China, a significant disruption in the construction or operation of our manufacturing facility in China, political unrest in China, tariffs, impact of outbreaks of health epidemics, such as the COVID-19 pandemic, or changes in social, political, trade, health, economic, environmental, or climate-related conditions or in laws, regulations and policies governing foreign trade could materially and adversely affect our business, financial condition and results of operations;

- we may be exposed to product liability claims and may not be able to obtain or maintain adequate product liability insurance;

- we are exposed to risks related to our international operations and failure to manage these risks may adversely affect our operating results and financial condition;

- the FDA approval process is time-consuming and complicated, and we may not obtain the FDA approval required for a product within the timeline we desire, or at all; additionally, we may lose FDA approval and/or our products may become subject to foreign regulations;

- the novel use of particle engineering or synthetic APIs for any of our product candidates, may not receive regulatory approval, and without regulatory approval we will not be able to market our product candidates;

- if clinical studies for our product candidates are unsuccessful or significantly delayed, we will be unable to meet our anticipated development and commercialization timelines, which would have an adverse impact on our business;

- if branded pharmaceutical companies are successful in limiting the use of generics through their legislative, regulatory and/or other efforts, our sales of generic products may suffer; and

- our success depends on our ability to obtain, protect, and enforce our intellectual property.

Risks Relating to our Business and Industry

Our success depends on our ability to develop and/or acquire and commercialize additional pharmaceutical products.

Our financial results depend upon our ability to commercialize additional generic and proprietary pharmaceutical products, and whether our products are accepted by patients and physicians and are reimbursed by payers. Commercialization requires that we successfully and cost-effectively develop, test and manufacture or otherwise acquire both generic and proprietary products. All of our products must receive regulatory approval and meet (and continue to comply with) regulatory standards and requirements, including continued safety and efficacy standards. If health, safety, or environmental concerns arise with respect to a product, we may be forced to withdraw it from the market and be exposed to greater liability, including product liability lawsuits. For example, as a result of environmental concerns over the use of chlorofluorocarbons, or CFCs, the FDA, issued a final rule on January 16, 2009, that required the phase-out of the CFC formulation of our Primatene MIST® product by December 31, 2011. As a result, in order to resume selling Primatene MIST® we had to develop a formulation of the product that uses hydrofluoroalkane, or HFA, as the propellant, and obtain FDA approval for the modified product, which took a significant amount of time and was not re-launched until December 2018. There can be no guarantee that our investment in research and development activities will result in FDA approval or produce commercially viable new products.

The development and commercialization process, particularly with respect to our proprietary products, is time-consuming, costly and involves a high degree of business risk. Our products currently under development, if and when fully developed and tested, may not perform as we expect. Necessary regulatory approvals may not be obtained in a timely manner, if at all, and we may not be able to produce and market such products successfully and profitably. For example, we filed an ANDA, for our enoxaparin product in March 2003, but FDA approval was not granted until September 2011 due to delays caused largely by the FDA's requirement that we perform immunogenicity studies and the receipt of an FDA warning letter and FDA Import Alert by the supplier of the starting material for our enoxaparin product. Following FDA approval, we became involved in litigation with Momenta Pharmaceuticals, Inc. and Sandoz Inc., which further delayed the commercial launch of our enoxaparin product until January 2012. Delays in any part of the process, or our inability to obtain regulatory approval of our products, including litigation with competitors and regulatory compliance of our suppliers and contractors, could adversely affect our operating results by restricting or delaying our introduction of new products, which could adversely impact our ability to market a prospective product. FDA and similar regulatory agencies may change or impose new regulatory requirements on our products, which could require us to perform additional studies, expand additional resources on regulatory compliance, or delay our commercialization plan. To the extent that we expend significant resources on research and development efforts and are not able, ultimately, to introduce successful new products as a result of those efforts, our business, financial position and results of operations may be materially and adversely affected, and the market value of our common stock could decline.

Our ability to introduce new generic products also depends upon our success in challenging patent rights held by third parties or in developing non-infringing products. Due to the emergence and development of competing products over time, our overall profitability depends on, among other things, our ability to introduce new products in a timely manner, to continue to manufacture products cost-effectively and to manage the life cycle of our product portfolio. If we are unable to cost-effectively maintain an adequate flow of successful generic and proprietary products and new indications and/or delivery methods for existing products sufficient to cover our substantial research and development costs and the decline in sales of older products that either become subject to generic competition, or are displaced by competing products or therapies, it could have a material adverse effect on our business, financial condition or results of operations.

Our Primatene MIST®, glucagon, epinephrine, lidocaine, phytonadione, and enoxaparin products collectively represent a significant portion of our net revenues. If the sales volume or pricing of our glucagon, epinephrine, lidocaine, phytonadione, and enoxaparin products decline, or if we are unable to satisfy market demand for these products, they could have a material adverse effect on our business, financial position and results of operations.

Sales from our Primatene MIST® product represented 17%, 17%, and 15% of our total net revenues for the years ended December 31, 2022, 2021, and 2020, respectively. Sales from our glucagon product, which we launched in February 2021 represented 11% and 11% of our total net revenues for the years ended December 31, 2022 and 2021, respectively. Sales from our epinephrine product represented 15%, 13%, and 7% of our total net revenues for the years ended December 31, 2022, 2021, and 2020, respectively. Sales from our lidocaine products represented 11%, 10%, and 12% of our total net revenues for the years ended December 31, 2022, 2021, and 2020, respectively. Sales from our phytonadione product represented 10%, 10%, and 12% of our total net revenues for the years ended December 31, 2022, 2021, and 2020, respectively, and sales of our enoxaparin product represented 7%, 8%, and 14% of our total net revenues for the years ended December 31, 2022, 2021, and 2020, respectively. We have experienced declining revenue from enoxaparin and some of our other existing products in the past. If the sales volume or pricing of enoxaparin continues to decline, or if the sales volume or pricing of lidocaine and phytonadione declines, or if we are unable to satisfy market demand for these products, our business, financial position and results of operations could be materially and adversely affected, and the market value of our common stock could decline. For example, our enoxaparin product continues to see increased competition in the market, which could result in declining per unit prices as well as lower market share due to intense pricing competition in the pharmaceutical industry. We have experienced significant declines in the per unit pricing and gross margins attributable to our enoxaparin product since its commercial launch. Our Primatene MIST®, glucagon, epinephrine, lidocaine, phytonadione, and enoxaparin products could be rendered obsolete or negatively impacted by numerous factors, many of which are beyond our control, including:

- decreasing average sales prices;
- development by others of new pharmaceutical products that are more effective than ours;
- entrance of new competitors into our markets;
- loss of key relationships with suppliers, group purchasing organizations or end-user customers;
- manufacturing or supply interruptions;
- increase in material input costs;
- changes in the prescribing practices of physicians;
- changes in third-party reimbursement practices;
- changes in applicable environmental law;
- product liability claims; and
- product recalls or safety alerts.

Any factor adversely affecting the sale of these products may cause our revenues to decline, and we may not be able to achieve and maintain profitability.

Our ability to develop new products and additional revenue streams depends upon our ability to invest ongoing revenue, borrow funds or raise additional capital when needed.

Developing a single product in the pharmaceutical industry is a very expensive proposition with no certainty of regulatory clearance or commercial success. Considerable amounts are invested into the research and development process. Our research and development expense was $74.8 million, $60.9 million, and $67.2 million for the years ended December 31, 2022, 2021, and 2020, respectively. As noted elsewhere herein, ongoing revenue from current operations is a critical component of being able to adequately fund ongoing research and development efforts in our product pipeline. Likewise, the ability to borrow funds at an attractive rate is another factor in being able to fund research and development activities. Finally, being able to access the raise additional funds through the capital markets on favorable terms, if at all, particularly during times of market volatility, changes in the interest rate environment, and general economic instability, is another factor in being able to fund research and development. If any one, or all, of these sources become unavailable, our research and development projects may become delayed or negatively impacted.

Our success depends on the integrity of our supply chain, including multiple single source suppliers, the disruption of which could negatively impact our business.

Some of our products are the result of complex manufacturing processes, and some require highly specialized raw materials. Because our business requires outsourcing in some instances, we are subject to inherent uncertainties related to product safety, availability and security. For some of our key raw materials, components and API used in certain of our products, we have only a single, external source of supply, and alternate sources of supply may not be readily available.

For example, in 2009, we purchased heparin USP as the starting material for producing our enoxaparin product exclusively from a single source supplier and, in 2009, this supplier received a warning letter from the FDA and was the subject of an FDA Import Alert. The resulting shortage of heparin USP resulted in significant delays to the FDA approval process for our enoxaparin product. There are no guarantees our supplier will not receive warning letters in the future or that we will be able to replace this single source supplier with an alternate supplier on a commercially reasonable and timely basis, or at all, to prevent a shortage of heparin USP. Subsequently, we received FDA approval to make heparin USP from crude heparin using processes at our ANP and IMS facilities. In 2013, our single source supplier of epinephrine API for our Primatene MIST® product received a warning letter from the FDA, which our supplier has since addressed. In the future, it is possible that our suppliers will receive warning letters from the FDA and be unsuccessful in their efforts to address the issues raised in such warning letters on a timely basis, or at all, or may discontinue production of raw materials, components or APIs used in our products or product candidates and would result in delays in commercialization and/or manufacturing of our products or product candidates if FDA approval for such products or product candidates is received. Furthermore, we may be unable to replace such supplier with an alternate supplier on a commercially reasonable and timely basis, or at all.

If we fail to maintain relationships with our current suppliers, we may not be able to complete development, commercialization or marketing of our products, which would have a material and adverse effect on our business. Third-party suppliers may not perform as agreed, may discontinue production, or may terminate their agreements with us. For example, because these third parties provide materials to a number of other pharmaceutical companies, they may experience capacity constraints or choose to prioritize one or more of their other customers over us. Any significant problem that our suppliers experience could delay or interrupt our supply of materials until the supplier cures the problem or until we locate, negotiate for, validate and receive FDA approval for an alternative source of supply, if one is available. In the near term, we do not anticipate that the FDA will approve alternative sources to back up our primary suppliers. Therefore, if our primary suppliers become unable or unwilling to manufacture or deliver materials, we could experience protracted delays or interruptions in the supply of materials. This would ultimately delay our manufacture of products for commercial sale, which could materially and adversely affect our development programs, commercial activities, operating results and financial condition.

Additionally, any failure by us to forecast demand for, or to maintain an adequate supply of, the raw material and finished product could result in an interruption in the supply of certain products and a decline in sales of that product.

Underutilization of our manufacturing capacity could negatively impact our gross margins.

We have invested significantly in our manufacturing capacity in order to vertically integrate our business, contain the costs of raw materials and reduce the risks imposed by relying on third-party single source suppliers. We currently own and operate facilities that manufacture raw materials and APIs for our products and product candidates and those of our

customers and partners, including insulin API for MannKind. However, if market demand decreases or if market supply surpasses demand, whether because of macroeconomic factors, pharmaceutical industry volatility, or deficiencies specific to our customers, we may not be able to reduce manufacturing expenses or overhead costs proportionately. For example, a significant portion of our manufacturing capacity in our facility in Éragny-sur-Epte, France is utilized for the manufacturing of insulin API for MannKind, and a significant portion of our manufacturing capacity in Rancho Cucamonga is utilized for the manufacture of enoxaparin. In November 2016, we amended our supply agreement with MannKind, or the Supply Agreement and our option purchase agreement with MannKind, or the Option Agreement, to modify and extend the annual minimum purchase commitments under the Supply Agreement and the Option Agreement to cover calendar years 2014 through 2023. Additionally, in December 2018, we again amended our supply agreement with MannKind to modify and extend the annual minimum purchase commitments under the Supply Agreement and the Option Agreement to cover calendar years 2019 through 2024. In August 2019, we amended the Supply Agreement with MannKind to modify and extend the annual minimum purchase commitment under the Supply Agreement for an additional two years through 2026. In May 2021, we amended the Supply Agreement with MannKind to modify and extend the annual minimum purchase commitments under the Supply Agreement for an additional year through 2027. While the aggregate total purchase commitment remains unchanged, the amendments to the Supply Agreement and the Option Agreement have resulted and will continue to result in reduced sales of API for MannKind on an annual basis.

If an increase in supply outpaces the increase in market demand, or if demand decreases, such as a further reduction in sales of insulin API for MannKind, the resulting oversupply could adversely impact our sales and result in the underutilization of our manufacturing capacity, high inventory levels, changes in revenue mix and rapid price erosion, which would lower our margins and adversely impact our financial results. In addition, in order to offset fixed manufacturing overhead costs and utilize our current facilities and personnel, it may at times be in our best interest to continue to produce and sell products that are not profitable in the near term, although this would negatively impact our gross margins.

We face significant competition in the pharmaceutical industry with respect to both our proprietary and generic drugs, which may result in others developing or commercializing products before or more successfully than we do, which could significantly limit our growth and materially and adversely affect our financial results.

The majority of our marketed products are generic products. We face and will face significant competition for our products and product candidates from pharmaceutical companies that focus on the generic injectable and inhalation markets such as Pfizer, Inc., Sagent Pharmaceuticals, Inc., Akorn, Inc., Sandoz Inc., Viatris Inc., Fresenius Kabi USA, Nexus Pharmaceuticals, Apotex Corp., Amneal Biosciences, American Regent, Inc., Hikma Pharmaceuticals USA, Par Pharmaceuticals, Cipla USA Inc., Meitheal Pharmaceuticals, Dr, Reddy's Laboratories, Inc., Eli Lilly and Co., and Teva Pharmaceutical Industries Ltd. Competition in the generic pharmaceutical industry has increased as producers of branded products have entered the business by creating generic drug subsidiaries, purchasing generic drug companies, or licensing their products to generic manufacturers prior to patent expiration and/or as their patents expire.

We face similar competition with respect to our over-the-counter product. Our product competes with other products that are owned and marketed by companies with much greater financial resources to reach consumers and market their products to influence end-customer buying decisions. There can be no assurance that we will be able to profitably market our over-the-counter product and money spent on such marketing efforts may reduce our ability to focus on and develop our pharmaceutical products.

Our business operates in the pharmaceutical industry, which is an industry characterized by intense competition. Many of our competitors have longer operating histories and greater financial, research and development, marketing and other resources than we do. Consequently, many of our competitors may be able to develop products and/or processes competitive with, or superior to, our own. For example, a competitor has received FDA approval for their intranasal naloxone product in the markets for which we are currently seeking approval. We are concentrating the majority of our efforts and resources on developing product candidates utilizing our proprietary technologies. The commercial success of products utilizing such technologies will depend, in large part, on the intensity of competition, labeling claims approved by the FDA for our products compared to claims approved for competitive products and the relative timing and sequence for commercial launch of new products by other companies that compete with our new products. If alternative technologies or other therapeutic approaches are adopted prior to our new product approvals, then the market for our new products may be substantially decreased, thus reducing our ability to generate future profits.

This intensely competitive environment requires an ongoing, extensive search for technological innovations and the ability to market products effectively, including the ability to communicate the effectiveness, safety and value of our

products to healthcare professionals in private practice, group practices and managed care organizations. Our competitors vary depending upon product categories and, within each product category, upon dosage strengths and upon drug-delivery systems. Based on total assets, annual revenues and market capitalization, we are smaller than many of our national and international competitors with respect to both our generic and proprietary pharmaceutical products and product candidates. Many of our competitors have been in business for a longer period of time than us, have a greater number of products on the market and have greater financial and other resources than we do. Furthermore, recent trends in this industry are toward further market consolidation of large drug companies into a smaller number of very large entities, further concentrating financial, technical and market strength and increasing competitive pressure in the industry. If we directly compete with large entities for the same markets and/or products, their financial strength could prevent us from capturing a profitable share of those markets. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. It is possible that developments by our competitors will make our products or technologies noncompetitive or obsolete.

If we fail to obtain exclusive marketing rights for our generic pharmaceutical products or fail to introduce these generic products on a timely basis, our revenues, gross margin and operating results may decline significantly.

The Hatch-Waxman amendments to the Federal Food, Drug, and Cosmetic Act, or FFDCA, provide for a period of 180 days of generic marketing exclusivity for any applicant that is first-to-file an ANDA containing a certification of invalidity, non-infringement or unenforceability related to a patent listed with respect to the corresponding brand drug, which we refer to as a Paragraph IV certification. The holder of an approved ANDA containing a Paragraph IV certification that is successful in challenging the applicable brand drug patent(s) is often able to price the applicable generic drug to yield relatively high gross margins during this 180-day marketing exclusivity period. ANDAs that contain Paragraph IV certifications challenging patents, however, generally become the subject of patent litigation that can be both lengthy and costly. There is no certainty that we will prevail in any such litigation, that we will be the first-to-file and granted the 180-day marketing exclusivity period or, if we are granted the 180-day marketing exclusivity period, that we will not forfeit such period. Even where we are awarded marketing exclusivity, we may be required to share our exclusivity period with other ANDA applicants who submit Paragraph IV certifications. In addition, brand companies often authorize a generic version of the corresponding brand drug to be sold during any period of marketing exclusivity that is awarded, which reduces gross margins during the marketing exclusivity period. Brand companies may also reduce the price of their brand product to compete directly with generics entering the market, which similarly would have the effect of reducing gross margins. Furthermore, timely commencement of litigation by the patent owner imposes an automatic stay of ANDA approval by the FDA for 30 months, unless the case is decided in the ANDA applicant's favor during that period. Finally, if the court's decision is adverse to the ANDA applicant, the ANDA approval will be delayed until the challenged patent expires, and the applicant will not be granted the 180-day marketing exclusivity.

Accordingly, our revenues and future profitability are dependent, in large part, upon our ability or the ability of our development partners to file ANDAs with the FDA timely and effectively or to enter into contractual relationships with other parties that have obtained marketing exclusivity. We may not be able to develop and introduce successful products in the future within the time constraints necessary to be successful. If we or our development partners are unable to continue to timely and effectively file ANDAs with the FDA or to partner with other parties that have obtained marketing exclusivity, our revenues, gross margin and operating results may decline significantly, and our prospects and business may be materially adversely affected.

Our generic products face, and our generic product candidates will face, additional competitive pressures that are specific to the generic pharmaceutical industry.

With respect to our generic pharmaceutical business, revenues and gross profit derived from the sales of generic pharmaceutical products tend to follow a pattern based on certain regulatory and competitive factors. As patents and exclusivities protecting a brand name product expire, the first manufacturer to receive regulatory approval for a generic version of the product is generally able to achieve significant market penetration. Therefore, our ability to increase or maintain revenues and profitability in our generics business is largely dependent on our success in challenging patents and developing non-infringing formulations of proprietary products. As competing manufacturers receive regulatory approvals on generic products or as brand manufacturers launch generic versions of their products (for which no separate regulatory approval is required), market share, revenues and gross profit typically decline, often significantly and rapidly. Accordingly, the level of market share, revenue and gross profit attributable to a particular generic product normally is related to the number of competitors in that product's market and the timing of that product's regulatory approval and launch, in relation to competing approvals and launches. For example, enoxaparin is currently marketed by Sanofi, under the brand name Lovenox®. Sanofi also markets its authorized generic enoxaparin product through its

subsidiary, Winthrop, Fresenius Kabi USA, Apotex Corp. and Meithael Pharmaceuticals, Inc. also either market or plan to market a generic version of enoxaparin. Other companies may have received FDA approval of enoxaparin but have not launched the product, while other companies have filed ANDAs for enoxaparin with the FDA. The presence of these current and prospective competitive products has had, and may continue to have, an adverse effect on our market share, revenue and gross profit from our enoxaparin product. Since the commercial launch of our enoxaparin product, we have experienced significant declines in sales volume, per unit pricing and gross margins attributable to this product. Consequently, we must continue to develop and introduce new generic products in a timely and cost-effective manner to maintain our revenues and gross margins. We may have fewer opportunities to launch significant generic products in the future, as the number and size of proprietary products that are subject to patent challenges is expected to decrease in the next several years compared to historical levels. Additionally, as new competitors enter the market, there may be increased pricing pressure on certain products, which may result in lower gross margins. In addition to our enoxaparin product, we have experienced pricing pressure on many of our other products, including naloxone, and we expect this trend to continue in the future.

Competition in the generic drug industry has also increased due to the proliferation of authorized generic pharmaceutical products. "Authorized generics" are generic pharmaceutical products that are introduced by brand companies, either directly or through partnering arrangements with other generic companies. Authorized generics are equivalent to the brand companies' brand name drugs, but are sold at relatively lower prices than the brand name drugs. An authorized generic product can be marketed during the 180-day exclusivity granted to the first manufacturer or manufacturers to submit an ANDA with a Paragraph IV certification for a generic version of the brand product. The sale of authorized generics adversely impacts the market share of a generic product that has been granted 180-day exclusivity. For example, with respect to our enoxaparin product, Sanofi currently markets an authorized generic enoxaparin product through its subsidiary, Winthrop. This is a significant source of competition for us because brand companies do not face any regulatory barriers to introducing authorized generics of their products. Because authorized generics may be sold during our exclusivity periods, if any, they can materially decrease the profits that we could otherwise receive as an exclusive marketer of a generic alternative. Such actions have the effect of reducing the potential market share and profitability of our generic products and may inhibit us from developing and introducing generic pharmaceutical products corresponding to certain brand name drugs.

Such competition can also result from the entry of generic versions of another product in the same therapeutic class as one of our drugs, or in another competing therapeutic class, or from the compulsory licensing of our products by governments, or from a general weakening of intellectual property laws in certain countries around the world.

In addition, the goals established under the Generic Drug User Fee Act, and increased funding of the FDA's Office of Generic Drugs, have led to more and faster generic approvals, and consequently increased competition for some of our products. The FDA has stated that it has established new steps to enhance competition, promote access and lower drug prices and is approving record-breaking numbers of generic applications. While these FDA improvements are expected to benefit our generic product pipeline, they will also benefit competitors that seek to launch products in established generic markets where we currently offer products.

If the market for a reference brand product, such as Lovenox®, significantly declines, sales or potential sales of our generic and biosimilar products and product candidates may suffer and our business would be materially impacted.

Proprietary products face competition on numerous fronts as technological advances are made or new products are introduced. As new products are approved that compete with the reference proprietary product to our generic products and generic or biosimilar product candidates, such as Lovenox®, which is the reference brand product for our enoxaparin product, sales of the reference brand products may be significantly and adversely impacted and may render the reference brand product obsolete. In addition, brand companies may pursue life cycle management strategies that also impact our generic products.

If the market for a reference brand product is impacted, we in turn may lose significant market share or market potential for our generic or biosimilar products and product candidates, and the value for our generic or biosimilar pipeline could be negatively impacted. As a result, our business, including our financial results and our ability to fund future discovery and development programs, would suffer.

Health care providers may not be receptive to our products, particularly those that incorporate our proprietary drug delivery platforms.

The commercial success of our products will depend on acceptance by health care providers and others that such products are clinically effective, affordable and safe. Our products utilizing our proprietary drug delivery technologies may not be accepted by health care providers and others. Factors that may materially affect market acceptance of our products include but are not limited to:

- the relative therapeutic advantages and disadvantages of our products compared to competitive products;
- the relative timing of commercial launch of our products compared to competitive products;
- the relative safety and efficacy of our products compared to competitive products;
- the product labeling approved by the FDA for our products and for competing products;
- the willingness of third-party payers to reimburse for our prescription products and the level of any reimbursement provided for our prescription products;
- the willingness of pharmacy chains to stock our new products;
- the willingness of consumers to pay for our products; and
- legislative and regulatory efforts implemented by federal, state, or foreign governments to contain health care costs and prescription drug pricing, including measures that increase our reporting obligations to regulatory authorities and that impact how our customers purchase our drug products.

Our products, if successfully developed and commercially launched, will compete with both currently marketed products and new products launched in the future by other companies. Health care providers may not accept or utilize some of our products. Physicians and other prescribers may not be inclined to prescribe our prescription products unless our products demonstrate commercially viable advantages over other products currently marketed for the same indications. Pharmacy chains may not be willing to stock certain of our new products, and pharmacists may not recommend such products to consumers. Further, consumers may not be willing to purchase some of our products. If our products do not achieve market acceptance, we may not be able to generate significant revenues or become profitable.

If we are unable to maintain our group purchasing organization relationships, our revenues could decline and future profitability could be jeopardized.

Many of the existing and potential customers for our products have combined to form group purchasing organizations in an effort to lower costs. Group purchasing organizations negotiate pricing arrangements with medical supply manufacturers and distributors, and these negotiated prices are made available to a group purchasing organization's affiliated hospitals and other members. Group purchasing organizations provide end-users access to a broad range of pharmaceutical products from multiple suppliers at competitive prices and, in certain cases, exercise considerable influence over the drug purchasing decisions of such end-users. Hospitals and other end-users contract with the group purchasing organization of their choice for their purchasing needs. We currently derive, and expect to continue to derive, our revenue from end-user customers that are members of group purchasing organizations. Maintaining our strong relationships with these group purchasing organizations will require us to continue to be a reliable supplier, offer a broad product line, remain price competitive, comply with FDA regulations and provide high-quality products. Although our group purchasing organization pricing agreements are typically multi-year in duration, most of them may be terminated by either party with 60 or 90 days' notice. The group purchasing organizations with which we have relationships may have relationships with manufacturers that sell competing products, and such group purchasing organizations may earn higher margins from these competing products or combinations of competing products or may prefer products other than ours for other reasons. If we are unable to maintain our group purchasing organization relationships, sales of our products and revenue could decline.

Consolidation in the health care industry could lead to demands for price concessions or for the exclusion of some suppliers from certain of our markets, which could have an adverse effect on our business, financial condition or results of operations.

Because health care costs have risen significantly, numerous initiatives and reforms by legislatures, regulators and third-party payers to curb these cost increases have resulted in a trend in the health care industry to consolidate product suppliers and purchasers. As the health care industry consolidates, competition among suppliers to provide products to purchasers has become more intense. This in turn has resulted and will likely continue to result in greater pricing pressures and the exclusion of certain suppliers from important market segments as group purchasing organizations and large single accounts continue to use their market power to influence product pricing and purchasing decisions. As the U.S. payer market concentrates further and as more drugs become available in generic form, biopharmaceutical companies may face greater pricing pressure from private third-party payers, who will continue to drive more of their patients to use lower cost generic alternatives. This drive towards generic alternatives could adversely affect sales of our proprietary products and increase competition among generic manufacturers.

Sales of our products may be adversely affected by the continuing consolidation of our customer base.

A significant proportion of our sales are made to relatively few U.S. wholesalers and group purchasing organizations. These customers are continuing to undergo significant consolidation. Sales to three of these customers for the years ended December 31, 2022, 2021, and 2020, respectively, accounted for approximately 62%, 61%, and 62% of our total net revenues, respectively. Such consolidation has provided and may continue to provide them with additional purchasing leverage, and consequently may increase the pricing pressures that we face.

Moreover, we are exposed to a concentration of credit risk as a result of this concentration among our customers. If one or more of our major customers experienced financial difficulties, the effect on us would be substantial. This could have a material adverse effect on our business, financial condition and results of operations.

Our net sales and quarterly growth comparisons may also be affected by fluctuations in the buying patterns of retail chains, major distributors and other trade buyers, whether resulting from seasonality, pricing, wholesaler buying decisions or other factors. In addition, because a significant portion of our U.S. revenues is derived from relatively few customers, any financial difficulties experienced by a single customer, or any delay in receiving payments from a single customer, could have a material adverse effect on our business, financial condition and results of operations.

At the same time, the traditional model for distribution of pharmaceutical products is also undergoing disruption as a result of the entry or potential entry of new competitors and significant mergers among key industry participants. For example, in 2020 Amazon.com launched its pharmaceutical distribution business. In addition, several major hospital systems in the United States formed a nonprofit company that will provide U.S. hospitals with a number of generic drugs. These changes to the traditional supply chain could lead to our customers having increased negotiation leverage and to additional pricing pressure and price erosion.

If our business partners do not fulfill their obligations with respect to our distribution or collaboration agreements, our revenues and our business will suffer.

Pursuant to certain distribution or collaboration agreements, the success of some of our products or product candidates also depends on the success of the collaboration with our business partners, who are responsible for certain aspects of researching, developing, marketing, distributing or commercializing our products or product candidates. If any such agreement were to be terminated in accordance with its terms, including due to a party's failure to perform its obligations or responsibilities under the agreement, revenues could be delayed or diminished from these products and our revenues and/or profit share for these products could be adversely impacted.

We depend upon our key personnel, the loss of whom could adversely affect our operations. If we fail to attract and retain the talent required for our business, our business could be materially harmed.

We depend to a significant degree on our key management employees, including our Chief Executive Officer and Chief Science Officer, Jack Y. Zhang, and our Chief Operating Officer and Chief Scientist, Mary Z. Luo. The loss of services from any of these persons may significantly delay or prevent the achievement of our product development or business objectives. We do not carry key man life insurance on any key personnel. Competition among pharmaceutical companies for qualified employees is intense, and the ability to attract and retain qualified individuals is critical to our success. We have experienced attrition among our executive officers in the past, and any future loss of key members of our

organization or any inability to continue to attract high-quality employees may delay or prevent the achievement of major business objectives. Our productivity may be adversely affected if we do not integrate or train our new employees quickly and effectively.

Competition for highly-skilled personnel is often intense, especially in Southern California, where we have a substantial presence and need for highly-skilled personnel. We may not be successful in attracting, integrating or retaining qualified personnel to fulfill our current or future needs. Also, to the extent we hire personnel from competitors, we may be subject to allegations that we have improperly solicited, or that they have divulged proprietary or other confidential information, or that their former employers own their inventions or work product.

Our business may be adversely affected by the ongoing COVID-19 pandemic and the related challenging macroeconomic conditions globally.

The ongoing COVID-19 pandemic, including the emergence of variants, has continued to impact worldwide economic activity and financial markets, and remains a potential challenge to our business until it is abated. Mass and rapid production of the vaccines, for example, has placed increased pressure on the availability of supplies that are also used in our products, such as glass vials and needles. The COVID-19 pandemic may also disrupt the operations of our customers, suppliers and partners for an indefinite period of time, including as a result of travel restrictions and/or business shutdowns, all of which could negatively impact our business and results of operations, including cash flows. Disruptions to our manufacturing partners and suppliers could result in disruption to the production of our products and failure to satisfy demand. More generally, the ongoing COVID-19 pandemic could continue to adversely affect economies and financial markets globally and nationally, including inflationary pressures and changes in interest rates, which could decrease spending and adversely affect demand for our products and harm our business and results of operations. To the extent macroeconomic uncertainty persists or the COVID-19 pandemic or macroeconomic conditions worsen, we may experience a continuing adverse effect on the demand for some of our products. The degree of impact of the COVID-19 pandemic and the related challenging macroeconomic conditions globally on our business will depend on several factors, such as the duration and the extent of the pandemic, as well as actions taken by governments, businesses, and consumers in response to the pandemic and the challenging macroeconomic conditions globally, all of which continue to evolve and remain uncertain at this time.

As a result of the consequences of the COVID-19 pandemic, FDA has issued various COVID-19 related guidance documents applicable to biopharmaceutical manufacturers and clinical trial sponsors. For example, in March 2020, the FDA issued a guidance, which the FDA subsequently updated, on conducting clinical trials during the pandemic, which describes a number of considerations for sponsors of clinical trials impacted by the pandemic, including the requirement to include in the clinical trial report contingency measures implemented to manage the clinical trial, among others. The FDA also issued a guidance on good manufacturing practice considerations for responding to COVID-19 infection in employees in drug products manufacturing, and a guidance on review timelines for applicant responses to Complete Response Letters when a facility assessment is needed during the COVID-19 public health emergency. These and future guidance documents and regulatory requirements, including future legislation, may require us to develop and implement new policies and procedures, make significant adjustments to our clinical trials, or increase the amount time and resources needed for regulatory compliance, which may impact our clinical development plans and timelines.

Some of our ongoing clinical trials have experienced short term interruptions in the recruitment of patients due to the COVID-19 pandemic, as hospitals prioritized their resources toward the COVID-19 pandemic and governments imposed travel restrictions. Additionally, protocols at certain clinical sites have changed which could slow down the pace of clinical trials while also increasing their cost. These conditions may in turn delay spending and delay the results of these trials. Additionally, certain suppliers delayed shipments to us in 2021 and 2022. These delays may have been caused by manufacturing disruptions due to the COVID-19 pandemic. For example, in the first quarter of 2022, increases in COVID-19 cases in Shanghai, China, led to shutdowns and delays at the ports in Shanghai, which led to temporary delays in shipping certain APIs and starting materials. Future shutdowns could have an adverse impact on our operations. However, the extent of the impact of any future shutdown or delay is highly uncertain and difficult to predict. Shanghai's delays did not ultimately cause delays in our manufacturing, but future delays could cause manufacturing disruptions at our factories.

Any of the negative impacts of the ongoing COVID-19 pandemic and the related challenging macroeconomic conditions, including, among others, those described above, alone or in combination with others, may have a material adverse effect on our business and operations, results of operations, financial condition, and cash flows. It is not possible at this time to estimate the complete impact that the COVID-19 pandemic and the related challenging economic conditions could have

on our business, as the impact will depend on future developments, which are highly uncertain and cannot be predicted. Macroeconomic conditions may continue to worsen leading to changes in monetary policy and other responses from governmental bodies, infections may resurge or become more widespread and the limitation on our ability to travel and timely sell and distribute our products, as well as any closures or supply disruptions, may be enacted or extended for longer periods of time, each of which alone or in combination with others, would have a negative impact on our business, financial condition and operating results. We will continue to monitor the impact of the COVID-19 pandemic and the related challenging macroeconomic conditions on all aspects of our business.

We may be exposed to product liability claims and may not be able to obtain or maintain adequate product liability insurance.

Our business exposes us to potential product liability risks, which are inherent in the testing, manufacturing, marketing and sale of pharmaceutical products. Product liability claims might be made by patients, health care providers or others who sell or consume our products. These claims may be made even with respect to those products that possess regulatory approval for commercial sale.

Our reputation is the foundation of our relationships with physicians, patients, group purchasing organizations and other customers. If we are unable to effectively manage real or perceived issues that could negatively impact sentiments toward us, our business could suffer. Our customers may have a number of concerns about the safety of our products whether or not such concerns have a basis in generally accepted science or peer-reviewed scientific research. These concerns may be increased by negative publicity, even if the publicity is inaccurate. Any negative publicity, whether accurate or inaccurate, about the efficacy, safety or side effects of our products or product categories, whether involving us, a competitor or a reference drug, could materially reduce market acceptance of our products, cause consumers to seek alternatives to our products, result in product withdrawals and cause our stock price to decline. Negative publicity could also result in an increased number of product liability claims, whether or not these claims have a basis in scientific fact.

We currently maintain a $10.0 million product liability insurance policy, which covers Amphastar, IMS, Armstrong, and AFP, products, but our insurance coverage is subject to deductibles and may not reimburse us or may not be sufficient to reimburse us for all expenses or losses we may suffer from any product liability claims. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. Large judgments have been awarded in class action lawsuits based on drug products that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

If serious adverse events or deaths are identified relating to any of our products once they are on the market, we may be required to withdraw our products from the market, which would hinder or preclude our ability to generate revenues.

We are required to report to relevant regulatory authorities adverse events or deaths associated with our product candidates or approved products. Based on such events, regulatory authorities may withdraw their approvals of such products or take enforcement actions. We may be required to reformulate our products, and/or we may have to recall the affected products from the market and may not be able to reintroduce them into the market. Furthermore, our reputation in the marketplace may suffer and we may become the target of lawsuits, including class actions suits. Any of these events could harm or prevent sales of the affected products and could have a material adverse effect upon our business and financial condition.

Any acquisitions of technologies, products and businesses may be difficult to integrate, could adversely affect our relationships with key customers and/or could result in significant charges to earnings.

We plan to regularly review potential acquisitions of technologies, products and businesses complementary to our business. Acquisitions typically entail many risks and could result in difficulties in integrating operations, personnel, technologies and products. If we are not able to successfully integrate our acquisitions, we may not obtain the advantages and synergies that the acquisitions were intended to create, which may have a material adverse effect on our business, results of operations, financial condition and cash flows, our ability to develop and introduce new products and the market price of our stock. In addition, some acquisitions may require regulatory approvals before products may be sold by us, which may not be obtained on a timely basis, or at all. For example, in August 2016, our UK subsidiary acquired IMS UK. We are in the process of transferring the manufacturing of the purchased products to our facility in California.

The transfer will require approval of the UK Medicines and Healthcare products Regulatory Agency and other related agencies before the products can be sold by us. It is possible that the integration of some acquired technologies, information systems and data could increase our risk of experiencing a data security or privacy incident. In addition, in connection with acquisitions, we could experience disruption in our business, technology and information systems, customer or employee base, including diversion of management's attention from our continuing operations. There is also a risk that key employees of companies that we acquire or key employees necessary to successfully commercialize technologies and products that we acquire may seek employment elsewhere, including with our competitors. Furthermore, there may be overlap between our products or customers and the companies that we acquire that may create conflicts in relationships or other commitments detrimental to the integrated businesses. If we are unable to successfully integrate technologies, products, businesses or personnel that we acquire, we could incur significant impairment charges or other adverse financial consequences.

Identifying, executing and realizing attractive returns on acquisitions is highly competitive and involves a high degree of uncertainty. We expect to encounter competition for potential target businesses from both strategic and financial buyers. Some of these competitors may be well established and have extensive experience in identifying and consummating business combinations. Some of these competitors may possess greater technical, human and other resources than us, and our financial resources may be relatively limited when contrasted with those of our competitors. We may lose acquisition opportunities if we do not match our competitors' pricing, terms and structure criteria for such acquisitions. If we are forced to match these criteria to make acquisitions, we may not be able to achieve acceptable returns on our acquisitions or may bear substantial risk of capital loss. In addition, target companies may not be willing to sell assets at valuations which are attractive to us. Furthermore, the terms of our existing or future indebtedness may hinder or prevent us from making additional acquisitions of technologies, products or businesses. Because of these factors, we may not be able to consummate an acquisition on attractive terms, if at all.

