



**2025 Annual Meeting of Stockholders Notice and  
Proxy Statement**



**2024 Annual Report on Form 10-K**





**ARDELYX, INC.**  
**400 Fifth Avenue, Suite 210, Waltham, MA 02451**

**NOTICE OF ANNUAL MEETING OF STOCKHOLDERS  
TO BE HELD ON JUNE 18, 2025**

To the Stockholders of Ardelyx, Inc.:

The 2025 Annual Meeting of Stockholders, or the 2025 Annual Meeting, of Ardelyx, Inc., a Delaware corporation, or the Company, will be held on June 18, 2025 at 8:30 a.m. Eastern Time. The 2025 Annual Meeting will be held entirely online. You will be able to attend the meeting online where you will be able to listen to the meeting live and vote. The 2025 Annual Meeting will be held for the following purposes:

- (1) To elect two Class II directors to hold office until the 2028 Annual Meeting of Stockholders and until their successors are elected and qualified;
- (2) To approve, on a non-binding, advisory basis, the compensation of our named executive officers, as disclosed in the proxy statement accompanying this notice pursuant to the compensation disclosure rules of the Securities and Exchange Commission, or Say-on-Pay;
- (3) To ratify the selection, by the Audit and Compliance Committee of our board of directors, of Ernst & Young LLP as the independent registered public accounting firm of the Company for the fiscal year ending December 31, 2025;
- (4) To adopt the amendment (the “Equity Plan Amendment”) to the Amended and Restated 2014 Equity Incentive Award Plan (the “Restated Plan”) to increase the number of shares reserved for issuance under the Restated Plan by 10,000,000 shares; and
- (5) To transact such other business as may properly come before the 2025 Annual Meeting or any adjournment or postponement thereof.

The foregoing items of business are more fully described in the proxy statement accompanying this Notice of Annual Meeting of Stockholders. Only stockholders who owned the Company’s common stock at the close of business on Monday, April 21, 2025 may vote at the 2025 Annual Meeting or any adjournments that take place.

You are cordially invited to attend the virtual 2025 Annual Meeting online via live audio-only webcast at [www.virtualshareholdermeeting.com/ARDX2025](http://www.virtualshareholdermeeting.com/ARDX2025). Whether or not you plan to attend the 2025 Annual Meeting online, please vote as soon as possible. You may vote over the internet or by a toll-free telephone number, or by mailing a complete, signed and dated proxy card or voting instruction card in the envelope provided. Please note that any stockholder attending the 2025 Annual Meeting may vote online at the 2025 Annual Meeting, even if the stockholder has already voted over the internet or by phone or returned a proxy card or voting instruction card by mail.

Our board of directors recommends that you vote “**FOR**” the election of the director nominees named in Proposal No. 1 of the proxy statement, “**FOR**” the approval, on a non-binding, advisory basis, of the Say-on-Pay proposal as described in Proposal No. 2 of the proxy statement, “**FOR**” the ratification of the appointment of Ernst & Young LLP as our independent registered public accounting firm for the year ending December 31, 2025 as described in Proposal No. 3 of the proxy statement and “**FOR**” the approval of the Equity Plan Amendment, as described in Proposal No. 4 of the proxy statement.

By Order of the Board of Directors:

/s/ Elizabeth Grammer

Elizabeth Grammer, Esq.

Chief Legal and Administrative Officer

Waltham, Massachusetts

April 30, 2025

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**ARDELYX, INC.**

**400 Fifth Avenue, Suite 210  
Waltham, MA 02451**

**PROXY STATEMENT  
FOR THE ANNUAL MEETING OF STOCKHOLDERS  
TO BE HELD ON JUNE 18, 2025**

**IMPORTANT NOTICE REGARDING THE INTERNET AVAILABILITY OF PROXY MATERIALS  
FOR THE ANNUAL MEETING OF STOCKHOLDERS TO BE HELD ON JUNE 18, 2025**

This proxy statement and our Annual Report on Form 10-K for the fiscal year ended December 31, 2024 are available on our website at [www.ardelyx.com](http://www.ardelyx.com) and at [www.proxyvote.com](http://www.proxyvote.com). The references to our web address contained in this proxy statement do not constitute incorporation by reference of the information contained at or available through our website.

Unless the context requires otherwise, in this proxy statement the terms “Ardelyx,” “we,” “us,” “our” and “the Company” refer to Ardelyx, Inc.

**QUESTIONS AND ANSWERS REGARDING THE PROXY MATERIALS AND THE VOTING  
PROCESS**

**Why am I receiving these proxy materials?**

We have delivered paper proxy materials to you, because the board of directors of Ardelyx is soliciting your proxy to vote at the 2025 Annual Meeting of Stockholders, or the 2025 Annual Meeting, or any adjournments that take place. The 2025 Annual Meeting will be held online on June 18, 2025 at 8:30 a.m. Eastern Time via live audio-only webcast at [www.virtualshareholdermeeting.com/ARDX2025](http://www.virtualshareholdermeeting.com/ARDX2025). As a stockholder, you are invited to attend the 2025 Annual Meeting online and are requested to vote on the proposals described in this proxy statement. However, you do not need to attend the 2025 Annual Meeting to vote.

**What is included in the proxy materials?**

The proxy materials include:

- This proxy statement, which includes information regarding the proposals to be voted on at the 2025 Annual Meeting, the voting process, corporate governance, the compensation of our directors and certain executive officers, and other required information;
- Our Annual Report on Form 10-K for the fiscal year ended December 31, 2024; and
- The proxy card or a voting instruction card for the 2025 Annual Meeting.

The proxy materials are being mailed on or about May 1, 2025, and are available at [www.ardelyx.com](http://www.ardelyx.com).

**Who can vote at the 2025 Annual Meeting?**

Only stockholders of record at the close of business on April 21, 2025, or the Record Date, will be entitled to vote at the 2025 Annual Meeting. On this Record Date, there were 239,255,212 shares of common stock outstanding and entitled to vote.

***Stockholder of Record: Shares Registered in Your Name***

If, at the close of business on April 21, 2025, your shares were registered directly in your name with our transfer agent, Equiniti Trust Company, LLC, then you are a stockholder of record. As a stockholder of record, you may vote online at the 2025 Annual Meeting or vote by proxy. Whether or not you plan to attend the 2025 Annual Meeting, please vote as soon as possible by internet, telephone or by mail as instructed below to ensure your vote is counted.