We intend to conduct an extensive due diligence investigation for any business we consider acquiring. Intensive due diligence is often time consuming and expensive due to the operations, finance and legal professionals who may be involved in the due diligence process. Even if we conduct extensive due diligence on a target business which we acquire, we may not identify all material issues that are present inside a particular target business. If our due diligence fails to discover or identify material issues relating to a target business, industry or the environment in which the target business operates, we may be forced to later write-down or write-off assets, restructure the target business' operations or incur impairment or other charges that could result in losses to us.

Charges to earnings resulting from acquisitions could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Under U.S. generally accepted accounting principles, or GAAP, business combination accounting standards, we recognize the identifiable assets acquired, the liabilities assumed and any non-controlling interests in acquired companies generally at their acquisition date fair values and, in each case, separately from goodwill. Goodwill as of the acquisition date is measured as the excess amount of consideration transferred, which is also generally measured at fair value, and the net of the acquisition date amounts of the identifiable assets acquired and the liabilities assumed. Our estimates of fair value are based upon assumptions believed to be reasonable but which are inherently uncertain. After we complete an acquisition, the following factors could result in material charges and adversely affect our operating results and may adversely affect our cash flows:

- costs incurred to combine the operations of companies we acquire, such as transitional employee expenses and employee retention, redeployment or relocation expenses;
- impairment of goodwill or intangible assets, including acquired in-process research and development;
- amortization of intangible assets acquired;
- a reduction in the useful lives of intangible assets acquired;
- identification of or changes to assumed contingent liabilities, including, but not limited to, contingent purchase price consideration, income tax contingencies and other non-income tax contingencies, after our final determination of the amounts for these contingencies or the conclusion of the measurement period (generally up to one year from the acquisition date), whichever comes first;

- charges to our operating results to eliminate certain duplicative pre-acquisition activities, to restructure our operations or to reduce our cost structure; and

- charges to our operating results resulting from expenses incurred to effect the acquisition.

A significant portion of these adjustments could be accounted for as expenses that will decrease our net income and earnings per share for the periods in which those costs are incurred. Such charges could cause a material adverse effect on our business, financial position and results of operations and could cause the market value of the common stock to decline.

We may evaluate asset dispositions and other transactions that may impact our results of operations, and we may not achieve the expected results from these transactions.

From time to time, we may enter into agreements to dispose of certain assets. However, we cannot assure you that we will be able to dispose of any such assets at any anticipated prices, or at all, or that any such sale will occur during any anticipated time frame. In addition, we may engage in business combinations, purchases of assets or contractual arrangements or joint ventures. Subject to the agreements governing our existing debt or otherwise, some of these transactions may be financed with our additional borrowings. We may suffer a loss of key employees, customers or suppliers, loss of revenues, increases in costs or other difficulties in connection with these transactions. Other transactions may advance future cash flows from some of our businesses, thereby yielding increased short-term liquidity, but consequently resulting in lower cash flows from these operations over the longer term. The failure to realize the expected long-term benefits of any one or more of these transactions could have a material adverse effect on our financial condition or results of operations.

Significant balances of intangible assets, including goodwill, are subject to impairment testing and may result in impairment charges, which may materially and adversely affect our results of operations and financial condition.

A significant amount of our total assets is related to goodwill and intangible assets. As of December 31, 2022, the value of our goodwill and intangible assets net of accumulated amortization was $37.3 million. Goodwill and other intangible assets are tested for impairment annually when events occur or circumstances change that could potentially reduce the fair value of the reporting unit or intangible asset. Impairment testing compares the fair value of the reporting unit or intangible asset to its carrying amount. Any future goodwill or other intangible asset impairment, if any, would be recorded in operating income and could have a material adverse effect on our results of operations and financial condition.

Our outstanding loan agreements contain restrictive covenants that may limit our operating flexibility.

Our loan agreements are collateralized by substantially all of our presently existing and subsequently acquired personal property assets and subject us to certain affirmative and negative covenants, including limitations on our ability to transfer or dispose of assets, merge with or acquire other companies, make investments, pay dividends, incur additional indebtedness and liens and conduct transactions with affiliates. We are also subject to certain covenants that require us to maintain certain financial ratios and are required under certain conditions to make mandatory prepayments of outstanding principal. As a result of these covenants and ratios, we have certain limitations on the manner in which we can conduct our business, and we may be restricted from engaging in favorable business activities or financing future operations or capital needs until our current debt obligations are paid in full or we obtain the consent of our lenders, which we may not be able to obtain. We may not be able to generate sufficient cash flow or revenue to meet the financial covenants or pay the principal and interest on our debt, and in the past we have not been in compliance with certain financial covenants. In addition, upon the occurrence of an event of default, our lenders, among other things, can declare all indebtedness due and payable immediately, which would adversely impact our liquidity and reduce the availability of our cash flows to fund working capital needs, capital expenditures and other general corporate purposes. An event of default includes our failure to pay any amount due and payable under the loan agreements, the occurrence of a material adverse change in our business as defined in the loan agreements, our breach of any covenant in the loan agreements, subject to a grace period in some cases, or an involuntary insolvency proceeding. Additionally, a lender could exercise its lien on substantially all of our assets and our future working capital, borrowings or equity financing may not be available to repay or refinance any such debt.

Counterfeit versions of our products could harm our patients and reputation.

Our industry has been increasingly challenged by the vulnerability of distribution channels to illegal counterfeiting and the presence of counterfeit products in a growing number of markets and over the Internet. Counterfeit products are frequently unsafe or ineffective, and can be potentially life-threatening. To distributors and patients, counterfeit products may be visually indistinguishable from the authentic version. Reports of adverse reactions to counterfeit drugs or increased levels of counterfeiting could materially affect patient confidence in the authentic product, and harm the business of companies such as ours. Additionally, it is possible that adverse events caused by unsafe counterfeit products would mistakenly be attributed to the authentic product. If a product of ours was the subject of counterfeits, we could incur substantial reputational and financial harm in the longer term.

Our business and operations have been impacted in the past, and may be impacted in the future, in the event of system breach or failure.

We, our collaborators, third-party providers, distributors, customers and other contractors utilize information technology systems and networks to transmit, store and otherwise process electronic data in connection with our business activities, including our supply chain processes, operations and communications including, in some cases, our clinical data and business proprietary information, and Electronic Data Interchange, or EDI, on purchase orders, invoices, chargebacks, among other things. We, and our collaborators, third-party providers, distributors and other contractors, also collect, transmit, store and otherwise process certain data relating to individuals, including about our personnel, business partners, and others, which may be subject to applicable data protection, security and privacy laws and regulations that require adoption of minimum information security standards. The cost of compliance with applicable data protection, security and privacy laws and regulations have increased and may increase in the future.

Despite our implementation of security measures to protect the confidentiality, integrity, and availability of the systems, networks and data within our control from various threats (e.g., cyber-attacks, system breaches, malware, viruses, hacking, fraudulent use, social engineering attacks, phishing attacks, ransomware attacks, credential-stuffing attacks, denial-of-service attacks, unauthorized access, insider threats, accidental disclosures, intellectual property theft and economic espionage, exploitable vulnerabilities, defects or bugs in our or our third-party providers' systems, natural disasters, war, terrorism, telecommunications and electrical outages, breakdowns, damage, interruptions), we have experienced and may continue to experience cyber-attacks of varying degrees from time to time. For example, in the first quarter of 2022, our Chinese subsidiary, ANP, was subject to a security incident that resulted in a temporary disruption to some of their internal computer systems. We worked with ANP to improve and implement additional security measures to their systems and networks. We have incurred costs to respond to the ANP incident. In addition, in the second quarter of 2020, we were subject to a security incident that resulted in a temporary disruption to some of our internal computer systems. In response to this incident, we engaged a third-party forensic expert to investigate, and determined that cyber criminals illegally obtained certain personal information of certain current and former employees. We notified affected individuals and regulators, as we deemed was required or appropriate. We have incurred cost to respond to this incident, and we expect to continue to incur cost to support our efforts to enhance our security measures. Our systems and networks and the systems and networks of third parties that support us and our services may be breached or disrupted due to these threats. The size and complexity of our systems may make them potentially vulnerable to breakdown or interruption, whether due to computer viruses or other causes, which may result in loss of data or the impairment of production and other supply chain processes, adversely affecting our business.

Techniques used to sabotage or obtain unauthorized access to systems and networks are constantly evolving and, in some instances, are not identified until or after they are launched against a target. We and our third-party providers may be unable to anticipate these techniques, discover threats and react in a timely manner, or implement adequate preventative or mitigating measures. Further, system breaches, malware, ransomware, computer hacking, and insider threats have become more prevalent. For example, companies have experienced an increase in phishing and social engineering attacks from third parties in connection with working remotely as a result of the ongoing COVID-19 pandemic. We and our third-party providers who may be operating in remote work environments may have increased security risks, due to increased use of home Wi-Fi networks and virtual private networks, as well as increased disbursement of physical machines. Also, due to political uncertainty and military actions associated with Russia's invasion of Ukraine, we and our third-party providers are vulnerable to heightened risks of cyber threats and cyber-attacks from or affiliated with nation-state actors, including attacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our products and services. While we implement security measures designed to reduce these risks, there is no guarantee that these measures will be adequate to safeguard all systems and networks. Any failure to maintain performance, reliability, security and availability of our systems and networks may result in accidental or

unlawful destruction, damage, loss, unavailability, alteration, impairment, misuse, unauthorized disclosure of, or unauthorized access to our data, including personal information.

In addition, potential legal, regulatory, contractual, financial, operational, and reputational harm may arise from the accidental or unlawful destruction, damage, loss, unavailability, alteration, impairment, misuse, unauthorized disclosure of, or unauthorized access to our systems, networks, or data, including data which is transmitted, stored or otherwise processed by us or by collaborators, third-party providers, distributors and other contractors on our behalf. For example:

- The accidental or unlawful loss, unavailability or alteration of clinical trial data from completed or ongoing clinical trials for any of our product candidates could affect our ability to operate, result in delays in our development and regulatory approval efforts, and significantly increase our costs to recover or reproduce the data.

- Any security incident may require costly response and remediation efforts, trigger notification obligations under breach notification laws or contractual notification requirements, result in litigation or adverse regulatory action arising from or related to such an incident or event, damage our reputation, and result in significant additional expense to implement further data protection measures. Integrating the systems and data of any acquired entity may increase these risks due to unforeseen threats and vulnerabilities.

- Similarly, any security incident experienced by our collaborators, third-party providers, distributors and other contractors may hinder our product development, supply chain, other business operations, or our regulatory and contractual obligations to others and could also give rise to litigation or adverse regulatory action.

In an effort to ensure appropriate oversight of cyber security issues and risks, management now updates the Board of Directors on cyber security matters on a quarterly basis, and the Board of Directors has assigned oversight of cyber security to the Audit Committee. Additionally, the Company has a security training and compliance program, which employees with access to information technology, must complete annually or more often, if deemed necessary or appropriate.

There can be no assurance that we will be successful in preventing security incidents nor that we will be successful in mitigating their effects, despite the implementation of security measures for systems, networks and data within our control. Similarly, there can be no assurance that our collaborators, third-party providers, distributors and other contractors will be successful in protecting our data on their systems or in protecting other systems upon which we may rely. Furthermore, breach notification laws are not consistent among jurisdictions, and compliance and other measures in the event of a security incident could result in a substantial cost and diversion of resources and distract management and technical personnel in efforts to investigate or correct the security incident, address and eliminate vulnerabilities and prevent future security incidents, and remediate the security incident, which repairing systems and responding to claims of damages for actual or asserted contract breaches. Any such security incident could have a material adverse effect on our business and prospects.

Although we maintain cyber insurance coverage that may cover certain of our losses in connection with a security incident, we cannot be certain our insurance coverage will be adequate for losses actually incurred, that insurance will continue to be available to us on commercially reasonable terms (if at all) or that any insurer will not deny coverage as to any future claim. The successful assertion of one or more large claims against us that exceed available insurance coverage, the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, or denials of coverage, could have a material adverse effect on our business, including our financial condition, results of operations and reputation.

We have incurred losses in the past and we may operate at a loss in future years while continuing to invest in developing new products.

Although we achieved net income in the years ended December 31, 2022, 2021 and 2020, we may incur operating and net losses and negative cash flow from operations in the future. Our business may generate operating losses if we do not successfully commercialize our product candidates, maintain sales of and profits from existing products, and generate sufficient revenues to support our level of operating expenses, especially as we continue our investment in developing new products. Because of the numerous risks and uncertainties associated with our commercialization efforts and future product development, we are unable to predict whether we will be able to maintain profitability.

Risks Relating to Regulatory Matters

The FDA approval process is time-consuming and complicated, and we may not obtain the FDA approval required for a product within the timeline we desire, or at all. Additionally, we may lose FDA approval and/or our products may become subject to foreign regulations.

The development, testing, manufacturing, marketing and sale of generic and proprietary pharmaceutical products and biological products are subject to extensive federal, state and local regulation in the U.S. and other countries. Satisfaction of all regulatory requirements, which typically takes years for drugs that require regulatory approval in ANDAs, NDAs, biological license applications, or BLAs, or biosimilar applications is dependent upon the type, complexity and novelty of the product candidate and requires the expenditure of substantial resources for research (including qualification of suppliers and their supplied materials), development, in vitro and in vivo (including nonclinical and clinical trials) studies, manufacturing process development and commercial scale up. Some of our products are drug-device combination products that are regulated as drug products by the FDA, with consultation from the FDA's Center for Device and Radiological Health. These combination products require the submission of drug applications to the FDA. All of our products are subject to compliance with the FFDCA and/or the Public Health Service Act, or PHSA, and with the FDA's implementing regulations. Failure to adhere to applicable statutory or regulatory requirements by us or our business partners would have a material adverse effect on our operations and financial condition. In addition, in the event we are successful in developing product candidates for distribution and sale in other countries, we would become subject to regulation in such countries. Such foreign regulations and product approval requirements are expected to be time consuming and expensive as well.

We may encounter delays or agency rejections during any stage of the regulatory review and approval process based upon a variety of factors, including without limitation the failure to provide clinical data demonstrating compliance with the FDA's requirements for safety, efficacy and quality. Those requirements may become more stringent prior to submission of our applications for approval or during the review of our applications due to changes in the law or changes in FDA policy or the adoption of new regulations. After submission of an application, the FDA may refuse to file the application, deny approval of the application or require additional testing or data. The FDA can convene an Advisory Committee to assist the FDA in examining specific issues related to the application. For example, we initially filed an NDA, for our Primatene MIST® product in July 2013, but FDA approval was not granted until November 2018 due to delays caused by the FDA's requirement that we provide additional non-clinical information, label revision and follow-up studies (including label comprehension and behavioral/human factor studies), and that we make packaging and label revisions. Additionally, we received Complete Response Letters, or CRLs, from the FDA asking for more information before they could approve the ANDA for our epinephrine vial product. These CRLs have delayed the approval of this product.

Under various user fee enactments, the FDA has committed to timelines for its review of NDAs, ANDAs, BLAs and biosimilar applications. However, the FDA's timelines described in its guidance on these statutes are flexible and subject to changes based on workload and other potential review issues that may delay the FDA's review of an application. Further, the terms of approval of any applications may be more restrictive than our expectations and could affect the marketability of our products.

The FDA also has the authority to revoke or suspend approvals of previously approved products for cause, to debar companies and individuals from participating in the approval process for ANDAs, to request recalls of allegedly violative products, to seize allegedly violative products, to obtain injunctions that may, among other things, close manufacturing plants that are not operating in conformity with cGMP and stop shipments of potentially violative products and to prosecute companies and individuals for violations of the FFDCA. In the event that the FDA takes any such action relating to our products or product candidates, such actions would have a material adverse effect on our operations and financial condition.

Clinical failure can occur at any stage of clinical development. The results of earlier clinical trials are not necessarily predictive of future results and any product candidate we advance through clinical trials may not have favorable results in later clinical trials or receive regulatory approval.

Clinical failure can occur at any stage of our clinical development. Clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Success in preclinical studies and

early clinical trials does not ensure that subsequent clinical trials will generate the same or similar results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in Phase 3 clinical trials, even after seeing promising results in earlier clinical trials.

In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well-advanced. Further, clinical trials of potential products often reveal that it is not practical or feasible to continue development efforts. If any of our product candidates are found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for them and our business would be harmed.

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in composition of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Our clinical trials may not demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. If we are unable to bring any of our current or future product candidates to market, or to acquire any marketed, previously approved products, our ability to create long-term stockholder value will be limited.

If clinical studies for our product candidates are unsuccessful or significantly delayed, we will be unable to meet our anticipated development and commercialization timelines, which would have an adverse impact on our business.

Some of our new drug candidates must be approved in NDAs based on clinical studies demonstrating safety and/or effectiveness. For these types of studies, we rely on our investigational teams, who mainly are medical experts working in multicenter hospitals, to execute our study protocols with our product candidates. As a result, we have less control over our development program than if we were to perform the studies entirely on our own. Third parties may not perform their responsibilities according to our anticipated schedule. Delays in our development programs could significantly increase our product development costs and delay product commercialization.

The commencement of clinical trials on our product candidates may be delayed for several reasons, including but not limited to delays in demonstrating sufficient pre-clinical safety required to obtain regulatory clearance to commence a clinical trial, reaching agreements on acceptable terms with prospective contract research organizations, clinical trial sites and licensees, manufacturing and quality assurance release of a sufficient supply of a product candidate for use in our clinical trials, delays in recruiting sufficient subjects for a clinical trial and/or obtaining institutional review board approval to conduct a clinical trial at a prospective clinical site. Once a clinical trial has begun, it may be delayed, suspended or terminated by us or by regulatory authorities for a variety of reasons, including without limitation ongoing discussions with regulatory authorities regarding the scope or design of our clinical trials, a determination by us or regulatory authorities that continuing a trial presents an unreasonable health risk to participants, failure to conduct clinical trials in accordance with regulatory requirements, lower than anticipated recruitment or retention rate of patients in clinical trials, inspection of the clinical trial operations or trial sites by regulatory authorities, the imposition of a clinical hold by the FDA, lack of adequate funding to continue clinical trials and/or negative or unanticipated results of clinical trials.

Patient enrollment, a significant factor in the time required to complete a clinical study, is affected by many factors, including the size and nature of the study subject population, the proximity of patients to clinical sites, the eligibility criteria for the study, the design of the clinical study, competing clinical studies and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to available alternatives, including without limitation therapies being investigated by other companies. Further, completion of a clinical study and/or the results of a clinical study may be adversely affected by failure to retain subjects who enroll in a study but withdraw due to, among other things, adverse side effects, lack of efficacy, improvement in condition before treatment has been completed or for personal issues or who fail to return for or complete post-treatment follow-up.

Changes in governmental regulations and guidance relating to clinical studies may occur and we may need to amend study protocols to reflect these changes. Protocol amendments may require us to resubmit protocols to institutional review boards for reexamination or renegotiate terms with contract research organizations and study sites and investigators, all of which may adversely impact the costs or timing of or our ability to successfully complete a trial.

Clinical trials required by the FDA for approval of our products may not produce the results we need to move forward in

product development or to submit or obtain approval of an NDA. Success in pre-clinical testing and early phase clinical trials does not assure that late phase clinical trials will be successful. Even if the results of any future Phase 3 clinical trials are positive, we may have to commit substantial time and additional resources to conduct further pre-clinical and clinical studies before we can submit NDAs or obtain FDA approval for our product candidates.

Clinical trials are expensive and at times difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Further, if participating subjects or patients in clinical studies suffer drug-related adverse reactions during the course of such trials, or if we or the FDA believes that participating patients are being exposed to unacceptable health risks, we may suspend the clinical trials. Failure can occur at any stage of the trials, and we could encounter problems that would cause us to abandon clinical trials and/or require additional clinical studies relating to a product candidate.

Even if our clinical trials and laboratory testing are completed as planned, their results may fail to provide support for approval of our products or for label claims that will make our products commercially viable.

Positive results in nonclinical testing and early phase clinical studies do not ensure that late phase clinical studies will be successful or that our product candidates will be approved by the FDA. To obtain FDA approval of our proprietary product candidates, we must demonstrate through nonclinical testing and clinical studies that each product is safe and effective for each proposed indication. Further, clinical study results frequently are susceptible to varying interpretations. Medical professionals, investors and/or regulatory authorities may analyze or weigh study data differently than we do. In addition, determining the value of clinical data typically requires application of assumptions and extrapolations to raw data. Alternative methodologies may lead to differing conclusions, including with respect to the safety or efficacy of our product candidates.

In addition, if we license rights to third parties to develop our product candidates in other geographic areas or for other indications, we may have limited control over nonclinical testing or clinical studies that may be conducted by such third-party licensees in those territories or for those indications. If data from third-party testing identifies a safety or efficacy concern, such data could adversely affect our or another licensee's development of such product.

There is significant risk that our products could fail to show anticipated results in nonclinical testing and/or clinical studies and, as a result, we may elect to discontinue the development of a product for a particular indication or altogether. A failure to obtain requisite regulatory approvals or to obtain approvals of the scope requested may delay or preclude us from marketing our products or limit the commercial use of the products, and would have a material adverse effect on our business, financial condition and results of operations.

The novel use of particle engineering or synthetic APIs for any of our product candidates, may not receive regulatory approval, and without regulatory approval we will not be able to market our product candidates.

We are engaging in particle engineering for certain product candidates and there is no guarantee that we will obtain regulatory approval or, upon commercialization, market acceptance of these products.

The development of a product candidate and issues relating to its approval and marketing are subject to extensive regulations by the FDA in the U.S. and regulatory authorities in other countries, with regulations differing from country to country. We are not permitted to market our product candidates in the U.S. until we receive approval of an NDA from the FDA. NDA approvals may require extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. NDAs must include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. If we submit an NDA to the FDA, the FDA must decide whether to accept or reject the submission for filing. Any submissions may not be accepted for filing and review by the FDA. Even if a product is approved, the FDA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require additional expensive and time-consuming post-approval clinical trials or reporting as conditions of approval. Regulators of other countries and jurisdictions have their own procedures for approval of product candidates with which we must comply prior to marketing in those countries or jurisdictions. Obtaining regulatory approval for marketing of a product candidate in one country does not necessarily ensure that we will be able to obtain regulatory approval in any other country.

In addition, delays in approvals or rejections of marketing applications in the U.S. or other countries may be based upon many factors, including regulatory requests for additional analyses, reports, data, preclinical studies and clinical trials,

regulatory questions regarding different interpretations of data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding our product candidates or other products. Also, regulatory approval for any of our product candidates may be withdrawn.

We also have plans to develop synthetic APIs. Our ongoing trials and studies may not be successful or regulators may not agree with our conclusions regarding the preclinical studies and clinical trials we have conducted to date or approve the use of such synthetic APIs.

If we are unable to obtain approval from the FDA or other regulatory agencies for our product candidates or synthetic APIs, we will not be able to market such product candidates and our ability to achieve profitability may be materially impaired.

A fast track designation by the regulatory agencies, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.

We do not currently have fast track designation for any of our product candidates. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for fast track designation. The FDA has broad discretion whether or not to grant this designation. Even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive fast track designation, we may not experience a faster development process, review or approval compared to conventional procedures adopted by the FDA. In addition, the FDA may withdraw fast track designation if they believe that the designation is no longer supported by data from our clinical development program or if a competitor's product candidate is approved. For example, we were granted a fast track designation for our intranasal naloxone product, but this designation was withdrawn after a competitor's intranasal naloxone was approved. Many drugs that have received fast track designation have failed to obtain FDA approval.

The commercial success of our NDA product candidates will depend in significant measure on the scope of the indication(s) and claims that the FDA approves for such products.

The scientific foundation of our NDA product candidates will be based on our various proprietary technologies and the commercial success of these product candidates will depend in significant measure upon our ability to obtain FDA approval of labeling describing such products' indication(s) and expected features or benefits. Failure to achieve FDA approval of product labeling containing adequate information on features or benefits will prevent or substantially limit our advertising and promotion of such features in order to differentiate our proprietary technologies from those products that already exist in the market. This failure would have a material adverse impact on our business.

Our ANDA products are also subject to FDA approval of their labeling and the labeling of the referenced drug products.

Even if we are able to obtain regulatory approval for our generic products, state pharmacy boards or state agencies may conclude that our products are not substitutable at the pharmacy level for the reference listed drug. If our generic products are not substitutable at the pharmacy level for their reference listed drugs, or if our drug products do not gain the acceptance of healthcare providers, payors, and patients, this could materially reduce sales of our products and our business would suffer.

Although the FDA may determine that a generic product is therapeutically equivalent to a brand product and indicate this therapeutic equivalence by providing it with an "A" rating in the FDA's Orange Book, this designation is not binding on state pharmacy boards or state agencies. As a result, in states that do not deem our product candidates substitutable at the pharmacy level, physicians may be required to specifically prescribe our product or a generic product alternative in order for our product to be dispensed. Should this occur with respect to one of our generic product candidates, it could materially reduce sales in those states, which would substantially harm our business. Further, to the extent patients or their physicians are slow to adopt our generic products or do not consider our generic products as therapeutically equivalent, physicians may prescribe the branded products or otherwise instruct pharmacists to not substitute for our generic products, which would substantially harm our business.

Our investments in biosimilar products may not result in products that are approved by the FDA or other foreign regulatory authorities and, even if approved by such authorities, may not result in commercially successful products.

We plan to build on our existing platforms to produce biosimilar products in the future. In 2010, Congress amended the PHSA to create an abbreviated approval pathway for follow-on biologics. This approval pathway is available for "biosimilar" products, which are products that are highly similar to previously approved biologics notwithstanding minor differences in inactive components. The process for bringing a biosimilar product to market is uncertain and may be drawn out for an extended period of time. Approval of biosimilar applications may be delayed by exclusivity on the BLA for the reference product for up to 12 years. Biosimilar applicants are also subjected to a patent resolution process that will require biosimilar applicants to share the contents of their application and information concerning its manufacturing processes with counsel for the company holding the BLA for the reference drug and to engage in a patent litigation process that could delay or prevent the commercial launch of a product for many years.

Biosimilar products are not presumed to be substitutable for the reference drug under the Biologics Price Competition and Innovation Act, or BPCIA. Biosimilar applicants must seek a separate FDA determination that they are "interchangeable" with the reference drug, meaning that they can be expected to produce the same clinical result in any given patient without an increase in risk due to switching from the brand product. The first interchangeable biosimilar product, an insulin glargine product, was approved in July 2021. The statutory standards for determining biosimilarity and interchangeability are broad and subject to change, and the FDA has broad discretion to determine the nature and extent of product characterization, nonclinical testing and clinical testing on a product-by-product basis.

Products approved based on biosimilarity without an FDA determination of interchangeability may not be substitutable at the retail pharmacy level. Some states have passed laws limiting pharmacy substitution to biosimilar products that the FDA has determined to be interchangeable, as well as restrictions on the substitution of interchangeable biosimilar products. These restrictions include, among other things, requirements for informing the patient and the prescribing physician of the substitution or proposed substitution, authority for the prescribing physician and the patient to preclude substitution and recordkeeping requirements. There is no certainty that other states will not impose similar restrictions or that states will not impose further restrictions or preclude substitution of interchangeable biosimilar products entirely.

Our competitive advantage in this area will depend on our success in demonstrating to the FDA that platform technology provides a level of scientific assurance that facilitates determinations of interchangeability, reduces the need for expensive clinical or other testing and raises the scientific quality requirements for our competitors to demonstrate that their products are highly similar to a brand product. Our ability to succeed will depend in part on our ability to invest in new programs and develop data in a timeframe that enables the FDA to consider our approach as the FDA begins to implement the new law. BLA holders will develop strategies and precedents for delaying or impeding approvals of biosimilar products and determinations of interchangeability. For example, the lengthy 12-year exclusivity protection provides the BLA holder for the reference drug with an opportunity to develop and replace its original product with a modified product that may avoid a determination of interchangeability and that may qualify for an additional 12-year marketing exclusivity period, reducing the potential opportunity for substitution at the retail pharmacy level for interchangeable biosimilars. As brand and biosimilar companies gain greater understanding of and experience with the new regulatory pathway, we expect to see new and unexpected company strategies, FDA decisions and court decisions that will pose unexpected challenges that will prevent, delay or make more difficult biosimilar approvals.

In addition, the BPCIA was passed as part of the Affordable Care Act. If the Affordable Care Act is amended or is repealed with respect to the biosimilar approval pathway, our opportunity to develop biosimilars (including interchangeable biologics) could be materially impaired and our business could be materially and adversely affected.

Some of our products are used with drug delivery or companion diagnostic devices which have their own regulatory, manufacturing, reimbursement and other risks.

Some of our products or product candidates may be used in combination with a drug delivery device, such as an injector, inhaler or other delivery system. Although the drug delivery devices we currently use in our products and product candidates are provided by third parties, we have entered into collaboration agreements with various medical device manufacturers to develop drug delivery systems to be used for our pipeline products. These drug-device combination products are particularly complex, expensive and time-consuming to develop due to the number of variables involved in the final product design, including ease of patient and doctor use, establishing clinical efficacy, reliability and cost of manufacturing, regulatory approval requirements and standards and other important factors. We will be responsible for any regulatory filings arising from this collaboration and, although we have significant in-house and external regulatory

expertise, we have never prepared or submitted an NDA to the FDA for a drug-device combination product. Our product candidates intended for use with such drug delivery, or expanded indications that we may seek for our products used with such devices, may not be approved or may be substantially delayed in receiving approval if the devices do not gain and/or maintain their own regulatory approvals or clearances. Where approval of the drug product and device is sought under a single application, the increased complexity of the review process may delay approval.

Some of the drug delivery devices utilized in our products and product candidates are provided by single source unaffiliated third-party companies. We are dependent on the sustained cooperation and effort of those third-party companies both to supply the devices and to maintain regulatory compliance with the FDA quality system regulations applicable to medical device, and, in some cases, to conduct the studies required for approval or other regulatory clearance of the devices. We are also dependent on those third-party companies continuing to maintain such approvals or clearances once they have been received. Failure of third-party companies to supply the devices, to successfully complete studies on the devices in a timely manner, or to obtain or maintain required approvals or clearances of the devices could result in increased development costs, delays in or failure to obtain regulatory approval and delays in product candidates reaching the market or in gaining approval or clearance for expanded labels for new indications. We filed a Field Alert Report for enoxaparin in June 2013, as required by the FDA for certain quality issues with safety implications, because the product did not meet functionality criteria. The needle-shielding component was breaking during shipping, preventing correct administration of the medication. While the specific issues related to this Field Alert Report were resolved, we may experience similar issues in the future. In addition, loss of regulatory approval or clearance of a device that is used with our product may result in the removal of our product from the market.

The drug delivery devices used with our products are also subject to many of the same reimbursement risks and challenges to which our products are subject. A reduction in the availability of, or the coverage and/or reimbursement for, drug delivery devices used with our products could have a material adverse effect on our product sales, business and results of operations.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions. Failure to obtain regulatory approval in foreign jurisdictions would prevent our product candidates from being marketed abroad.

In addition to regulations in the United States, to market and sell our products in the European Union, many Asian countries and other jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements, both from a clinical and manufacturing perspective. Approval by the FDA does not ensure approval by regulatory or payor authorities in other countries or jurisdictions, and approval by one regulatory or payor authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. A product candidate that has been approved for sale in a particular country may not receive reimbursement approval in that country. We may not be able to obtain approvals from regulatory authorities or payor authorities outside the United States on a timely basis, if at all.

Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we are unable to obtain approval of any of our product candidates by regulatory or payor authorities in the European Union, Asia or elsewhere, or if we fail to comply with the regulatory requirements in foreign jurisdictions, the commercial prospects of that product candidate may be significantly diminished, and our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials, which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries.

Further, in Europe, the implementation of the Clinical Trials Regulation depends on confirmation of full functionality of the Clinical Trials Information System (CTIS) through an independent audit, which commenced in September 2020. This new clinical trial portal and database will be maintained by the EMA in collaboration with the European Commission and the European Union Member States. The objectives of the new regulation include consistent rules for conducting trials throughout the European Union, consistent data standards and adverse events listing, and consistent information on the authorization status. Information on the conduct and results of each clinical trial carried out in the European Union will be made publicly available. In addition, a new pan-European clinical trial data information database has been created that will be complementary to the database established for pharmacovigilance (Regulation (EC) No 726/2004 with respect to centrally authorized medicinal products). The Commission Implementing Regulation (EU) No 520/2012 outlines the practical implications for marketing authorization holders, national competent authorities, and the EMA. Also, Commission Delegated Regulation (EU) No 357/2014 on post-authorization efficacy studies specifies the situations in which such studies may be required. Post-authorization efficacy studies may be required where concerns relating to some aspects of efficacy of the medicinal product are identified and can be resolved only after the medicinal product has been marketed, or where the understanding of the disease, the clinical methodology or the use of the medicinal product under real-life conditions indicate that previous efficacy evaluations might have to be revised significantly. Brexit is also expected to disrupt the operation of pre- and post-authorization clinical trial infrastructure. The rules around GMP and pharmacovigilance in the UK currently remain similar to the EU requirements, but new UK-specific requirements or changes to current requirements could be implemented in the future, which could expose us to liability under UK-specific laws and regulations and increased costs associated with compliance with such new laws and regulations. Within the UK, requirements for clinical trials, marketing authorization, and post-approval compliance in Great Britain may differ from those of Northern Ireland, Scotland, and/or Wales. Satisfying these and other regulatory requirements can be costly, time consuming, uncertain and subject to unanticipated delays.

In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or fail to obtain and maintain required approvals, our ability to realize the full market potential of our products will be harmed.

Uncertainty in the regulatory framework and future legislation can lead to disruption in the execution of international multi-center clinical trials, the monitoring of adverse events in through pharmacovigilance programs, the evaluation of the benefit-risk profiles of new medicinal products, and determination of marketing authorization across different jurisdictions. There could also be disruption to the supply and distribution as well as the import/export both of active pharmaceutical ingredients and finished product. Such a disruption could create supply difficulties for ongoing clinical trials and may damage the integrity of the pharmacovigilance database for the safety of new products. The cumulative effects of the disruption to the regulatory framework, uncertainty in future regulation, and changes to existing regulations may add considerably to the development lead time to marketing authorization and commercialization of products in the European Union and/or the United Kingdom and increase our costs. We cannot predict the impact of such changes and future regulation on our business or the results of our operations.

If branded pharmaceutical companies are successful in limiting the use of generics through their legislative, regulatory and/or other efforts, our sales of generic products may suffer.

Many pharmaceutical companies producing proprietary drugs have increasingly used state and federal legislative and regulatory means to delay, impede and/or prevent generic competition. These efforts have included but are not limited to the following:

- making changes to the formulation of their product and arguing that potential generic competitors must demonstrate bioequivalence and/or comparable abuse-resistance to the reformulated brand product;

- pursuing new patents for existing products which may be granted immediately prior to the expiration of earlier patents, which could extend patent protection for additional years or otherwise delay the launch of generics;
- selling the brand product as an authorized generic, either by the brand company directly, through an affiliate, or by a marketing partner;
- using the FDA's Citizen Petition process to request amendments to FDA standards or otherwise delay generic drug approvals;
- challenging FDA denials of Citizen Petitions in court and seeking injunctive relief to reverse approval of generic drug applications;
- seeking changes to standards in the U.S. Pharmacopeia/National Formulary, which are compendial drug standards that are recognized by industry and, in some instances, are enforceable under the FFDCA;
- attempting to use the legislative and regulatory process to have drugs reclassified or rescheduled by the DEA;
- using the legislative and regulatory process to set standards and requirements for abuse deterrent formulations that are patented or that will otherwise impede or prevent generic competition;
- seeking special patent-term extensions through amendments to non-related federal legislation;
- engaging in initiatives to enact state legislation that would restrict the substitution of certain generic drugs, including products that we are developing;
- entering into agreements with pharmacy benefit management companies that block the dispensing of generic products;
- seeking patents on methods of manufacturing certain API;
- settling patent lawsuits with generic companies in a manner that leaves the patent as an obstacle for approval of other companies' generic drugs;
- settling patent litigation with generic companies in a manner that avoids forfeiture of or otherwise protects or extends the exclusivity period;
- providing medical education or other information to physicians, third-party payers and federal and state regulators that take the position that certain generic products are inappropriate for approval or for substitution after approval;
- seeking state law restrictions on the substitution of generic and biosimilar products at the pharmacy level without the instruction or permission of a physician; and
- seeking federal or state regulatory restrictions on the use of the same non-proprietary name as the reference brand product for a biosimilar or interchangeable biologic.

If pharmaceutical companies or other third parties are successful in limiting the use of generic products through these or other means, our sales of generic products may decline. If we experience a material decline in generic product sales, our results of operations, financial condition and cash flows will suffer.

Our revenues may be adversely affected if we fail to obtain insurance coverage or adequate reimbursement for our products from third-party payers and administrators.

Our ability to successfully commercialize our products may depend in part on the availability of reimbursement for and insurance coverage of our prescription products from government health administration authorities, private health insurers and other third-party payers and administrators, including Medicaid and Medicare. Third-party payers and administrators, including state Medicaid programs and Medicare, have been challenging the prices charged for

pharmaceutical products. Government and other third-party payers increasingly are limiting both coverage and the level of reimbursement for new drugs. Third-party insurance coverage may not be available to patients for some of our products candidates. The continuing efforts of government and third-party payers to contain or reduce the costs of health care may limit our commercial opportunity. If government and other third-party payers do not provide adequate coverage and reimbursement for certain of our products, health care providers may not prescribe them or patients may ask their health care providers to prescribe competing products with more favorable reimbursement.