***Beneficial Owner: Shares Registered in the Name of a Broker or Bank***

If, at the close of business on April 21, 2025, your shares were not held in your name, but rather in an account at a brokerage firm, bank, dealer or other similar organization, then you are the beneficial owner of shares held in “street name” and these proxy materials are being forwarded to you by that organization. The organization

holding your account is considered to be the stockholder of record for purposes of voting at the 2025 Annual Meeting. As a beneficial owner, you have the right to direct your broker or other agent how to vote the shares in your account. If you are a beneficial owner of shares registered in the name of your broker, bank, dealer or other similar organization, you should have received a proxy card and voting instructions with these proxy materials from that organization rather than from us. Simply complete and mail the proxy card to ensure that your vote is counted. Alternatively, you may vote by internet or telephone as instructed by your broker or other agent. To vote online at the 2025 Annual Meeting, you must obtain a valid proxy from your broker or other agent. Follow the instructions from your broker or other agent included with these proxy materials, or contact your broker or bank to request a proxy form. In order to login to the online 2025 Annual Meeting, you will need the unique account number which appears in your proxy materials and the instructions that accompanied the proxy materials. In the event that you do not have a control number, please contact your broker, bank, or other nominee as soon as possible so that you can be provided with a control number.

### **What proposals are scheduled for a vote?**

There are four proposals scheduled for a vote at the 2025 Annual Meeting:

- Proposal No. 1 – To elect two Class II directors to hold office until the 2028 Annual Meeting of Stockholders and until their successors are elected and qualified;
- Proposal No. 2 – To approve, on a non-binding, advisory basis, the compensation of our named executive officers, as disclosed in this proxy statement pursuant to the compensation disclosure rules of the SEC, or Say-on-Pay;
- Proposal No. 3 – To ratify the selection, by the Audit and Compliance Committee of our board of directors, of Ernst & Young LLP as the independent registered public accounting firm of the Company for the fiscal year ending December 31, 2025; and
- Proposal No. 4 – To approve an amendment (the “Equity Plan Amendment”) to the Amended and Restated 2014 Equity Incentive Award Plan (the “Restated Plan”) to increase the maximum number of shares of Common Stock that may be delivered pursuant to awards granted under the Restated Plan by 10,000,000 shares.

### **How do I vote?**

For Proposal No. 1, you may either vote “**FOR**” all nominees to the board of directors or you may “**WITHHOLD**” your vote for any nominee you specify. For Proposals No. 2, No. 3, and No. 4, you may either vote “**FOR**” or “**AGAINST**” or you may abstain from voting.

The procedures for voting are as follows:

#### ***Stockholder of Record: Shares Registered in Your Name***

If you are a stockholder of record, you may vote online at the virtual 2025 Annual Meeting or vote by internet, telephone or by mail. Whether or not you plan to attend the 2025 Annual Meeting online, please vote as soon as possible to ensure your vote is counted. You may still attend the 2025 Annual Meeting online and vote online even if you have already voted by proxy.

- **By Attending the 2025 Annual Meeting Online.** You may vote online at the 2025 Annual Meeting by attending the 2025 Annual Meeting online via live audio-only webcast at [www.virtualshareholdermeeting.com/ARDX2025](http://www.virtualshareholdermeeting.com/ARDX2025).
- **To vote by proxy by internet or telephone.** You may submit your proxy by following the instructions provided with your proxy materials and on your proxy card or voting instruction card.
- **To vote by proxy by mail.** You may submit your proxy by mail by completing and signing your proxy card and mailing it in the enclosed envelope. Your shares will be voted as you have instructed.

#### ***Beneficial Owner: Shares Registered in the Name of Broker or Bank***

If you are a beneficial owner of shares registered in the name of your broker, bank, dealer or other similar organization, you should have received a proxy card and voting instructions with these proxy materials from that organization rather than from us. Simply complete and mail the proxy card to ensure that your vote is counted.

Alternatively, you may vote by internet or telephone as instructed by your broker or other agent. To vote online at the 2025 Annual Meeting, you must obtain a valid proxy from your broker or other agent. Follow the instructions from your broker or other agent included with these proxy materials, or contact your broker or bank to request a proxy form.

### **How many votes do I have?**

On each matter to be voted upon, you have one vote for each share of the Company's common stock you owned as of April 21, 2025.

### **What if I return a proxy card but do not make specific choices?**

If you return a signed and dated proxy card without marking any voting selections, your shares will be voted **"FOR"** the election of each nominee for director (Proposal No. 1), **"FOR"** the approval, on a non-binding, advisory basis, of the Say-on-Pay proposal (Proposal No. 2), **"FOR"** the ratification of the selection of Ernst & Young LLP as the independent registered public accounting firm of the Company for the fiscal year ending December 31, 2025 (Proposal No. 3) and **"FOR"** the approval of the Equity Plan Amendment (Proposal No. 4). If any other matter is properly presented at the 2025 Annual Meeting, your proxyholder (one of the individuals named on your proxy card) will vote your shares using his or her best judgment.

### **Who is paying for this proxy solicitation?**

We will pay for the entire cost of soliciting proxies. In addition to these mailed proxy materials, our directors, officers and employees may also solicit proxies in person, by telephone or by other means of communication. Directors, officers and employees will not be paid any additional compensation for soliciting proxies. We have engaged Morrow Sodali, LLC, or Morrow, as the proxy solicitor for the 2025 Annual Meeting for an approximate fee of \$25,000 plus fees for additional services, if needed. We have also agreed to reimburse Morrow for its reasonable out-of-pocket expenses.

### **What does it mean if I receive more than one proxy card?**

If you receive more than one proxy card, your shares are registered in more than one name or are registered in different accounts. In order to vote all the shares you own, you must return each proxy card.

### **Can I change my vote after submitting my proxy?**

Yes. You can revoke your proxy at any time before the final vote at the 2025 Annual Meeting. If you are the stockholder of record of your shares, you may revoke your proxy in any one of three ways:

- You may submit another properly completed proxy, bearing a date later than the date of the original proxy.
- You may send a timely written notice, bearing a date later than the date of the original proxy, that you are revoking your proxy to the Company's Chief Legal and Administrative Officer at the following email address: [general-counsel@ardelyx.com](mailto:general-counsel@ardelyx.com).
- You may attend the virtual 2025 Annual Meeting and vote online. Simply attending the 2025 Annual Meeting online will not, by itself, revoke your proxy.

If your shares are held in "street name" by your broker or other agent, you should follow the instructions provided by your broker or agent to change your vote.

### **What is the quorum requirement?**

A quorum of stockholders is necessary to hold a valid meeting. A quorum will be present if stockholders holding at least a majority of the outstanding shares entitled to vote are present in attendance at the virtual 2025 Annual Meeting. On the Record Date, there were 239,255,212 shares outstanding and entitled to vote. Accordingly, the holders of 119,627,607 shares must be present at the 2025 Annual Meeting to have a quorum. Your shares will be counted toward the quorum at the 2025 Annual Meeting only if you vote online at the meeting, or you submit a valid proxy vote.



Abstentions and broker non-votes (as described below) will be counted towards the quorum requirement. If there is no quorum, the chairperson of the meeting or the holders of a majority of shares present and entitled to vote at the meeting or represented by proxy may adjourn the 2025 Annual Meeting to another date.

### **How are votes counted?**

With respect to the election of directors (Proposal No. 1), you may vote **“FOR”** or **“WITHHOLD”** authority to vote for each of the nominees for the board of directors. If you **“WITHHOLD”** authority to vote with respect to one or more director nominees, your vote will have no effect on the election of such nominees. Broker non-votes will have no effect on the election of the nominees.

With respect to the Say-on-Pay proposal (Proposal No. 2), you may vote **“FOR,” “AGAINST”** or **“ABSTAIN.”** Abstentions and broker non-votes will have no effect on the vote for this proposal.

With respect to the ratification of Ernst & Young LLP as of our independent registered public accounting firm for the year ending December 31, 2025 (Proposal No. 3), you may vote **“FOR,” “AGAINST”** or **“ABSTAIN.”** Abstentions and broker non-votes will have no effect on the vote for this proposal.

With respect to the approval of the Equity Plan Amendment (Proposal No. 4), you may vote **“FOR,” “AGAINST”** or **“ABSTAIN.”** Abstentions and broker non-votes will have no effect on the vote for this proposal.

Votes will be counted by the Inspector of Elections appointed for the 2025 Annual Meeting. The Inspector of Elections will separately count **“FOR”** votes for the election of directors (Proposal No. 1), **“FOR”** and **“AGAINST”** votes, abstentions and, if any, broker non-votes for the approval, on a non-binding, advisory basis, of the Say-on-Pay (Proposal No. 2), **“FOR”** and **“AGAINST”** votes, abstentions and, if any, broker non-votes for the ratification of the selection of Ernst & Young LLP as the independent registered accounting firm of the Company for the fiscal year ending December 31, 2025 (Proposal No. 3) and **“FOR”** and **“AGAINST”** votes, abstentions and, if any, broker non-votes for the Equity Plan Amendment (Proposal No. 4).

If your shares are held by your broker or other agent as your nominee (that is, held beneficially in “street name”), you will need to obtain a proxy form from the institution that holds your shares and follow the instructions included on that form regarding how to instruct your broker or other agent to vote your shares. If you do not give voting instructions to your broker or other agent, your broker or other agent can only vote your shares with respect to “routine” matters (as described below).

### **What are “broker non-votes”?**

If you hold shares beneficially in street name and do not provide your broker with voting instructions, your shares may constitute “broker non-votes.” Broker non-votes occur on a matter when a broker is not permitted to vote on that matter without instructions from the beneficial owner and instructions are not given. These matters are referred to as “non-routine” matters. Proposal No. 1 to elect directors, Proposal No. 2 to approve the Say-on-Pay and Proposal No. 4 to approve the Equity Plan Amendment are “non-routine” matters, but Proposal No. 3 to ratify the selection of Ernst & Young LLP as the independent registered public accounting firm for the Company for the fiscal year ending December 31, 2025 is a “routine” matter.

### **How many votes are needed to approve each proposal?**

- Proposal No. 1 – To elect two Class II directors to hold office until the 2028 Annual Meeting of Stockholders and until their successors are elected and qualified. Directors shall be elected by a plurality of the votes cast, which means that the two nominees receiving the most **“FOR”** votes (from the votes of shares present in attendance or represented by proxy and entitled to vote on the election of directors) will be elected. **“WITHHOLD”** votes and broker non-votes will not be counted towards the vote total for this proposal.
- Proposal No. 2 – To approve, on a non-binding, advisory basis, the Say-on-Pay proposal. The Say-on-Pay proposal requires the affirmative vote of the majority of the votes cast (excluding abstentions and broker non-votes), which means the number of shares voted **“FOR”** the proposal must exceed the number of shares voted **“AGAINST”** such proposal. Abstentions and broker non-votes are not considered votes cast for the foregoing purpose, and will have no effect on the vote for this

proposal. Because the vote on Proposal No. 2 is advisory, it will not be binding on the board of directors, the compensation committee of the board of directors or the Company. With respect to Proposal No. 2, the board of directors will review the voting results and take them into consideration when making future decisions about executive compensation.

- Proposal No. 3 – To ratify the selection of Ernst & Young LLP as the independent registered public accounting firm of the Company for the fiscal year ending December 31, 2025. The ratification of Ernst & Young LLP as our independent registered public accounting firm for the year ending December 31, 2025 requires the affirmative vote of the majority of the votes cast (excluding abstentions and broker non-votes), which means the number of shares voted “**FOR**” the proposal must exceed the number of shares voted “**AGAINST**” such proposal. Abstentions and broker non-votes are not considered votes cast for the foregoing purpose, and will have no effect on the vote for this proposal. Because Proposal No. 3 is considered a “routine” matter, no broker non-votes are expected in connection with this proposal.
- Proposal No. 4 – To approve the Equity Plan Amendment to increase the numbers of shares reserved under the Restated Plan. This proposal requires the affirmative vote of the majority of the votes cast (excluding abstentions and broker non-votes), which means the number of shares voted “**FOR**” the proposal must exceed the number of shares voted “**AGAINST**” such proposal. Abstentions and broker non-votes are not considered votes cast for the foregoing purpose, and will have no effect on the vote for this proposal.

### **How do I attend the Virtual Annual Meeting?**

This year’s Annual Meeting will be held entirely online. Stockholders of record as of April 21, 2025 will be able to attend and participate in the 2025 Annual Meeting online via live audio-only webcast at [www.virtualshareholdermeeting.com/ARDX2025](http://www.virtualshareholdermeeting.com/ARDX2025). You will be able to vote your shares electronically by Internet and submit questions online during the meeting by logging in to the website listed above and using the 16-digit control number included on your proxy card or on the instructions that accompanied your proxy materials. The virtual meeting has been designed to provide the same rights to participate as you would have at an in-person meeting.

Even if you plan to attend the 2025 Annual Meeting online, we recommend that you also vote by proxy as described herein so that your vote will be counted if you decide not to attend the 2025 Annual Meeting.

**Access to the Audio Webcast of the 2025 Annual Meeting.** The live audio webcast of the 2025 Annual Meeting will begin promptly at 8:30 a.m. Eastern Time. Online check-in will begin at 8:15 a.m. Eastern Time and should allow ample time for the check-in procedures. We encourage our stockholders to access the meeting prior to the start time.

**Log in Instructions.** To attend the online 2025 Annual Meeting, you will need to login at [www.virtualshareholdermeeting.com/ARDX2025](http://www.virtualshareholdermeeting.com/ARDX2025). To attend the 2025 Annual Meeting, you will need the 16-digit control number included on your proxy card or on the instructions that accompanied your proxy materials.

**Voting. You may vote online during the 2025 Annual Meeting.** To do so, go to [www.virtualshareholder.com/ARDX2025](http://www.virtualshareholder.com/ARDX2025) and have available the 16-digit control number included on your proxy card or on the instructions that accompanied your proxy materials.