Managed care organizations and other private insurers frequently adopt their own payment or reimbursement reductions. Consolidation among managed care organizations has increased the negotiating power of these entities. Private third-party payers, as well as governments, increasingly employ formularies to control costs by negotiating discounted prices in exchange for formulary inclusion. While these approaches generally favor generic products over brands, generic competition is stronger. Our existing products and our product candidates include proprietary products and generic products. Failure to obtain timely or adequate pricing or formulary placement for our products or obtaining such pricing or placement at unfavorable pricing could adversely impact revenue. In addition to formulary tier co-pay differentials, private health insurance companies and self-insured employers have been raising co-payments required from beneficiaries, particularly for proprietary pharmaceuticals and biotechnology products. Private health insurance companies also are increasingly imposing utilization management tools, such as requiring prior authorization for a proprietary product if a generic product is available or requiring the patient to first fail on one or more generic products before permitting access to a proprietary medicine. We do not currently have any managed care organization agreements and do not intend to have managed care organization agreements in the future.

We must manufacture our drug products at our facilities in conformity with cGMP regulations; failure to maintain compliance with cGMP regulations may prevent or delay the manufacture or marketing of our products or product candidates and may prevent us from gaining approval of our products.

All of our products and product candidates for use in clinical studies must be manufactured, packaged, labeled and stored in accordance with cGMP. For our approved products, modifications, enhancements, or changes in manufacturing processes and sites may require supplemental FDA approval, which may be subject to a lengthy application process or which we may be unable to obtain.

All facilities of Amphastar and our subsidiaries are periodically subject to inspection by the FDA and other governmental entities, and operations at these facilities could be interrupted or halted if the FDA or another governmental entity deems such inspections as unsatisfactory. For example, our facilities in Rancho Cucamonga, CA, South El Monte, CA and Nanjing, China were all subject to FDA cGMP inspections during 2019 as well as pre-approval, routine and other inspections by the FDA, state, and other regulatory authorities in the future per applicable law. Products manufactured in our facilities must be made in a manner consistent with cGMP or similar standards in each territory in which we manufacture. Compliance with such standards requires substantial expenditures of time, money and effort in such areas as production and quality control to ensure full technical compliance. Failure to comply with cGMP or with other state, federal, or foreign requirements may result in unanticipated compliance expenditures, total or partial suspension of production or distribution, suspension of review of applications submitted for approval of our product candidates, termination of ongoing research, disqualification of data derived from studies on our products and/or enforcement actions such as recall or seizure of products, injunctions, civil penalties and criminal prosecutions of the company and company officials. Any suspension of production or distribution would require us to engage contract manufacturing organizations to manufacture our products or to accept a hiatus in marketing our products. Any contract manufacturing organization we engage will require time to learn our methods of production and to scale up to full production of our products in accordance with cGMP requirements. Any delays caused by the transfer of manufacturing to a contract manufacturing organization may have a material adverse effect on our results of operations. Additionally, any contract manufacturing organization that we engage will be subject to the same cGMP regulations as us, and any failure on their part to comply with FDA or other governmental regulations will result in similar consequences.

Our operations are subject to environmental, health and safety and other laws and regulations, with which compliance is costly and which exposes us to penalties for non-compliance.

Our business, products and product candidates are subject to federal, state and local laws and regulations relating to the protection of the environment, natural resources and worker health and safety and the use, management, storage and disposal of hazardous substances, waste and other regulated materials. Because we own and operate real property, various environmental laws also may impose liability on us for the costs of cleaning up and responding to hazardous substances that may have been released on our property, including releases unknown to us. These environmental laws

and regulations also could require us to pay for environmental remediation and response costs at third-party locations where we dispose of or recycle hazardous substances. The costs of complying with these various environmental requirements, as they now exist or as may be altered in the future, could adversely affect our financial condition and results of operations. For example, as a result of environmental concerns about the use of CFCs, the FDA issued a final rule on January 16, 2009 that required the phase-out of the CFC version of our Primatene MIST® product by December 31, 2011. This phase out caused us to discontinue sales of the CFC version of our Primatene MIST® product subsequent to December 31, 2011 and write off our inventory for the product, which had an adverse effect on our financial results.

Similarly, on December 27, 2020, the American Innovation in Manufacturing Act of 2020, or AIM Act, was enacted. The AIM Act directs the United States Environmental Protection Agency to address usage of hydrofluorocarbons, or HFC, by reducing production and consumption of certain HFCs. One of our products, Primatene MIST®, utilizes HFCs subject to the AIM Act's reduction mandate. Moreover, many of our inhalation pipeline assets use HFCs subject to the AIM Act's reduction mandate. There can be no assurance that we will be able to acquire adequate supplies of HFCs for current and future commercialization of our products as a result of the AIM Act or other similar statutes and regulations. Moreover, changes to the ingredients of our proprietary and generic products requires FDA approval and there can be no assurance that we will be able to obtain such approval or the timing of such approval.

The Affordable Care Act and certain legislation and regulatory proposals may increase our costs of compliance and negatively impact our profitability over time.

In March 2010, former President Barack Obama signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, which we refer to collectively as the Affordable Care Act. The Affordable Care Act made extensive changes to the delivery of health care in the United States. We expect that the rebates, discounts, taxes and other costs resulting from the Affordable Care Act over time will have a negative effect on our expenses and profitability in the future. Furthermore, the Independent Payment Advisory Board created by the Affordable Care Act to reduce the per capita rate of growth in Medicare spending could potentially limit access to certain treatments or mandate price controls for our products. Moreover, expanded government investigative authority and increased disclosure obligations may increase the cost of compliance with new regulations and programs.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, or ACA. In June 2021, the United States Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case without specifically ruling on the constitutionality of the ACA. Accordingly, the ACA remains in effect in its current form. It is unclear how this Supreme Court decision, future litigation, or healthcare measures promulgated by the Biden administration will impact our business, financial condition and results of operations. Complying with any new legislation or changes in healthcare regulation could be time-intensive and expensive, resulting in material adverse effect on our business.

In addition, there have been a number of other legislative and regulatory proposals aimed at changing the pharmaceutical industry. For example, in November 2013, Congress passed the Drug Quality and Security Act, or the DQSA. The DQSA establishes federal pedigree tracking standards requiring drugs to be labeled and tracked at the lot level, preempts state drug pedigree requirements, and will eventually require all supply-chain stakeholders to participate in an electronic, interoperable prescription drug track and trace system. The DQSA also establishes new requirements for drug wholesale distributors and third party logistics providers, including licensing requirements in states that had not previously licensed such entities. As a result of these and other new proposals, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could have a material adverse effect on our business, financial condition and results of operations.

Former President Barack Obama also signed into law the Food and Drug Administration Safety and Innovation Act. The law and related agreements make several significant changes to the FFDCA and FDA's processes for reviewing marketing applications that could have a significant impact on the pharmaceutical industry, including, among other things, the following:

- reauthorizes the Prescription Drug User Fee Act, which increases the amount of associated user fees, and, for certain types of applications, increases the expected time frame for FDA review of NDAs;

- permanently reauthorizes and makes some revisions to the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act, which provide for pediatric exclusivity and mandated pediatric assessments for certain types of applications, respectively;

- revises certain standards and requirements for FDA inspections of manufacturing facilities and the importation of drug products from foreign countries;
- creates incentives for the development of certain antibiotic drug products;
- modifies the standards for accelerated approval of certain new medical treatments;
- expands the reporting requirements for potential and actual drug shortages;
- requires the FDA to issue a report on, among other things, ensuring the safety of prescription drugs that have the potential for abuse;
- requires the FDA to hold a public meeting regarding the potential rescheduling of drug products containing hydrocodone, which was held in October 2012; and
- requires electronic submission of certain marketing applications following the issuance of final FDA regulations.

The full impact of new laws and regulations and changes to any existing regulations by the Biden administration is uncertain; however, we anticipate that it will have an adverse effect on our results of operations.

There has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs will be eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at increasing competition for prescription drugs. In August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. The impact of these legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the Biden administration on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our approved products.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, in September 2020, the Governor of California signed legislation that brings California one step closer to establishing its own generic drug label, which could have significant impact on the generic drug industry and generic drug pricing. A number of states are also considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws.

Additionally, we encounter similar regulatory and legislative issues in most other countries. In the European Union, or EU, and some other international markets, the government provides health care at low cost to consumers and regulates pharmaceutical prices, patient eligibility or reimbursement levels to control costs for the government-sponsored health care system. This international system of price regulations may lead to inconsistent prices.

If significant additional reforms are made to the U.S. health care system, or to the health care systems of other markets in which we operate, those reforms could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Complying with laws in the U.S., Europe, and other jurisdictions that impose restrictive regulations addressing the collection, use, and other processing of personal information may be expensive, and failure to comply with such laws and regulations could cause substantial harm to our business.

We also must comply with data protection, security and privacy requirements. Compliance with laws, rules and regulations regarding privacy, security and protection of personal information, including about our personnel, business partners, and others, could result in higher compliance and technology costs for us. Significant fines, penalties, damages and harm to our global reputation and our brand could result from actual or perceived non-compliance.

We collect, process, use, store, transmit and transfer personal information from individuals located in the EU in connection with our business. The collection, processing, storage, transmission, transfer and use of personal information in the EU are governed by the provisions of the General Data Protection Regulation ((EU) 2016/679), or the GDPR. This legislation imposes requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside of the European Economic Area, to third countries that have not been found to provide adequate protection to such personal information, including to the U.S., providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal information to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments and record-keeping. The GDPR imposes significant responsibilities and liabilities in relation to personal information that we process, and we may be required to put in place additional mechanisms designed to comply with the GDPR. Failure to comply with the requirements of the GDPR and related national data protection laws of the member states of the EU may result in investigations, substantial fines up to the greater of €20 million or 4% of annual global turnover, civil claims, and damages being brought against us, which could have a material adverse effect on our business, financial condition and results of operations.

While the GDPR applies uniformly across the EU, each EU member State is permitted to issue nation-specific data protection legislation, which has created inconsistencies on a country-by country basis. Further, the United Kingdom's exit from the EU, often referred to as Brexit, and ongoing developments in the United Kingdom have created further uncertainty with regard to the regulation of data protection and privacy in the United Kingdom. The United Kingdom has implemented legislation that substantially implements the GDPR, and the European Commission and issued an adequacy decision under the GDPR and the Law Enforcement Directive on June 28, 2021, pursuant to which personal information generally may be transferred from the EU to the United Kingdom without restriction; however, this adequacy decision is subject to a four-year "sunset" period, after which the European Commission's adequacy decision may be renewed. During that period, the European Commission will monitor the legal situation in the United Kingdom and may intervene at any time with respect to its adequacy decision. The United Kingdom's adequacy determination therefore is subject to future uncertainty and may be subject to modification or revocation in the future, with the United Kingdom potentially being considered an inadequate third country under the GDPR and transfers of personal information from the European Economic Area to the United Kingdom will require a transfer mechanism. Furthermore, there will be increasing scope for divergence in application, interpretation and enforcement of the data protection law as between the United Kingdom and European Economic Area.

In addition, U.S. states are adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements related to personal information. For example, California enacted the California Consumer Privacy Act, or the CCPA, on June 28, 2018, which took effect on January 1, 2020 and has been dubbed the first "GDPR-like" law in the United States. The CCPA gives California residents, among other things, expanded rights to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA also provides for civil penalties for violations, as well as a private right of action for certain data breaches that may increase data breach litigation. The CCPA will be expanded substantially on January 1, 2023 when the California Privacy Rights Act of 2020, or the CPRA, which was approved by California voters in November 2020, becomes fully operative. The CPRA will, among other things, give consumers the ability to limit use of information deemed to be sensitive, establish the California Privacy Protection Agency to implement and enforce the CPRA and impose administrative fines. Aspects of the CCPA and CPRA, and their interpretation and enforcement remain uncertain. The potential effects of the CCPA and CPRA are far-

reaching and may require us to modify our data processing practices and policies and to incur substantial costs and expenses in an effort to comply.

The CCPA and CPRA could mark the beginning of a trend toward more stringent data protection, security and privacy legislation in the U.S. The CCPA has prompted a number of proposals for federal and state privacy legislation. For example, in March 2021, Virginia enacted the Virginia Consumer Data Protection Act, or CDPA, a comprehensive privacy statute that became effective on January 1, 2023 and shares similarities with the CCPA and the CPRA, but also imposes security and assessment requirements for businesses. In addition, on July 7, 2021, Colorado enacted the Colorado Privacy Act, or CPA, which closely resembles the CDPA. Also, in March 2022, Utah enacted the Utah Consumer Privacy Act, which becomes effective on December 31, 2023, and in May 2022, Connecticut enacted the Act Concerning Personal Data and Online Monitoring, which becomes effective on July 1, 2023, both of which differ from the CPRA, CDPA, and CPA. These new state privacy laws will be enforced by the respective states' Attorney General and/or district attorneys. Similar laws have been proposed in other states and at the federal level, reflecting a trend toward more stringent data protection, security and privacy legislation in the U.S. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging.

We may also publicly post privacy policies and other documentation regarding our collection, use, storage, transmission, transfer and other processing of personal information. Although we endeavor to comply with our public policies and documentation, we may at times fail to do so or be alleged to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our employees or contractors fail to comply with our published policies and documentation. Such failures can subject us to potential regulatory action if they are found to be deceptive, unfair or misrepresentative of our actual practices.

Additionally, other jurisdictions are considering new or expanded laws or regulations relating to privacy, security and data protection. With these laws, regulations and other obligations relating to privacy, security and data protection imposing new and relatively burdensome obligations, which may be inconsistent between jurisdictions or in conflict with each other due to differing applications and interpretations, and with substantial uncertainty over further interpretation and application of these and other obligations, we may face challenges in addressing their requirements, putting in place additional compliance mechanisms and making necessary changes to our policies, contracts and practices, and may incur significant costs and expenses in an effort to do so. Additionally, if we or third parties we work with, such as our third-party providers, violate applicable laws or regulations or our policies, such violations may also put our data at risk and could in turn have an adverse effect on our business. Any failure or perceived failure by us or our service providers to comply with our applicable policies or notices relating to privacy, security or data protection, our contractual or other obligations to third parties, or any of our other legal obligations relating to privacy, security or data protection, may result in public criticism, governmental investigations or enforcement actions, litigation, claims and other proceedings, and could result in significant fines, penalties, and other liability. Additionally, defending against any claims, litigation, regulatory proceedings, or other proceedings can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions or proceedings that may be brought against us, our business may be impaired, and we may suffer reputational and other harm.

Our products may be subject to federal and state laws and certain initiatives relating to cost control, which may decrease our profitability.

In the U.S., we expect there may be federal and state proposals for cost controls. We expect that increasing emphasis on managed care in the U.S. will continue to put pressure on the pricing of pharmaceutical products. In addition, we are required to pay rebates to states, which are generally calculated based on the prices for our products that are paid by state Medicaid programs. Cost control initiatives could decrease the price that we charge, and increase the rebate amounts that we must provide, for any of our products in the future. Further, cost control initiatives could impair our ability to commercialize our products and our ability to earn significant revenues from commercialization. The continuing efforts of the government, insurance companies, managed care organizations, and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our products, if we obtain regulatory approval;
- our ability to receive or set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;

- the level of taxes that we are required to pay; and

- the availability of capital.

In the U.S., all of our pharmaceutical products are subject to increasing pricing pressures. Such pressures have increased as a result of the Medicare Prescription Drug Improvement and Modernization Act of 2003, or the MMA, due to the enhanced purchasing power of the private sector plans that negotiate on behalf of Medicare beneficiaries. For example, in November 2021, the Biden administration also announced a prescription drug plan in Build Back Better framework, which proposes allowing Medicare to negotiate prescription drug prices, imposing a tax penalty if drug companies increase their prices faster than inflation, and directly lowering out-of-pocket costs for seniors. In August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. The impact of these legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the Biden administration on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our approved products.

Our reporting and payment obligations under the Medicare and/or Medicaid drug rebate programs and other governmental purchasing and rebate programs are complex and may involve subjective decisions that could change as a result of new business circumstances, new regulatory guidance or advice of legal counsel. Any determination of failure to comply with those obligations could subject us to penalties and sanctions which could have a material adverse effect on our business, financial position and results of operations and the market value of our common stock could decline.

The regulations regarding reporting and payment obligations with respect to Medicare and/or Medicaid reimbursement and rebates and other governmental programs are complex. Because our processes for these calculations and the judgments involved in making these calculations involve, and will continue to involve, subjective decisions and complex methodologies, these calculations are subject to the risk of errors. In addition, they are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could result in material changes.

In January 2016, the Centers for Medicare and Medicaid Services, or CMS, issued a final rule that helped to clarify many of the changes made to the Medicaid Drug Rebate Program by the Affordable Care Act. The final rule attempts to provide drug manufacturers with the regulatory guidance necessary to ensure proper calculation and reporting of drug product and pricing information. Specifically, the final rule attempts to clarify the definition of what constitutes a manufacturer's "best price" and aligns it, where appropriate, to the definition of "Average Manufacturer Price", which is used to calculate drug rebates. Notwithstanding the final rule's guidance, a number of state and federal government agencies will continue to conduct investigations of manufacturers' reporting practices with respect to Average Wholesale Prices, or AWP, in which reports of inflated AWP may lead to excessive payments for prescription drugs. These investigations could have a material adverse effect on our business, financial position and results of operations. Under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs will be eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. In August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. The impact of these legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the Biden administration on us and the pharmaceutical industry as a whole is unclear.

Any governmental agencies that have commenced, or may commence, an investigation of our business relating to the sales, marketing, pricing, quality or manufacturing of pharmaceutical products could seek to impose, based on a claim of

violation of fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties and possible exclusion from federal health care programs including Medicare and/or Medicaid. Some of the applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity with regard to how to properly calculate and report payments — and even in the absence of any such ambiguity — a governmental authority may take a position contrary to a position we have taken, and may impose civil and/or criminal sanctions. Any such penalties or sanctions could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

We may be subject to enforcement action if we engage in the off-label promotion of our products.

Our promotional materials and training methods must comply with the FFDCA and other applicable laws and regulations, including restraints and prohibitions on the promotion of off-label, or unapproved, use. Physicians may prescribe our products for off-label use without regard to these prohibitions, as the FFDCA does not restrict or regulate a physician's choice of treatment within the practice of medicine. However, if the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including but not limited to the issuance of an untitled letter or warning letter, and a judicial action seeking injunction, product seizure and civil or criminal penalties. It is also possible that other federal, state or non-U.S. enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products could be impaired. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us and harm our reputation.

The pharmaceutical industry is highly regulated and pharmaceutical companies are subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act.

Healthcare fraud and abuse regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include:

- the federal Anti-kickback statue, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new 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 payor (e.g., public or private) and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security, and transmission of individually identifiable health information;

- the FFDCA and similar laws regulating advertisement and labeling;

- the federal Physician Payment Sunshine Act, created under the ACA, and its implementing regulations, require applicable manufacturers of drugs, devices, biologicals, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services under the Open Payments Program, information related to certain payments and other transfers of value made in the previous year to physicians (defined to include doctors of medicine and osteopathy, dentists, podiatrists, optometrists and licensed chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others), and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members;

- the U.S. Foreign Corrupt Practices Act, which prohibits corrupt payments, gifts or transfers of value to non-U.S. officials;

- non-U.S. and U.S. state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers;

- state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines, and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources;

- state and local laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration, and items of value provided to healthcare professionals and entities;

- state and local laws that require the registration of pharmaceutical sales representatives; and

- state and foreign laws also govern the privacy, protection and security of personal information (including health information) in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

The federal false claims laws have been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers or formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Most states also have statutes or regulations similar to the federal anti-kickback law and federal false claims laws, which apply to items and services covered by Medicaid and other state programs, or, in several states, apply regardless of the type of payer. Administrative, civil and criminal sanctions may be imposed under these federal and state laws. In addition, we are also subject to federal and state consumer protection and unfair competition laws that broadly regulate marketplace activities and activities that potentially harm consumers.

Further, the Affordable Care Act, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity can now be found guilty under the Affordable Care Act without actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. Possible sanctions for violation of these anti-kickback laws include monetary fines, civil and criminal penalties, imprisonment, exclusion from federal health care programs and forfeiture of amounts collected in violation of such prohibitions. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

To enforce compliance with the federal laws, the U.S. Department of Justice, or DOJ, has increased its scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Dealing with investigations can be time- and resource-consuming and can divert management's attention from the business. Additionally, if a healthcare provider

settles an investigation with the DOJ or other law enforcement agencies, we may be forced to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

Over the past few years, a number of pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates.

In addition, there has been a trend of increased federal and state regulation of payments made to physicians for marketing. Some states, such as California, Massachusetts and Vermont, mandate implementation of commercial compliance programs, along with the tracking and reporting of gifts, compensation and other remuneration to physicians. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may run afoul of one or more of the requirements.

If the activities of any of our business partners are found to be in violation of these laws or any other federal and state fraud and abuse laws, they may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of its activities with regard to the commercialization of our products, which could harm the commercial success of our products and materially affect our business, financial condition and results of operations. While we have implemented numerous risk mitigation measures to comply with such regulations in this complex operating environment, we cannot guarantee that we will be able to effectively mitigate all operational risks. While we have developed and instituted a corporate compliance program, we cannot guarantee that we, our employees, our consultants or our contractors are or will be in compliance with all potentially applicable U.S. federal and state regulations and/or laws, all potentially applicable foreign regulations and/or laws and/or all requirements of the corporate integrity agreement. Because of the far-reaching nature of these laws, we may be required to alter or discontinue one or more of our business practices to be in compliance with these laws. If we fail to adequately mitigate our operational risks or if we or our agents fail to comply with any of those regulations, laws and/or requirements, a range of actions could result, including, but not limited to, the termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, withdrawal of our products from the market, significant fines, exclusion from government healthcare programs or other sanctions or litigation. Such occurrences could have a material and adverse effect on our product sales, business and results of operations.

The scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal or state regulatory authorities might challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations and financial condition. In addition, efforts to ensure that our business arrangements with third parties will comply with these laws and regulations and will involve substantial costs. Any state or federal regulatory review of us or the third parties with whom we contract, regardless of the outcome, would be costly and time-consuming.

Our employees, independent contractors, consultants, commercial partners, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud, misconduct, or other illegal activity by our employees, independent contractors, consultants, commercial partners, and vendors. Misconduct by these parties could include intentional, reckless, and negligent conduct that fails to:

- comply with the laws of the FDA, EMA, and other comparable foreign regulatory authorities;
- provide true, complete, and accurate information to the FDA, EMA, and other comparable foreign regulatory authorities;
- comply with manufacturing standards we have established;
- comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or

- report financial information or data accurately or to disclose unauthorized activities to us.

Our business operations, including research, sales, marketing, education, and other business arrangements, in the healthcare industry are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, educating, marketing and promotion, sales and commission, certain customer incentive programs, and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. While we have a code of conduct and ethics, it is not always possible to identify and deter misconduct by employees and third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Risks Relating to our International Business

Because a portion of our manufacturing takes place in China, a significant disruption in the construction or operation of our manufacturing facility in China, political unrest in China, tariffs, impact of outbreaks of health epidemics, such as the COVID-19 pandemic, or changes in social, political, trade, health, economic, environmental, or climate-related conditions or in laws, regulations and policies governing foreign trade could materially and adversely affect our business, financial condition and results of operations.

We currently manufacture the starting material for Amphadase® and enoxaparin as well as the APIs for isoproterenol and nitroprusside at our manufacturing facility in China, and we plan to use this facility to manufacture several of the APIs for products in our pipeline. Additionally, we intend to continue to invest in the expansion of this manufacturing facility. Our manufacturing facility and operations in China involve significant risks, including:

- disruptions in the construction of the manufacturing facility;

- interruptions to our operations in China or the inability of our manufacturing facility to produce adequate quantities of raw materials or APIs to meet our needs as a result of natural catastrophic events or other causes beyond our control such as power disruptions or widespread disease outbreaks, including the recent outbreaks that impact animal-derived products, such as the importation of pig-derived crude heparin from countries impacted by the African swine flu, and the ongoing COVID-19 pandemic, which has resulted in and may in the future result in, business closures, transportation restrictions, import and export complications, and otherwise cause shortages in the supply of raw materials or cause disruptions in our manufacturing capability;

- product supply disruptions and increased costs as a result of heightened exposure to changes in the policies of the Chinese government, political unrest or unstable economic conditions in China, including China's policies with respect to COVID-19;

- the imposition of additional tariffs, export controls or other trade barriers as a result of changes in social, political, and economic conditions or in laws, regulations, and policies governing foreign trade, including U.S. and foreign export controls such as U.S. controls preventing the export of a wide-range of items to Russia, new controls impacting the ability to send certain products and technology, specifically related to semi-conductor manufacturing and supercomputing to China without an export license, and the addition of new China-based entities to certain U.S. restricted party lists including the Entity List and Unverified List, trade sanctions and import laws and regulations, the tariffs previously implemented and additional tariffs that have been proposed by the U.S. government on various imports from China and by the Chinese government on certain U.S. goods, the scope and duration of which, if implemented, remain uncertain;

- the nationalization or other expropriation of private enterprises or intellectual property by the Chinese government, which could result in the total loss of our investment in China; and

- interruptions to our manufacturing or business operations resulting from geo-political actions, including war and terrorism such as the war in Ukraine, natural disasters including earthquakes, typhoons, floods, and fires, or outbreaks of health epidemics, or outbreaks in livestock or animals that impact or restrict importation, use,

or distribution of animal-derived products.

Any of these matters could materially and adversely affect our business and results of operations. These interruptions or failures could impair our ability to operate our business, impede the commercialization of our product candidates or delay the introduction of new products, impact our product quality, or impair our competitive position.

We are actively monitoring and assessing the ongoing impact of the COVID-19 pandemic on our business. This includes evaluating the impact on our employees, suppliers, and logistics providers as well as evaluating governmental actions being taken to curtail the spread of the virus. For example, in the first quarter of 2022, increases in COVID-19 cases in Shanghai, China, led to shutdowns and delays at the ports in Shanghai. However, the extent of any future shutdown or delay is highly uncertain and difficult to predict. Any material adverse effect on our employees, suppliers, and logistics providers could have a material adverse effect on our manufacturing operations in China or the supply of raw materials or APIs originating from China.

We are exposed to risks related to our international operations and failure to manage these risks may adversely affect our operating results and financial condition.

We have operations both inside and outside the U.S. For example, we have suppliers in Asia and Europe, and we own manufacturing facilities in Nanjing, China, and Éragny-sur-Epte, France. As a result, a significant portion of our operations is conducted by and/or rely on entities outside the markets in which our products are sold, and, accordingly, we import a substantial number of products into such markets. We may, therefore, be denied access to our customers or suppliers or denied the ability to ship products from any of our sites as a result of a closing of the borders of the countries in which we sell our products, or in which our operations are located, due to economic, legislative, political and military conditions in such countries.

International operations are subject to a number of other inherent risks, and our future results could be adversely affected by a number of factors, including:

- requirements or preferences for domestic products or solutions, which could reduce demand for our products;
- differing existing or future regulatory and certification requirements, including additional or new U.K. – specific regulatory requirements for commercialization of our products in the U.K. following the end of Brexit transition period on December 31, 2020;
- management communication and integration problems resulting from cultural and geographic dispersion;
- greater difficulty in collecting accounts receivable and longer collection periods;
- difficulties in enforcing contracts;
- difficulties and costs of staffing and managing non-U.S. operations;
- difficulty hiring and retaining appropriate personnel due to intense competition for such resources and resulting wage inflation in the cities where our operations are located;
- different labor regulations, especially in the European Union, where labor laws are generally more advantageous to employees as compared to the United States, including deemed hourly wage and overtime regulations in these locations;
- the uncertainty of protection for intellectual property rights in some countries and resulting exposure to misappropriation of intellectual property or information that is proprietary to us, our customers and other third parties;
- tariffs and trade barriers, export regulations and other regulatory and contractual limitations on our ability to sell our products;
- changes in social, political, and economic conditions or in laws, regulations and policies governing foreign trade, manufacturing, development and investment both domestically as well as in other countries and

jurisdictions into which we manufacture or sell our products;

- exposure to liabilities under both U.S. and foreign laws, including export and antitrust regulations, anti-corruption and anti-money laundering laws, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, and similar applicable laws and regulations in other jurisdictions, and any trade regulations ensuring fair trade practices;

- uneven electricity supply that can negatively impact manufacturing;

- heightened risk of unfair or corrupt business practices in certain geographies and of improper or fraudulent sales arrangements that may impact financial results and result in restatements of, or irregularities in, financial statements;

- fluctuations in currency exchange rates and regulatory compliance;

- delays, inefficiencies, and other challenges inherent to efficiently managing an increased number of employees over large geographic distances, including the need to implement appropriate systems, policies, benefits, and compliance programs;

- potentially adverse tax consequences, including multiple and possibly overlapping tax structures; and

- interruptions to our manufacturing or business operations resulting from trade restrictions, political and economic instability, political unrest, war, terrorism, natural disasters including earthquakes, typhoons, floods, and fires, or outbreaks of health epidemics such as the coronavirus and African swine flu outbreaks.

Furthermore, weak domestic or global economic conditions or fear or anticipation of such conditions could adversely affect our business, financial condition, results of operations and prospects in a number of ways, including lower prices for our products, reduced sales and lower or no growth. For example, the global macroeconomic environment could be negatively affected by, among other things, instability in global economic markets resulting from increased U.S. trade tariffs and trade disputes between the U.S. and other countries, instability in the global credit markets, the impact and uncertainty regarding global central bank monetary policy, rising interest rates and increased inflation, the instability in the geopolitical environment as a result of the United Kingdom's "Brexit" decision to withdraw from the European Union, economic challenges in China and ongoing U.S. and foreign governmental debt concerns. Such challenges have caused, and are likely to continue to cause, uncertainty and instability in local economies and in global financial markets, particularly if any future sovereign debt defaults or significant bank failures or defaults occur. Market uncertainty and instability in Europe or Asia could intensify or spread further, particularly if ongoing stabilization efforts prove insufficient. Continuing or worsening economic instability could adversely affect sales of our products. Continued turmoil in the geopolitical environment in many parts of the world may also affect the overall demand for our products. Although we do not believe that our business, financial condition, results of operations and prospects have been significantly adversely affected by economic and political uncertainty in Europe, Asia or other countries to date, deterioration of such conditions may harm our business, financial condition, results of operations and prospects in the future. A prolonged period of economic uncertainty or a downturn may also significantly affect financing markets, the availability of capital and the terms and conditions of financing arrangements, including the overall cost of financing. Circumstances may arise in which we need, or desire, to raise additional capital, and such capital may not be available on commercially reasonable terms, or at all.

In addition, the expansion of our existing international operations, including our facility expansion in Nanjing, China, and entry into additional international markets, including our acquisition of a manufacturing business in Éragny-sur-Epte, France, have required and will continue to require significant management attention and financial resources. These and other factors could harm our ability to gain future revenues and, consequently, materially impact our business, results of operations and financial condition.

Adverse changes to import restrictions relating to certain animal-derived products or raw materials we use from affected countries could disrupt our supply chain and result in delays in the manufacturing of our products.

Some of our raw materials, such as certain animal-derived materials, sourced from foreign sources are subject to import regulations and permit requirements, including from the USDA. The APHIS within the USDA has regulatory oversight over certain animals and animal-derived products that could pose a risk to domestic agriculture. Recently, USDA has

increased its African swine flu surveillance efforts, including additional testing and enhanced restrictions on importation of certain porcine products from affected countries, like China. In February 2020, we received a notice of non-renewal of our permit to import or transport crude heparin USP from one of our third-party heparin supplies in China due to the recent outbreak of the African swine flu in China, requiring additional information on the processing flow providing all treatment parameters and times for the porcine heparin material. Accordingly, our import permit has expired as of February 2020, but we continue to work with APHIS on renewing our import permit for the importation of heparin USP from China. We anticipate that our current supply of heparin USP in the United States is useable and sufficient for our manufacturing needs for the foreseeable future, and we are investigating the use of heparin USP produced at ANP. If we are unable to import raw materials, rely upon existing supplies of raw materials or manufacture raw materials in sufficient amounts for our manufacturing needs, we may be required to find alternative suppliers or sources of such materials, which could disrupt or delay the manufacturing of our products. The success of our business operations and sales with respect to our heparin products will also depend on our continued efforts to maintain the proper product quality and safety profile of the crude heparin obtained either from China or an alternative source.

Enhanced trade tariffs, import restrictions, export restrictions, Chinese regulations or other trade barriers may materially harm our business.

We are continuing to expand our international operations as part of our growth strategy. There is currently significant uncertainty about the future relationship between the United States and various other countries, most significantly China, with respect to trade policies, treaties, government regulations and tariffs. There is a possibility that the United States could continue to impose greater restrictions on international trade and significant increases in tariffs on goods imported into the United States. In September 2018, the U.S. Trade Representative (the "USTR") enacted a tariff on the import of other Chinese products, with a combined import value of approximately $200 billion. Since that time USTR has modified these tariff rates and imposed tariffs on additional goods. Tariffs on imports of APIs and starting materials used in our products, or retaliatory trade measures taken by China or other countries, including restricted access to APIs or starting materials used in our products, causing us to raise prices or make changes to our products, could materially harm our business, financial condition and results of operations. Further, the continued threats of tariffs, trade restrictions, and trade barriers could have a generally disruptive impact on the global economy and, therefore, negatively impact our sales. Although the United States and China signed a phase one trade deal on January 15, 2020, given the relatively fluid regulatory environment in China and the United States and the focus that the current U.S. Administration has shown on issues related to China, including the imposition of new restrictions on exports related to semi-conductor manufacturing and supercomputing and the addition of entities based in China to various restricted party lists, along with uncertainty regarding how the U.S. or foreign governments will act with respect to tariffs, international trade agreements and policies, a trade war, further governmental action related to tariffs or international trade policies, or additional tax or other regulatory changes in the future could occur and could directly and adversely impact our financial results and results of operations.

We are subject to various governmental export control and trade sanctions laws and regulations that could impair our ability to compete in international markets or subject us to liability if we violate these controls.

In some cases, our products are subject to export control laws and regulations, including the Export Administration Regulations administered by the U.S. Department of Commerce, and our activities may be subject to trade and economic sanctions, including those administered by the United States Department of the Treasury's Office of Foreign Assets Control, or OFAC, (collectively, "Trade Controls"). As such, a license may be required to export or re-export our products, or provide related services, to certain countries and end-users, and for certain end-uses. The process for obtaining necessary licenses may be time-consuming or unsuccessful, potentially causing delays in sales or losses of sales opportunities and these licenses may not be issued.

Trade Controls are complex and dynamic regimes and monitoring and ensuring compliance can be challenging. Although we have procedures in place designed to ensure our compliance with Trade Controls, any failure to comply could subject us to both civil and criminal penalties, including substantial fines, possible incarceration of responsible individuals for willful violations, possible loss of our export or import privileges, and reputational harm. Although we have no knowledge that our activities have resulted in violations of Trade Controls, any failure by us or our partners to comply with applicable laws and regulations would have negative consequences for us, including reputational harm, government investigations, and penalties.

The Chinese government may exert substantial influence over the manner in which we conduct our business operations in China.

The Chinese government has exercised, and continues to exercise, substantial control over virtually every sector of the Chinese economy through regulation and state ownership. Our ability to conduct our proposed manufacturing operations in China may be harmed by changes in its laws and regulations, including those relating to taxation, import and export tariffs, environmental regulations, land use rights, property ownership and other matters. We believe that our operations in China are in material compliance with all applicable legal and regulatory requirements. However, the central or local governments of the jurisdictions in which we operate may impose new, stricter regulations or interpretations of existing regulations that would require additional expenditures and efforts on our part to ensure our compliance with such regulations or interpretations. Accordingly, government actions in the future, including any decision not to continue to support economic reforms and to return to a more centrally planned economy or regional or local variations in the implementation of economic policies, could have a significant effect on economic conditions in China or particular regions thereof and could require us to divest ourselves of any interest we then hold in Chinese properties or entities, including our Chinese operating subsidiary, ANP.

The Chinese legal system can be uncertain and could limit the legal protections available to us.

Unlike common law systems, such as the United States, the Chinese legal system is based on written statutes and decided legal cases have little precedential value. Our Chinese operating subsidiary, ANP, is subject to laws and regulations applicable to foreign investments in China in general and laws and regulations applicable to foreign invested enterprises in particular. ANP is also subject to laws and regulations governing the formation and conduct of domestic Chinese companies. Relevant Chinese laws, regulations and legal requirements may change frequently, and their interpretation and enforcement involve uncertainties. For example, we may have to resort to administrative and court proceedings to enforce the legal protections under law or contract. However, since Chinese administrative and court authorities have significant discretion in interpreting and implementing statutory and contract terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and our level of legal protection in China compared to other legal systems. Such uncertainties, including the inability to enforce our contracts and intellectual property rights, could materially and adversely affect our business and operations. In addition, confidentiality protections in China may not be as effective as in the U.S. or other countries. Accordingly, future developments in the Chinese legal system, including the promulgation of new laws, changes to existing laws or the interpretation or enforcement thereof, or the preemption of local requirements by national laws, could limit the legal protections available to us.

Our financial performance is impacted by the financial performance of our Chinese operating subsidiary, ANP.

Because we consolidate ANP's financial results in our results of operations, our financial performance is impacted by the financial performance of ANP. ANP's financial performance may be affected by a number of factors, including, but not limited to:

- ANP's ability to execute on its expansion plans;
- the commercial success of ANP's APIs, starting materials and finished pharmaceutical products;
- results of clinical trials of our product candidates or those of ANP's customers;
- pricing actions by competitors;
- the timing of orders or any cancellation of orders from ANP's customers;
- manufacturing or supply interruptions;
- actions taken by current and potential business partners;
- actions by regulatory bodies, such as the FDA or the CFDA;
- changes or developments in laws or regulations;

- disputes or other developments relating to patents or other proprietary rights;
- litigation or investigations involving ANP, our industry, or both; and
- ANP's ability to control costs, including its operating expenses.

Our business may be affected by new sanctions and export controls targeting Russia and other responses to Russia's invasion of Ukraine.

As a result of Russia's invasion of Ukraine, the U.S., the U.K. and the EU governments, among others, have developed coordinated sanctions and export-control measure packages.

Based on the public statements to date, these packages include:

- comprehensive financial sanctions against major Russian banks (including SWIFT cut off);
- additional designations of Russian individuals with significant business interests and government connections;
- designations of individuals and entities involved in Russian military activities; and
- enhanced export controls and trade sanctions targeting Russia's imports of a wide range of goods as a whole, including potentially tighter controls on exports and reexports of items previously subject to only a low level of control, stricter licensing policy with respect to issuing export licenses, and/or increased use of "end-use" controls to block or impose licensing requirements on exports.

We currently sell APIs indirectly to Russian customers. The imposition of enhanced export controls and economic sanctions on transactions with Russia and Russian entities by the U.S., the U.K., and/or the EU could prevent us from selling our products to Russian customers. In addition, even if a Russian entity is not formally subject to sanctions, customers of such Russian entity may decide to reevaluate, or cancel projects with such entity, and such actions could have a similar impact on us as if sanctions were applied directly as described above. Depending on the extent and breadth of new sanctions or export controls that may be imposed against Russia, it is possible that our business, results of operations and financial condition could be adversely affected.

Risks Relating to our Intellectual Property

Our success depends on our ability to obtain, protect, and enforce our intellectual property.

In addition to obtaining FDA approval for our generic and proprietary drug candidates, our success also depends on our ability to obtain and maintain patent protection for new products developed utilizing our technologies, in the U.S. and in other countries, and to enforce these patents. The patent positions of pharmaceutical firms, including us, are generally uncertain and involve complex legal and factual issues. Any of our patent claims in our approved and pending non-provisional and provisional patent applications relating to our technologies may not be issued or, if issued, any of our existing and future patent claims may not be held valid and enforceable against third-party infringement. Moreover, any patent claims relating to our technologies may not be sufficiently broad to protect our products. In addition, issued patent claims may be challenged, potentially invalidated, or potentially circumvented. Our patent claims may not afford us protection against our competitors. We currently have a number of U.S. and foreign patents issued. However, issuance of a patent is not conclusive evidence of its validity or enforceability. We may not be granted patents for any of our pending patent applications or any patent applications that we may file in the future and our issued patents may not be upheld if challenged. Further, we may not be able to detect an unauthorized use of our intellectual property rights if a competitor uses our intellectual property confidentially, in-house, with no public disclosure.

In March 2013, the U.S. transitioned to a first inventor to file system in which, assuming the other requirements for patentability are met, the first inventor to file a patent application is entitled to receive a patent (rather than the first to invent as was the case under prior U.S. law). Accordingly, it is possible that potentially invalidating prior art may become available in between the time that we develop an invention and file a patent application that covers the invention. In addition, we may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark

Office, or USPTO, or become involved in opposition, derivation, reexamination, inter parties review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third party patent rights.

Past enforcement of intellectual property rights in countries outside the U.S., including China in particular, has been limited or non-existent. Future enforcement of patents and proprietary rights in many other countries will likely be problematic or unpredictable, particularly in other countries where intellectual property rights are not highly developed or protected. Moreover, the issuance of a patent in one country does not assure the issuance of a similar patent in another country. Patent claim interpretation and infringement laws vary by nation, so the extent of any patent protection is uncertain and may vary in different jurisdictions.

Enforcement of our intellectual property rights may not be pursued in some situations in which an alleged infringer may have a more dominant intellectual property position or for other business reasons.

We also rely on, or intend to rely on, our trademarks, trade names and brand names to distinguish our products from the products of our competitors and have registered or applied to register our own trademarks. However, our trademark applications may not be granted. Third parties may also oppose our trademark applications or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our product, which could result in loss of brand recognition and could require us to devote significant resources to advertising and marketing these new brands. Further, our competitors may infringe our trademarks or we may not have adequate resources to enforce our trademarks.

We are currently, have in the past and in the future may become involved in patent litigations or other intellectual property proceedings relating to our future product approvals, which could result in liability for damages or delay or stop our development and commercialization efforts.

The pharmaceutical industry has been characterized by significant litigation and other proceedings regarding patents, patent applications and other intellectual property rights. The situations in which we may become parties to such litigation or proceedings may include any third parties initiating litigation claiming that our products infringe their patent or other intellectual property rights; in such case, we will need to defend against such proceedings. For example, the field of generic pharmaceuticals is characterized by frequent litigation that occurs in connection with generic pharmaceutical companies filing ANDAs, Paragraph IV certifications and attempting to invalidate the patents of the proprietary reference drug. Any non-generic products that we successfully develop may be subject to such challenge by third parties. As a generic pharmaceutical company, we also expect to file ANDAs and Paragraph IV certifications and to attempt to invalidate patents of third party reference drugs for which we seek to develop generic versions.

The costs of resolving any patent litigation or other intellectual property proceeding, even if resolved in our favor, could be substantial. Many of our potential competitors will be able to sustain the cost of such litigation and proceedings more effectively than we can because of their substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other intellectual property proceedings may also consume significant management time.

In the event that a competitor infringes upon our patent or other intellectual property rights, enforcing those rights may be costly, difficult and time-consuming. Even if successful, litigation to enforce our intellectual property rights or to defend our patents against challenge could be expensive and time-consuming and could divert our management's attention. We may not have sufficient resources to enforce our intellectual property rights or to defend our patent or other intellectual property rights against a challenge. If we are unsuccessful in enforcing and protecting our intellectual property rights and protecting our products, it could materially harm our business.

For example, we received a complaint on December 20, 2018, related to our ANDA submitted seeking approval to engage in the commercial manufacture, use and sale of a proposed generic vasopressin injection USP. Additionally, we have also been involved in patent litigation and antitrust litigation related to our sales of enoxaparin. For further details, see the section titled Litigation in Note 20 in the accompanying "Notes to Consolidated Financial Statements" in this Annual Report on Form 10-K. The protracted litigations involved, and may continue to involve, large legal expenses and the diversion of management's time and effort away from the business. Any future adverse determinations in a judicial

or administrative proceeding or failure to obtain necessary licenses, whether in these litigations or in other litigations, could result in substantial monetary damage awards and could prevent us from manufacturing and selling our products, which could have a material and adverse effect on our financial condition.

There may also be situations where we use our business judgment and decide to market and sell products, notwithstanding the fact that allegations of patent infringement(s) have not been finally resolved by the courts, which situation is commonly referred to as an at-risk launch. The risk involved in doing so can be substantial because the remedies available to the owner of a patent for infringement may include, among other things, damages measured by the profits lost by the patent owner and not necessarily by the profits earned by the infringer as well as injunctive relief, which would halt our ability to market and sell such products altogether. In the case of a willful infringement, the definition of which is subjective, such damages may be increased up to three times. Moreover, because of the discount pricing typically involved with generic products, patented proprietary products generally realize a substantially higher profit margin than generic products. An adverse decision in a case such as this or in other similar litigation could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

With respect to our proprietary products, if we fail to adequately protect or enforce our intellectual property rights, we could lose sales to generic versions of our proprietary products which could cause a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

The success of our proprietary products depends in part on our ability to obtain, maintain and enforce patents and trademarks, and to protect trade secrets, know-how and other proprietary information and technologies. Our ability to commercialize any proprietary product successfully will largely depend upon our ability to obtain and maintain patents of sufficient scope to prevent third parties from developing substantially equivalent products. In the absence of patent and trade secret protection, competitors may adversely affect our proprietary products business by independently developing and marketing substantially equivalent products. It is also possible that we could incur substantial costs if we are required to initiate litigation against others to protect or enforce our intellectual property rights.

We have filed patent applications covering compositions of, methods of making and/or methods of using, our proprietary products and proprietary product candidates. We may not be issued patents based on patent applications already filed or that we may file in the future, and if patents are issued, they may be insufficient in scope to cover our proprietary products. The issuance of a patent in one country does not ensure the issuance of a similar patent in any other country, or that we will even seek patent protection in all countries worldwide. Furthermore, the patent position of companies in the pharmaceutical industry generally involves complex legal and factual questions and has been and remains the subject of much litigation. Legal standards relating to scope and validity of patent claims are evolving and may differ in various countries. Any patents we have obtained, or will obtain in the future, may be challenged, invalidated or circumvented. Moreover, the USPTO or any other governmental agency, as well as third parties, may commence interference, opposition or other related third party proceedings involving our patents or patent applications. Any challenge to, or invalidation or circumvention of, our patents or patent applications would be costly, would require significant time and attention of our management, could cause a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Our unpatented trade secrets, know-how, confidential and proprietary information and technology may be inadequately protected.

We rely on unpatented trade secrets, know-how and technology. This intellectual property is difficult to protect, especially in the pharmaceutical industry, where much of the information about a product must be submitted to regulatory authorities during the regulatory approval process. We seek to protect trade secrets, know-how, confidential or proprietary information and technologies, in part, by entering into confidentiality and invention assignment agreements with employees, consultants and others. These parties may breach or terminate these agreements, and we may not have adequate remedies for such breaches. Furthermore, these agreements may not provide meaningful protection for our trade secrets, know-how, or other confidential or proprietary information and technologies or result in the effective assignment to us of intellectual property, and may not provide an adequate remedy in the event of unauthorized use or disclosure of confidential information or other breaches of the agreements. Despite our efforts to protect our trade secrets, know-how, and our other confidential and proprietary information and technologies, we or our collaboration partners, board members, employees, consultants, contractors, or scientific and other advisors may unintentionally or willfully disclose our proprietary information to competitors. In addition, we may not be able to detect any unauthorized

disclosure of our trade secrets, know-how and our other confidential and proprietary information and technologies if such disclosure was conducted confidentially without public disclosure.

There is a risk that our trade secrets, know-how, and other confidential and proprietary information and technologies could have been, or could, in the future, be shared by any of our former employees with, and be used to the benefit of, any company that competes with us.

If we fail to maintain trade secret protection or fail to protect the confidentiality of our know-how, and other confidential and proprietary information and technologies, our competitive position may be adversely affected. Enforcement of claims that a third party has illegally obtained and is using trade secrets, know-how, and other confidential and proprietary information and technologies, is expensive, time consuming and uncertain. If our competitors independently develop equivalent knowledge, methods, know-how and trade secrets, we may not be able to prevail in an intellectual property litigation against them, which could have a material adverse effect on our business.

There can be no assurance of timely patent and trademark review and approval to minimize competition and generate sufficient revenues.

There can be no assurance that the USPTO will have sufficient resources to review and grant our patent and trademark applications in a timely manner. Consequently, our patent and trademark applications may be delayed for many years (if they issue at all), which would prevent intellectual property protection for our products. If we fail to successfully commercialize our products due to the lack of intellectual property protection, we may be unable to generate sufficient revenues to meet or grow our business according to our expected goals and this may have a materially adverse effect on our profitability, financial condition and operations.

We may be subject to claims that we, our board members, employees or consultants have used or disclosed alleged trade secrets or other proprietary information belonging to third parties and any such individuals who are currently affiliated with one of our competitors may disclose our proprietary technology or information.

As is commonplace in the biotechnology and pharmaceutical industries, some of our board members, employees and consultants are or have been employed at, or associated with, other biotechnology or pharmaceutical companies that compete with us. While employed at or associated with these companies, these individuals may become exposed to or involved in research and technology similar to the areas of research and technology in which we are engaged. We may be subject to claims that we, or our employees, board members or consultants have inadvertently, willfully or otherwise used or disclosed alleged trade secrets or other proprietary information of those companies. Litigation may be necessary to defend against such claims.

We have entered into confidentiality agreements with our executives and key consultants. However, we do not have, and are not planning to enter into, any confidentiality agreements with our non-executive directors because they have a fiduciary duty of confidentiality as directors. Our former board members, employees or consultants who are currently employed at, or associated with, one of our competitors may unintentionally or willfully disclose our proprietary technology or information.

Risks Related to Ownership of our Common Stock

Sales of substantial amounts of our common stock, or indications of an intent to sell, may cause our stock price to decline.

If we or our existing stockholders sell, or indicate an intent to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. We maintain a shelf registration statement on Form S-3 pursuant to which we may, from time to time, sell up to an aggregate of $250 million of our common stock, preferred stock, depositary shares, warrants, units, or debt securities. We may also issue shares of common stock or securities convertible into our common stock from time to time in connection with financings, acquisitions, investments or otherwise. Any such issuances would result in dilution to our existing stockholders and could cause our stock price to fall.

In addition, we have registered approximately 16.3 million shares subject to options and RSUs outstanding or reserved for future issuance under our equity compensation plans. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Jack Y. Zhang and Mary Z. Luo, each of whom serves as a director and an executive officer, own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of December 31, 2022, Jack Y. Zhang and Mary Z. Luo, or Drs. Zhang and Luo, each of whom serves as one of our directors and executive officers, and their affiliates beneficially own approximately 25.7% of our outstanding common stock, including shares of common stock subject to options exercisable within 60 days of December 31, 2022. Our directors, executive officers and each of our stockholders who own greater than 5% of our outstanding common stock and their affiliates, in the aggregate, own approximately 27.8% of the outstanding, including shares of our common stock, based on the number of shares outstanding and shares of our common stock subject to options exercisable within 60 days of December 31, 2022. As a result, these stockholders, if acting together, will be able to influence or control matters requiring approval by our stockholders, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. They may also have interests that differ from yours and may vote in a way with which you disagree and which may be adverse to your interests. This concentration of ownership may have the effect of delaying, preventing or deterring a change of control of our company, depriving our stockholders of an opportunity to receive a premium for their common stock as part of a sale of the Company and might ultimately affect the market price of our common stock.

Jack Y. Zhang and Mary Z. Luo have each pledged shares of our common stock to secure funds borrowed under existing credit lines from three financial institutions. Each of the lenders has varying rights as a lender, including one which has the right to conduct a forced sale at its sole discretion. An action by one of the lenders could include a sale of certain shares of our common stock pledged as collateral, the sale of which could cause the price our common stock to decline. An action to cure and cover indebtedness by any one of the lenders could also have other negative impacts on our business.

Since September 2015, UBS Bank USA, or UBS Utah, has made extensions of credit up to the amount of $8.0 million to Applied Physics & Chemistry Laboratories, Inc., or APCL, which is controlled by Jack Y. Zhang and Mary Z. Luo. In May 2019, the credit amount was increased to $11.0 million. Since February 2017, UBS AG has also provided an extension of credit up to the amount of $8.0 million to APCL. In 2021, the outstanding UBS AG credit line was transferred to UBS Utah due to a UBS organizational change. As of February 16, 2023, the total outstanding UBS combined credit lines were $11.0 million. The UBS credit lines are secured by a pledge of 1,750,000 shares of our common stock currently held by APCL. Interest on the loans accrues at market rates. UBS has an unlimited and unilateral right to call each of the credit lines for any reason whatsoever.

In October 2017, East West Bank, or East West, entered into an agreement with Drs. Zhang and Luo whereby East West would loan them up to $5.0 million. As of February 16, 2023, the loan is secured by a pledge of 600,000 shares of our common stock held by Dr. Zhang. Interest on the loan accrues at market rates. East West Bank has acceleration rights to protect itself in the event of a default.

During 2021, Drs. Zhang and Luo repaid and terminated a previous loan with Cathay Bank, which had been secured by a pledge of 3,800,000 shares of our common stock held by APCL or Drs. Zhang and Luo.

We are not a party to these loans, which are full recourse against APCL and each of Drs. Zhang and Luo, respectively, and are secured by pledges of a portion of the shares of our common stock currently held by APCL and each of Drs. Zhang and Luo.

In 2021, we created a pledging policy to restrict the pledging of shares by our executive officers and directors. The policy prohibits our executive officers and directors from entering into any transaction whereby the executive officer or director, directly or indirectly, pledges, hypothecates, or otherwise encumbers more than twenty (20) percent of shares of common stock held by the individual or more than five (5) percent of our total outstanding shares of common stock as of the date of the transaction, whichever is lower, as collateral for indebtedness. This restriction extends to any hedging or similar transaction designed to decrease the risks associated with holding our securities. For already existing pledges made by executive officers and directors, those existing pledges must be reduced to no more than twenty (20) percent of the shares of our common stock held by such individual as collateral for indebtedness within three (3) years of December 31, 2021. As a result of this policy, Drs. Zhang and Luo reduced their total number of pledged shares to 2,350,000 in May 2022 from 3,182,898 in February 2022, and 8,582,898 in February 2021.

If the price of our common stock declines, Drs. Zhang and Luo may be forced by these financial institutions to provide additional collateral for the loans or to sell shares of our common stock held by them in order to remain within the

margin limitations imposed under the terms of their loans. Furthermore, the pledged shares of our common stock may be acquired and sold by the lenders. These factors may limit Drs. Zhang and Luo's ability to either pledge additional shares of our common stock or sell shares of our common stock held by them as a means to avoid or satisfy a margin call with respect to their pledged shares of our common stock in the event of a decline in our stock price that is large enough to trigger a margin call. Any significant sales of shares of our common stock by one or more of these three lenders could cause the price of our common stock to decline further.

We do not intend to pay dividends for the foreseeable future.

The continued operation and expansion of our business will require substantial funding. Accordingly, we do not anticipate that we will pay any cash dividends on shares of our common stock for the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our Board of Directors and will depend upon results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our Board of Directors deems relevant. In addition, our existing loan agreements restrict, and any future indebtedness may restrict, our ability to pay dividends. Investors seeking cash dividends should not purchase our common stock. Accordingly, realization of a gain on your investment will depend on the appreciation of the price of our common stock, which may never occur.

While we have engaged in repurchases of our common stock, any future decisions to reduce or discontinue repurchasing our common stock pursuant to our previously announced repurchase program could cause the market price for our common stock to decline.

Although our Board has authorized a share repurchase program, and we repurchased approximately 1.3 million of our shares during 2022 for $39.9 million, any determination to continue to execute our stock repurchase program as planned will be subject to, among other things, our financial position and results of operations, available cash and cash flow, capital requirements, and other factors, as well as our Board's continuing determination that the repurchase program is in the best interests of our shareholders and is in compliance with all laws and agreements applicable to the repurchase program. Our stock repurchase program does not obligate us to acquire any specific number of shares. If we fail to meet any expectations related to stock repurchases, the market price of our stock could decline significantly, and could have a material adverse impact on investor confidence. Additionally, price volatility of our stock over a given period may cause the average price at which we repurchase our own stock to exceed the stock market price at a given point in time.

We may further increase or decrease the amount of repurchases of our common stock in the future. Any reduction or discontinuance by us of repurchases of our common stock pursuant to our current share repurchase authorization program could cause the market price of our common stock to decline. Moreover, in the event repurchases of our common stock are reduced or discontinued, our failure or inability to resume repurchasing common stock at historical levels could result in a lower market valuation of our common stock.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws, as well as provisions of the Delaware General Corporation Law, or the DGCL, could depress the trading price of our common stock by making it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions include:

- authorizing the issuance of undesignated preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders;
- establishing advance notice requirements for nominations for election to the Board of Directors or for proposing matters that can be acted upon at stockholder meetings;

- establishing a classified Board of Directors, whereby only one-third of the members of our Board of Directors are elected at one time; and

- providing that vacancies on our board of directors may be filled only by a majority of directors then in office; and

- advance notice procedures apply for stockholders to nominate candidates for election as directors or to bring matters before an annual meeting of stockholders.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors, which is responsible for appointing the members of our management. Furthermore, our amended and restated certificate of incorporation provides that unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a breach of fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders; (iii) any action asserting a claim arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation, or our amended and restated bylaws; or (iv) any action asserting a claim against us that is governed by the internal affairs doctrine. This provision is not intended to apply to actions arising under the Securities Act or the Exchange Act, or any claim for which the federal courts have exclusive jurisdiction. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to this provision. This exclusive-forum provision may discourage lawsuits against us or our directors, officers, and employees. In addition, we are subject to Section 203 of the DGCL, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our Board of Directors. This provision could delay or prevent a change of control, whether or not it is desired by or beneficial to our stockholders, which could also affect the price that some investors are willing to pay for our common stock.

General Risk Factors

We could be materially and adversely affected by violations of the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws.

The U.S. Foreign Corrupt Practices Act of 1977, as amended and similar applicable laws and regulations in other jurisdictions generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Our policies mandate compliance with these anti-bribery laws, which often carry substantial penalties. We are currently expanding our operations abroad, including expanding our facilities in China, a country which has experienced governmental and private sector corruption to some degree, and in certain circumstances, strict compliance with anti-bribery laws may conflict with certain local customs and practices. Our internal control policies and procedures may not always protect us from acts committed by our affiliates, employees or agents which may violate these laws and regulations. Violations of foreign and U.S. laws and regulations could result in fines and penalties, criminal sanctions against us, our officers or our employees, prohibitions on the conduct of our business and on our ability to offer our products in one or more countries, and could also materially affect our brand, our international growth efforts, our ability to attract and retain employees, our business, and our operating results. There can be no assurance that our partners, our employees, contractors, or agents will not subject us to potential claims or penalties. Any violations of these laws, or allegations of such violations, could have a material adverse effect on our business, financial position, and results of operations and could cause the market value of our common stock to decline.

Movements in foreign currency exchange rates could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

A portion of our revenues, indebtedness and other liabilities and our costs are denominated in foreign currencies, including the Chinese yuan and the euro. We report our financial results in U.S. dollars. Our results of operations and, in some cases, cash flows may in the future be adversely affected by certain movements in exchange rates. We also expect that certain exchange rates may be more volatile than normal as a result of the Russian invasion of Ukraine and related events, the COVID-19 pandemic, and uncertain macroeconomic conditions. From time to time, we may implement currency hedges intended to reduce our exposure to changes in foreign currency exchange rates. However, any such hedging strategies may not be successful, and any of our unhedged foreign exchange exposures will continue to be

subject to market fluctuations. These risks could cause a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Global macroeconomic conditions may negatively affect us and may magnify certain risks that affect our business.

Our business is sensitive to general economic conditions, both inside and outside the U.S. Slower global economic growth, credit market crises, high levels of unemployment, reduced levels of capital expenditures, government deficit reduction, changes in inflation and interest rate environments, sequestration and other austerity measures and other challenges affecting the global economy adversely affects us and our distributors, customers and suppliers. It is uncertain how long these effects will last or whether economic and financial trends will worsen or improve. Changes in economic conditions and supply chain constraints and steps taken by governments and central banks could lead to higher inflation than previously experienced or expected, which could, in turn, lead to an increase in costs. In an inflationary environment, we may be unable to raise the prices of our products sufficiently to keep up with the rate of inflation. Such uncertain economic times may have a material adverse effect on our revenues, results of operations, financial condition and, if circumstances worsen, our ability to raise capital at reasonable rates. If slower growth in the global economy or in any of the markets we serve continues for a significant period, if there is significant deterioration in the global economy or such markets or if improvements in the global economy don't benefit the markets we serve, our business and financial statements could be adversely affected.

Additionally, as a result of any future global economic downturn, our third-party payers may delay or be unable to satisfy their reimbursement obligations. Sales of our principal products are dependent, in part, on the availability and extent of reimbursement from third-party payers, including government programs such as Medicare and Medicaid and private payer healthcare and insurance programs. A reduction in the availability or extent of reimbursement from government and/or private payer healthcare programs could have a material adverse effect on the sales of our products, our business and results of operations.

Current economic conditions may adversely affect the ability of our distributors, customers, suppliers and service providers to obtain the liquidity required to pay for our products or to buy necessary inventory or raw materials and to perform their obligations under agreements with us, which could disrupt our operations, and could negatively impact our business and cash flow. Although we make efforts to monitor these third parties' financial condition and their liquidity, our ability to do so is limited, and some of them may become unable to pay their bills in a timely manner, or may even become insolvent, which could negatively impact our business and results of operations. These risks may be elevated with respect to our interactions with third parties with substantial operations in countries where current economic conditions are the most severe, particularly where such third parties are themselves exposed to sovereign risk from business interactions directly with fiscally-challenged government payers.

At the same time, significant changes and volatility in the financial markets, in the consumer and business environment, in the competitive landscape and in the global political and security landscape make it increasingly difficult for us to predict our revenues and earnings into the future. As a result, any revenue or earnings guidance or outlook which we have given or might give may be overtaken by events, or may otherwise turn out to be inaccurate. Though we endeavor to give reasonable estimates of future revenues and earnings at the time we give such guidance, based on then-current conditions, there is a significant risk that such guidance or outlook will turn out to be, or to have been, incorrect.

Our results of operations can be adversely affected by labor shortages, turnover and labor cost increases.

Labor is a primary component of operating our business. A number of factors may adversely affect the labor force available to us or increase labor costs, including high unemployment levels, federal unemployment subsidies, including unemployment benefits offered in response to the COVID-19 pandemic, and other government regulations. We are also experiencing and may continue to experience additional pressure in our supply chain due to labor. A sustained labor shortage or increased turnover rates within our employee base, caused by COVID-19 or as a result of general macroeconomic factors, could lead to increased costs, such as increased overtime to meet demand and increased wage rates to attract and retain employees, and could negatively affect our ability to efficiently operate our manufacturing and distribution facilities and overall business. If we are unable to hire and retain employees capable of performing at a high-level, or if mitigation measures we may take to respond to a decrease in labor availability, such as overtime and third-party outsourcing, have negative effects, our business could be adversely affected. An overall labor shortage, lack of skilled labor, increased turnover or labor inflation, caused by COVID-19 or as a result of general macroeconomic factors, could have a material adverse impact on our business, financial condition or operating results.

Failure to maintain adequate internal controls or to implement new or improved controls could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective. We have in the past, identified a material weakness in our internal control over financial reporting, which was remediated; however, our remediation efforts may not enable us to avoid a material weakness in the future. Ensuring that we have adequate internal financial and accounting controls and procedures in place to help produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be evaluated frequently.

We are required to disclose changes made in our internal control and procedures on a quarterly basis. Our independent registered public accounting firm is required to report on the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act. Our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operating. In addition, we may encounter problems or delays in completing the implementation of any requested improvements and receiving a favorable attestation by our independent registered public accounting firm.

In the event that our Chief Executive Officer, Chief Financial Officer, or independent registered public accounting firm determines that our internal control over financial reporting is not effective as defined under Section 404, we could be subject to one or more investigations or enforcement actions by state or federal regulatory agencies, stockholder lawsuits, breaches of the covenants under our credit facilities, or other adverse actions requiring us to incur defense costs, pay fines, make settlements or seek judgments, which may adversely affect investor perceptions and potentially result in a decline in our stock price.

Our reported financial results may be adversely affected by changes in accounting principles generally accepted in the United States.

Generally accepted accounting principles in the United States are subject to interpretation by the Financial Accounting Standards Board, or FASB, the SEC and various bodies formed to promulgate and interpret appropriate accounting principles. A change in these principles or interpretations could have a significant effect on our reported financial results and could affect the reporting of transactions completed before the announcement of a change. For example, in May 2014, the FASB issued ASU No. 2014-09, Revenue From Contracts With Customers (Topic 606), or ASC 606, as subsequently amended, which supersedes nearly all existing revenue recognition guidance under GAAP. ASC 606 became effective for us beginning the first quarter of fiscal 2018, and we have adopted it using the modified retrospective transition method. In addition, were we to change our critical accounting estimates, our results of operations could be significantly impacted. These or other changes in accounting principles could adversely affect our financial results. See Note 2 of the Notes to Consolidated Financial Statements in Part II - Item 8 of this Annual Report on Form 10-K for information regarding the effect of new accounting pronouncements on our financial statements. Any difficulties in implementing these pronouncements could cause us to fail to meet our financial reporting obligations, which could result in regulatory discipline and harm investors' confidence in us.

There are inherent uncertainties involved in estimates, judgments and assumptions used in the preparation of financial statements in accordance with GAAP. Any future changes in estimates, judgments and assumptions used or necessary revisions to prior estimates, judgments or assumptions or changes in accounting standards could lead to a restatement or revision to previously consolidated financial statements, which could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, as discussed in greater detail in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" 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. Our operating results may be adversely affected if our assumptions change or if actual circumstances differ from those in our assumptions, which could cause our operating results to fall below the expectations of securities analysts and investors, resulting in a decline in our stock price. Significant assumptions and estimates used in preparing our consolidated financial statements include those related to revenue recognition, provision for chargebacks and rebates, accruals for product returns, valuation of inventory, impairment of intangibles and long-lived assets, accounting for income taxes and share-based compensation. Furthermore, although we have recorded reserves for litigation related contingencies based on estimates of probable future costs, such litigation related contingencies could result in substantial further costs. Also, any new or revised accounting standards may require adjustments to previously issued financial statements. Any such changes could result in corresponding changes to the amounts of liabilities, revenues, expenses and income. Any such changes could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Changes in financial accounting standards or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and varying interpretations of accounting pronouncements have occurred and may occur in the future. Changes to existing rules or the questioning of current practices may adversely affect our business and financial results.

Changes in income tax laws, tax rulings and other factors may have a significantly adverse impact on our effective tax rate and tax expense, which could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Changes in tax laws, tax rulings, or the way in which such laws and rulings are interpreted or implemented, could adversely affect our effective tax rate and tax expense. For example, on December 22, 2017, the U.S. government enacted the Tax Act, which includes significant changes to the taxation of business entities. These changes include, among others, a federal statutory rate reduction from 35% to 21% effective January 1, 2018, the elimination or reduction of certain domestic deductions and credits, limitations on the deductibility of executive compensation and interest, and a one-time transition tax on earnings of certain foreign subsidiaries that were previously tax deferred. Our financial statements for the current year now reflect the effects of the Tax Act based on current guidance, including remeasurement of our deferred tax assets and liabilities, as well as the effects of the reduced rate of the U.S. corporate income tax and certain other provisions of the Tax Act on our effective tax rate and operating results. The U.S. Treasury Department, the IRS, and state tax authorities will continue to interpret or issue guidance on how provisions of the Tax Act will be applied or otherwise administered. As future guidance is issued, we may make adjustments to amounts that we have previously recorded that may materially impact our financial statements in the period in which the adjustments are made. In addition, in 2022 the U.S. government enacted the Inflation Reduction Act, which imposes a 1% excise tax on certain stock repurchases (including potentially pursuant to our stock repurchase program) and a 15% alternative minimum tax on adjusted financial statement income.

In addition to income taxes in the United States, we are subject to income taxes in many foreign jurisdictions. Significant judgment is required in determining our worldwide provision for income taxes. In the ordinary course of business, there are many transactions and calculations where the ultimate tax determination is uncertain. The final determination of any tax audits or related litigation could be materially different from our historical income tax provisions and accruals.

In addition, tax laws are dynamic and subject to change as evidenced by the Tax Act and the Inflation Reduction Act. As new laws are passed and new interpretations of the law are issued or applied, our provision for income taxes may be affected. Changes to U.S. tax laws, including taxation of earnings outside of the U.S., the introduction of a base erosion anti-abuse tax and the disallowance of tax deductions for certain book expenses, as well as changes to U.S. tax laws that may be enacted in the future, could impact the tax treatment of our earnings, as well as cash and cash equivalent balances we currently maintain. Furthermore, due to shifting economic and political conditions, tax policies or rates in various jurisdictions may be subject to significant change.

Additionally, increases in our effective tax rate as a result of a change in the mix of earnings in countries with differing statutory tax rates, changes in our overall profitability, changes in the valuation of deferred tax assets and liabilities, the results of audits and the examination of previously filed tax returns by various taxing authorities and continuing assessments of our tax exposures could impact our tax liabilities and affect our income tax expense, which could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

The facilities we use for our headquarters, laboratory and research and development activities are located in earthquake-prone areas of California. A significant percentage of the facilities we use for our manufacturing, packaging, warehousing, distribution and administration offices are also located in these areas. Earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our facilities, that damaged critical infrastructure, such as our manufacturing facilities, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans.

Our quarterly and annual operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

Our operating results may be subject to quarterly and annual fluctuations as a result of a number of factors, including the following:

- the commercial success of our key products and those of our customers;
- results of clinical trials of our product candidates or those of our competitors;
- pricing actions by competitors;
- the timing of orders or any cancellation of orders from our customers;
- manufacturing or supply interruptions;
- actions by regulatory bodies, such as the FDA, that have the effect of delaying or rejecting approvals of our product candidates;
- changes in the prescription practices of physicians;
- changes or developments in laws or regulations applicable to our product candidates;
- introduction of competitive products or technologies;
- failure to meet or exceed financial projections we provide to the public;
- actual or anticipated variations in quarterly operating results;
- failure to meet or exceed the estimates and projections of securities analysts or investors;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, capital commitments or achievement of significant milestones;
- changes in, or termination of our agreements with our business partners;
- developments concerning our sources of manufacturing supply;
- disputes or other developments relating to patents or other proprietary rights;
- litigation or investigations involving us, our industry, or both;

- additions or departures of key scientific or management personnel;
- announcements or issuances of debt, equity or convertible securities;
- sales of our common stock by our stockholders;
- changes in the market valuations of similar companies;
- major catastrophic events;
- major changes in our Board of Directors or management or departures of key personnel;
- our overall effective tax rate, including impacts caused by any reorganization in our corporate structure, and any new legislation or regulatory developments, including the Tax Act;
- general economic and market conditions and overall fluctuations in U.S. equity markets; or
- the other factors described in this "Item 1A, Risk Factors" section.

Any one of the factors above, or the cumulative effect of some of the factors referred to above, may result in significant fluctuations in our quarterly or annual operating results. This variability and unpredictability could result in our failing to meet our revenue, billings or operating results expectations or those of securities analysts or investors for any period. In addition, a significant percentage of our operating expenses are fixed in nature and based on forecasted revenue trends. Accordingly, in the event of revenue shortfalls, we are generally unable to mitigate the negative impact on operating results in the short term. If we fail to meet or exceed such expectations for these or any other reasons, our business could be materially adversely affected and our stock price could fluctuate or decline substantially.

In addition, if the market for pharmaceutical company stocks or the stock market in general, experiences a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, operating results or financial condition. The trading price of our common stock might also decline in reaction to events that affect other companies in our industry even if these events do not directly affect us. Our stock price may also be affected by sales of large blocks of our stock or an interruption or change in our stock buyback program.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. If our stock price is volatile, we may become the target of securities litigation. Securities litigation could result in substantial costs and divert our management's attention and resources from our business, and this could have a material adverse effect on our business, operating results and financial condition.

The requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain executive management and qualified board members.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Act, the listing requirements of the Nasdaq Stock Market LLC and other applicable securities rules and regulations. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and increase demand on our systems and resources. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could adversely affect our business and operating results. Although we have already hired additional employees to comply with these requirements, we may need to hire more employees in the future or engage outside consultants, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply

with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected.

Failure to comply with these requirements could also subject us to enforcement actions by the SEC, further increase costs and divert management's attention, damage our reputation and adversely affect our business, operating results or financial condition.

We also believe that being a public company and these rules and regulations make it more expensive for us to obtain director and officer liability insurance.

As a result of disclosure of information in this Annual Report on Form 10-K and in filings required of a public company, our business and financial condition are more visible, which we believe may result in threatened or actual litigation by competitors and other third parties. If such claims are successful, our business and operating results could be adversely affected. Even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and adversely affect our business and operating results.

We may become involved in securities class action litigation that could divert management's attention from our business and adversely affect our business and could subject us to significant liabilities.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of pharmaceutical companies. These broad market fluctuations as well as a broad range of other factors, including the realization of any of the risks described in this section, may cause the market price of our common stock to decline. 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 generally experience significant stock price volatility. We may become involved in this type of litigation in the future. Litigation is often expensive and could divert management's attention and resources from our primary business, which could adversely affect our business. Any adverse determination in any such litigation or any amounts paid to settle any such actual or threatened litigation could require that we make significant payments.

We may become involved in litigation that may materially adversely affect us.

From time to time, we may be involved in a variety of claims, lawsuits, investigations and proceedings relating to securities laws, product liability, patent infringement, contract disputes and other matters relating to various claims that arise in the normal course of our business in addition to governmental and other regulatory investigations and proceedings. For example, former employees have filed claims against us under California's Private Attorneys General Act, or PAGA. PAGA allows an aggrieved staff member to bring a lawsuit on behalf of other current and former staff members for labor code violations. In addition, third parties may, from time to time, assert claims against us in the form of letters and other communications. Such matters can be time-consuming, divert management's attention and resources, cause us to incur significant expenses or liability and/or require us to change our business practices. Because of the potential risks, expenses and uncertainties of litigation, we may, from time to time, settle disputes, even where we have meritorious claims or defenses, by agreeing to settlement agreements. Because litigation is inherently unpredictable, we cannot assure you that the results of any of these actions will not have a material adverse effect on our business, financial condition, results of operations and prospects.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our manufacturing facilities are located in Rancho Cucamonga and South El Monte, California; Canton, Massachusetts; Éragny-sur-Epte, France; and Nanjing, China. We own or lease a total of 56 buildings at six locations in the U.S., France and China, that comprise 1.8 million square feet of manufacturing, research and development, distribution, packaging, laboratory, office and warehouse space. Our facilities are regularly inspected by the FDA in connection with our product approvals, and we believe that all of our facilities are being operated in material compliance with the FDA's cGMP regulations.