**Submitting Questions During the Virtual 2025 Annual Meeting.** During the 2025 Annual Meeting, you will be able to submit questions in the question box provided at [www.virtualshareholdermeeting.com/ARDX2025](http://www.virtualshareholdermeeting.com/ARDX2025). We will respond to as many inquiries at the 2025 Annual Meeting as time allows.

**Technical Assistance.** Beginning 15 minutes prior to the start of and during the virtual 2025 Annual Meeting, we will have a support team ready to assist stockholders with any technical difficulties they may have accessing or hearing the virtual meeting. If you encounter difficulties accessing the virtual 2025 Annual Meeting during check-in or meeting time, please call the technical support number that will be posted on the 2025 Annual Meeting website log-in page.

**How can I find out the results of the voting at the 2025 Annual Meeting?**

We will disclose final voting results in a Current Report on Form 8-K filed with the Securities and Exchange Commission within four business days after the 2025 Annual Meeting. If final voting results are unavailable at that time, then we intend to file a Current Report on Form 8-K to disclose preliminary voting results and file an amended Current Report on Form 8-K within four business days after the date the final voting results are available.

**When are stockholder proposals due for next year's annual meeting?**

To be considered for inclusion in the proxy materials for the 2026 Annual Meeting of Stockholders, your proposal must be submitted in writing by January 1, 2026, to the Company's Corporate Secretary at Ardelyx, Inc., 400 Fifth Avenue, Suite 210, Waltham, Massachusetts 02451. However, if the meeting is more than 30 days before or after June 18, 2026, then the deadline will be a reasonable time before we begin to print and mail our proxy materials for that meeting.

If you wish to submit a proposal before the stockholders or nominate a director at the 2026 Annual Meeting of Stockholders, but you are not requesting that your proposal or nomination be included in the proxy materials for that meeting, then you must follow the procedures set forth in our Amended and Restated Bylaws and, among other things, notify the Company's Corporate Secretary in writing between February 18, 2026 and March 20, 2026. However, if the date of the 2026 annual meeting of stockholders is more than 30 days before or more than 60 days after June 18, 2026, notice must be received not later than the 90th day prior to the date of the 2026 annual meeting of stockholders or, if later, the 10th day following the day on which public disclosure of the date of the 2026 annual meeting of stockholders is first made. You are also advised to review our Amended and Restated Bylaws, which contain additional requirements regarding advance notice of stockholder proposals and director nominations. In addition to satisfying the foregoing requirements under our Amended and Restated Bylaws, to comply with the universal proxy rules, stockholders who intend to solicit proxies in support of director nominees other than our nominees must provide notice that sets forth the information required by Rule 14a-19 under the Securities Exchange Act of 1934, as amended, no later than no later than 60 days prior to the anniversary of the previous year's annual meeting (no later than April 19, 2026 for the 2026 annual meeting of stockholders). If the date of the 2026 annual meeting of stockholders is changed by more than 30 days from the anniversary of the 2025 Annual Meeting, then notice must be provided by the later of 60 days prior to the date of the 2026 annual meeting of stockholders or the 10th calendar day following the day on which public announcement of the date of the 2026 annual meeting of stockholders is first made.

## **PROPOSAL NO. 1 ELECTION OF DIRECTORS**

Our board of directors is divided into three classes. Each class consists, as nearly as possible, of one-third of the total number of directors, and each class has a three-year term. Except as otherwise provided by law, vacancies on the board of directors may be filled only by individuals elected by a majority of the remaining directors. A director elected by the board of directors to fill a vacancy in a particular class, including a vacancy created by an increase in the number of directors, shall serve for the remainder of the full term of that class and until such director's successor is elected and qualified, or until such director's earlier death, resignation or removal.

Our board of directors currently consists of eight directors divided into the following three classes:

- The Class II directors are David Mott and Michael Raab, and their terms will expire at the 2025 Annual Meeting of Stockholders;
- The Class III directors are Robert Bazemore, Muna Bhanji, R.Ph, and Richard Rodgers, and their terms will expire at the 2026 Annual Meeting of Stockholders; and
- The Class I directors are William A. Bertrand, Jr., Esq., Onaiza Cadoret-Manier and Merdad Parsey, M.D., Ph.D., and their terms will expire at the 2027 Annual Meeting of Stockholders.

Our current Class II directors, David Mott and Michael Raab, have each been nominated to serve as Class II directors and have agreed to stand for election.

If the nominees for Class II are elected at the 2025 Annual Meeting, then each nominee will serve for a three-year term expiring at the 2028 Annual Meeting of Stockholders, and until his successor is elected and qualified, or until his earlier death, resignation or removal. Our directors are elected by a plurality of the votes cast. If a choice is specified on the proxy card by a stockholder, the shares will be voted as specified. If a choice is not specified on the proxy card, and authority to do so is not withheld, the shares will be voted **"FOR"** the election of the two nominees for Class II above. If any of the nominees becomes unavailable for election as a result of an unexpected occurrence, shares that would have been voted for the nominee will instead be voted for the election of a substitute nominee proposed by our management or the board of directors. Each person nominated for election has agreed to serve if elected. Our management has no reason to believe that any nominee will be unable to serve.

The following is a brief biography and discussion of the specific attributes, qualifications, experience and skills of each nominee for director and each director whose term will continue after the 2025 Annual Meeting, including information with respect to their ages as of March 31, 2025. Our board of directors and management encourage each nominee for director and each continuing director to attend the 2025 Annual Meeting.

### **THE BOARD OF DIRECTORS RECOMMENDS A VOTE "FOR" EACH OF THE TWO CLASS II NOMINEES FOR DIRECTOR.**

**CLASS II NOMINEES FOR DIRECTOR** - *To be elected for a three-year term expiring at the 2028 Annual Meeting of Stockholders*

**David Mott**, age 59, has served on our board of directors since March 2009 and as the chairperson of the board of directors since March 2014. Mr. Mott is currently a private investor through Mott Family Capital. Mr. Mott served as a general partner of New Enterprise Associates, or NEA, an investment firm focused on venture capital and growth equity investments from September 2008 to February 2020, where he led the healthcare investing practice. From 1992 until 2008, Mr. Mott worked at MedImmune Limited, a biotechnology company and subsidiary of AstraZeneca Plc (NYSE: AZN), and served in numerous roles during his tenure, including from October 2000 to July 2008 as President and Chief Executive Officer, and previously as Chief Financial Officer, and as President and Chief Operating Officer. During that time, Mr. Mott also served as Executive Vice President of AstraZeneca Plc from June 2007 to July 2008 following AstraZeneca Plc's acquisition of MedImmune Limited in June 2007. Prior to joining MedImmune Limited, Mr. Mott was a Vice President in the healthcare investment banking group at Smith Barney, Harris Upham & Co. Inc. Mr. Mott received a B.A. in Economics and Government from Dartmouth College. Mr. Mott serves as the chairperson of the board of directors for Adaptimmune (Nasdaq: ADAP), and Mersana Therapeutics, Inc. (Nasdaq: MRSN), and serves on the board of directors of Novavax, Inc. (Nasdaq: NVAX). Additionally, he served as the chairperson of the board of directors of Imara Inc. from April 2016 to its acquisition by Enliven Therapeutics, Inc (Nasdaq: ELVN) in February 2023,

and as the chairperson of the board of directors of Epizyme, Inc. (Nasdaq: EPZM) from December 2009 to its acquisition by Ipsen (Euronext: IPN; ADR: IPSEY) in August 2022. Mr. Mott also served as the chairperson of the board of directors of Tesaro, Inc. (Nasdaq: TSRO) and as a director of Nightstar Therapeutics plc (Nasdaq: IMRA). We believe that Mr. Mott is qualified to serve on our board of directors due to his extensive experience in the life sciences industry as a senior executive, his investment experience, strategic leadership track record and service on other boards of directors of life sciences companies.

**Michael Raab**, age 60, has served as our President and Chief Executive Officer since March 2009 and as a director since 2008. From 2002 to 2009, Mr. Raab was a partner at NEA, an investment firm focused on venture capital and growth equity investments, where he focused on investments in the biotechnology and pharmaceutical sectors. Prior to joining NEA, Mr. Raab spent 15 years in commercial and operating leadership roles in the biotech and pharmaceutical industries, including serving as Senior Vice President, Therapeutics and General Manager of the Renal Division at Genzyme Corporation, or Genzyme, a biotechnology company. Mr. Raab also spent two years with Genzyme's diagnostic products and services division. Before Genzyme, Mr. Raab held business development and sales and marketing positions at Repligen Corporation, a life sciences company, and Bristol-Myers Corporation. Mr. Raab is currently the lead independent director of Amicus Therapeutics, Inc. (Nasdaq: FOLD) and also serves as the chairperson of the board of directors of Tempest Therapeutics (Nasdaq CM: TPST). Mr. Raab also currently serves as a member of the Emerging Companies Section Governing Board and the Health Section Governing Board of the Biotechnology Innovation Organization. Mr. Raab received a B.A. from DePauw University. We believe Mr. Raab is qualified to serve on our board of directors based on his role as our President and Chief Executive Officer, his senior management experience in the life sciences sector, his investment experience and his current and past service on other boards of directors of public companies.

### **CLASS III DIRECTORS** - *To continue in office until the 2026 Annual Meeting of Stockholders*

**Robert Bazemore**, age 57, has served on our board of directors since June 2016. Mr. Bazemore served as President and Chief Executive Officer and a director of Epizyme, Inc., a biopharmaceutical company, from September 2015 until the company was acquired by Ipsen S.A. (Euronext: IPN; ADR: IPSEY) in August 2022. Prior to joining Epizyme, Mr. Bazemore served as Chief Operating Officer of Synageva BioPharma Corp., a biopharmaceutical company, which was acquired by Alexion Pharmaceuticals, a pharmaceutical company and subsidiary of AstraZeneca, for \$8.4 billion in July 2015. Prior to that, Mr. Bazemore was President of Janssen Biotech, part of the Janssen Pharmaceutical Companies of Johnson & Johnson (NYSE: JNJ). Mr. Bazemore currently serves on the board of directors of Nuvation Bio, Inc. (NYSE: NUVB) and Akari Therapeutics, PLC (Nasdaq: AKTX). Additionally, he served on the board of directors of Neon Therapeutics, Inc. from November 2018 to its acquisition by Biopharmaceuticals New Technologies, or BioNTech (Nasdaq: BNTX), in May 2020. Mr. Bazemore received his B.S. in Biochemistry from the University of Georgia. We believe that Mr. Bazemore is qualified to serve on our board of directors due to his significant life science industry experience, including as a chief executive officer, and service on the boards of directors of life sciences companies.

**Muna Bhanji, R.Ph.**, age 62, has served on our board of directors since March 2021. Ms. Bhanji has served as the founder and principal of Tiba Global Access, LLC, an independent senior advisory practice focused on commercialization and market access strategy development, since January 2021. Ms. Bhanji previously served in roles of increasing responsibility at Merck & Co. (NYSE: MRK) between 1986 and January 2021. Most recently, Ms. Bhanji served as Senior Vice President, Global Market Access from 2010 until 2021 and as Senior Vice President, Hospital & Specialty Franchises from 2014 until 2017. Ms. Bhanji currently serves on the boards of directors of Veracyte, Inc. (Nasdaq: VCYT), Cytokinetics Incorporated (Nasdaq: CYTK), Intellia Therapeutics (Nasdaq: NTLA), and Corus International, an international humanitarian organization committed to poverty alleviation. Ms. Bhanji also serves as a Member of the Strategic Advisory Board of Humanity. Ms. Bhanji received her B.Sc. in Pharmacy from the Rutgers School of Pharmacy, and her M.B.A. from Saint Joseph's University. We believe that Ms. Bhanji is qualified to serve on our board of directors due to her extensive U.S. and global commercial and operational experience within the pharmaceutical industry.

**Richard Rodgers**, age 58, has served on our board of directors since March 2014. From March 2010 until August 2013, Mr. Rodgers was co-founder, Executive Vice President, Chief Financial Officer, Secretary and Treasurer of Tesaro, Inc., a biopharmaceutical company, which was acquired by GlaxoSmithKline plc (LSE/NYSE: GSK) in January 2019. Mr. Rodgers previously served as the Chief Financial Officer of Abraxis BioScience, Inc., a biotechnology company, from June 2009 to February 2010. Prior to that, Mr. Rodgers served



as Senior Vice President, Controller and Chief Accounting Officer of MGI PHARMA, Inc., a biopharmaceutical company, from 2004 until its acquisition by Eisai Co. Ltd. (OTC: ESALF), a pharmaceutical company, in January 2008. Mr. Rodgers has held finance and accounting positions at several private and public companies, including Arthur Anderson & Co. Mr. Rodgers currently serves as a director of Novavax, Inc. (Nasdaq: NVAX), and Opus Genetics, Inc. (Nasdaq: IRD). Mr. Rodgers received a B.S. in Financial Accounting from St. Cloud State University and his M.B.A. in Finance from the University of Minnesota, Carlson School of Business. We believe that Mr. Rodgers is qualified to serve on our board of directors due to his financial background, significant industry experience, and service on other boards of directors of publicly-traded life sciences companies.