We continue to expand our facility in Nanjing, China and expect further significant investment.

The following table provides a summary of our owned properties as of December 31, 2022:

Location	Aggregate Facility Size (in square feet)	Primary Use	Segment
Rancho Cucamonga, CA	267,674	Headquarters, research and development, laboratories, manufacturing, packaging, warehousing and administrative offices	Finished pharmaceutical products
Éragny-sur-Epte, France	251,983	Manufacturing, laboratories, warehousing and administrative offices	API
Canton, MA	251,750	Manufacturing, packaging, warehousing, distribution and administrative offices	Finished pharmaceutical products
Nanjing, China	406,042	Manufacturing, procurement, research and development, warehousing, and administrative offices	Finished pharmaceutical products
Chino, CA	57,968	Research and development, and laboratories	Finished pharmaceutical products
South El Monte, CA	21,200	Manufacturing	Finished pharmaceutical products

The properties leased by us have expiration dates ranging from 2023 to 2034 (including certain renewal options). The following table provides a summary of our leased properties:

Location	Aggregate Facility Size (in square feet)	Primary Use	Segment
Rancho Cucamonga, CA	180,019	Warehousing, distribution and administrative offices	Finished pharmaceutical products
South El Monte, CA	335,013	Manufacturing, packaging, warehousing, distribution and administrative offices	Finished pharmaceutical products

We believe that our current manufacturing capacity is adequate for the near term. We have in the past approached capacity at one of our facilities largely as a result of the FDA's request that we reintroduce certain previously discontinued products to help cope with a nationwide shortage of these products. We believe that these capacity issues have been ameliorated as a result of certain other manufacturers re-entering the market and increasing the production of the products that were subject to the shortage.

Item 3. Legal Proceedings.

The disclosure under Note 20 of Notes to the Consolidated Financial Statements included elsewhere in this report is incorporated by reference in this Part I, Item 3.

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.

Our common stock is listed on the Nasdaq Global Select Market and has traded under the symbol "AMPH" since our initial public offering on June 25, 2014. Prior to this date, there was no public market for our common stock.

Dividend Policy

We have not declared or paid any dividends on our common stock since our initial public offering. We currently anticipate that we will retain future earnings, if any, for the development, operation and expansion of our business and do not anticipate declaring or paying any dividends in the foreseeable future. Additionally, our ability to pay dividends on our common stock is limited by restrictions under the terms of our existing credit facilities. Any future determinations related to dividend policy will be made at the discretion of our Board of Directors.

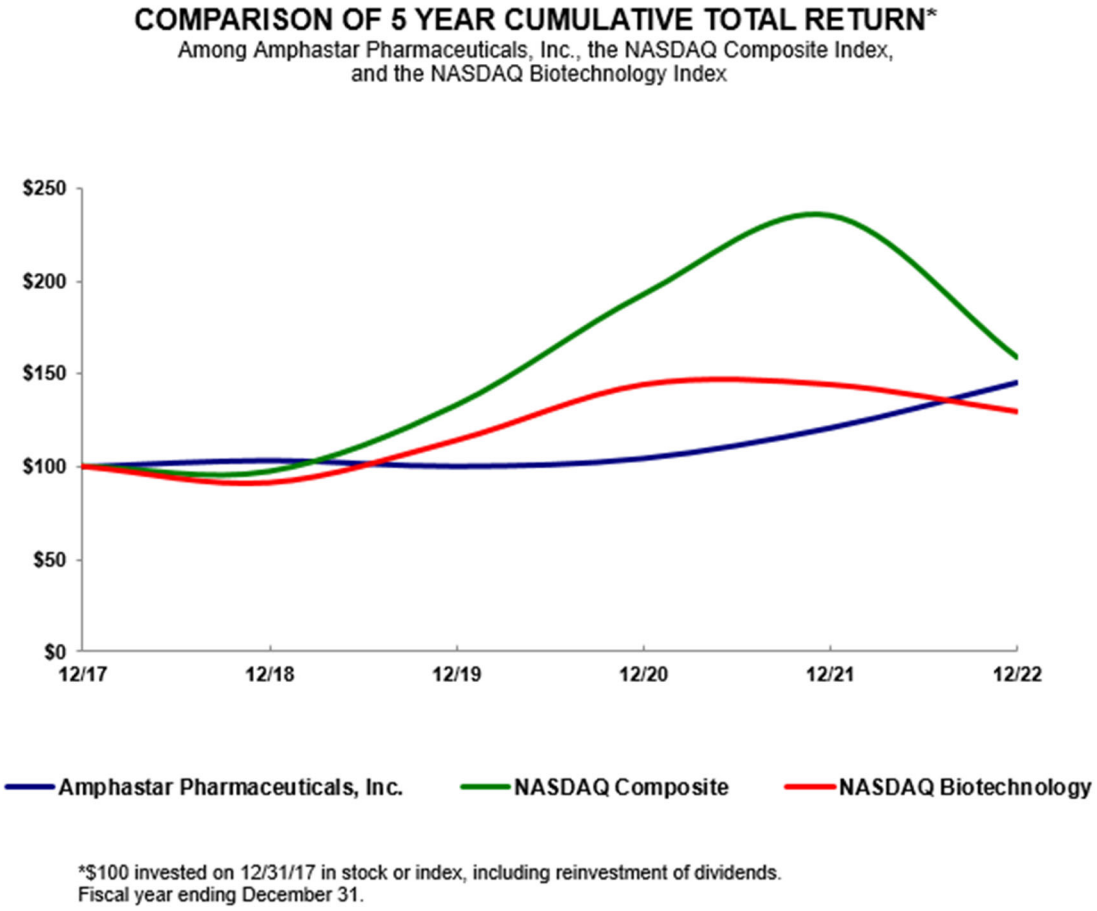
Holders of Record

At February 22, 2023, we had 47,896,820 shares of common stock outstanding held by approximately 135 stockholders of record of our common stock. We believe the actual number of stockholders is greater than this number of record holders, including stockholders who are beneficial owners but whose shares are held in "street" name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Stock Performance Graph

This graph shall not be deemed "soliciting material" or to be "filed" with the Securities and Exchange Commission for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any filing of Amphastar Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Exchange Act.

The following graph illustrates a comparison of the total cumulative stockholder return on our common stock since December 31, 2017, with the cumulative stockholder return since December 31, 2017, on two indices: the Nasdaq Composite Index and the Nasdaq Biotechnology Index. The graph assumes an initial investment of $100 on December 31, 2017, both in our common stock and each index. It also assumes reinvestment of dividends, if any. Historical stockholder return shown is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.



Issuer Purchases of Equity Securities During the Quarter Ended December 31, 2022

The table below provides information with respect to repurchases of our common stock.

Period	Total Number of Shares Purchased [1]	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
October 1 – October 31, 2022	285,518	$ 29.27	285,518	—
November 1 – November 30, 2022	186,084	29.58	186,084	—
December 1 – December 31, 2022	144,663	29.01	144,663	—

[1] On November 7, 2022, we announced that our Board of Directors authorized an increase of $50.0 million to our share buyback program. As of December 31, 2022, $43.6 million remained available for repurchase under such program. The share buyback program does not have an expiration date.

Recent Sales of Unregistered Securities

None.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following is a discussion and analysis of the consolidated operating results, financial condition, liquidity and cash flows of our company as of and for the periods presented below. The following discussion and analysis should be read in conjunction with the audited consolidated financial statements and the related notes thereto included in Item 8 under the heading "Financial Statements and Supplementary Data." This discussion contains forward-looking statements that are based on the beliefs of our management, as well as assumptions made by and information currently available to, our management. Actual results could differ materially from those discussed in or implied by forward-looking statements. These risks, uncertainties and other factors include among others, those identified under the "Special Note About Forward-Looking Statements," above and described in greater detail elsewhere in this Annual Report on Form 10-K, particularly in Item 1A, "Risk Factors."

In this section, we generally discuss the results of our operations for the year ended December 31, 2022, compared to the year ended December 31, 2021. For a discussion of the year ended December 31, 2021, to the year ended December 31, 2020, please refer to Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 11, 2022, which discussion is hereby incorporated herein by reference.

Overview

We are a bio-pharmaceutical company focusing primarily on developing, manufacturing, marketing, and selling technically challenging generic and proprietary injectable, inhalation, intranasal, and insulin API products. We currently manufacture and sell over 20 products.

Our largest products by net revenues currently include Primatene MIST®, epinephrine, glucagon, lidocaine, phytonadione, and enoxaparin sodium. In April 2022, the FDA approved our ganirelix acetate injection 250mg/0.5mL prefilled syringe, which we launched in June 2022. In July 2022, the FDA approved our vasopressin injection, USP 20 Units/mL, 1 mL single-dose vial, which we launched in August 2022. In May 2022, the FDA approved our regadenoson injection, 0.08mg/mL, 5mL, single-dose prefilled syringe. The timing of the launch of this product is subject to a confidential settlement agreement with the product's innovator.

We are currently developing a portfolio of generic abbreviated new drug applications, or ANDAs, biosimilar insulin product candidates, and proprietary product candidates, which are in various stages of development and target a variety of indications. Three of the ANDAs and one new drug application, or NDA, are currently on file with the FDA.

To complement our internal growth and expertise, we have made several strategic acquisitions of companies, products, and technologies. These acquisitions collectively have strengthened our core injectable and inhalation product technology infrastructure by providing additional manufacturing, marketing, and research and development capabilities, including the ability to manufacture raw materials, API, and other components for our products.

In 2021, we completed the restructuring of our Chinese subsidiary, ANP, resulting in the reduction of ANP's ownership of Hanxin Pharmaceutical Technology Co., Ltd, or Hanxin to 14%. See Note 3 in the accompanying "Notes to Consolidated Financial Statements" in this Annual Report on Form 10-K. As a result of the restructuring, we determined that we have significant influence over Hanxin and as such the retained non-controlling investment in Hanxin is accounted for as an equity method investment. Hanxin continues to be a related party subsequent to the restructuring.

COVID-19 Pandemic

The ongoing COVID-19 pandemic and the resulting containment measures that have been in effect from time to time in various countries and territories since early 2020 have had a number of substantial negative impacts on businesses around the world and on global, regional, and national economies, including widespread disruptions in supply chains for a wide variety of products and resulting increases in the prices of many goods and services. Currently, our production facilities in all of our locations continue to operate as they had before the COVID-19 pandemic with few changes other than for enhanced safety measures intended to prevent the spread of the virus.

Some of our ongoing clinical trials experienced short-term interruptions in the recruitment of patients due to the COVID-19 pandemic, as hospitals prioritized their resources towards the COVID-19 pandemic and governments imposed travel restrictions. Some clinical trials experienced increased expenses due to new protocols to protect participants from COVID-19. Additionally, certain suppliers had difficulties meeting their delivery commitments, and we are experiencing longer lead times for components. For example, in the first quarter of 2022, increases in COVID-19 cases in Shanghai, China, led to shutdowns and delays at the ports in Shanghai, which led to temporary delays in shipping certain APIs and starting materials from our facility in China to our U.S. business. Future shutdowns could have an adverse impact on our operations. However, the extent of the impact of any future shutdown or delay is highly uncertain and difficult to predict.

It is not possible at this time to estimate the complete impact that COVID-19 could have on our business, including our customers and suppliers, as the effects will depend on future developments, which are highly uncertain and cannot be predicted. Infections may resurge or become more widespread, including due to new variants and the limitation on our ability to travel and timely sell and distribute our products, as well as any closures or supply disruptions may be prolonged for extended periods, all of which would have a negative impact on our business, financial condition, and operating results.

Even after the COVID-19 pandemic has subsided, we may continue to experience an adverse impact on our business due to the continued global economic impact of the COVID-19 pandemic. We cannot anticipate all of the ways in which health epidemics such as COVID-19 could adversely impact our business. See Item 1A, "Risk Factors" for further discussion of the possible impact of the COVID-19 pandemic on our business.

Macroeconomic Trends and Uncertainties

The Russia-Ukraine conflict and resulting sanctions and other actions against Russia have led to uncertainty and disruption in the global economy. Although the conflict has not had a direct material adverse impact on our revenues or other financial results, one of our insulin API customers in Western Europe, that previously bought our product and resold it into Russia, did not purchase API from us this year. We are closely monitoring the events of the Russia-Ukraine conflict and its impact on Europe and throughout the rest of the world. It is not clear at this time how long the conflict will endure, or if it will escalate further, which could further compound the adverse impact to the global economy and consequently affect our results of operations.

Certain other worldwide events and macroeconomic factors, such as international trade relations, new legislation and regulations, taxation or monetary policy changes, political and civil unrest, supply chain disruptions, inflationary pressures, and rising interest rates, among other factors, also increase volatility in the global economy. For example, the United States has recently experienced historically high levels of inflation. According to the U.S. Department of Labor, the annual inflation rate for the United States was approximately 6.5% as of December 2022. The existence of inflation in the United States, and global economy has and may continue to result in higher interest rates and capital costs, increased costs of labor, weakening exchange rates and other similar effects.

See Item 1A, "Risk Factors" for further discussion of the possible impact of the Russia-Ukraine conflict and other macroeconomic factors on our business.

Business Segments

As of December 31, 2022, our performance is assessed and resources are allocated based on the following two reportable segments: (1) finished pharmaceutical products and (2) API products. The finished pharmaceutical products segment manufactures, markets and distributes Primatene MIST®, epinephrine, glucagon, phytonadione, lidocaine, enoxaparin, naloxone, as well as various other critical and non-critical care drugs. The API segment manufactures and distributes RHI API and porcine insulin API for external customers and internal product development. Information reported herein is consistent with how it is reviewed and evaluated by our chief operating decision maker. Factors used to identify our segments include markets, customers and products.

For more information regarding our segments, see "Part II – Item 8. Financial Statements and Supplementary Data – Notes to Consolidated Financial Statements – Segment Reporting Information."

Results of Operations

Year ended December 31, 2022 compared to year ended December 31, 2021

Net revenues

	Year Ended December 31,		Change	
	2022	2021	Dollars	%
		(in thousands)		
Net revenues				
Finished pharmaceutical products	$ 486,505	$ 419,570	$ 66,935	16 %
API	12,482	18,198	(5,716)	(31)%
Total net revenues	$ 498,987	$ 437,768	$ 61,219	14 %
Cost of revenues				
Finished pharmaceutical products	$ 229,795	$ 209,855	$ 19,940	10 %
API	20,332	28,174	(7,842)	(28)%
Total cost of revenues	$ 250,127	$ 238,029	$ 12,098	5 %
Gross profit	$ 248,860	$ 199,739	$ 49,121	25 %
as % of net revenues	*50 %*	*46 %*		

The increase in net revenues of finished pharmaceutical products for 2022 was primarily due to the following changes:

	Year Ended December 31,		Change	
	2022	2021	Dollars	%
		(in thousands)		
Finished pharmaceutical products net revenues				
Primatene MIST®	$ 84,309	$ 73,113	$ 11,196	15 %
Epinephrine	74,204	57,530	16,674	29 %
Glucagon	55,322	47,639	7,683	16 %
Lidocaine	52,539	44,413	8,126	18 %
Phytonadione	49,500	45,498	4,002	9 %
Enoxaparin	34,950	35,962	(1,012)	(3)%
Naloxone	26,269	27,540	(1,271)	(5)%
Other finished pharmaceutical products	109,412	87,875	21,537	25 %
Total finished pharmaceutical products net revenues	$ 486,505	$ 419,570	$ 66,935	16 %

Primatene MIST® sales continued to grow in 2022 as a result of increased unit volumes, which was primarily a result of the continued success of our advertising campaign. The increase in sales of epinephrine was primarily due to an increase in unit volumes, due to an increase in demand caused by competitor shortages, contributing $9.0 million in sales, as well as a higher average selling price, which contributed $7.7 million to the increase in sales. The increase in sales of glucagon was primarily due to an increase in unit volumes as the prior year period did not include a full year of sales due to glucagon's launch in the first quarter of 2021. The increase in sales of lidocaine was primarily due to an increase in unit volumes, which contributed $4.4 million, as well as a higher average selling price, which contributed $3.8 million to the increase in sales. The increase in sales of phytonadione was due to a higher average selling price. The decrease in sales of naloxone was primarily due to a decrease in average selling price, which caused a decrease of $3.2 million, which was partially offset by an increase in unit volumes contributing $1.9 million. The increase in other finished pharmaceutical products was primarily due to higher unit volumes of calcium chloride, dextrose and sodium bicarbonate, due to increased demand caused by competitor shortages, as well as the launch of ganirelix and vasopressin in June 2022 and August 2022, respectively.

We anticipate that sales of naloxone and enoxaparin will continue to fluctuate in the future as a result of changing levels of competition. We also anticipate that sales of epinephrine and other finished pharmaceutical products will continue to fluctuate depending on the ability of our competitors to supply market demands.

Sales of API primarily depend on the timing of customer purchases. One of our insulin API customers in Western Europe that previously bought our product and resold it into Russia did not purchase API this year, which resulted in a decline of $2.0 million in API sales.

In May 2021, we amended the Supply Agreement with MannKind Corporation, whereby MannKind's aggregate total commitment of RHI API under the Supply Agreement was modified and extended for an additional year through 2027, which timeframe would have previously lapsed after calendar year 2026. MannKind agreed to pay us an amendment fee of $2.0 million. We received the first payment of the amendment fee of $1.0 million in June 2021, which we recognized in net revenues during the year ended December 31, 2021. The remaining $1.0 million of the amendment fee was received in January 2022, which we recognized in net revenues during the year ended December 31, 2022 and relates to the amendments to the 2022 supply level. We anticipate that sales of API will continue to fluctuate and may decrease due to the inherent uncertainties related to sales to MannKind pursuant to our supply agreement with them. In addition, most of our API sales are denominated in euros, and the fluctuation in the value of euros versus the U.S. dollar has had, and may continue to have, an impact on API sales revenues in the near term.

A significant portion of our customer shipments in any period relate to orders received and shipped in the same period, generally resulting in low product backlog relative to total shipments at any time. However, as of December 31, 2022, we experienced a backlog of approximately $7.0 million for various products, partially as a result of competitor shortages, supplier constraints and labor shortages at our facilities in California. We are currently working on resolving backlog related issues and believe that we will be able to reduce the backlog in the near future. Historically, our backlog has not been a meaningful indicator in any given period of our ability to achieve any particular level of overall revenue or financial performance.

Gross Margins

The increase in sales of Primatene MIST®, epinephrine and glucagon, which are higher-margin products, helped increase our gross margins for the year ended December 31, 2022. These increases in gross margins were partially offset by an overall increase in labor and input costs.

We are experiencing increased costs for labor and certain purchased components. Additionally, the cost of heparin may fluctuate, which could put downward pressure on our gross margins. However, we believe that this trend will be offset by increased sales of our higher-margin products, including Primatene MIST®, glucagon, vasopressin, ganirelix and our pipeline products.

Selling, distribution, and marketing, and general and administrative

	Year Ended December 31,		Change	
	2022	2021	Dollars	%
		(in thousands)		
Selling, distribution, and marketing	$ 21,531	$ 17,486	$ 4,045	23 %
General and administrative	45,061	51,434	(6,373)	(12)%

The increase in selling, distribution and marketing expenses was primarily due to increased freight expenses and an increase in advertising spending for Primatene MIST®. The decrease in general and administrative expense was primarily due to a decrease in legal expenses and a decrease in expenses in China due to the ANP restructuring in 2021.

We expect that selling, distribution and marketing expenses will continue to increase due to the increase in marketing expenditures for Primatene MIST®. Legal fees may fluctuate from period to period due to the timing of patent challenges and other litigation matters.

Research and development

	Year Ended December 31,		Change	
	2022	2021	Dollars	%
	(in thousands)			
Salaries and personnel-related expenses	$ 25,786	$ 27,461	$ (1,675)	(6)%
Clinical trials	5,689	3,053	2,636	86 %
FDA fees	268	443	(175)	(40)%
Materials and supplies	25,630	11,150	14,480	130 %
Depreciation	10,061	11,008	(947)	(9)%
Other expenses	7,337	7,817	(480)	(6)%
Total research and development expenses	$ 74,771	$ 60,932	$ 13,839	23 %

The increase in research and development expenses is primarily due to an increase in materials and supplies as a result of an increase in expenditures on raw materials and components for our AMP-018 and insulin products. Additionally, clinical trial expense increased due to external studies related to our insulin and inhalation product pipeline. Reductions of salaries, depreciation and other expenses are related to the restructuring of our subsidiary in China.

Research and development costs consist primarily of costs associated with the research and development of our product candidates including the cost of developing APIs. We expense research and development costs as incurred.

We have made, and expect to continue to make, substantial investments in research and development to expand our product portfolio and grow our business. We expect that research and development expenses will increase on an annual basis due to increased clinical trial costs related to our insulin and inhalation product candidates. These expenditures will include costs of APIs developed internally as well as APIs purchased externally, the cost of purchasing reference listed drugs and the costs of performing the clinical trials. As we undertake new and challenging research and development projects, we anticipate that the associated costs will increase significantly over the next several quarters and years. Over the past year, some of our ongoing clinical trials experienced short term interruptions in the recruitment of patients due to the COVID-19 pandemic, as hospitals prioritized their resources towards the COVID-19 pandemic and trial sites changed their operating protocols to protect participants from COVID-19. These conditions may continue to increase the costs of clinical trials and also delay spending and results of these trials.

Other income (expense), net

	Year Ended December 31,		Change	
	2022	2021	Dollars	%
	(in thousands)			
Other income (expenses), net	$ 9,068	$ 14,536	$ (5,468)	(38)%

In January 2022, we received a settlement of $5.4 million in connection with the Regadenoson patent litigation. For more information regarding our litigation matters, see Note 19 in the accompanying “Notes to Consolidated Financial Statements” in this Annual Report on Form 10-K. In the third quarter of 2021, we completed the restructuring of ANP, whereby our ownership interest in ANP increased to 100% and ANP’s ownership interest in Hanxin and its subsidiaries was reduced to approximately 14%. As a result of the loss in control over Hanxin, we deconsolidated Hanxin and recorded a $13.6 million gain on deconsolidation. For more information regarding our ANP restructuring, see Note 3 in the accompanying “Notes to Consolidated Financial Statements” in this Annual Report on Form 10-K.

Income tax provision

	Year Ended December 31,		Change	
	2022	2021	Dollars	%
	(in thousands)			
Income tax provision	$ 23,477	$ 20,630	$ 2,847	14 %
Effective tax rate	*20 %*	*25 %*		

Our effective tax rate for the year ended December 31, 2022 decreased in comparison to the year ended December 31, 2021, primarily due to differences in pre-tax income positions and excess tax benefit from share-based compensation. For more information regarding our income taxes, see Note 15 to the consolidated financial statements.

Liquidity and Capital Resources

Cash Requirements and Sources

We need capital resources to maintain and expand our business. We expect our cash requirements to increase significantly in the foreseeable future as we sponsor clinical trials for, seek regulatory approvals of, and develop, manufacture and market our current development stage product candidates and pursue strategic acquisitions of businesses or assets. Our future capital expenditures include projects to upgrade, expand, and improve our manufacturing facilities in the United States and China, including a significant increase in capital expenditures in 2023 We plan to fund this facility expansion with cash flows from operations. Our cash obligations include the principal and interest payments due on our existing loans and lease payments, as described below and throughout this Annual Report on Form 10-K.

As of December 31, 2022, our foreign subsidiaries collectively held $15.2 million in cash and cash equivalents. Cash or cash equivalents held at foreign subsidiaries are not available to fund the parent company's operations in the United States. We believe that our cash reserves, operating cash flows, and borrowing availability under our credit facilities will be sufficient to fund our operations for at least the next 12 months. We expect additional cash flows to be generated in the longer term from future product introductions, although there can be no assurance as to the receipt of regulatory approval for any product candidates that we are developing or the timing of any product introductions, which could be lengthy or ultimately unsuccessful.

We maintain a shelf registration statement on Form S-3 pursuant to which we may, from time to time, sell up to an aggregate of $250 million of our common stock, preferred stock, debt securities, depositary shares, warrants, subscription rights, purchase contracts, or units. If we require or elect to seek additional capital through debt or equity financing in the future, we may not be able to raise capital on terms acceptable to us or at all. To the extent we raise additional capital through the sale of equity or convertible debt securities, the issuance of such securities will result in dilution to our stockholders. If we are required and unable to raise additional capital when desired, our business, operating results and financial condition may be adversely affected.

Working capital increased $69.2 million to $283.5 million at December 31, 2022, compared to $214.3 million at December 31, 2021.

Cash Flows from Operations

The following table summarizes our cash flows from operating, investing, and financing activities for the years ended December 31, 2022 and 2021.

	Year Ended December 31,	
	2022	2021
	(in thousands)	
Statement of Cash Flow Data:		
Net cash provided by (used in)		
Operating activities	$ 89,181	$ 97,994
Investing activities	(32,777)	(28,672)
Financing activities	(26,439)	(37,018)
Effect of exchange rate changes on cash	(220)	(223)
Net increase in cash, cash equivalents, and restricted cash	$ 29,745	$ 32,081

Sources and Use of Cash

Operating Activities

Net cash provided by operating activities was $89.2 million for the year ended December 31, 2022, which included net income of $91.4 million. Non-cash items comprised primarily of $28.7 million of depreciation and amortization and $17.9 million of share-based compensation expense.

Additionally, for the year ended December 31, 2022, there was a net cash outflow from changes in operating assets and

liabilities of $32.2 million, which resulted from an increase in accounts receivables; an increase in inventories, as we increased purchases of certain raw materials and components; as well as a decrease in accounts payable and accrued liabilities. Accounts payable and accrued liabilities decreased primarily due to the timing of payments. The increase in accounts receivables was due to both increases in sales and timing of sales.

Net cash provided by operating activities was $98.0 million for the year ended December 31, 2021, which included net income of $63.3 million. Non-cash items comprised primarily of $26.8 million of depreciation and amortization, $18.7 million of share-based compensation expense and a $13.6 million gain relating to the deconsolidation of Hanxin and its subsidiaries as result of the ANP restructuring during the third quarter of 2021. Additionally, for the year ended December 31, 2021, there was a net cash outflow from changes in operating assets and liabilities of $2.0 million, which resulted from an increase in accounts receivable, which was partially offset by a decrease in inventory, as well as an increase in accounts payable and accrued liabilities. Accounts payable and accrued liabilities increased primarily due to the timing of payments. The increase in accounts receivable was due to both increases in sales and the timing of sales.

Investing Activities

Net cash used in investing activities was $32.8 million for the year ended December 31, 2022, primarily as a result of $24.0 million in purchases of property, plant, and equipment, which included $15.4 million incurred in the United States, $1.4 million in France, and $7.2 million in China. Additionally, net cash outflows from purchases and sales of short-term investments during the period was $7.8 million.

Net cash used in investing activities was $28.7 million for the year ended December 31, 2021, primarily as a result of $27.5 million in purchases of property, plant, and equipment, which included $15.3 million incurred in the United States, $0.8 million in France, and $11.4 million in China.

Financing Activities

Net cash used in financing activities was $26.4 million for the year ended December 31, 2022, primarily as a result of purchases of $39.9 million of treasury stock, which was partially offset by $15.7 million in net proceeds from the settlement of share-based compensation awards under our equity plan. Additionally, we also made $1.8 million in principal payments on our long-term debt.

Net cash used in financing activities was $37.0 million for the year ended December 31, 2021, primarily as a result of $53.6 million in payments relating to the purchase of additional ANP ownership interest in connection with the ANP restructuring completed during the third quarter of 2021 (For more information, see Note 3 in the accompanying “Notes to Consolidated Financial Statements” in this Annual Report on Form 10-K). We borrowed $70.0 million in connection with a credit agreement with Capital One N.A., which was partially offset by $37.9 million in principal payments on our long-term debt and lines of credit. We used $28.9 million to purchase treasury stock and received $15.9 million in net proceeds from the settlement of share-based compensation awards under our equity plans.

Debt and Borrowing Capacity

Our outstanding debt obligations are summarized as follows:

	December 31,		
	2022	2021	Change
		(in thousands)	
Short-term debt and current portion of long-term debt	$ 3,046	$ 2,202	$ 844
Long-term debt	72,839	74,776	(1,937)
Total debt	$ 75,885	$ 76,978	$ (1,093)

As of December 31, 2022, we had $84.6 million in unused borrowing capacity under revolving lines of credit with Capital One N.A. and China Merchant Bank.

The weighted average interest rates on lines of credit as of December 31, 2022 and 2021 were 5.2% and 1.8%, respectively. For our loans with Capital One N.A. and East West Bank, we have entered into fixed interest rate swap contracts to exchange the variable interests for fixed interest rates.

For more information regarding our outstanding indebtedness, see "Part II – Item 8. Financial Statements and Supplementary Data – Notes to Consolidated Financial Statements – Debt."

Operating Lease Obligations

As discussed in Note 18 to the consolidated financial statements, as of December 31, 2022 we had a total of $32.4 million of minimum rental payments under operating leases. Of that amount, $4.1 million is due within 12 months as of December 31, 2022.

Purchase obligations

We have certain purchase obligations under which we are required to make minimum payments for items including, but not limited to, inventory and pharmaceutical manufacturing and laboratory equipment. As of December 31, 2022, we had an aggregate amount of approximately $58.2 million.

Critical Accounting Policies

We prepare our consolidated financial statements in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates. In some cases, changes in the accounting estimates are reasonably likely to occur from period to period. Accordingly, actual results could differ materially from our estimates. To the extent that there are material differences between these estimates and actual results, our financial condition and results of operations will be affected. We base our estimates on past experience and other assumptions that we believe are reasonable under the circumstances, and we evaluate these estimates on an ongoing basis. We refer to accounting estimates of this type as critical accounting policies, which we discuss further below. While our significant accounting policies are more fully described in Note 2 to our audited consolidated financial statements, we believe that the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our audited consolidated financial statements.

Revenue Recognition

Our net revenues consist principally of revenues generated from the sale of our pharmaceutical products. We also generate a small amount of revenues from contract manufacturing services. Generally, we recognize revenues at the time of product delivery to our customers in accordance with ASC, 606 *Revenue from Contracts with Customers*. In some cases, revenues are recognized at the time of shipment when stipulated by the terms of the sale agreements. Revenues derived from contract manufacturing services are recognized when third-party products are shipped to customers, after the customer has accepted test samples of the products to be shipped.

The consideration we receive in exchange for our goods or services is only recognized when it is probable that a significant reversal will not occur. The consideration to which we expect to be entitled includes a stated list price, less various forms of variable consideration. We make significant estimates for related variable consideration at the point of sale, including chargebacks, rebates, product returns, other discounts and allowances.

Provision for estimated chargebacks, rebates, discounts, product returns and credit losses is made at the time of sale and is analyzed and adjusted, if necessary, at each balance sheet date.

If actual future payments for the discounts, returns, fees, rebates and chargebacks exceed the estimates we made at the time of sale, our financial position, results of operations and cash flows would be negatively impacted. As discussed under "Accrual for Product Returns" below, we are generally obligated to accept from our customers the return of pharmaceuticals that have reached or will soon reach their expiration dates. We establish reserves for such amounts based on historical experience and other information available at the time of sale, but the actual returns will not occur until several years after the sale. Although we believe that our estimates and assumptions are reasonable as of the date when made, actual results may differ significantly from these estimates. Our financial position, results of operations and cash flows may be materially and negatively impacted if actual returns exceed our estimated allowances for returns.

We establish allowances for estimated chargebacks, rebates and product returns based on a number of qualitative and quantitative factors, including:

- contract pricing and return terms of our agreements with customers;
- wholesaler inventory levels and turnover;
- historical chargeback and product return rates;
- shelf lives of our products, which is generally two years, as is the case with enoxaparin;
- direct communication with customers;
- anticipated introduction of competitive products or authorized generics; and
- anticipated pricing strategy changes by us and/or our competitors.

Service revenues derived from research and development contracts is recognized over time based on progress toward completion of the performance obligation. For each performance obligation satisfied over time, we assess the proper method to be used for revenue recognition, either an input method to measure progress toward the satisfaction of services or an output method of determining the progress of completion of performance obligation. For the years ended December 31, 2022 and 2021, revenue from research and development services at ANP were $4.3 million and $5.1 million, respectively.

Provision for Chargebacks and Rebates

The provision for chargebacks and rebates is a significant estimate used in the recognition of revenue. Wholesaler chargebacks relate to sales terms under which we agree to reimburse wholesalers for differences between the gross sales prices at which we sell our products to wholesalers and the actual prices of such products that wholesalers resell them under our various contractual arrangements with third parties such as hospitals and group purchasing organizations in the United States. Rebates include primarily amounts paid to retailers, payers, and providers in the United States, including those paid to state Medicaid programs, and are based on contractual arrangements or statutory requirements. We estimate chargebacks and rebates using the expected value method at the time of sale to wholesalers based on wholesaler inventory stocking levels, historic chargeback and rebate rates, and current contract pricing.

The provision for chargebacks and rebates is reflected as a component of net revenues. The following table is an analysis of the chargeback and rebate provision:

	Year Ended December 31,	
	2022	2021
	(in thousands)	
Beginning balance	$ 20,167	$ 20,380
Provision for chargebacks and rebates	208,081	201,133
Credits and payments issued to third parties	(201,642)	(201,346)
Ending balance	$ 26,606	$ 20,167

Changes in the chargeback provision from period to period are primarily dependent on our sales to its wholesalers, the level of inventory held by wholesalers, and the wholesalers' customer mix. Changes in the rebate provision from period to period are primarily dependent on retailer's and other indirect customers' purchases. The approach that we use to estimate chargebacks and rebates has been consistently applied for all periods presented. Variations in estimates have been historically small. We continually monitor the provision for chargebacks and rebates and make adjustments when we believe that the actual chargebacks and rebates may differ from the estimates. The settlement of chargebacks and rebates generally occurs within 20 days to 60 days after the sale to wholesalers. Accounts receivable and/or accounts payable and accrued liabilities are reduced and/or increased by the chargebacks and rebate amounts depending on whether we have the right to offset with the customer. Of the provision for chargebacks and rebates as of December 31, 2022 and 2021, $20.5 million and $15.6 million were included as a reduction to accounts receivable, net, on the

consolidated balance sheets, respectively. The remaining provision as of December 31, 2022 and 2021, was $6.1 million and $4.6 million, respectively, were included in accounts payable and accrued liabilities on the consolidated balance sheets.

Accrual for Product Returns

We offer most customers the right to return qualified excess or expired inventory for partial credit; however, API product sales are generally non-returnable. Our product returns primarily consist of the returns of expired products from sales made in prior periods. Returned products cannot be resold. At the time product revenue is recognized, we record an accrual for product returns estimated using the expected value method. The accrual is based, in part, upon the historical relationship of product returns to sales and customer contract terms. We also assesses other factors that could affect product returns including market conditions, product obsolescence, and new competition. Although these factors do not normally give our customers the right to return products outside of the regular return policy, we realize that such factors could ultimately lead to increased returns. We analyze these situations on a case-by-case basis and make adjustments to the product return reserve as appropriate.

The provision for product returns is reflected as a component of net revenues. The following table is an analysis of the product return liability:

	Year Ended December 31,	
	2022	2021
	(in thousands)	
Beginning balance	$ 21,677	$ 14,204
Provision for product returns	4,405	15,005
Credits issued to third parties	(6,631)	(7,532)
Ending balance	$ 19,451	$ 21,677

Of the provision for product returns as of December 31, 2022 and 2021, $14.9 million and $16.0 million were included in accounts payable and accrued liabilities on the consolidated balance sheets, respectively. The remaining provision as of December 31, 2022 and 2021, of $4.6 million and $5.7 million were included in other long-term liabilities, respectively. For the years ended December 31, 2022 and 2021, our aggregate product return rate was 1.4% and 1.7% of qualified sales, respectively.

Inventory

Inventories consist of currently marketed products and products manufactured under contract. Inventories are stated using the first-in, first-out method, on a consistent basis. Inventory is stated at the lower of cost or net realizable value. We adjust inventories to their net realizable value: (i) if a launch of a new product is delayed and inventory may not be fully utilized and could be subject to impairment, (ii) when a product is close to expiration and not expected to be sold, (iii) when a product has reached its expiration date, (iv) when a product is not expected to be sellable, and (v) when the estimated net realizable value is below cost. In determining the estimated net realizable value of an inventory item, we consider factors such as the forecasted average net selling price, the amount of inventory on hand, its remaining shelf life, its regulatory approval status, and current and expected market conditions, including management forecasts and levels of competition.

The largest adjustment to the net realizable value of our inventory has historically been related to enoxaparin. The adjustment of enoxaparin inventory to its net realizable value has been driven primarily by increases in the prices of heparin, the starting material for the production of the API in our enoxaparin product. Other cost increases relate to labor and overhead also impacted the cost of producing enoxaparin. Additionally, fluctuations in the forecasted average net selling price impact this estimate. The average net selling price has fluctuated due to competitor entries and exits from the market.

Impairment of Intangible and Long-Lived Assets

We review long-lived assets and definite-lived identifiable intangible assets or asset groups for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Such events and

circumstances include decisions by the FDA regarding evidence of effectiveness of proprietary drug candidates or bioequivalence (sameness) of our generic product candidates as compared to the reference drug, communication with the regulatory agencies regarding the safety and efficacy of our products under review, the use of the asset in current research and development projects, any potential alternative uses of the asset in other research and development projects in the short-to-medium term, clinical trial results and research and development portfolio management options. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset or asset groups and its eventual disposition. If the sum of the expected future undiscounted cash flows is less than the carrying amount of the asset or asset groups, further impairment analysis is performed. An impairment loss is measured as the amount by which the carrying amount exceeds the fair value of the asset or asset groups (assets to be held and used) or fair value less cost to sell (assets to be disposed of). All of our impairments relate primarily to the isolated write-off of certain manufacturing equipment related to abandoned projects. Since we periodically assess our product candidates and make changes to product development plans, we incur impairment charges from time to time which can fluctuate significantly from period to period.