**CLASS I DIRECTORS** - *To continue in office until the 2027 Annual Meeting of Stockholders*

**William Bertrand, Jr., Esq.**, age 60, has served on our board of directors since October 2015. Mr. Bertrand has served as the Chief Operating Officer at Adaptimmune Therapeutics Plc (Nasdaq: ADAP) since March 2017. From October 2015 to September 2016, Mr. Bertrand served as the Executive Vice President, General Counsel of Infinity Pharmaceuticals, Inc. (Nasdaq: INFI). From July 2013 to August 2015, Mr. Bertrand held a variety of positions with Salix Pharmaceuticals, Ltd., a biopharmaceutical company, including Senior Vice President, General Counsel, Acting Chief Operating Officer, and most recently, General Manager of Salix Pharmaceuticals following its acquisition by Valeant Pharmaceuticals International (NYSE: VRX) in April 2015. Prior to that, Mr. Bertrand completed a 12-year career at Medimmune Limited, a biotechnology company and subsidiary of AstraZeneca Plc (NYSE: AZN), serving in numerous roles of increasing responsibility, including as Executive Vice President and General Counsel from 2008 to 2013. Mr. Bertrand received his B.S. in Biology from Wayne State University and his J.D. from the University of Wisconsin-Madison. We believe that Mr. Bertrand is qualified to serve on our board of directors due to his legal and compliance background and significant life science industry experience.

**Onaiza Cadoret-Manier**, age 61, has served on our board of directors since March 2020. Ms. Cadoret-Manier has served as the Chief Executive Officer, President and Board Member of Yemaya Bio, a biotechnology company, since March 2024. From March 2022 to March 2024, Ms. Cadoret-Manier served as Chief Global Product Strategy and Operations Officer at Ionis Pharmaceuticals (Nasdaq: IONS), and from January 2020 to March 2022, Ms. Cadoret-Manier served as Chief Corporate Development and Commercial Officer at Ionis Pharmaceuticals. Prior to that, Ms. Cadoret-Manier was the Chief Commercial Officer for Grail Biosciences, an early detection genomics company, from June 2018 until June 2019. Prior to Grail, from April 2011 until June 2018, she was Vice President of the Respiratory Franchise at Genentech, a biopharmaceutical company. Ms. Cadoret-Manier also has held multiple senior management positions overseeing corporate strategy, alliances, and marketing and sales for numerous disease areas for Genentech, Pfizer and Amylin Pharmaceuticals. Ms. Cadoret-Manier serves on the board of directors of Ventyx Biosciences (Nasdaq: VTYX). She has an M.B.A. from the University of Chicago and a bachelor's degree in economics and accounting from City University of New York Queens College. We believe that Ms. Cadoret-Manier is qualified to serve on our board of directors due to her extensive commercial and strategic operational experience with life sciences companies.

**Merdad Parsey, M.D., Ph.D.**, age 62, has served as a member of our board of directors since April 2025. Dr. Parsey served as the Chief Medical Officer of Gilead Sciences, Inc. (Nasdaq: GILD) from November 2019 until April 2025. From October 2015 to November 2019, Dr. Parsey served as senior vice president of early clinical development at Genentech, Inc. Prior to Genentech, Dr. Parsey served as President and Chief Executive Officer of 3-V Biosciences Inc. (now Sagimet BioSciences Inc. (Nasdaq: SGMT)), held development roles at Sepracor, Regeneron, and Merck, and was Assistant Professor of Medicine and Director of Critical Care Medicine at the New York University School of Medicine. He currently serves on the board of directors for Sagimet BioSciences Inc. and Arrivent Biopharma (Nasdaq: AVBP). Additionally, Dr. Parsey previously served on the boards of Arcus Biosciences, Inc. (NYSE: RCUS) and the Gilead Foundation. Dr. Parsey received his B.S. in microbiology and biochemistry from the University of Maryland, his M.D. and Ph.D. in immunology from the University of Maryland at Baltimore. He completed his internal medicine residency at Stanford University and his pulmonary and critical care fellowship at the University of Colorado. We believe Dr. Parsey is well-suited to serve on our board of directors due to his years of experience in clinical drug development and his extensive scientific and medical experience.

## **BOARD AND CORPORATE GOVERNANCE MATTERS**

### **Board Composition**

#### ***Director Independence***

Our board of directors currently consists of eight members. Our board of directors has determined that all of our directors, other than Mr. Raab, qualify as “independent” directors in accordance with the Nasdaq listing requirements. Mr. Raab is not considered independent because he is an employee of our company. The Nasdaq independence definition includes a series of objective tests, such as that the director is not, and has not been for at least three years, one of our employees, and that neither the director nor any of their family members has engaged in various types of business dealings with us. In addition, as required by Nasdaq rules, our board of directors has made a subjective determination as to each independent director and director nominee that no relationships exist, which, in the opinion of our board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In making these determinations, our board of directors reviewed and discussed information provided by the directors and us with regard to each director’s and each nominee’s business and personal activities and relationships as they may relate to us and our management. There are no family relationships among any of our directors, nominees for election to our board of directors or our executive officers.

As described more fully below, the board of directors has also determined that each current member of the compensation committee, the audit and compliance committee and the nominating and corporate governance committee meets the independence standards applicable to those committees prescribed by Nasdaq, the SEC and the Internal Revenue Service.

#### ***Classified Board of Directors***

In accordance with our amended and restated certificate of incorporation, our board of directors is divided into three classes with staggered, three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election.

### **Leadership Structure of the Board**

Our amended and restated bylaws and corporate governance guidelines provide our board of directors with flexibility to combine or separate the positions of chairperson of the board of directors and chief executive officer and/or the implementation of a lead independent director in accordance with its determination that utilizing one or the other structure would be in the best interests of our company. Mr. Mott currently serves as the chairperson of the board of directors. In that role, Mr. Mott presides over the executive sessions of the board of directors in which Mr. Raab does not participate and serves as a liaison to Mr. Raab and management on behalf of the board of directors.

Our board of directors has concluded that our current leadership structure is appropriate at this time. However, our board of directors will continue to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

### **Role of Board in Risk Oversight Process**

#### ***General Risk Oversight***

Risk assessment and oversight are an integral part of our governance and management processes. Our board of directors encourages management to promote a culture that incorporates risk management into our corporate strategy and day-to-day business operations. Management discusses strategic and operational risks at regular management meetings, and conducts specific strategic planning and review sessions during the year that include a focused discussion and analysis of the risks facing us. Throughout the year, senior management reviews these risks with the board of directors at regular board meetings as part of management presentations that focus on particular business functions, operations or strategies, and presents the steps taken by management to mitigate or eliminate such risks.

Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through our board of directors as a whole, as well as through various standing committees of

our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit and compliance committee is responsible for overseeing our major financial risk exposures and the steps our management has taken to monitor and control these exposures. The audit and compliance committee also monitors compliance with legal and regulatory requirements and considers and approves or disapproves any related-persons transactions. Our nominating and corporate governance committee monitors the effectiveness of our corporate governance guidelines. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking.

### ***Cybersecurity Governance***

Our board of directors also considers cybersecurity risk as part of its risk oversight function and has delegated to the audit and compliance committee oversight of cybersecurity and other information technology risks, including oversight of management's implementation of our cybersecurity risk management program, maintaining a strategic role in coordinating cyber risk initiatives and policies, and confirming their efficacy.

The audit and compliance committee receives annual reports from management on our cybersecurity posture. In addition, management updates the audit and compliance committee where it deems appropriate regarding any cybersecurity incidents it considers to be significant or potentially significant.

The audit and compliance committee and our management team take steps to stay informed about and monitor efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include briefings from internal security personnel, threat intelligence and other information obtained from governmental, public or private sources, including external consultants engaged by us and alerts and reports produced by security tools deployed in the IT environment.

### **Meetings of the Board of Directors and Committees**

During 2024, the board of directors met nine times, the audit and compliance committee met four times, the compensation committee met three times and the nominating and corporate governance committee met two times. In that year, each director attended at least 75% of the aggregate number of meetings of the board of directors and the committees on which they served. As required under Nasdaq rules and regulations, our independent directors meet in regularly scheduled executive sessions at which only independent directors are present.

### **Board Committees**

#### ***Audit and Compliance Committee***

Our audit and compliance committee oversees our corporate accounting and financial reporting process, the audits of our financial statements, cybersecurity risk and our compliance with legal and regulatory requirements. Among other matters, the audit and compliance committee:

- appoints our independent registered public accounting firm;
- evaluates the independent registered public accounting firm's qualifications, independence and performance;
- determines the engagement of the independent registered public accounting firm;
- reviews and approves the scope of the annual audit and the audit fee;
- discusses with management and the independent registered public accounting firm the results of the annual audit and the review of our quarterly financial statements;
- discusses with management and the independent registered public accounting firm regarding the effectiveness of internal controls over financial reporting;
- approves the retention of the independent registered public accounting firm to perform any proposed permissible audit and non-audit services;
- monitors the rotation of partners of the independent registered public accounting firm on our engagement team as required by law;



- is responsible for reviewing our financial statements and our management’s discussion and analysis of financial condition and results of operations to be included in our annual and quarterly reports to be filed with the SEC;
- reviews our critical accounting policies and estimates;
- is responsible for being knowledgeable about the content and operation of our global compliance program and exercising oversight over its implementation and effectiveness;
- maintains a strategic role in coordinating cyber risk initiatives and policies, and confirming their efficacy; and
- reviews the audit and compliance committee charter and the committee’s performance.

In 2024, Messrs. Rodgers, Bertrand and Mott served as members of the audit and compliance committee, and they comprise the current members of our audit and compliance committee. Mr. Rodgers serves as the chairperson of the committee. Each of the members of the committee during 2024 met, and each of the current members of our audit and compliance committee meets, the requirements for financial literacy under the applicable rules and regulations of the SEC and Nasdaq. Our board of directors has determined that Mr. Rodgers is an audit committee financial expert as defined under the applicable rules of the SEC and has the requisite financial sophistication as defined under the applicable rules and regulations of Nasdaq. Under the rules of the SEC, members of the audit committee must also meet heightened independence standards. Our board of directors has determined that each of the members of our audit and compliance committee during 2024 was, and each of the current members of our audit and compliance committee is an “independent director” under the heightened independence standards under the applicable rules of Nasdaq. Our audit and compliance committee has been established in accordance with the rules and regulations of the Securities Exchange Act of 1934, as amended. The audit and compliance committee operates under a written charter that satisfies the applicable standards of the SEC and Nasdaq. A copy of the audit and compliance committee charter is available to security holders on the Company’s website at <http://ir.ardelyx.com/corporate-governance>.

### ***Compensation Committee***

Our compensation committee reviews and recommends policies relating to compensation and benefits of our officers, employees and directors. The compensation committee reviews and approves corporate goals and objectives relevant to compensation of our chief executive officer and other executive officers, evaluates the performance of these officers in light of those goals and objectives, and sets the compensation of these officers, other than the chief executive officer, based on such evaluations. The compensation committee also periodically reviews the compensation of directors and makes recommendations to the board of directors. The board of directors retains the authority to determine and approve, upon the recommendation of the compensation committee, the compensation of the chief executive officer and our board of directors. Our executive officers submit proposals to the board of directors and compensation committee regarding our executive and director compensation. The compensation committee’s charter permits it to delegate its authority and responsibilities to a subcommittee of compensation committee members, to the extent consistent with our amended and restated certificate of incorporation and Amended and Restated Bylaws.

The compensation committee also approves grants of stock options and other awards under our stock plans. The compensation committee has delegated authority to the chief executive officer to grant stock options to purchase shares of common stock and restricted stock units under our Restated Plan to existing and new non-senior management team employees, with such individual grants to be consistent with equity grant guidelines provided by our compensation consultant and approved by the compensation committee. The compensation committee reviews and evaluates, at least annually, the performance of the compensation committee and its members, including compliance of the compensation committee with its charter.

In 2024, Messrs. Mott, Bazemore, and Rodgers and Ms. Bhanji served as members of the compensation committee. Messrs. Mott, Bazemore, and Rodgers, and Ms. Bhanji comprise the current members of our compensation committee. Mr. Mott serves as the chairperson of the committee. Each of the members of our compensation committee during 2024 was, and each of the current members of our compensation committee is an “independent director” under the applicable rules and regulations of The Nasdaq Global Market, a “non-employee director” as defined in Rule 16b-3 promulgated under the Securities Exchange Act of 1934, as amended, and an “outside director” as that term is defined in Section 162(m) of the U.S. Internal Revenue Code

of 1986, as amended. The compensation committee operates under a written charter that satisfies the applicable standards of the SEC and Nasdaq. A copy of the compensation committee charter is available to security holders on the Company's website at <http://ir.ardelyx.com/corporate-governance>.

For fiscal year 2024, the compensation committee retained Pearl Meyer & Partners, LLC, or Pearl Meyer, a national executive compensation consulting firm, to conduct market research and analysis on our various executive positions, to assist the committee in developing appropriate incentive plans for our executives on an annual basis, to provide the committee and our board of directors with advice and ongoing recommendations regarding material executive compensation decisions, to provide the committee with advice regarding appropriate compensation for our non-employee directors, and to review compensation proposals of management. In compliance with the disclosure requirements of the SEC regarding the independence of compensation consultants, Pearl Meyer addressed each of the six independence factors established by the SEC with the compensation committee. Its responses affirmed the independence of Pearl Meyer on executive and director compensation matters. Based on this assessment, the compensation committee determined that the engagement of Pearl Meyer did not raise any conflicts of interest or similar concerns. The compensation committee also evaluated the independence of other outside advisors to the compensation committee, including outside legal counsel, considering the same independence factors and concluded their work for the compensation committee does not raise any conflicts of interest.

#### ***Nominating and Corporate Governance Committee***

The nominating and corporate governance committee is responsible for making recommendations to our board of directors regarding candidates for directorships and the size and composition of our board of directors. In addition, the nominating and corporate governance committee is responsible for overseeing our corporate governance policies and reporting and making recommendations to our board of directors concerning governance matters.