The indefinite-lived intangible asset, the Primatene® trademark acquired in June 2008, and goodwill are tested for impairment annually, in the fourth quarter, or more frequently if indicators of impairment are present. An impairment loss is recorded if the asset's fair value is less than its carrying value. We also periodically review the Primatene® trademark to determine if events and circumstances continue to support an indefinite useful life. When we choose to perform a qualitative assessment, we evaluate economic, industry and company-specific factors as an initial step. If we determine it is more likely than not that the Primatene® trademark is impaired or the fair value of a reporting unit is less than its carrying amount, further quantitative impairment process is then performed; otherwise, no further testing is required. If the life is no longer indefinite, the asset is tested for impairment, and the carrying value, after recognition of any impairment loss, is amortized over its remaining useful life. No impairment of indefinite-lived intangible asset and goodwill was recorded during the years ended December 31, 2022, 2021, or 2020, respectively.

Deferred Income Taxes

We utilize the liability method of accounting for income taxes under which deferred taxes are determined based on the temporary differences between the financial statements and the tax basis of assets and liabilities using enacted tax rates. A valuation allowance is recorded when it is more likely than not that the deferred tax assets will not be realized.

A number of years may elapse before an uncertain tax position for which we have established a tax reserve is audited and finally resolved. The number of years for which we can be subject to audit varies depending on the tax jurisdiction. While it is often difficult to predict the final outcome or the timing of the resolution of an audit, we believe that our reserves for uncertain tax benefits reflect the outcome of tax positions that is more likely than not to occur. The resolution of a matter could be recognized as an adjustment to our provision for income taxes and our effective tax rate in the period of resolution, and may also require a use of cash.

Share-Based Compensation

Options issued under our 2015 Equity Incentive Award Plan, or the 2015 Plan, and our Amended and Restated 2005 Equity Incentive Award Plan, or 2005 Plan, are granted at exercise prices equal to or greater than the fair value of the underlying common shares on the date of grant and vest based on continuous service. There have been no awards with performance conditions and no awards with market conditions. The options have a contractual term of five to ten years and generally vest over a three- to five-year period.

We use the Black-Scholes option pricing model to determine the fair value of options awards. The Black-Scholes option pricing model has various inputs such as the common share price on the date of grant, exercise price, the risk-free interest rate, volatility, expected life and dividend yield, all of which are estimates. We used the risk free rate on U.S. Treasury securities at the time of grant for instruments with maturities commensurate with the expected term of the stock option. Our volatility estimate was based on the weighted average historical volatility of our stock price since IPO. Our dividend yield was assumed to be 0%, because we have no plans to pay dividends. We estimate the expected term of options with consideration of vesting date, contractual term, and historical experience for employee exercise and post-vesting employment termination behavior after our common stock has been publicly traded. The expected term of "plain vanilla" options is estimated based on the midpoint between the vesting date and the end of the contractual term under the simplified method.

The fair value of each share-based compensation award is amortized into compensation expense on a straight-line basis between the grant date for the option and the vesting date net of expected forfeitures. We estimate forfeitures at the time of grant and revise those estimates in subsequent periods if actual numbers differ from such estimates. The change of any of these inputs could significantly impact the determination of the fair value of our options as well as significantly impact our results of operations.

Recent Accounting Pronouncements

There have been no recent accounting pronouncements or changes in accounting pronouncements during the year ended December 31, 2022 that could have a material impact on our balance sheets or statement of operations.

Off Balance Sheet Arrangements

We do not have any relationships or financial partnerships with unconsolidated entities, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts.

Government Regulation

Our products and facilities are subject to regulation by a number of federal and state governmental agencies. The FDA in particular, maintains oversight of the formulation, manufacture, distribution, packaging, and labeling of all of our products. The Drug Enforcement Administration, or DEA, maintains oversight over our products that are considered controlled substances.

From May 17 through May 25, 2022, our IMS facility in South El Monte, California was subject to routine cGMP inspection by the FDA. The inspection included a review of compliance with FDA regulations relating to Good Manufacturing Practices. The inspection resulted in one observation on Form 483. We responded to that observation. We believe that our response to the observation will satisfy the requirements of the FDA and that no significant further actions will be necessary.

From May 17, 2022 to June 30, 2022, five of our clinical trial sites were subject to pre-approval biomonitoring inspections by the FDA. The inspections included a review of the clinical trial data to support one of our pending applications. Each inspection resulted in no Form 483 findings. No further actions will be necessary.

On June 21, 2022, our IMS facility in South El Monte, California was subject to routine inspection by the DEA. The inspection included a review of manufacture, storage and handling of our controlled substances. The inspection resulted in no findings. No further actions will be necessary.

From July 18 through July 21, 2022, our Amphastar facility in Rancho Cucamonga, California was subject to a remote pre-approval inspection by the FDA. The inspection included a review of the analytical clinical trial sample testing data to support one of our pending applications. The inspection resulted in no Form 483 findings. No further actions will be necessary.

From November 22 through November 25, 2022, our AFP facility in France was subject to a GMP inspection from ANSM, the French Health Authority. The inspection included a review of compliance with French regulations relating to Good Manufacturing Practices. The inspection resulted in three observations that were provided during the inspection. A final report from ANSM is forthcoming at which time we will provide a response.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

The following discussion provides forward-looking quantitative and qualitative information about our potential exposure to market risk. Market risk represents the potential loss arising from adverse changes in the value of financial instruments. The risk of loss is assessed based on the likelihood of adverse changes in fair values, cash flows or future earnings. We are exposed to market risk for changes in the market values of our investments (Investment Risk), the impact of interest rate changes (Interest Rate Risk), and the impact of foreign currency exchange changes (Foreign Currency Exchange Risk).

Investment Risk

We regularly review the carrying value of our investments and identify and recognize losses, for income statement purposes, when events and circumstances indicate that any declines in the fair values of such investments below our accounting basis are other than temporary. As of December 31, 2022, none of our investments experienced any declines in fair value that are other than temporary. We do not enter into investments for trading or speculative purposes.

As of December 31, 2022, we had $14.1 million deposited in four banks located in China, $0.7 million deposited in one bank located in France, and $0.4 million deposited in one bank located in the United Kingdom. We also maintained $130.2 million in cash equivalents that include money market accounts as of December 31, 2022. Additionally, we maintain approximately $15.1 million in investment grade corporate and municipal bonds as of December 31, 2022. The remaining amounts of our cash equivalent as of December 31, 2022, are in non-interest bearing accounts.

As of December 31, 2021, we had $13.1 million deposited in seven banks located in China, $1.2 million deposited in one bank located in France, and $0.3 million deposited in one bank located in the United Kingdom. We also maintained $102.9 million in cash equivalents that include money market accounts as of December 31, 2021. Additionally, we maintain approximately $6.5 million in investment grade corporate and municipal bonds as of December 31, 2021. The remaining amounts of our cash equivalent as of December 31, 2021, are in non-interest bearing accounts.

Interest Rate Risk

Our primary exposure to market risk is interest rate sensitive investments and credit facilities, which are affected by changes in the general level of U.S. interest rates. Due to the nature of our short-term investments, we believe that we are not subject to any material interest rate risk with respect to our short-term investments.

As of December 31, 2022, we had $75.9 million in long-term debt and finance leases outstanding. Of this amount, $13.3 million had variable interest rates which were not locked-in through fixed interest rate swap contracts. The debt with variable interest rate exposure had a weighted-average interest rate of 5.2% at December 31, 2022. An increase in the index underlying these rates of 1% (100 basis points) would increase our annual interest expense on the debt with variable interest rate exposure by approximately $0.1 million per year.

As of December 31, 2021, we had $77.0 million in long-term debt and finance leases outstanding. Of this amount, $14.9 million had variable interest rates which were not locked-in through fixed interest rate swap contracts. The debt with variable interest rate exposure had a weighted-average interest rate of 1.8% at December 31, 2021.

Foreign Currency Exchange Risk

Our finished pharmaceutical products are primarily sold in the U.S. domestic market, and have little exposure to foreign currency price fluctuations. Our API manufacturing business in France is exposed to market risk related to changes in foreign currency exchange rates, because our insulin sales contracts are frequently denominated in euros, which are subject to fluctuations relative to the USD.

Our Chinese subsidiary, ANP, maintains its books of record in Chinese yuan. These books are remeasured into the functional currency of USD, using the current or historical exchange rates. The resulting currency remeasurement adjustments and other transactional foreign exchange gains and losses are reflected in our statement of operations.

Our French subsidiary, AFP, maintains its books of record in euros. AUK's subsidiary, IMS UK, maintains its books of record in British pounds. These local currencies have been determined to be the subsidiaries' respective functional currencies. Activities in the statements of operations are translated to USD using average exchange rates during the period. Assets and liabilities are translated at the rate of exchange prevailing on the balance sheet date. Equity is translated at the prevailing rate of exchange at the date of the equity transactions. Translation adjustments are reflected in stockholders' equity and are included as a component of other accumulated comprehensive income (loss). The unrealized gains or losses of intercompany foreign currency transactions that are of a long-term investment nature are reported in other accumulated comprehensive income (loss).

We are also exposed to the potential earnings effects from intercompany foreign currency assets and liabilities that arise from normal trade receivables and payables and other intercompany loans.

As of December 31, 2022, a 10% unfavorable change in the exchange rate of the U.S. dollar strengthening against the foreign currencies to which we have exposure would result in approximately $2.6 million reduction of foreign currency gains, and approximately $1.6 million reduction in other comprehensive income.

As of December 31, 2021, a 10% unfavorable change in the exchange rate of the U.S. dollar strengthening against the foreign currencies to which we have exposure would result in approximately $1.7 million reduction of foreign currency gains, and approximately $2.8 million reduction in other comprehensive income.

As of December 31, 2022 and 2021, our foreign subsidiaries had cash balances denominated in foreign currencies in the amount of $2.5 million and $5.7 million, respectively.

Item 8. Financial Statements and Supplementary Data.

Index to Amphastar Pharmaceuticals, Inc. Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Amphastar Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Amphastar Pharmaceuticals, Inc. (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2022, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2022, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 1, 2023 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

Critical Audit Matters

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

Provision for chargebacks estimate

Description of the Matter	The Company's provision for chargebacks estimate totaled $20.5 million at December 31, 2022. As described in Note 4 to the consolidated financial statements, a provision for chargebacks is made at the time of sale and is analyzed and adjusted, if necessary, at each balance sheet date. Auditing the provision for chargebacks estimate, the resulting impact of which is netted on the statement of operations against product sales, was complex, requires significant judgment, and the

amounts involved are material to the financial statements taken as a whole. The significant judgment primarily relates to the estimation of the future wholesale customer mix and related contract pricing, which determine the rates at which future chargebacks on current sales will be paid. Revenue from product sales is recognized upon transfer of control of a product to a customer, generally upon delivery, and is based on an amount that reflects the consideration to which the Company expects to be entitled, which represents an amount that is net of the estimated provision for chargebacks, among other deductions. The estimated provision for chargebacks is based on wholesaler inventory levels, historic chargeback rates, and current contract pricing and wholesaler customer mix.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of internal controls over the provision for chargebacks estimation process. This included testing controls over management's review of significant assumptions and inputs used in the provision for chargebacks estimate, including actual sales, historical experience, wholesaler inventory levels, customer mix and contract pricing.

To test the provision for chargebacks estimate, we obtained management's calculations and performed the following procedures, among others. We evaluated the appropriateness of the Company's models and methodology, including recalculating the estimate using those models and testing the completeness and accuracy of the inputs by comparing to internal and external data. We evaluated the reasonableness of significant assumptions (e.g., estimated wholesale customer mix and related contract pricing) by comparing rates at different time periods, including historical and subsequent periods, obtaining an understanding of the facts supporting the selected rates, and performing sensitivity analyses over those rates. We evaluated subsequent events to assess whether there was any new information that would require adjustment to the initial provision.

Enoxaparin inventory lower of cost or net realizable value estimate

Description of the Matter

The Company's inventories totaled $103.6 million as of December 31, 2022 which is net of, amongst other things, provisions to reduce the value of enoxaparin inventory to the lower of its cost and net realizable value. Total charges of $14.9 million related to enoxaparin inventory and related purchase commitments were included in cost of revenues in the Company's consolidated statement of operations for the year ended December 31, 2022. As explained in Note 2 to the consolidated financial statements, the Company states inventory at the lower of cost and net realizable value. Net realizable value is determined using the estimated selling price, in the ordinary course of business, less estimated costs to complete and dispose of the inventory.

Auditing management's estimate in determining the net realizable value of enoxaparin inventory involved subjective auditor judgment because the estimation of the average selling price relies on a number of factors that are affected by market conditions outside the Company's control. In particular, the estimated selling price forecast is sensitive to changes in significant assumptions, including demand for the Company's products, customer mix, and expected competition.

How We Addressed the

We obtained an understanding, evaluated the design, and tested the operating effectiveness of internal controls over the Company's lower of cost or net realizable value estimate process. This included controls over management's assessment of assumptions such as future demand, customer

Matter in Our Audit	mix and expected competition and data underlying the estimate, including but not limited to the completeness of the underlying inventory.

Our substantive audit procedures included, among others, evaluating the significant assumptions stated above and the accuracy and completeness of the underlying data management used to value enoxaparin inventory. We compared the cost of on-hand enoxaparin inventory and related purchase commitments to the estimated net realizable value estimated based on selling price forecasts. We also evaluated adjustments to the estimated selling price for specific considerations, such as new significant customers, competitors, or planned price changes. We evaluated the reasonableness of management's forecasted selling price and whether expected changes in demand, competition, or customer mix were appropriate in comparison with the Company's experience. We also assessed the historical accuracy of management's estimates by performing retrospective reviews over prior periods' forecasted average selling prices and performed sensitivity analyses over the Company's significant assumptions.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 1998.

Irvine, California

March 1, 2023

AMPHASTAR PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share data)

	December 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 156,098	$ 126,353
Restricted cash	235	235
Short-term investments	19,664	10,320
Restricted short-term investments	2,200	2,200
Accounts receivable, net	88,804	78,804
Inventories	103,584	92,807
Income tax refunds and deposits	171	126
Prepaid expenses and other assets	7,563	7,274
Total current assets	378,319	318,119
Property, plant, and equipment, net	238,266	244,244
Finance lease right-of-use assets	753	353
Operating lease right-of-use assets	25,554	26,894
Investment in unconsolidated affiliate	2,414	3,985
Goodwill and intangible assets, net	37,298	38,870
Other assets	20,856	16,665
Deferred tax assets	38,527	22,399
Total assets	$ 741,987	$ 671,529
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 84,242	$ 89,545
Income taxes payable	4,571	9,081
Current portion of long-term debt	3,046	2,202
Current portion of operating lease liabilities	3,003	2,982
Total current liabilities	94,862	103,810
Long-term reserve for income tax liabilities	7,225	6,531
Long-term debt, net of current portion and unamortized debt issuance costs	72,839	74,776
Long-term operating lease liabilities, net of current portion	23,694	24,703
Deferred tax liabilities	144	534
Other long-term liabilities	14,565	15,653
Total liabilities	213,329	226,007
Commitments and contingencies		
Stockholders' equity:		
Preferred stock: par value $0.0001; 20,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock: par value $0.0001; 300,000,000 shares authorized; 58,110,231 and 48,112,069 shares issued and outstanding as of December 31, 2022 and 56,440,202 and 47,714,912 shares issued and outstanding as of December 31, 2021, respectively	6	6
Additional paid-in capital	455,077	422,423
Retained earnings	271,723	180,337
Accumulated other comprehensive loss	(8,624)	(6,765)
Treasury stock	(189,524)	(150,479)
Total equity	528,658	445,522
Total liabilities and stockholders' equity	$ 741,987	$ 671,529

See accompanying notes to consolidated financial statements.

AMPHASTAR PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	Year Ended December 31,		
	2022	2021	2020
Net revenues	$ 498,987	$ 437,768	$ 349,846
Cost of revenues	250,127	238,029	206,506
Gross profit	248,860	199,739	143,340
Operating expenses:			
Selling, distribution, and marketing	21,531	17,486	14,780
General and administrative	45,061	51,434	50,377
Research and development	74,771	60,932	67,229
Total operating expenses	141,363	129,852	132,386
Income from operations	107,497	69,887	10,954
Non-operating income (expenses):			
Interest income	1,321	601	642
Interest expense	(1,846)	(885)	(374)
Other income (expenses), net	9,068	14,536	(6,585)
Total non-operating income (expenses), net	8,543	14,252	(6,317)
Income before income taxes	116,040	84,139	4,637
Income tax provision	23,477	20,630	3,540
Income before equity in losses of unconsolidated affiliate	92,563	63,509	1,097
Equity in losses of unconsolidated affiliate	(1,177)	(208)	—
Net income	$ 91,386	$ 63,301	$ 1,097
Net income (loss) attributable to non-controlling interests	$ —	$ 1,185	$ (306)
Net income attributable to Amphastar Pharmaceuticals, Inc.	$ 91,386	$ 62,116	$ 1,403
Net income per share attributable to Amphastar Pharmaceuticals, Inc. stockholders:			
Basic	$ 1.88	$ 1.30	$ 0.03
Diluted	$ 1.74	$ 1.25	$ 0.03
Weighted-average shares used to compute net income per share attributable to Amphastar Pharmaceuticals, Inc. stockholders:			
Basic	48,551	47,777	47,038
Diluted	52,427	49,784	49,124

See accompanying notes to consolidated financial statements.

AMPHASTAR PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(in thousands)

	Year Ended December 31,		
	2022	2021	2020
Net income attributable to Amphastar Pharmaceuticals, Inc.	$ 91,386	$ 62,116	$ 1,403
Other comprehensive income (loss) attributable to Amphastar Pharmaceuticals, Inc., net of income taxes			
Reclassification of adjustment for amounts included in net income	—	(362)	—
Foreign currency translation adjustment	(2,335)	(2,943)	1,121
Change in pension obligations	476	261	(155)
Total other comprehensive income (loss) attributable to Amphastar Pharmaceuticals, Inc.	(1,859)	(3,044)	966
Total comprehensive income attributable to Amphastar Pharmaceuticals, Inc.	$ 89,527	$ 59,072	$ 2,369

See accompanying notes to consolidated financial statements.

AMPHASTAR PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (loss)	Treasury Stock		Total Amphastar Stockholders' Equity	Non-controlling Interest	Total
	Shares	Amount				Shares	Amount			
Balance as of December 31, 2019	52,495,483	5	367,305	116,370	(4,687)	(5,918,515)	(97,627)	381,366	46,162	427,528
Net income attributable to Amphastar Pharmaceuticals, Inc.	—	—	—	1,403	—	—	—	1,403	—	1,403
Other comprehensive income attributable to Amphastar Pharmaceuticals, Inc.	—	—	—	—	966	—	—	966	—	966
Acquisition of additional ownership interest in ANP	—	—	—	—	—	—	—	—	(106)	(106)
Net loss attributable to non-controlling interest	—	—	—	—	—	—	—	—	(306)	(306)
Purchase of treasury stock	—	—	—	—	—	(1,366,915)	(24,425)	(24,425)	—	(24,425)
Issuance of treasury stock in connection with the Company's equity plans	—	—	(240)	—	—	19,947	240	—	—	—
Issuance of common stock in connection with the Company's equity plans	2,265,439	—	23,165	—	—	—	—	23,165	—	23,165
Share-based compensation expense	—	—	19,831	—	—	—	—	19,831	667	20,498
Balance as of December 31, 2020	54,760,922	5	410,061	117,773	(3,721)	(7,265,483)	(121,812)	402,306	46,417	448,723
Net income attributable to Amphastar Pharmaceuticals, Inc.	—	—	—	62,116	—	—	—	62,116	—	62,116
Other comprehensive loss attributable to Amphastar Pharmaceuticals, Inc.	—	—	—	—	(2,682)	—	—	(2,682)	—	(2,682)
ANP restructuring (see Note 3)	—	—	(22,162)	448	(362)	—	—	(22,076)	(46,641)	(68,717)
Net income attributable to non-controlling interest	—	—	—	—	—	—	—	—	1,185	1,185
Purchase of treasury stock	—	—	—	—	—	(1,477,305)	(28,873)	(28,873)	—	(28,873)
Issuance of treasury stock in connection with the Company's equity plans	—	—	(206)	—	—	17,498	206	—	—	—
Issuance of common stock in connection with the Company's equity plans	1,679,280	1	15,924	—	—	—	—	15,925	—	15,925
Share-based compensation expense	—	—	18,806	—	—	—	—	18,806	(961)	17,845
Balance as of December 31, 2021	56,440,202	6	422,423	180,337	(6,765)	(8,725,290)	(150,479)	445,522	—	445,522
Net income attributable to Amphastar Pharmaceuticals, Inc.	—	—	—	91,386	—	—	—	91,386	—	91,386
Other comprehensive loss attributable to Amphastar Pharmaceuticals, Inc.	—	—	—	—	(1,859)	—	—	(1,859)	—	(1,859)
Purchase of treasury stock	—	—	—	—	—	(1,335,528)	(39,909)	(39,909)	—	(39,909)
Issuance of treasury stock in connection with the Company's equity plans	—	—	(864)	—	—	62,656	864	—	—	—
Issuance of common stock in connection with the Company's equity plans	1,670,029	—	15,658	—	—	—	—	15,658	—	15,658
Share-based compensation expense	—	—	17,860	—	—	—	—	17,860	—	17,860
Balance as of December 31, 2022	58,110,231	$ 6	$ 455,077	$ 271,723	$ (8,624)	(9,998,162)	$ (189,524)	$ 528,658	$ —	$ 528,658

See accompanying notes to consolidated financial statements.

AMPHASTAR PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2022	**2021**	**2020**
Cash Flows From Operating Activities:			
Net income	$ 91,386	$ 63,301	$ 1,097
Reconciliation to net cash provided by operating activities:			
Loss on disposal of assets	141	348	240
Gain on deconsolidation of subsidiary	—	(13,587)	—
(Gain) loss on interest rate swaps and foreign currency transactions, net	(2,196)	27	(2,173)
Depreciation of property, plant, and equipment	23,815	22,196	20,491
Amortization of product rights, trademarks, and patents	1,420	1,290	1,036
Operating lease right-of-use asset amortization	3,506	3,266	3,653
Equity in losses of unconsolidated affiliate	1,177	208	—
Share-based compensation expense	17,860	18,687	20,498
Changes in reserve for uncertain tax positions	694	1,821	1,285
Changes in deferred taxes, net	(16,445)	2,388	(162)
Changes in operating assets and liabilities:			
Accounts receivable, net	(10,132)	(14,921)	(20,160)
Inventories	(11,746)	1,258	15,297
Prepaid expenses and other assets	(1,854)	2,927	643
Income tax refunds, deposits, and payable, net	(4,555)	8,349	(972)
Operating lease liabilities	(3,154)	(3,198)	(3,597)
Accounts payable and accrued liabilities	(736)	3,634	20,090
Net cash provided by operating activities	89,181	97,994	57,266
Cash Flows From Investing Activities:			
Purchases and construction of property, plant, and equipment	(24,034)	(27,456)	(33,855)
Proceeds from the sale of property, plant and equipment	421	—	—
Purchase of investments	(35,761)	(17,375)	(13,557)
Maturity of investments	27,969	18,771	12,411
Payment of deposits and other assets	(1,372)	(2,612)	(1,414)
Net cash used in investing activities	(32,777)	(28,672)	(36,415)
Cash Flows From Financing Activities:			
Acquisition of additional ownership interest in ANP	—	—	(106)
ANP restructuring (see Note 3)	—	(53,592)	—
Proceeds from equity plans, net of withholding tax payments	15,658	15,925	23,165
Purchase of treasury stock	(39,909)	(28,873)	(24,425)
Settlement of ANP equity awards	—	(839)	—
Debt issuance costs	(407)	(1,738)	—
Proceeds from borrowing under lines of credit	—	—	1,238
Repayments under lines of credit	—	(1,161)	—
Proceeds from issuance of long-term debt	—	70,000	6,283
Principal payments on long-term debt	(1,781)	(36,740)	(8,401)
Net cash used in financing activities	(26,439)	(37,018)	(2,246)
Effect of exchange rate changes on cash	(220)	(223)	352
Net increase in cash, cash equivalents, and restricted cash	29,745	32,081	18,957
Cash, cash equivalents, and restricted cash at beginning of period	126,588	94,507	75,550
Cash, cash equivalents, and restricted cash at end of period	$ 156,333	$ 126,588	$ 94,507
Noncash Investing and Financing Activities:			
Capital expenditure included in accounts payable	$ 5,256	$ 9,488	$ 11,136
Operating lease right-of-use assets in exchange for operating lease liabilities	$ 2,166	$ 11,041	$ 4,819
Equipment acquired under finance leases	$ 642	$ 107	$ 61
Supplemental Disclosures of Cash Flow Information:			
Interest paid, net of capitalized interest	$ 3,023	$ 2,109	$ 2,199
Income taxes paid	$ 44,442	$ 8,096	$ 3,411

See accompanying notes to consolidated financial statements

AMPHASTAR PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Business

Amphastar Pharmaceuticals, Inc., a Delaware corporation (together with its subsidiaries, hereinafter referred to as the "Company") is a bio-pharmaceutical company that focuses primarily on developing, manufacturing, marketing, and selling technically challenging generic and proprietary injectable, inhalation, and intranasal products, including products with high technical barriers to market entry. Additionally, the Company sells insulin active pharmaceutical ingredient, or API, products. Most of the Company's products are used in hospital or urgent care clinical settings and are primarily contracted and distributed through group purchasing organizations and drug wholesalers. The Company's insulin API products are sold to other pharmaceutical companies for use in their own products and are being used by the Company in the development of injectable finished pharmaceutical products. The Company's inhalation product, Primatene MIST®, is primarily distributed through drug retailers.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements include the accounts of the Company and its subsidiaries, and are prepared in accordance with United States generally accepted accounting principles, or GAAP. Certain prior period amounts have been reclassified within the operating activities of the consolidated statements of cash flows to conform to the current period presentation. All intercompany activity has been eliminated in the preparation of the consolidated financial statements. In the opinion of management, the accompanying consolidated financial statements include all adjustments, which are of a normal recurring nature, necessary to present fairly the consolidated financial position, results of operations, and cash flows of the Company.

The Company's subsidiaries include: (1) International Medication Systems, Limited, or IMS, (2) Armstrong Pharmaceuticals, Inc., or Armstrong, (3) Amphastar Nanjing Pharmaceuticals Inc., or ANP, (4) Amphastar France Pharmaceuticals, S.A.S., or AFP, (5) Amphastar UK Ltd., or AUK, and (6) International Medication Systems (UK) Limited, or IMS UK.

Investments in Unconsolidated Affiliate

The Company applies the equity method of accounting for investments when it has significant influence, but not controlling interest in the investee. Judgment regarding the level of influence over each equity method investment includes key factors such as ownership interest, representation on the board of directors, participation in policy-making decisions and material intercompany transactions. The Company's proportionate share of the earnings or losses resulting from these investments is reported as "Equity in losses of unconsolidated affiliate" in the accompanying consolidated statements of operations. Investments accounted for using the equity method may be reported on a lag of up to three months if financial statements of the investee are not available in sufficient time for the investor to apply the equity method as of the current reporting date. The determination of whether an investee's results are recorded on a lag is made on an investment-by-investment basis.

The carrying value of equity method investments is reported as "Investment in unconsolidated affiliate" in the accompanying consolidated balance sheets. The Company's equity method investments are reported at cost and adjusted each period for the Company's share of the investee's earnings or losses and dividends paid, if any.

The Company assesses equity method investments for impairment whenever events or changes in circumstances indicate that the carrying value of an investment may not be recoverable. If the decline in value is considered to be other than temporary, the investment is written down to its estimated fair value, which establishes a new cost basis in the investment. No such impairment was identified for any of the periods presented.

Use of Estimates

The preparation of consolidated financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates. The principal accounting estimates include: determination of allowances for credit losses, fair value of financial instruments, allowance for discounts, provision for chargebacks and rebates, provision for product returns, adjustment of inventory to its net realizable value, impairment of investments, long-lived and intangible assets and goodwill, accrual for workers' compensation liabilities, litigation reserves, stock price volatility for share-based compensation expense, valuation allowances for deferred tax assets, and liabilities for uncertain income tax positions.

Foreign Currency

The functional currency of the Company, its domestic subsidiaries, its Chinese subsidiary ANP, and its U.K. subsidiary, AUK, is the U.S. Dollar, or USD. ANP maintains its books of record in Chinese yuan. These books are remeasured into the functional currency of USD using the current or historical exchange rates. The resulting currency remeasurement adjustments and other transactional foreign currency exchange gains and losses are reflected in the Company's accompanying consolidated statements of operations.

The Company's French subsidiary, AFP, maintains its book of record in euros. AUK's subsidiary, IMS UK, maintains its book of record in British pounds. These local currencies have been determined to be the subsidiaries' respective functional currencies. Activities in the statements of operations are translated to USD using average exchange rates during the period. Assets and liabilities are translated at the rate of exchange prevailing on the balance sheet date. Equity is translated at the prevailing rate of exchange at the date of the equity transactions. Translation adjustments are reflected in stockholders' equity and are included as a component of other accumulated comprehensive income (loss). The unrealized gains or losses of intercompany foreign currency transactions that are of a long-term investment nature are reported in other accumulated comprehensive income (loss).

The unrealized gains and losses of intercompany foreign currency transactions that are of a long-term investment nature for the years ended December 31, 2022, 2021, and 2020 were a $1.8 million loss, a $2.6 million loss, and a $3.0 million gain, respectively.

Comprehensive Income

The Company's comprehensive income includes its foreign currency translation gains and losses as well as its share of other comprehensive income from its equity method investments. There was no material income tax provision allocated to other comprehensive loss for the years ended December 31, 2022 and 2021. Income tax expense of $0.9 million was allocated to other comprehensive income for the year ended December 31, 2020.

Shipping and Handling Costs

For the years ended December 31, 2022, 2021, and 2020, the Company included shipping and handling costs of approximately $7.4 million, $4.3 million and $4.3 million, respectively, in selling, distribution and marketing expenses in the accompanying consolidated statements of operations.

Advertising Expense

Advertising expenses, primarily associated with Primatene MIST®, are recorded as they are incurred, except for expenses related to the development of a major commercial or media campaign, which are expensed in the period in which the commercial or campaign is first presented, and are reflected as a component of selling, distribution and marketing in the

Company's consolidated statements of operations. For the years ended December 31, 2022, 2021, and 2020, advertising expenses were $8.7 million, $8.1 million, and $5.8 million, respectively.

Research and Development Costs

Research and development costs are charged to expense as incurred and consist of costs incurred to further the Company's research and development activities. These include salaries and related employee benefits, costs associated with clinical trials, nonclinical research and development activities, regulatory activities, research-related overhead expenses and fees paid to external service providers.

The Company may produce or purchase inventories prior to or with the expectation of receiving regulatory approval in the near term, based on operational decisions about the most effective use of existing resources. This inventory is referred to as pre-launch inventory. It is the Company's accounting policy that the pre-launch inventory is capitalized if it has a probable future economic benefit at the time it is purchased or manufactured. If regulatory approval is received and previously expensed pre-launch inventory is sold, such sales may contribute up to a 100% margin to the Company's operating results. Pre-launch inventory costs include cost of work in process, materials, and finished drug products. As of December 31, 2022, 2021, and 2020, the Company did not have material capitalized pre-launch inventory.

Financial Instruments

The carrying amounts of cash and cash equivalents, short-term investments, restricted cash and short-term investments, accounts receivable, accounts payable, accrued expenses, and short-term borrowings approximate fair value due to the short maturity of these items. The majority of the Company's long-term obligations consist of variable rate debt, and their carrying value approximates fair value as the stated borrowing rates are comparable to rates currently offered to the Company for instruments with similar maturities. The Company at times enters into interest rate swap contracts to manage its exposure to interest rate changes and its overall cost of long-term debt. The Company's interest rate swap contracts exchange the variable interest rates for fixed interest rates.

The Company from time to time may enter into forward currency contracts to lock in currency exchange rates to manage its foreign currency exchange rate exposure. The Company's interest rate swaps and forward currency contracts have not been designated as hedging instruments and, therefore are recorded at their fair values at the end of each reporting period with changes in fair value recorded in other income (expenses) on the consolidated statements of operations. As of December 31, 2022, the Company had an unsettled forward currency contract to purchase foreign currency with a fair value of approximately $0.2 million based on Level 2 inputs, which was recorded as a liability in the accounts payable and accrued liabilities line in the accompanying consolidated balance sheets.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash, money market accounts, certificates of deposit and highly liquid investments with original maturities of three months or less.

Investments

Investments as of December 31, 2022 and 2021 consisted of certificates of deposit and investment grade corporate and municipal bonds with original maturity dates between three and fifteen months.

Restricted Cash

Restricted cash is collateral required for the Company to guarantee certain vendor payments in France. As of December 31, 2022 and 2021, the restricted cash balance was $0.2 million.

Restricted Short-Term Investments

Restricted short-term investments consist of certificates of deposit that are collateral for standby letters of credit to qualify for workers' compensation self-insurance. The certificates of deposit have original maturities greater than three months, but less than one year. As of December 31, 2022 and 2021, the balance of restricted short-term investments was $2.2 million.

Allowance for Credit Losses

The Company evaluates the collectability of accounts receivable based on a combination of factors. When the Company is aware of circumstances that may impair a customer's ability to pay subsequent to the original sale, the Company records a specific allowance to reduce the amounts receivable to the amount that the Company reasonably believes to be collectable. For all other customers, the Company recognizes an allowance for credit losses based on factors that include the length of time the receivables are past due, industry and geographic concentrations, the current economic conditions and historical collection experience. As of December 31, 2022 and 2021, the Company's allowance for credit losses was $2.7 million and $2.3 million, respectively.

Inventories

Inventories consist of currently marketed products and products manufactured under contract. Inventories are stated using the first-in, first-out method, on a consistent basis. The Company states inventory at the lower of cost or net realizable value. Provisions are made for slow moving, unsellable, or obsolete items. Net realizable value is determined using the estimated selling price, in the ordinary course of business, less estimated costs to complete and dispose.

Property, Plant and Equipment

Property, plant and equipment are stated at cost or, in the case of assets acquired in a business combination, at fair value on the purchase date. Depreciation and amortization expense is computed using the straight line method over the estimated useful lives of the related assets as follows:

Buildings	20 - 31 years
Machinery and equipment	3 - 12 years
Furniture and fixtures	3 - 7 years
Automobiles	4 - 5 years
Leasehold improvements	Lesser of remaining lease term or useful life

Intangible Assets

Intangible assets with finite lives are amortized using the straight-line method over the period the asset is expected to contribute directly or indirectly to the future cash flows of the Company as follows:

Product rights	10 - 15 years
Patents	10 - 20 years
Land-use rights	37 - 50 years

Impairment of Long-Lived Assets, including Identifiable Definite-Lived Intangible Assets

The Company assesses long-term and identifiable definite-lived intangible assets or asset groups for impairment when events or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable. If the sum of the expected future undiscounted cash flows is less than the carrying amount of the asset or an asset group, further impairment analysis is performed. An impairment loss is measured as the amount by which the carrying amount

of the asset or asset groups exceeds the fair value (assets to be held and used) or fair value less cost to sell (assets to be disposed of). The Company also assesses the useful lives of its assets periodically to determine whether events and circumstances warrant a revision to the remaining useful life. Changes in the useful life are adjusted prospectively by revising the remaining period over which the asset is amortized.

Deferred Income Taxes

The Company utilizes the liability method of accounting for income taxes, under which deferred taxes are determined based on the temporary differences between the financial statements and the tax basis of assets and liabilities using enacted tax rates. A valuation allowance is recorded when it is more likely than not that the deferred tax assets will not be realized.

Impairment of Indefinite-Lived Intangible Asset and Goodwill

The Company assesses indefinite lived intangible asset and goodwill for impairment in the fourth quarter of each year or more frequently if indicators of impairment are present. When the Company chooses to perform a qualitative assessment, it evaluates economic, industry and company-specific factors as an initial step. If the Company determines it is more likely than not that the indefinite-lived intangible asset is impaired or the fair value of a reporting unit is less than its carrying amount, further quantitative impairment testing is then performed; otherwise, no further testing is required. An impairment loss is recorded if the asset's fair value is less than its carrying value. The Company also periodically assesses its indefinite-lived intangible asset to determine if events and circumstances continue to support an indefinite useful life. If the life is no longer indefinite, the asset is tested for impairment. The carrying value, after recognition of any impairment loss, is amortized over its remaining useful life.

Self-Insured Claims

The Company is primarily self-insured, up to certain limits, for workers' compensation claims. The Company has purchased stop-loss insurance, which will reimburse the Company for individual claims in excess of $350,000 or aggregate minimum attachment of $4.4 million annually. The cost of claims reported and an estimate of claims incurred but not reported are charged to operating expenses. A liability for unpaid claims and the associated claim expenses, including incurred but not reported losses, is actuarially determined and reflected in accrued liabilities in the accompanying consolidated balance sheets. Total expense under the program was approximately $0.3 million, $0.5 million, and $0.5 million, for the years ended December 31, 2022, 2021 and 2020, respectively. The self-insured claims liability was $3.7 million and $4.1 million at December 31, 2022 and 2021, respectively. The determination of such claims and expenses and the appropriateness of the related liability is reviewed periodically and updated, as necessary. Changes in estimates are recorded in the period identified.

Litigation, Commitments and Contingencies

Litigation, commitments and contingencies are accrued when management, after considering the facts and circumstances of each matter as then known to management, has determined it is probable a liability will be found to have been incurred and the amount of the loss can be reasonably estimated. When only a range of amounts is reasonably estimable and no amount within the range is more likely than another, the low end of the range is recorded. Legal fees are expensed as incurred. Due to the inherent uncertainties surrounding gain contingencies, the Company generally does not recognize potential gains until they are realized.

In the fourth quarter of 2021, the Company settled a legal dispute with an unaffiliated third party and subsequently received a settlement payment, net of contingent legal fees, in the amount of $2.7 million. The net amount of $2.7 million was recorded as other income in the other income (expense), net line in the consolidated statements of operations for the year ended December 31, 2021.

Recent Accounting Pronouncements

The Company does not believe that any recently issued effective pronouncements, or pronouncements issued but not yet effective, if adopted, would have a material effect on the accompanying financial statements.

Note 3. ANP Restructuring

As a result of the ANP restructuring that was completed during the third quarter of 2021, and subsequent investments by other equity holders of Hanxin, the Company has a 14% noncontrolling investment in Hanxin as of December 31, 2022 that is accounted for as an equity method investment.

In addition to the retained noncontrolling investment in Hanxin, the Company maintains a seat on Hanxin's board of directors, and Henry Zhang, a relative of Dr. Jack Zhang and Dr. Mary Luo, is an equity holder, general manager, and chairman of the board of directors of Hanxin. As a result, it was determined that the Company has significant influence over Hanxin and as such the retained noncontrolling investment in Hanxin is accounted for as an equity method investment.

Hanxin continues to be a related party after the deconsolidation.

Note 4. Revenue Recognition

In accordance with Accounting Standard Codification, or ASC, *606 Revenue from Contracts with Customers*, revenue is recognized at the time that the Company's customers obtain control of the promised goods.

Generally, revenue is recognized at the time of product delivery to the Company's customers. In some cases, revenue is recognized at the time of shipment when stipulated by the terms of the sale agreements.

The consideration the Company receives in exchange for its goods or services is only recognized when it is probable that a significant reversal will not occur. The consideration to which the Company expects to be entitled includes a stated list price, less various forms of variable consideration. The Company makes significant estimates for related variable consideration at the point of sale, including chargebacks, rebates, product returns, other discounts and allowances.

The Company's payment terms vary by types and locations of customers and the products or services offered. Payment terms differ by jurisdiction and customers, but payment is generally required in a term ranging from 30 to 75 days from date of shipment or satisfaction of the performance obligation. For certain products or services and certain customer types, the Company may require payment before products are delivered or services are rendered to customers.

Provisions for estimated chargebacks, rebates, discounts, product returns and credit losses are made at the time of sale and are analyzed and adjusted, if necessary, at each balance sheet date.

Revenues derived from contract manufacturing services are recognized when third-party products are shipped to customers.

The Company's accounting policy is to review each agreement involving contract development and manufacturing services to determine if there are multiple revenue-generating activities that constitute more than one unit of accounting. Revenues are recognized for each unit of accounting based on revenue recognition criteria relevant to that unit. The Company does not have any revenue arrangements with multiple performance obligations.

Service revenues derived from research and development contracts is recognized over time based on progress toward completion of the performance obligation. For each performance obligation satisfied over time, the Company assesses the proper method to be used for revenue recognition, either an input method to measure progress toward the satisfaction

of services or an output method of determining the progress of completion of performance obligation. Revenue from research and development services at ANP was $4.3 million and $5.1 million for the years ended December 31, 2022 and 2021, respectively.

Provision for Chargebacks and Rebates

The provision for chargebacks and rebates is a significant estimate used in the recognition of revenue. Wholesaler chargebacks relate to sales terms under which the Company agrees to reimburse wholesalers for differences between the gross sales prices at which the Company sells its products to wholesalers and the actual prices of such products that wholesalers resell under the Company's various contractual arrangements with third parties such as hospitals and group purchasing organizations in the United States. Rebates include primarily amounts paid to retailers, payers, and providers in the United States, including those paid to state Medicaid programs, and are based on contractual arrangements or statutory requirements. The Company estimates chargebacks and rebates using the expected value method at the time of sale to wholesalers based on wholesaler inventory stocking levels, historic chargeback and rebate rates, and current contract pricing.

The provision for chargebacks and rebates is reflected as a component of net revenues. The following table is an analysis of the chargeback and rebate provision:

	Year Ended December 31,	
	2022	2021
	(in thousands)	
Beginning balance	$ 20,167	$ 20,380
Provision for chargebacks and rebates	208,081	201,133
Credits and payments issued to third parties	(201,642)	(201,346)
Ending balance	$ 26,606	$ 20,167

Changes in the chargeback provision from period to period are primarily dependent on the Company's sales to its wholesalers, the level of inventory held by wholesalers, and the wholesalers' customer mix. Changes in the rebate provision from period to period are primarily dependent on retailer's and other indirect customers' purchases. The approach that the Company uses to estimate chargebacks has been consistently applied for all periods presented. Variations in estimates have been historically small. The Company continually monitors the provision for chargebacks and rebates and makes adjustments when it believes that the actual chargebacks and rebates may differ from the estimates. The settlement of chargebacks and rebates generally occurs within 20 days to 60 days after the sale to wholesalers. Accounts receivable and/or accounts payable and accrued liabilities are reduced and/or increased by the chargebacks and rebate amounts depending on whether the Company has the right to offset with the customer. Of the provision for chargebacks and rebates as of December 31, 2022 and 2021, $20.5 million and $15.6 million were included as a reduction to accounts receivable, net, on the consolidated balance sheets, respectively. The remaining provision as of December 31, 2022 and 2021 was $6.1 million and $4.6 million, respectively, which were included in accounts payable and accrued liabilities in the accompanying consolidated balance sheets.

Accrual for Product Returns

The Company offers most customers the right to return qualified excess or expired inventory for partial credit; however, API product sales are generally non-returnable. The Company's product returns primarily consist of the returns of expired products from sales made in prior periods. Returned products cannot be resold. At the time product revenue is recognized, the Company records an accrual for product returns estimated using the expected value method. The accrual is based, in part, upon the historical relationship of product returns to sales and customer contract terms. The Company also assesses other factors that could affect product returns including market conditions, product obsolescence, and new competition. Although these factors do not normally give the Company's customers the right to return products outside of the regular return policy, the Company realizes that such factors could ultimately lead to increased returns. The

Company analyzes these situations on a case-by-case basis and makes adjustments to the product return reserve as appropriate.

The provision for product returns is reflected as a component of net revenues. The following table is an analysis of the product return liability:

	Year Ended December 31,	
	2022	2021
	(in thousands)	
Beginning balance	$ 21,677	$ 14,204
Provision for product returns	4,405	15,005
Credits issued to third parties	(6,631)	(7,532)
Ending balance	$ 19,451	$ 21,677

Of the provision for product returns as of December 31, 2022 and 2021, $14.9 million and $16.0 million were included in accounts payable and accrued liabilities on the accompanying consolidated balance sheets, respectively. The remaining provision as of December 31, 2022 and 2021, of $4.6 million and $5.7 million were included in other long-term liabilities, respectively. For the years ended December 31, 2022 and 2021, the Company's aggregate product return rate was 1.4% and 1.7% of qualified sales, respectively.

Note 5. Income per Share Attributable to Amphastar Pharmaceuticals, Inc. Stockholders

Basic net income per share attributable to Amphastar Pharmaceuticals Inc. stockholders is calculated based upon the weighted-average number of shares outstanding during the period. Diluted net income per share attributable to Amphastar Pharmaceuticals, Inc. stockholders gives effect to all potential dilutive shares outstanding during the period, such as stock options, non-vested restricted stock units, and shares issuable under the Company's Employee Stock Purchase Plan, or ESPP.

For the year ended December 31, 2022, options to purchase 704,483 shares of stock with a weighted-average exercise price of $34.79 per share were excluded from the computation of diluted net income per share attributable to Amphastar Pharmaceuticals, Inc. stockholders because their effect would be anti-dilutive.

For the year ended December 31, 2021, options to purchase 1,906,029 shares of stock with a weighted-average exercise price of $20.82 per share and the reallocation of net income attributable to non-controlling interest were excluded from the computation of diluted net income per common share attributable to Amphastar Pharmaceuticals, Inc. stockholders because their effect would be anti-dilutive.

For the year ended December 31, 2020, options to purchase 1,917,437 shares of stock with a weighted-average exercise price of $20.85 per share and the reallocation of net income attributable to non-controlling interest were excluded from the computation of diluted net income per common share attributable to Amphastar Pharmaceuticals, Inc. stockholders because their effect would be anti-dilutive.

The following table provides the calculation of basic and diluted net income per share attributable to Amphastar Pharmaceuticals, Inc. shareholders for each of the periods presented:

	Year Ended December 31,		
	2022	2021	2020
	(in thousands, except per share data)		
Basic and dilutive numerator:			
Net income attributable to Amphastar Pharmaceuticals, Inc.	$ 91,386	$ 62,116	$ 1,403
Denominator:			
Weighted-average shares outstanding — basic	48,551	47,777	47,038
Net effect of dilutive securities:			
Incremental shares from equity awards	3,876	2,007	2,086
Weighted-average shares outstanding — diluted	52,427	49,784	49,124
Net income per share attributable to Amphastar Pharmaceuticals, Inc. stockholders — basic	$ 1.88	$ 1.30	$ 0.03
Net income per share attributable to Amphastar Pharmaceuticals, Inc. stockholders — diluted	$ 1.74	$ 1.25	$ 0.03

Note 6. Segment Reporting

The Company's business is the development, manufacture, and marketing of pharmaceutical products. The Company has identified two reporting segments that each report to the Chief Operating Decision Maker, or CODM, as defined in ASC 280, Segment Reporting. The Company's performance is assessed and resources are allocated by the CODM based on the following two reportable segments:

- Finished pharmaceutical products
- APIs

The finished pharmaceutical products segment manufactures, markets and distributes Primatene MIST®, glucagon, enoxaparin, naloxone, phytonadione, lidocaine, epinephrine, various critical and non-critical care drugs, as well as certain contract manufacturing and contract research revenues. The API segment manufactures and distributes recombinant human insulin API and porcine insulin API for external customers and internal product development.

Selected financial information by reporting segment is presented below:

	Year Ended December 31,		
	2022	2021	2020
		(in thousands)	
Net revenues:			
Finished pharmaceutical products	$ 486,505	$ 419,570	$ 331,368
API	12,482	18,198	18,478
Total net revenues	498,987	437,768	349,846
Gross profit (loss):			
Finished pharmaceutical products	256,710	209,715	151,645
API	(7,850)	(9,976)	(8,305)
Total gross profit	248,860	199,739	143,340
Operating expenses	141,363	129,852	132,386
Income from operations	107,497	69,887	10,954
Non-operating income (expenses)	8,543	14,252	(6,317)
Income before income taxes	$ 116,040	$ 84,139	$ 4,637

The Company manages its business segments to the gross profit level and manages its operating and other costs on a company-wide basis. The Company does not identify total assets by segment for internal purposes, as the Company's CODM does not assess performance, make strategic decisions, or allocate resources based on assets.

The amount of net revenues in the finished pharmaceutical product segment is presented below:

	Year Ended December 31,		
	2022	2021	2020
		(in thousands)	
Finished pharmaceutical products net revenues:			
Primatene MIST®	$ 84,309	$ 73,113	$ 51,725
Epinephrine	74,204	57,530	23,799
Glucagon	55,322	47,639	—
Lidocaine	52,539	44,413	41,113
Phytonadione	49,500	45,498	42,646
Enoxaparin	34,950	35,962	48,681
Naloxone	26,269	27,540	33,416
Other finished pharmaceutical products	109,412	87,875	89,988
Total finished pharmaceutical products net revenues	$ 486,505	$ 419,570	$ 331,368

The amount of depreciation and amortization expense included in cost of revenues, by reporting segment is presented below:

	Year Ended December 31,		
	2022	2021	2020
		(in thousands)	
Depreciation and amortization expense			
Finished pharmaceutical products	$ 8,884	$ 6,003	$ 5,766
API	3,713	4,222	3,264
Total depreciation and amortization expense	$ 12,597	$ 10,225	$ 9,030

Net revenues and carrying values of long-lived assets by geographic regions are as follows:

	Net Revenue Year Ended December 31,			Long-Lived Assets December 31,	
	2022	2021	2020	2022	2021
			(in thousands)		
United States	$ 486,833	$ 419,869	$ 333,093	$ 136,328	$ 134,731
China	4,697	6,020	3,161	88,647	91,876
France	7,457	11,879	13,592	39,598	44,884
Total	$ 498,987	$ 437,768	$ 349,846	$ 264,573	$ 271,491

Note 7. Customer and Supplier Concentration

Customer Concentrations

Three large wholesale drug distributors, AmerisourceBergen Corporation, or AmerisourceBergen, Cardinal Health, Inc., or Cardinal, and McKesson Corporation, or McKesson, are all distributors of the Company's products, as well as suppliers of a broad range of health care products. The Company considers these three customers to be its major customers, as each individually and these customers collectively, represented a significant percentage of the Company's net revenue for the years ended December 31, 2022, 2021, and 2020, and accounts receivable as of December 31, 2022 and 2021, respectively. The following table provides accounts receivable and net revenue information for these major customers:

	% of Total Accounts Receivable		% of Net Revenue Year Ended December 31,		
	December 31, 2022	December 31, 2021	2022	2021	2020
AmerisourceBergen	16 %	13 %	23 %	24 %	23 %
McKesson	32 %	30 %	22 %	21 %	22 %
Cardinal Health	19 %	20 %	17 %	16 %	17 %

Supplier Concentrations

The Company depends on suppliers for raw materials, APIs, and other components that are subject to stringent FDA requirements. Some of these materials may only be available from one or a limited number of sources. Establishing additional or replacement suppliers for these materials may take a substantial period of time, as suppliers must be approved by the FDA. Furthermore, a significant portion of raw materials may only be available from foreign sources. If the Company is unable to secure, on a timely basis, sufficient quantities of the materials it depends on to manufacture and market its products, it could have a materially adverse effect on the Company's business, financial condition, and results of operations.

Note 8. Fair Value Measurements

GAAP defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the principal or most advantageous market for the asset or liability at the measurement date (an exit price). These standards also establish a hierarchy that prioritizes observable and unobservable inputs used in measuring fair value of an asset or liability, as described below:

- *Level 1* – Inputs to measure fair value are based on quoted prices (unadjusted) in active markets on identical assets or liabilities;

- *Level 2* – Inputs to measure fair value are based on the following: a) quoted prices in active markets on similar assets or liabilities, b) quoted prices for identical or similar instruments in inactive markets, or c) observable (other than quoted prices) or collaborated observable market data used in a pricing model from which the fair value is derived; and

- *Level 3* – Inputs to measure fair value are unobservable and the assets or liabilities have little, if any, market activity; these inputs reflect the Company's own assumptions about the assumptions that market participants would use in pricing the assets or liabilities based on best information available in the circumstances.

As of December 31, 2022, cash equivalents include money market accounts and corporate and municipal bonds with original maturities of less than three months. Investments consist of certificates of deposit as well as investment-grade corporate and municipal bonds with original maturity dates between three and twelve months. The certificates of deposit are carried at amortized cost in the Company's consolidated balance sheets, which approximates their fair value determined based on Level 2 inputs. The corporate and municipal bonds are classified as held-to-maturity and are carried at amortized cost net of allowance for credit losses, which approximates their fair value determined based on Level 2 inputs. The restrictions on restricted cash and investments have an immaterial effect on the fair value of these financial assets.

The fair value of the Company's financial assets and liabilities measured on a recurring basis as of December 31, 2022 and 2021, are as follows:

	Total	(Level 1)	(Level 2)	(Level 3)
		(in thousands)		
Cash equivalents	$ 130,249	$ 130,249	$ —	$ —
Restricted cash	235	235	—	—
Short-term investments	4,600	—	4,600	—
Restricted short-term investments	2,200	—	2,200	—
Corporate, agency and municipal bonds	23,453	—	23,453	—
Interest rate swaps related to variable rate loans	6,048	—	6,048	—
Fair value measurement as of December 31, 2022	$ 166,785	$ 130,484	$ 36,301	$ —
Cash equivalents	$ 102,863	$ 102,863	$ —	$ —
Restricted cash	235	235	—	—
Short-term investments	5,103	—	5,103	—
Restricted short-term investments	2,200	—	2,200	—
Corporate and municipal bonds	6,984	—	6,984	—
Interest rate swaps related to variable rate loans	596	—	596	—
Fair value measurement as of December 31, 2021	$ 117,981	$ 103,098	$ 14,883	$ —

The Company does not hold any Level 3 instruments that are measured at fair value on a recurring basis.

Nonfinancial assets and liabilities are not measured at fair value on a recurring basis but are subject to fair value adjustments in certain circumstances. These items primarily include investments in unconsolidated affiliates, long-lived assets, goodwill, and intangible assets for which the fair value is determined as part of the related impairment test. As of December 31, 2022 and 2021, there were no significant adjustments to fair value for nonfinancial assets or liabilities.

The deferred compensation plan assets are valued using the cash surrender value of the life insurance policies and are not included in the table above.

Note 9. Investments

A summary of the Company's investments that are classified as held-to-maturity are as follows:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
		(in thousands)		
Corporate and agency bonds (due within 1 year)	$ 21,612	$ —	$ (60)	$ 21,552
Municipal bonds (due within 1 year)	1,903	—	(2)	1,901
Total investments as of December 31, 2022	$ 23,515	$ —	$ (62)	$ 23,453
Corporate bonds (due within 1 year)	$ 2,481	$ —	$ (3)	$ 2,478
Corporate bonds (due within 1 to 3 years)	1,248	—	(3)	1,245
Municipal bonds (due within 1 year)	3,263	—	(2)	3,261
Total investments as of December 31, 2021	$ 6,992	$ —	$ (8)	$ 6,984

At each reporting period, the Company evaluates securities for impairment when the fair value of the investment is less than its amortized cost. The Company evaluated the underlying credit quality and credit ratings of the issuers, noting neither a significant deterioration since purchase nor any other factors that would indicate a material credit loss.

The Company measures expected credit losses on held-to-maturity investments on a collective basis. All the Company's held-to-maturity investments were considered to be one pool. The estimate for credit losses considers historical loss information that is adjusted for current conditions and reasonable and supportable forecasts. Expected credit losses on held-to-maturity investments were not material to the consolidated financial statements.

Investment in unconsolidated affiliate

The Company accounts for its share of the earnings or losses of its unconsolidated affiliate (Hanxin) with a reporting lag of three months, as the financial statements of Hanxin are not completed on a basis that is sufficient for the Company to apply the equity method on a current basis. The Company's share of Hanxin's losses for the years ended December 31, 2022 and 2021 was $1.2 million and $0.2 million, respectively, which was recorded in the "Equity in losses of unconsolidated affiliate" line on the accompanying consolidated statement of operations.

Note 10. Goodwill and Intangible Assets

The table below shows the weighted-average life, original cost, accumulated amortization, and net book value by major intangible asset classification:

	Weighted-Average Life (Years)	Original Cost	Accumulated Amortization	Net Book Value
		(in thousands)		
Definite-lived intangible assets				
IMS (UK) international product rights	10	$ 8,462	$ 5,430	$ 3,032
Patents	12	486	362	124
Land-use rights	39	2,540	749	1,791
Subtotal	11	11,488	6,541	4,947
Indefinite-lived intangible assets				
Trademark	*	29,225	—	29,225
Goodwill - Finished pharmaceutical products	*	3,126	—	3,126
Subtotal	*	32,351	—	32,351
As of December 31, 2022	*	$ 43,839	$ 6,541	$ 37,298

	Weighted-Average Life (Years)	Original Cost	Accumulated Amortization	Net Book Value
		(in thousands)		
Definite-lived intangible assets				
IMS (UK) international product rights	10	$ 9,445	$ 5,116	$ 4,329
Patents	12	486	340	146
Land-use rights	39	2,540	683	1,857
Subtotal	12	12,471	6,139	6,332
Indefinite-lived intangible assets				
Trademark	*	29,225	—	29,225
Goodwill - Finished pharmaceutical products	*	3,313	—	3,313
Subtotal	*	32,538	—	32,538
As of December 31, 2021	*	$ 45,009	$ 6,139	$ 38,870

* Intangible assets with indefinite lives have an indeterminable average life.

Goodwill

The changes in the carrying amounts of goodwill are as follows:

	December 31, 2022	December 31, 2021
	(in thousands)	
Beginning balance	$ 3,313	$ 3,940
ANP restructuring	—	(374)
Currency translation	(187)	(253)
Ending balance	$ 3,126	$ 3,313

Primatene® Trademark

In January 2009, the Company acquired the exclusive rights to the trademark, domain name, website and domestic marketing, distribution and selling rights related to Primatene MIST®, an over-the-counter bronchodilator product, recorded at the allocated fair value of $29.2 million, which is its carrying value as of December 31, 2022.

The trademark was determined to have an indefinite life. In determining its indefinite life, the Company considered the following: the expected use of the intangible; the longevity of the brand; the legal, regulatory and contractual provisions that affect their maximum useful life; the Company's ability to renew or extend the asset's legal or contractual life without substantial costs; effects of the regulatory environment; expected changes in distribution channels; maintenance expenditures required to obtain the expected future cash flows from the asset; and considerations for obsolescence, demand, competition and other economic factors.

Amortization

Included in cost of revenues for the years ended December 31, 2022, 2021 and 2020 is product rights amortization expense of $0.9 million, $1.0 million, and $1.2 million, respectively.

As of December 31, 2022, the expected amortization expense for all amortizable intangible assets during the next five fiscal years ended December 31 and thereafter is as follows:

	(in thousands)
2023	$ 1,035
2024	1,035
2025	1,035
2026	243
2027	79
Thereafter	1,520
Total amortizable intangible assets	4,947
Indefinite-lived intangibles	32,351
Total intangibles (net of accumulated amortization)	$ 37,298

Note 11. Inventories

Inventories consist of the following:

	December 31,	
	2022	2021
	(in thousands)	
Raw materials and supplies	$ 47,607	$ 41,853
Work in process	37,090	33,298
Finished goods	18,887	17,656
Total inventories	$ 103,584	$ 92,807

Charges of $17.2 million, $24.6 million, and $13.9 million were included in the cost of revenues in the Company's consolidated statements of operations for the years ended December 31, 2022, 2021, and 2020, respectively, to adjust the Company's inventory and related firm purchase commitments to their net realizable value. For the year ended December 31, 2022, the charge included $14.9 million in the cost of revenues to adjust the Company's enoxaparin inventory and related firm purchase commitments to their net realizable value. For the year ended December 31, 2021, the charge included $20.7 million as a result of an increase in the price of heparin as well as a decrease in the forecasted average selling price of enoxaparin. For the year ended December 31, 2020, the charge included $9.4 million as a result of an increase in the price of heparin as well as a decrease in the forecasted average selling price of enoxaparin.

Losses on firm purchase commitments related to raw materials on order as of December 31, 2022 and 2021 were $2.7 million and $7.1 million, respectively, which are recorded in cost of revenues in the Company's consolidated statement of operations.

Note 12. Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

	December 31,	
	2022	2021
	(in thousands)	
Buildings	$ 130,726	$ 130,582
Leasehold improvements	31,535	29,221
Land	7,451	7,615
Machinery and equipment	208,068	207,883
Furniture, fixtures, and automobiles	29,674	27,376
Construction in progress	50,842	41,186
Total property, plant, and equipment	458,296	443,863
Less accumulated depreciation	(220,030)	(199,619)
Total property, plant, and equipment, net	$ 238,266	$ 244,244

The Company incurred depreciation expense of $23.8 million, $22.2 million, and $20.5 million for the years ended December 31, 2022, 2021, and 2020, respectively.

Interest expense capitalized was approximately $1.4 million, $1.4 million, and $1.8 million, for the years ended December 31, 2022, 2021, and 2020, respectively.

Note 13. Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consisted of the following:

	December 31,	
	2022	2021
	(in thousands)	
Accrued customer fees and rebates	$ 14,198	$ 12,121
Accrued payroll and related benefits	22,847	23,256
Accrued product returns, current portion	14,867	16,028
Accrued loss on firm purchase commitments	2,686	7,133
Other accrued liabilities	9,143	8,793
Total accrued liabilities	63,741	67,331
Accounts payable	20,501	22,214
Total accounts payable and accrued liabilities	$ 84,242	$ 89,545

Note 14. Debt

Debt consists of the following:

	December 31,	
	2022	2021
	(in thousands)	
Term Loan		
Term loan with Capital One N.A. due August 2026	$ 68,250	$ 69,563
Mortgage Loans		
Mortgage payable with East West Bank due June 2027	8,188	8,353
Other Loans and Payment Obligations		
French government loans due December 2026	204	269
Line of Credit Facilities		
Line of credit facility with China Merchant Bank	—	—
Revolving line of credit facility with Capital One N.A. due August 2026	—	—
Equipment under Finance Leases	790	398
Total debt	77,432	78,583
Less current portion of long-term debt	3,046	2,202
Less: Loan issuance costs	1,547	1,605
Long-term debt, net of current portion and unamortized debt issuance costs	$ 72,839	$ 74,776

Credit Agreement

Credit Agreement with Capital One N.A. - Due August 2026

In August 2021, the Company entered into a $140.0 million credit agreement with Capital One N.A. acting as a lender and as agent for other lenders. Under the terms of the credit agreement, the Company borrowed $70.0 million in the form of a term loan. Proceeds from the loan were used to pay down certain of the Company's outstanding loans and revolving lines of credit with Cathay Bank and East West Bank. The interest rate on the term loan is based on a variable interest rate, plus an applicable margin rate ranging between 0.5% and 2.5%, determined based on the Company's net leverage ratio as defined by the terms of the agreement. The loan matures in August 2026.

The loan requires principal payments of $1.8 million per year for the first two years, which increases to $3.5 million during the third and fourth year and to $3.9 million in the fifth year, with the remaining balance due at maturity. The loan is secured by substantially all of the Company's assets, excluding the assets of ANP.

The credit agreement provides for a $70.0 million revolving credit facility, which bears a variable interest rate, plus a fixed margin.

In conjunction with the new credit agreement, the Company entered into an interest rate swap agreement with Capital One N.A., with a notional amount of $55.0 million to exchange the variable interest rate on the new term loan for a fixed rate of 0.93%.

As of December 31, 2022, the Company has incurred approximately $2.1 million in issuance costs in connection with this credit agreement, which are being amortized over the term of the loan.

Mortgage Loans

Mortgage Payable with East West Bank — Due June 2027

In May 2017, the Company entered into a mortgage term loan with East West Bank in the principal amount of $9.0 million, which matures in June 2027. The loan is payable in monthly installments with a final balloon payment of $7.4 million plus interest. The loan is secured by one of the buildings at the Company's Rancho Cucamonga, California, headquarters complex and two buildings at the Company's Chino, California, facility. The loan bears a variable interest rate at the one-month LIBOR rate plus 2.5%. As of December 31, 2022, the fair value of the loan approximates its book value. The interest rate used in the fair value estimation was determined to be a Level 2 input. The Company entered into a fixed interest rate swap contract on this loan to exchange the variable interest rate for a fixed interest rate of 4.79% until June 2024.

Line of Credit Facilities

Line of Credit Facility with China Merchant Bank – Due March 2023

In March 2020, the Company entered into a credit agreement with China Merchant Bank. The credit agreement allows the Company to borrow up to $14.6 million secured by buildings and land use rights held by ANP. The interest rate and other terms will be determined at the time of the borrowing, depending on the type of loan requested. The credit period is for 36 months and expires in March 2023.

Other Loans and Payment Obligations

Loans with Seine-Normandie Water Agency

In December 2018, the Company entered into two additional French government loans with the Seine-Normandie water agency in the aggregate amount $0.5 million. The loans have 8 year maturities, and include annual equal payments and bear no interest.

As of December 31, 2022, the payment obligation had an aggregate book value of $0.2 million, which approximates fair value.

Interest Rate Swap Contracts

As of December 31, 2022, the fair value of the loans listed above approximated their carrying amount. The interest rate used in the fair value estimation was determined to be a Level 2 input. For the mortgage loan with East West Bank, as well as the term loan with Capital One N.A., the Company has entered into fixed interest rate swap contracts to exchange the variable interest rates for fixed interest rates. The interest rate swap contracts are recorded at fair value in the other assets line in the condensed consolidated balance sheets. Gains from changes in the fair values of interest rate swaps were $5.5 million and $1.5 million for the years ended December 31, 2022 and 2021, respectively.

Covenants

At December 31, 2022 and 2021, the Company was in compliance with all of its debt covenants.

Long-Term Debt Maturities

As of December 31, 2022, the principal amounts of long-term debt maturities during each of the next five fiscal years ending December 31 are as follows:

	Long-term Debt
	(in thousands)
2023	$ 2,848
2024	3,733
2025	4,181
2026	58,440
2027	7,440
Thereafter	—
	$ 76,642

Note 15. Income Taxes

The Company's income (loss) before income taxes generated from its operations were:

	Year Ended December 31,		
	2022	2021	2020
	(in thousands)		
Income (loss) before income taxes:			
United States	$ 127,204	$ 86,236	$ 15,634
Foreign	(11,164)	(2,097)	(10,997)
Total income (loss) before taxes	$ 116,040	$ 84,139	$ 4,637

The Company's provision for income taxes consisted of the following:

	Year Ended December 31,		
	2022	2021	2020
	(in thousands)		
Current provision:			
Federal	$ 37,626	$ 14,088	$ 1,803
State	732	1,182	541
Foreign	998	1,676	279
Total current provision	39,356	16,946	2,623
Deferred provision (benefit):			
Federal	(16,119)	2,657	1,770
State	816	110	(1,489)
Foreign	(576)	917	636
Total deferred provision	(15,879)	3,684	917
Total provision for income taxes	$ 23,477	$ 20,630	$ 3,540

For tax years beginning after December 31, 2021, certain research and development costs are required to be capitalized and amortized over a five or fifteen-year period under the Tax Cuts and Jobs Act of 2017. The Company has reviewed and incorporated this change, which increases the current U.S. federal and state tax expense and cash taxes to be paid for the tax year ending December 31, 2022.

A reconciliation of the statutory federal income tax rate to the Company's effective tax rate is as follows:

	Year Ended December 31,		
	2022	2021	2020
Statutory federal income tax	21.0 %	21.0 %	21.0 %
State tax expense, net of federal tax benefit	1.1	1.2	(16.2)
Foreign tax rate differences	(0.3)	(2.0)	(20.1)
Foreign valuation allowance	2.6	5.5	89.5
Research and development credits	(3.1)	(3.2)	(65.1)
Share-based compensation	(3.5)	(0.2)	18.7
Executive compensation	2.3	2.3	48.1
Employee-related expenses	0.2	0.1	1.7
Other	(0.1)	(0.2)	(1.3)
Effective tax rate	20.2 %	24.5 %	76.3 %

The Company's effective tax rate for 2022 decreased in comparison to 2021 primarily due to differences in pre-tax income positions and excess tax benefit from share-based compensation.

Deferred Tax Assets and Liabilities

Deferred income taxes reflect the tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, tax credit carryforwards, and the tax effects of net operating loss carryforwards.

The significant components of the Company's deferred tax assets and liabilities are as follows:

	December 31,	
	2022	2021
	(in thousands)	
Deferred tax assets:		
Research and development credits	$ 15,418	$ 17,019
Net operating loss carryforward	20,019	17,568
Inventory capitalization and reserve	9,598	8,489
Share-based compensation	5,208	4,892
Operating leases	6,684	6,555
Accrued expenses	4,956	5,188
Accrued chargebacks	5,125	3,694
Product return allowance	5,464	5,611
Intangibles	2,124	2,124
Research and development capitalization	17,988	—
Total deferred tax assets	92,584	71,140
Deferred tax liabilities:		
Depreciation/amortization	13,272	13,525
Intangibles	8,564	7,893
Operating leases	6,398	6,368
Federal impact of state deferred taxes	3,800	3,966
Other	2,467	642
Total deferred tax liabilities	34,501	32,394
Valuation allowance	(19,700)	(16,881)
Net deferred tax assets	$ 38,383	$ 21,865

Net Operating Loss Carryforwards and Tax Credits

At December 31, 2022, the Company had no material U.S. federal or state net operating loss carryforwards, or NOL carryforwards. The Company had France and United Kingdom foreign NOL carryforwards of approximately $75.3 million and $2.5 million, respectively. The France and United Kingdom NOL carryforwards can be used annually with certain limitations and have an indefinite carryforward.

At December 31, 2022, the Company had California research and development tax credit carryforwards of approximately $21.9 million. The California research and development tax credit has an indefinite carryforward period.

The utilization of NOL and credit carryforwards and other tax attributes could be subject to an annual limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, or the Code, whereby they could be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period as defined in the Code.

Valuation Allowance

In assessing the need for a valuation allowance, management considers whether it is more likely than not that some portion or all of the deferred income tax assets will be realized. Ultimately, realization depends on the existence of future taxable income. Management considers sources of taxable income such as future reversal of existing deferred taxable temporary differences, tax-planning strategies, and projected future taxable income.

The Company continues to record a full valuation allowance on AFP's net deferred income tax assets and will continue to do so until AFP generates sufficient taxable income to realize its deferred income tax assets. As of December 31, 2022 and 2021, the Company had a full valuation allowance against the net deferred tax assets of AFP, which totaled $18.9 million and $16.9 million, respectively.

The Company records a valuation allowance on net deferred income tax assets in states where it files separately and will continue to do so until sufficient taxable income is generated to realize these state deferred income tax assets.

Undistributed Earnings from Foreign Operations

As of December 31, 2022 and 2021, deferred income taxes have not been provided for any undistributed earnings from foreign operations. The foreign subsidiaries have significant accumulated losses, and as such there are no earnings in which to provide taxes. It is the Company's plan not to repatriate future foreign earnings to the U.S. and indefinitely reinvest such earnings in the foreign jurisdiction.

Uncertain Income Tax Positions

A reconciliation of the beginning and ending balances of unrecognized tax benefits is as follows:

	December 31,		
	2022	2021	2020
		(in thousands)	
Balance at the beginning of the year	$ 11,796	$ 10,053	$ 8,331
Deductions based on tax positions related to prior year	(41)	—	—
Additions based on tax positions related to the current year	1,643	1,754	1,815
Deductions based on statute of limitations	(503)	(11)	(93)
Balance at the end of the year	$ 12,895	$ 11,796	$ 10,053

Included in the balance of unrecognized tax benefits as of December 31, 2022 and 2021, was $12.2 million and $11.4 million, respectively that represents the portion that would impact the effective income tax rate if recognized.

The Company recognizes interest and penalties related to unrecognized tax benefits in its income tax provision. For the years ended December 31, 2022, 2021 and 2020, the Company accrued interest of approximately $0.8 million, $0.5 million and $0.2 million, respectively, related to its uncertain tax positions.

The Company and/or one or more of its subsidiaries files income tax returns in the U.S. federal jurisdiction and various U.S. states and foreign jurisdictions. As of December 31, 2022, the Company does not have a tax examination in progress for federal, state, or foreign jurisdictions. The Company is subject to income tax audit by tax authorities for tax years 2019 to 2021 for federal, 2018 to 2021 for states, and 2012 to 2021 for foreign.

Note 16. Stockholders' Equity

Equity Plans

As of December 31, 2022, the Company has two equity plans: the Amended and Restated 2015 Equity Incentive Plan, or 2015 Plan, and the 2014 Employee Stock Purchase Plan or ESPP. Prior to the adoption of these plans, the Company granted options pursuant to the Amended and Restated 2005 Equity Incentive Award Plan. Upon termination of the predecessor plans, the shares available for grant at the time of termination, and shares subsequently returned to the plans upon forfeiture or option termination, were transferred to the successor plan in effect at the time of share return. The Company issues new shares of common stock upon exercise of stock options, vesting of restricted stock units, or RSU, and settlement of ESPP, with the exception of the awards granted to employees at AFP, which are settled through re-issuance of the Company’s treasury shares.

Amended and Restated 2015 Equity Incentive Plan

In March 2015, the Board of Directors adopted the Company’s 2015 Equity Incentive Plan, or the 2015 Plan, which was approved by the Company’s stockholders in May 2015 and is set to expire in March 2025. The 2015 Plan is designed to meet the needs of a publicly traded company, including the requirements for granting “performance based compensation” under Section 162(m) of the Internal Revenue Code. The 2015 Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights, performance units, performance shares, and other stock or cash awards to employees of the Company and its subsidiaries, members of the Board of Directors and consultants.

In November 2020, the Board of Directors approved the Amendment and Restated 2015 Equity Incentive Plan to provide that at least 95% of the shares awarded under the plan will be subject to a minimum vesting requirement of at least one year.

The Company initially reserved 5,000,000 shares of common stock for issuance under the 2015 Plan. This number will be increased by the number of shares available for issuance under the Company’s prior equity incentive plans or arrangements that are not subject to options or other awards, plus the number of shares of common stock related to options or other awards granted under the Company’s prior equity incentive plans or arrangements that are repurchased, forfeited, expired, or cancelled on or after the effective date of the 2015 Plan. The 2015 Plan also contains an “evergreen provision” that allows for an annual increase in the number of shares available for issuance on January 1 of each year during the 10 year term of the 2015 Plan, beginning January 1, 2016. The annual increase in the number of shares shall be the lesser of (i) 3,000,000 shares, (ii) two and one-half percent (2.5%) of the outstanding shares on the last day of the immediately preceding fiscal year, or (iii) such number of shares as determined by the Board of Directors. As of the effective date of the 2015 Plan, there were 5,300,296 shares available for grant under the 2015 Plan.

As of December 31, 2022, the Company reserved an aggregate of 6,499,954 shares of common stock for future issuance under the Amended and Restated 2015 Equity Incentive Plan, or the 2015 Plan, including 1,202,802 shares, which were reserved in January 2023 pursuant to the evergreen provision in the 2015 Plan.

Amended and Restated 2005 Equity Incentive Award Plan

The Amended and Restated 2005 Equity Incentive Award Plan, or 2005 Plan, provided for the grant of incentive stock options, or ISOs, nonqualified stock options, or NQSOs, restricted stock awards, restricted stock unit awards, stock appreciation rights, or SARs, dividend equivalents and stock payments to the Company's employees, members of the Board of Directors and consultants. Stock options under the 2005 Plan were granted with a term of up to ten years and at prices no less than the fair market value of the Company's common stock on the date of grant. To date, stock options granted to existing employees generally vest over three to five years and stock options granted to new employees vest over four years. Stock options granted to Board of Directors and consultants generally vested over one year.

As of March 2015, consequent to the 2015 Plan becoming effective, awards were no longer granted under the 2005 Plan.

2014 Employee Stock Purchase Plan

In June 2014, the Company adopted the ESPP in connection with its initial public offering. A total of 2,000,000 shares of common stock are reserved for issuance under this plan. The Company's ESPP permits eligible employees to purchase common stock at a discount through payroll deductions during defined offering periods. Under the ESPP, the Company may specify offerings with durations of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of its common stock will be purchased for employees participating in the offering. An offering may be terminated under certain circumstances. The price at which the stock is purchased is equal to 85% of the lower of the fair market value of the common stock at the beginning of an offering period or on the date of purchase.

As of December 31, 2022, the Company has issued 1,089,545 shares of common stock under the ESPP and 910,455 shares of its common stock remains available for issuance under the ESPP.

For the years ended December 31, 2022, 2021, and 2020, the Company recorded ESPP expense of $0.9 million, $0.7 million, and $0.8 million, respectively.

Share Buyback Program

As of December 31, 2022, the Company's Board of Directors have authorized a total of $235.0 million in the share buyback program. The primary goal of the program is to offset dilution created by the Company's equity compensation programs. The Company's share buyback program is expected to continue for an indefinite period of time.

Purchases are made through open market and private block transactions pursuant to Rule 10b5-1 plans, privately negotiated transactions or other means as determined by the Company's management and in accordance with the requirements of the SEC and applicable laws. The timing and actual number of treasury share purchases will depend on a variety of factors including price, corporate and regulatory requirements, and other conditions. These treasury share purchases are accounted for under the cost method and are included as a component of treasury stock in the Company's consolidated balance sheets.

Pursuant to the Company's existing share buyback program, the Company purchased 1,335,528 shares, 1,477,305 shares, and 1,366,384, shares of its common stock during the years ended December 31, 2022, 2021 and 2020, for total consideration of $39.9 million, $28.9 million, and $24.4 million, respectively.

Share-Based Award Activity and Balances (excluding the ANP Equity Plan)

The Company accounts for share-based compensation payments in accordance with ASC 718, which requires measurement and recognition of compensation expense at fair value for all share-based payment awards made to employees and directors. Under these standards, the fair value of option awards and the option components of the ESPP

awards are estimated at the grant date using the Black-Scholes option-pricing model. The fair value of RSUs is estimated at the grant date using the Company's common share price. Compensation cost for all share-based payments granted with service-based graded vesting schedules is recognized using the straight-line method over the requisite service period.

Options issued under the Company's 2015 Plan and 2005 Plan are granted at exercise prices equal to or greater than the fair value of the underlying common shares on the date of grant and vest based on continuous service. There have been no awards with performance conditions and no awards with market conditions. The options have a contractual term of five to ten years and generally vest over a three- to five-year period. The Black-Scholes option pricing model has various inputs such as the common share price on the date of grant, exercise price, the risk-free interest rate, volatility, expected term and dividend yield, all of which are estimates. The Company records share-based compensation expense net of expected forfeitures. The change of any of these inputs could significantly impact the determination of the fair value of the Company's options as well as significantly impact its results of operations.

The significant assumptions used in the Black-Scholes option-pricing are as follows:

- *Determination of Fair Value of the Underlying Common Stock.* For options and ESPP awards granted, the fair value for its underlying common stock is determined using the closing price on the date of grant as reported on the Nasdaq Global Select Market, or Nasdaq with consideration of whether there is material nonpublic information that could impact that estimated fair value when it is released.

- *Expected Volatility.* The Company estimates its volatility based on the historical volatility of its stock price since IPO.

- *Expected Term.* The expected term represents the period of time in which the options granted are expected to be outstanding. The Company estimates the expected term of options with consideration of vesting date, contractual term, and historical experience for exercise and post-vesting employment or contractual termination behavior after its common stock has been publicly traded. The expected term of "plain vanilla" options is estimated (using the simplified method as outlined in SAB Topic 14 due to a lack of sufficient historical exercise data) based on the midpoint between the vesting date and the end of the contractual term under the simplified method permitted by the SEC implementation guidance.

- *Risk-Free Rate.* The risk-free interest rate is selected based upon the implied yields in effect at the time of the option grant on U.S. Treasury zero-coupon issues with a term approximately equal to the expected life of the option being valued.

- *Dividends.* The Company does not anticipate paying cash dividends in the foreseeable future. Consequently, the Company uses an expected dividend yield rate of zero.

The Company estimates forfeitures at the time of grant and revises those estimates in subsequent periods if actual experience differs from those estimates. For the years ended December 31, 2022, 2021 and 2020, the Company estimated an average overall forfeiture rate of approximately 7%, 6%, and 5%, respectively, based on historical experience. Forfeiture rates are separately estimated for its (1) directors and officers, (2) management personnel and (3) other employees. Share-based compensation is recorded net of expected forfeitures. The Company periodically assesses the forfeiture rate and the amount of expense recognized based on estimated historical forfeitures as compared to actual forfeitures. Changes in estimates are recorded in the period they are identified.

Tax benefits resulting from tax deductions in excess of the share-based compensation cost recognized (excess tax benefits) are recorded in the statements of cash flows as financing activities.

The weighted-averages for key assumptions used in determining the fair value of options granted during the years ended

December 31, 2022, 2021, and 2020 are as follows:

	Year Ended December 31,		
	2022	2021	2020
Average volatility	41.0 %	42.1 %	43.1 %
Average risk-free interest rate	2.3 %	1.2 %	0.8 %
Weighted-average expected life in years	6.1	6.1	5.7
Dividend yield rate	— %	— %	— %

Stock Options

A summary of option activity under all plans for the year ended December 31, 2022, is presented below:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value[1] (in thousands)
Outstanding as of December 31, 2021	8,455,721	$ 15.67		
Options granted	792,441	34.35		
Options exercised	(1,222,147)	14.56		
Options cancelled	(91,251)	19.56		
Options expired	(5,614)	13.79		
Outstanding as of December 31, 2022	7,929,150	$ 17.66	4.94	87,025
Exercisable as of December 31, 2022	5,550,697	$ 15.69	3.64	68,413
Vested and expected to vest as of December 31, 2022	7,757,291	$ 17.51	4.87	85,920

(1) The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the estimated fair value of the Company's stock for those awards that have an exercise price below the estimated fair value at December 31, 2022.

During the years ended December 31, 2022, 2021, and 2020, the Company recorded expense of $8.5 million, $8.0 million, and $9.1 million, respectively, related to stock options granted under all plans.

Information relating to option grants and exercises is as follows:

	Year Ended December 31,		
	2022	2021	2020
	(in thousands, except per share data)		
Weighted-average grant date fair value per option share	$ 14.75	$ 7.62	$ 5.51
Intrinsic value of options exercised	21,279	7,906	9,169
Cash received from options exercised	19,202	16,757	24,357
Total fair value of the options vested during the period	8,174	8,177	9,978

A summary of the status of the Company's non-vested options as of December 31, 2022, and changes during the year ended December 31, 2022, are presented below:

	Options	Weighted-Average Grant Date Fair Value
Non-vested as of December 31, 2021	2,848,934	$ 6.95
Options granted	792,441	14.75
Options vested	(1,171,671)	6.98
Options forfeited	(91,251)	8.41
Non-vested as of December 31, 2022	2,378,453	9.48

As of December 31, 2022, there was $14.5 million of total unrecognized compensation cost, net of forfeitures, related to non-vested stock option based compensation arrangements granted under all plans. The cost is expected to be recognized over a weighted-average period of 2.5 years and will be adjusted for future changes in estimated forfeitures.

In April 2020, Jason Shandell resigned from his position as the Company's President and General Counsel and as a member of the Company's board of directors. In connection with his resignation, the Company and Mr. Shandell entered into a separation agreement. As part of the separation agreement, the Company agreed to accelerate 80% of his unvested stock options and extended the expiration date of certain vested stock option awards. As a result of this modification, the Company incurred share-based compensation expense of $0.7 million, which is included within general and administration expenses in the consolidated statement of operations for the year ended December 31, 2020.

Restricted Stock Units

The Company grants restricted stock units, or RSUs, to certain employees and members of the Board of Directors with a vesting period of up to five years. The grantee receives one share of common stock at a specified future date for each RSU awarded. The RSUs may not be sold or otherwise transferred until vested. The RSUs do not have any voting or dividend rights prior to the issuance of certificates of the underlying common stock. The share-based expense associated with these grants was based on the Company's common stock fair value at the time of grant and is amortized over the requisite service period, which generally is the vesting period, using the straight-line method. During the years ended December 31, 2022, 2021, and 2020, the Company recorded expenses of $8.4 million, $8.1 million, and $10.0 million, respectively, related to RSU awards granted under all plans.

As part of the separation agreement with Mr. Shandell, the Company agreed to accelerate the vesting of 80% of his RSU awards. As a result of this modification, the Company incurred share-based compensation expense of $1.6 million, which is included within general and administrative expenses in the consolidated statement of operations for the year ended December 31, 2020.

As of December 31, 2022, there was $15.3 million of total unrecognized compensation cost, net of forfeitures, related to non-vested RSU-based compensation arrangements granted under all plans. The cost is expected to be recognized over a weighted-average period of 2.5 years and will be adjusted for future changes in estimated forfeitures.

Information relating to RSU grants and deliveries is as follows:

	Total RSUs Issued	Total Fair Market Value of RSUs Issued[1] (in thousands)
RSUs outstanding at December 31, 2021	1,184,842	
RSUs granted	339,397	$ 11,675
RSUs forfeited	(39,119)	
RSUs vested[2]	(478,068)	
RSUs outstanding at December 31, 2022	1,007,052	

(1) The total FMV is derived from the number of RSUs granted times the current stock price on the date of grant.
(2) Of the vested RSUs, 181,547 shares of common stock were surrendered to fulfil tax withholding obligations.

The 2018 ANP Equity Incentive Plan

In December 2018, ANP's board of directors approved the 2018 Plan, which was set to expire in December 2023. The 2018 Plan permitted the grant of stock options and other equity awards in ANP shares to ANP employees.

During the second quarter of 2021, in connection with the ANP restructuring, the 2018 Plan was terminated.

At the time the 2018 Plan was terminated, the number of stock options outstanding under the 2018 Plan was 5,018,880. As part of the termination, ANP cash settled 4,091,080 stock options, of which 1,944,771 stock options were vested and 2,146,309 stock options were unvested, for $0.8 million which approximated the fair value of these awards at the time of the settlement. The cash settlement of these awards was recorded as a reduction in equity.

For the remaining 927,800 stock option awards that were outstanding under the 2018 Plan at the time the 2018 Plan was terminated, of which 56,925 stock options were vested and 870,875 were unvested, the Company cancelled these awards and issued replacement awards under the 2015 Plan. The modified awards vest over periods ranging from 1 to 2 years and have a 10-year contractual term. The cancellation and replacement of the awards was accounted for as a modification in accordance with ASC 718.

As a result of the modification, the cost to the Company was $2.3 million, of which $1.8 million was recorded as share-based compensation within general and administrative expenses in the consolidated statement of operations for the year ended December 31, 2021, and the remaining $0.5 million which will be recognized over the vesting period of the modified awards.

Prior to the termination of the 2018 Plan, for the years ended December 31, 2021 and 2020, the Company recorded expense of $0.5 million and $0.7 million related to stock options issued by ANP under the 2018 Plan, respectively.

Share-based Compensation Expense

The Company recorded share-based compensation expense, which is included in the Company's consolidated statement of operations as follows:

	Year Ended December 31,		
	2022	2021	2020
	(in thousands)		
Cost of revenues	$ 4,179	$ 3,778	$ 4,248
Operating expenses:			
Selling, distribution, and marketing	726	596	456
General and administrative	11,180	12,622	14,089
Research and development	1,775	1,691	1,705
Total share-based compensation	$ 17,860	$ 18,687	$ 20,498

Note 17. Employee Benefits

401(k) Plan

The Company has a defined contribution 401(k) plan, or the Plan, whereby eligible employees voluntarily contribute up to a defined percentage of their annual compensation. The Company matches contributions at a rate of 50% on the first 6% of employee contributions, and pays the administrative costs of the Plan. Total employer contributions for the years ended December 31, 2022, 2021, and 2020 were approximately $2.2 million, $2.0 million, and $1.9 million, respectively.

Defined Benefit Pension Plan

The Company's subsidiary, AFP, has an obligation associated with a defined-benefit plan for its eligible employees. This plan provides benefits to the employees from the date of retirement and is based on the employee's length of time employed by the Company. The calculation is based on a statistical calculation combining a number of factors that include the employee's age, length of service, and AFP employee turnover rate.

The liability under the plan is based on a discount rate of 3.75% and 1.00% as of December 31, 2022 and 2021, respectively. The liability is included in other long-term liabilities in the accompanying consolidated balance sheets. The plan is currently unfunded, and the benefit obligation under the plan was $2.2 million and $2.7 million at December 31, 2022 and 2021, respectively. The Company recorded an immaterial amount of expense under the plan for each of the years ended December 31, 2022, 2021 and 2020. Gain or loss due to change in actuarial valuation of the Company's defined benefit pension plan is recorded in other comprehensive income (loss).

Non-qualified Deferred Compensation Plan

In December 2019, the Company established a non-qualified deferred compensation plan. The plan allows certain eligible participants to defer a portion of their cash compensation and provides a matching contribution at the discretion of the Company. The plan obligations are payable upon retirement, termination of employment and/or certain other times in a lump-sum distribution or in installments, as elected by the participant in accordance with the plan. Participants can allocate their deferred compensation amongst various investment options with earnings accruing to the participant. The Company has established a Rabbi Trust to fund the plan obligations and to hold the plan assets. Eligible participants began contributing to the plan in January 2020. The plan assets were valued at approximately $4.5 million and $3.4 million as of December 31, 2022 and December 31, 2021, respectively. The plan liabilities were valued at approximately $4.6 million and $3.5 million as of December 31, 2022 and December 31, 2021, respectively. The plan assets and liabilities are included in other long-term assets and other long-term liabilities, respectively, on the Company's

consolidated balance sheets.

Note 18. Commitments and Contingencies

Lease Liabilities

Right-of-Use, or ROU, assets represent the Company's right to control an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. ROU assets and liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. Lease terms are generally based on their initial non-cancelable terms, unless there is a renewal option that is reasonably certain to be exercised. Various factors, including economic incentives, intent, past history, and business needs are considered to determine if a renewal option is reasonably certain to be exercised. As most of its leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the commencement date in determining the discount rate used to present value the lease payments. The Company has lease agreements with both lease and non-lease components, which are accounted for as a single component for all asset classes. The Company leases real and personal property, in the normal course of business, under various non-cancelable operating leases. The Company, at its option, can renew a substantial portion of its leases, at the market rate, for various renewal periods ranging from one to six years.

The components of lease costs for the years ended December 31, 2022, 2021 and 2020 were as follows:

	Year Ended December 31,		
	2022	2021	2020
	(in thousands)		
Operating lease costs	$ 4,709	$ 4,328	$ 4,462
Short-term lease costs	300	518	649
Finance lease costs			
Amortization of right-of-use assets	237	384	351
Interest on lease liabilities	26	26	33
Total finance lease costs	$ 263	$ 410	$ 384
Total lease costs	$ 5,272	$ 5,256	$ 5,495

Other information pertaining to leases is as follows:

	Year Ended December 31,		
	2022	2021	2020
	(in thousands, except lease term and discount rate)		
Cash paid for amounts included in the measurement of lease liabilities			
Operating cash flows from operating leases	$ 4,329	$ 4,446	$ 4,491
Operating cash flows from finance leases	18	25	33
Financing cash flows from finance leases	233	310	369
Right-of use assets obtained in exchange for lease liabilities			
Operating leases	2,166	11,041	4,819
Finance leases	642	110	61
Weighted-average remaining lease term (years)			
Operating leases	8.7	9.5	8.7
Finance leases	4.3	2.4	2.3
Weighted-average discount rate			
Operating leases	4.4 %	4.5 %	5.2 %
Finance leases	6.7 %	5.2 %	5.0 %

Future minimum rental payments under leases that have initial or remaining non-cancelable lease terms in excess of 12 months as of December 31, 2022, are as follows:

	Operating Leases	Finance Leases	Total
		(in thousands)	
2023	$ 4,078	$ 243	$ 4,321
2024	3,742	212	3,954
2025	3,635	189	3,824
2026	3,534	159	3,693
2027	3,364	104	3,468
Thereafter	14,080	—	14,080
Total lease payments	$ 32,433	$ 907	$ 33,340
Less: interest	5,736	117	5,853
Total	$ 26,697	$ 790	$ 27,487

Purchase Commitments

As of December 31, 2022, the Company has entered into commitments to purchase equipment and raw materials for an aggregate amount of approximately $58.2 million.

Note 19. Related-Party Transactions

ANP Restructuring

Subsequent to the ANP restructuring discussed in Note 3, which involved various related parties, Hanxin is no longer a wholly-owned subsidiary of the Company and was deconsolidated in the third quarter of 2021.

The Company determined that it has significant influence over Hanxin as a result of its 14% ownership interest, its seat on Hanxin's board of directors, and Henry Zhang's position as an equity holder, general manager, and chairman of the board of directors of Hanxin, given he is the son of Dr. Jack Zhang. Additionally, Dr. Mary Luo and Dr. Jack Zhang, through an affiliated entity, have an ownership interest in Hanxin and as such Hanxin continues to be a related party after the restructuring.

Contract manufacturing agreement with Hanxin

In April 2022, the Company's Chinese subsidiary, ANP, entered into a contract manufacturing agreement with Hanxin, a related party, whereby Hanxin will develop several active pharmaceutical ingredients and finished products for the Chinese market and will engage ANP to manufacture the products on a cost-plus basis. Hanxin will commit to purchase certain quantities from ANP subject to the terms and conditions set forth in the agreement, including Hanxin filing for and obtaining any required marketing authorizations.

During the year ended December 31, 2022, the Company recognized $0.4 million of revenue from manufacturing services provided to Hanxin. As of December 31, 2022, the Company did not have any Receivables from Hanxin.

Contract Research Agreement with Hanxin

In July 2022, the Company entered into a three-year contract research agreement with Hanxin, a related party, whereby Hanxin will develop Recombinant Human Insulin Research Cell Banks, or RCBs, for the Company and license the RCBs to the Company subject to a fully paid, exclusive, perpetual, transferable, sub-licensable worldwide license. The RCBs will be used by the Company to make Master Cell Banks for one of its product candidates. Per the terms of the agreement with Hanxin, all title to the RCBs developed, prepared and produced by Hanxin in conducting research and development will belong to the Company. The Company will also own any confidential and proprietary information, technology regarding development and manufacturing of the RCBs, which shall include engineering, scientific and practical information and formula, research data, design, and procedures and others to develop and manufacture the RCBs, in use or developed by Hanxin. The total cost of the agreement to the Company shall not exceed approximately $2.2 million, with payments adjusted based on the then current exchange rates. Any additional work or changes to the scope of work requested by the Company will be charged by Hanxin to the Company on a cost-plus basis, plus any applicable taxes.

During the year ended December 31, 2022, the Company paid $0.6 million under this agreement and has accrued an additional $0.4 million payable to Hanxin as of December 31, 2022.

Supply Agreement with Letop

In November 2022, the Company's Chinese subsidiary, ANP, entered in to a supply agreement with Nanjing Letop Biotechnology Co., Ltd., or Letop, a related party, whereby Letop would manufacture and deliver chemical intermediates for ANP on a cost-plus basis. The agreement is effective for three years and the total cost of the agreement shall not exceed approximately $1.5 million, with payments adjusted based on the then current exchange rates.

During the year ended December 31, 2022, ANP paid $0.2 million under this agreement. As of December 31, 2022, the Company did not have any additional accruals payable to Letop.

Retirement of James Luo

In December 2020, James Luo retired from his position as the Company's Senior Vice President of Engineering and President of AFP. Mr. Luo is a relative of the Company's Chief Operating Officer, Dr. Mary Luo. In connection with his retirement, the Company and Mr. Luo entered into a retirement agreement where the Company agreed to pay Mr. Luo approximately $1.0 million in cash compensation over a period of three years as well as provide health insurance coverage for a six year period beginning in 2021. As a result, the Company recorded a total of $1.1 million in general and administrative expense in the fourth quarter of 2020 related to this agreement.

Note 20. Litigation

Amphastar Pharmaceuticals, Inc. v Aventis Pharma, SA

In January 2009, the Company filed a *qui tam* complaint in the U.S. District Court for the Central District of California, alleging that Aventis Pharma S.A., or Aventis, through its acquisition of a patent through false and misleading statements to the U.S. Patent and Trademark Office, as well as through false and misleading statements to the FDA, overcharged the federal and state governments for its Lovenox® product (the "Aventis FCA Action").

On November 13, 2020, the Court issued an Order ("November Order") awarding Aventis $12.1 million in attorneys' fees and $0.7 million in costs and expenses. The Company recorded $12.8 million in other income (expenses) in the consolidated statement of operations for the year ended December 31, 2020.

On May 3, 2021, the Court issued a further Order based upon supplemental application to the Court seeking fees, expenses, and interest for the period after, and not covered by, the November Order. The Court awarded Aventis an additional $4.4 million bringing the total amount awarded to Aventis to $17.2 million.

On June 30, 2021, the Company and Aventis entered into a settlement agreement to settle the attorney fees' and expenses claim for $14.5 million. The additional $1.7 million was recorded in other income (expenses), in the consolidated statement of operations. The settlement was paid in full in the third quarter of 2021.

Hatch-Waxman Litigation

Regadenoson (0.4 mg/5 mL, 0.08 mg/mL) Patent Litigation

On February 25, 2020, Astellas US LLC, Astellas Pharma US, Inc., and Gilead Sciences, Inc. (collectively, "Astellas-Gilead") filed a Complaint in the United States District Court for the District of Delaware against IMS for infringement of U.S. Patent Nos. 8,106,183 (the "'183 patent"), RE47,301 (the "'301 patent"), and 8,524,883 (the "'883 patent") (collectively, "Astellas-Gilead Patents") with regard to IMS's ANDA No. 214,252 for approval to manufacture and sell 0.4 mg/5 mL (0.08 mg/mL) intravenous solution of Regadenoson. On March 4, 2020, IMS filed its Answer and Counterclaims. On March 30, 2020, the Court issued an Order allowing the Company to join pending consolidated litigation with five other generic Regadenoson ANDA filers involving similar claims. The Company's 30-month FDA stay expired August 10, 2022. On January 26, 2022, the Company and Astellas-Gilead reached an agreement to resolve the lawsuit. The parties submitted, and the Court granted on January 27, 2022, a Motion to Dismiss Without Prejudice for Astellas-Gilead's complaint of infringement against IMS. Under the terms of the agreement, the Company received $5.4 million from Astellas constituting saved litigation expenses. The Company recorded the settlement amount in the other income (expenses) line in its consolidated statement of operations for the year ended December 31, 2022.

Employee Litigations

In 2021 and 2020, the Company settled employee litigations relating to alleged violations of various California labor laws pertaining to wage and hour against the Company. For each of the years ended December 31, 2021 and 2020, the Company recorded $1.0 million, related to the settlement of employment litigation, in general and administrative expense in the Company's consolidated statements of operations.

Other Litigation

The Company is also subject to various other claims, arbitrations, investigations, and lawsuits from time to time arising in the ordinary course of business. In addition, third parties may, from time to time, assert claims against the Company in the forms of letters and other communications.

The Company records a provision for contingent losses when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. In the opinion of management, the ultimate resolution of any such matters is not expected to have a material adverse effect on its financial position, results of operations, or cash flows; however, the results of litigation and claims are inherently unpredictable and the Company's view of these matters may change in the future. Regardless of the outcome, litigation can have an adverse impact on the Company because of defense and settlement costs, diversion of management resources, and other factors.

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, under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, our principal executive and principal financial officers, respectively, conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act of 1934, as amended, as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures were effective (a) to ensure that information that we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms and (b) to include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in reports filed or submitted under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Under the supervision and with the participation of senior management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of our internal control over financial reporting based on the framework in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013. Based on the evaluation under that framework and applicable SEC rules, our management concluded that our internal control over financial reporting was effective as of December 31, 2022.

Our internal control over financial reporting as of December 31, 2022 has been audited by Ernst & Young, LLP, an independent registered public accounting firm, as stated in their report appearing below.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2022, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act).

Inherent Limitations of Internal Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal controls over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management overriding of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Amphastar Pharmaceuticals, Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Amphastar Pharmaceuticals, Inc. internal control over financial reporting as of December 31, 2022, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Amphastar Pharmaceuticals, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2022, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2022 and 2021, the related consolidated statements of operations, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2022, and the related notes and our report dated March 1, 2023 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

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

Definition and Limitations of Internal Control Over Financial Reporting

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

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

/s/ Ernst & Young LLP
Irvine, California
March 1, 2023

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information required by this item will be included in our Proxy Statement for our 2023 Annual Meeting of Stockholders to be filed within 120 days after our fiscal year end of December 31, 2022, or 2023 Proxy Statement, and is incorporated by reference into this Annual Report on Form 10-K.

Item 11. Executive Compensation.

Information required by this item will be included in our 2023 Proxy Statement and is incorporated by reference into this Annual Report on Form 10-K.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information required by this item will be included in our 2023 Proxy Statement and is incorporated by reference into this Annual Report on Form 10-K.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information required by this item will be included in our 2023 Proxy Statement and is incorporated by reference into this Annual Report on Form 10-K.

Item 14. Principal Accountant Fees and Services.

Information required by this item will be included in our 2023 Proxy Statement and is incorporated by reference into this Annual Report on Form 10-K.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) (1) Financial Statements filed as part of this report are listed in Part II, Item 8 of this report.

(2) No other financial schedules have been included because they are not applicable, not required or because required information is included in the consolidated financial statements or notes thereto.

(b) The following exhibits are filed as part of, or incorporated by reference into, this Annual Report on Form 10-K, in each case as indicated below.

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on July 1, 2014)
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on February 24, 2023)
4.1	Specimen common stock certificate (incorporated by reference to Exhibit 4.1 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on June 5, 2014)
4.2	Description of Securities Registered Under Section 12 of the Exchange Act (incorporated by reference to Exhibit 4.2 to the Company's Annual Report on Form 10-K filed with the SEC on March 15, 2021)
10.1+	Amended and Restated 2005 Equity Incentive Award Plan (incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.2+	Form of Stock Option Grant Notice and Stock Option Agreement under the Amended and Restated 2005 Equity Incentive Award Plan (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.3◊	Transfer Contract for the Right to the Use of State-owned Land, dated December 29, 2009, between Amphastar Nanjing Pharmaceuticals Co., Ltd. and Nanjing Xingang Hi-Tech Company Limited (incorporated by reference to Exhibit 10.13 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.4◊	Investment Agreement, dated July 5, 2010, between Amphastar Nanjing Pharmaceuticals Co., Ltd. and the Management Committee of the Nanjing Economic and Technological Development Zone (incorporated by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.5◊	Transfer Contract for the Right to the Use of State-owned Land, dated December 31, 2010, between Amphastar Nanjing Pharmaceuticals Co., Ltd. and Nanjing Xingang Hi-Tech Company Limited. (incorporated by reference to Exhibit 10.15 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.6+	2014 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.17 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.7+	Employment Agreement, dated May 19, 2014, between Amphastar Pharmaceuticals, Inc. and Jack Zhang (incorporated by reference to Exhibit 10.21 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.8+	Employment Agreement, dated May 19, 2014, between Amphastar Pharmaceuticals, Inc. and Mary Luo (incorporated by reference to Exhibit 10.22 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.9+	Employment Agreement, dated March 11, 2014, between Amphastar Pharmaceuticals, Inc. and William Peters (incorporated by reference to Exhibit 10.25 to the Company's Registration Statement on Form S-1 filed with the SEC on May 20, 2014)
10.10†	Supply Agreement, dated July 31, 2014, between MannKind Corporation and Amphastar France Pharmaceuticals, S.A.S. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 13, 2014)

10.11	First Amendment to Supply Agreement, dated October 31, 2014, by and between MannKind Corporation, Amphastar France Pharmaceuticals, S.A.S., and Amphastar Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 13, 2014)
10.12†	Second Amendment to Supply Agreement, dated November 9, 2016, by and between MannKind Corporation, Amphastar France Pharmaceuticals, S.A.S., and Amphastar Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.34 to the Company's Annual Report on Form 10-K filed with the SEC on March 15, 2017)
10.13	Business Loan Agreement, dated May 18, 2017, between Amphastar Pharmaceuticals, Inc. and East West Bank in the original principal sum of $9,000,000. (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2017)
10.14	Partnership Agreement by and between Zhang Chongqing, Bill Zhang and Applied Physics & Chemistry Laboratories, Inc. dated July 27, 2018. (incorporated by reference to Exhibit 10.9 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2018)
10.15	Fourth Amendment to Supply Agreement, dated December 24, 2018, by and between MannKind Corporation and Amphastar Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.45 to the Company's Annual Report on Form 10-K filed with the SEC on March 15, 2018)
10.16*	Fifth Amendment to the Supply Agreement by and between MannKind Corporation and Amphastar Pharmaceuticals, Inc., dated August 2, 2019. (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2019)
10.17	Amphastar Pharmaceuticals, Inc. Employee Deferred Compensation Plan, effective December 1, 2019. (incorporated by reference to Exhibit 10.39 to the Company's Annual Report on Form 10-K filed with the SEC on March 16, 2020)
10.18+	Amphastar Pharmaceuticals, Inc. 2015 Equity Incentive Plan, as amended and restated effective as of November 3, 2020 (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K filed with the SEC on November 6, 2020)
10.19*	Sixth Amendment to the Supply Agreement by and between MannKind Corporation and Amphastar Pharmaceuticals, Inc., dated May 24, 2021 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2021)
10.20*	Share Purchase Agreement by and between Amphastar Pharmaceuticals, Inc., Nanjing Zhongpan Enterprise Management Consulting Center (LLP), Nanjing Zhanrun Enterprise Management Consulting Center (LLP), and Listening Dragon Investment Company Limited, dated May 6, 2021 (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2021)
10.21*	Share Repurchase Agreement by and between Amphastar Pharmaceuticals, Inc., Nanjing Qianqia Enterprise Management Consulting (LLP), Nanjing Zhongpan Enterprise Management Consulting Center (LLP), and Nanjing Zhanrun Enterprise Management Consulting Center (LLP), dated May 6, 2021 (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2021)
10.22	Credit Agreement dated August 4, 2021, between Amphastar Pharmaceuticals, Inc. and Capital One N.A. in the original sum of $140,000,000 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 9, 2021)
10.23*	Share Purchase Agreement by and between Amphastar Pharmaceuticals, Inc. and Nanjing Quanqia Enterprise Management Consulting, LLP, dated August 19, 2021 (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 9, 2021)
10.24*	Contract Manufacturing Agreement by and between Amphastar Nanjing Pharmaceutical, Co. Ltd. and Nanjing Hanxin Pharmaceutical Technology Co., Ltd, dated April 19, 2022 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2022)

10.25*	Contract Research Agreement by and between Amphastar Pharmaceuticals, Inc. and Nanjing Hanxin Pharmaceutical Technology Co., Ltd., dated July 5, 2022 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 8, 2022)
10.26*	Supply Agreement by and between Amphastar Nanjing Pharmaceuticals, Inc. and Nanjing Letop Biotechnology Co. Ltd. dated November 15, 2022 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on November 18, 2022)
21.1	Subsidiaries of the Company
23.1	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney (included in signature pages hereto)
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14a of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14a of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1#	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2#	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
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
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definitions Linkbase Document
104	Cover Page Interactive File (formatted as Inline XBRL and contained in Exhibit 101)

The information in Exhibits 32.1 and 32.2 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act (including this Report), unless the registrant specifically incorporates the foregoing information into those documents by reference.

* Portions of this exhibit (indicated by asterisks) have been redacted in compliance with Regulation S-K Item 601(b)(10).

\+ Indicates a management contract or compensatory plan or arrangement.

◊ English translation of original Chinese document.

† Confidential treatment requested as to portions of the exhibit. Confidential materials omitted and file separately with the SEC.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements 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.

AMPHASTAR PHARMACEUTICALS, INC.
(Registrant)
By: **/s/ JACK Y. ZHANG**
Jack Y. Zhang
Chief Executive Officer
(Principal Executive Officer)

Date: March 1, 2023

AMPHASTAR PHARMACEUTICALS, INC.
(Registrant)
By: **/s/ WILLIAM J. PETERS**
William J. Peters
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: March 1, 2023

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints Jack Y. Zhang and William J. Peters, and each of them, as his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes, may lawfully do or cause to be done by virtue thereof.

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 date indicated:

Signature	Title	Date
/s/ JACK Y. ZHANG Jack Yongfeng Zhang	Chief Executive Officer, President, and Director (Principal Executive Officer)	March 1, 2023
/s/ MARY Z. LUO Mary Z. Luo	Chairman, Chief Operating Officer and Director	March 1, 2023
/s/ WILLIAM J. PETERS William J. Peters	Chief Financial Officer and Director (Principal Financial and Accounting Officer)	March 1, 2023
/s/ JACOB LIAWATIDEWI Jacob Liawatidewi	Executive Vice President of Sales and Marketing, Corporate Administration Center, and Director	March 1, 2023
/s/ GAYLE M. DEFLIN Gayle M. Deflin	Director	March 1, 2023
/s/ DIANE G. GERST Diane G. Gerst	Director	March 1, 2023
/s/ HOWARD LEE Howard Lee	Director	March 1, 2023
/s/ FLOYD PETERSEN Floyd Petersen	Director	March 1, 2023
/s/ RICHARD PRINS Richard Prins	Director	March 1, 2023
/s/ MICHAEL A. ZASLOFF Michael A. Zasloff	Director	March 1, 2023

Exhibit 21.1

SUBSIDIARIES OF THE COMPANY

Company Name	State of Incorporation/ Organization	Country of Incorporation/ Organization
International Medication Systems, Limited	California	United States of America
Armstrong Pharmaceuticals, Inc.	Massachusetts	United States of America
Amphastar Nanjing Pharmaceuticals, Inc.		China
Amphastar France Pharmaceuticals, S.A.S.		France
Amphastar UK Limited		United Kingdom
International Medication Systems (UK) Limited		United Kingdom

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

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

(1) Registration Statement (Form S-8 No. 333-197054) pertaining to the 1999-2002 Stock Option/Stock Issuance Plans, the Amended and Restated 2005 Equity Incentive Award Plan and the 2014 Employee Stock Purchase Plan of Amphastar Pharmaceuticals, Inc.,
(2) Registration Statement (Form S-8 No. 333-203017) pertaining to the Amended and Restated 2005 Equity Incentive Award Plan of Amphastar Pharmaceuticals, Inc.,
(3) Registration Statement (Form S-8 No. 333-205470) pertaining to the 2015 Equity Incentive Plan of Amphastar Pharmaceuticals, Inc.,
(4) Registration Statement (Form S-8 No. 333-210213) pertaining to the 2015 Equity Incentive Plan of Amphastar Pharmaceuticals, Inc.,
(5) Registration Statement (Form S-8 No. 333-216700) pertaining to the 2015 Equity Incentive Plan of Amphastar Pharmaceuticals, Inc.,
(6) Registration Statement (Form S-8 No. 333-223651) pertaining to the 2015 Equity Incentive Plan of Amphastar Pharmaceuticals, Inc.,
(7) Registration Statement (Form S-8 No. 333-230330) pertaining to the 2015 Equity Incentive Plan of Amphastar Pharmaceuticals, Inc.,
(8) Registration Statement (Form S-8 No. 333-237223) pertaining to the 2015 Equity Incentive Plan of Amphastar Pharmaceuticals, Inc.,
(9) Registration Statement (Form S-8 No. 333-254293) pertaining to the 2015 Equity Incentive plan of Amphastar Pharmaceuticals, Inc.
(10) Registration Statement (Form S-3 No. 333-260916) of Amphastar Pharmaceuticals, Inc., and
(11) Registration Statement (Form S-8 No. 333-263491) pertaining to the 2015 Equity Incentive plan of Amphastar Pharmaceuticals, Inc.

of our reports dated March 1, 2023, with respect to the consolidated financial statements of Amphastar Pharmaceuticals, Inc. and the effectiveness of internal control over financial reporting of Amphastar Pharmaceuticals, Inc. included in this Annual Report (Form 10-K) of Amphastar Pharmaceuticals, Inc. for the year ended December 31, 2022.

/s/ Ernst & Young LLP

Irvine, California
March 1, 2023