In 2024, Dr. Lundberg, Ms. Cadoret-Manier, and Mr. Bertrand served as members of the nominating and corporate governance committee. Ms. Cadoret-Manier, Mr. Bertrand and Dr. Parsey will comprise the members of our nominating and corporate governance committee during 2025, with Dr. Parsey's appointment to the committee effective June 18, 2025. Mr. Bertrand serves as the chairperson of the committee. In June 2024, Dr. Lundberg did not stand for reelection and resigned from the board of directors and all committees of the board upon the expiration of his term. Each of the members of our nominating and corporate governance committee during 2024 was, and each of the current members of our nominating and corporate governance committee is an "independent director" under the applicable rules and regulations of Nasdaq relating to nominating and corporate governance committee independence. The nominating and corporate governance committee operates under a written charter that satisfies the applicable standards of the SEC and Nasdaq. A copy of the nominating and corporate governance committee charter is available to security holders on the Company's website at <http://ir.ardelyx.com/corporate-governance>.

#### **Governance Policies and Principles**

##### ***Certain Relationships and Related Party Transactions***

To enable us to act in the best interest of our stockholders, our board of directors has adopted a related party transaction policy setting forth the policies and procedures for the review and approval or ratification of related person transactions.

##### ***Policies and Procedures for Related Party Transactions***

Our related party transaction policy covers, with certain exceptions set forth in Item 404 of Regulation S-K any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships in which we were or are to be a participant, where the amount involved exceeds \$120,000 and a related person had or will have a direct or indirect material interest, including, without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit and compliance committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction with an unrelated third party and the extent of the related person's interest in the transaction.

The following is a description of transactions either entered into since January 1, 2024 or entered into prior to January 1, 2024 which have continuing obligations and to which we have been a party, in which the amount involved exceeds or will exceed \$120,000, and in which any of our directors, executive officers or holders of more than 5% of our capital stock, or an affiliate or immediate family member thereof, had or will have a direct or indirect material interest:

- *Indemnification Agreements and Directors' and Officers' Liability Insurance.* We have entered into indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us to indemnify each director and executive officer to the fullest extent permitted by the General Corporation Law of the State of Delaware, including indemnification of expenses such as attorneys' fees, judgments, penalties fines and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person's services as a director or executive officer.

### **Code of Business Conduct and Ethics**

We have adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. The code of business conduct and ethics is available on our website at <http://ir.ardelyx.com/corporate-governance>. We expect that any substantive amendments to the code, or any waivers of its requirements, will be disclosed on our website.

### **Director Attendance at Annual Meetings**

Our board of directors has a policy of encouraging director attendance at our annual meetings of stockholders, but attendance is not mandatory. Our board of directors and management team encourage all of our directors to attend the 2025 Annual Meeting. All of our then-serving directors attended our 2024 annual meeting of stockholders (with the exception of Dr. Lundberg who did not stand for reelection and resigned from the board of directors and all committees of the board upon the expiration of his term at our 2024 annual meeting of stockholders).

### **Stockholder Communications with the Board of Directors**

A stockholder may communicate with the board of directors, or an individual director, by sending written correspondence to the Company's Chief Legal and Administrative Officer at Ardelyx, Inc., 400 Fifth Avenue, Suite 210, Waltham, Massachusetts 02541. The Chief Legal and Administrative Officer will review such correspondence and forward it to the board of directors, or an individual director, as appropriate.

### **Compensation Committee Interlocks and Insider Participation**

During 2024, Messrs. Mott, Bazemore and Rodgers, and Ms. Bhanji served as members of our compensation committee. None of Messrs. Mott, Bazemore and Rodgers, and Ms. Bhanji has at any time been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers on our board of directors or compensation committee.

### **Prohibition on Hedging, Pledging and Similar Transactions**

We have adopted an Insider Trading Compliance Policy governing the purchase, sale, and other dispositions of our securities by our directors, officers, and employees that we believe is reasonably designed to promote compliance with insider trading laws, rules and regulations, and listing standards applicable to us. A copy of our Insider Trading Compliance Policy is filed as Exhibit 19.1 to our Annual Report on Form 10-K for the year ended December 31, 2024.

All employees, officers, members of our board of directors and certain consultants of the Company are subject to our Insider Trading Compliance Policy. The policy prohibits the covered individuals from purchasing or selling any of our securities while in possession of material nonpublic information.

Our Insider Trading Compliance Policy also prohibits covered individuals, including our NEOs, from (i) making short sales of our securities, (ii) engaging in transactions in puts, calls or other options or derivative instruments related to our securities, (iii) engaging in any hedging or similar transaction designed to decrease the risks associated with holding our securities and (iv) purchasing our securities on margin or pledging our securities as collateral.

## Board Diversity

Our nominating and corporate governance committee is responsible for reviewing with the board of directors, on an annual basis, the appropriate characteristics, skills and experience required for the board of directors as a whole and its individual members. In evaluating the suitability of individual candidates (both new candidates and current members) and in recommending candidates for election, the nominating and corporate governance committee, and in approving (and, in the case of vacancies, appointing) such candidates, the board of directors, will take into account many factors, including the following:

- personal and professional integrity;
- ethics and values;
- experience in corporate management, such as serving as an officer or former officer of a publicly held company;
- experience in the industries in which we compete;
- diversity of expertise and experience in substantive matters pertaining to our business relative to other board members;
- conflicts of interest; and
- practical and mature business judgment.

Our nominating and corporate governance committee also considers numerous other qualities, skills and characteristics when evaluating director nominees, including whether the nominee has specific strengths that would augment existing skills and experience of the board, such as expertise and experience in healthcare commercialization and reimbursement, public policy, and finance and capital markets, and whether the nominee brings diversity or leadership experience as a board member or executive of another publicly held company. Our nominating and corporate governance committee may identify nominees using professional search firms that may utilize proprietary screening techniques to match candidates to the specific criteria of our nominating and governance committee.

Currently, our board of directors evaluates each individual in the context of the board of directors as a whole, with the objective of assembling a group that can best maximize the success of the business and represent stockholder interests through the exercise of sound judgment using its diversity of experience in these various areas. Our nominating and corporate governance committee does not have a regard to the consideration of director candidates recommended by our stockholders and will evaluate such candidates on a case-by-case basis. Our nominating and corporate governance committee believes that it is in the best position to identify, review, evaluate, and select qualified candidates for board membership, based on the comprehensive criteria for board membership approved by our board of directors. Stockholders wishing to recommend a candidate for membership on our board of directors for the next fiscal year should follow the procedures described in this proxy statement under the headings “When are stockholder proposals due for next year’s annual meeting?” and “Stockholder Communications with the Board of Directors.”

## NON-EMPLOYEE DIRECTOR COMPENSATION

Our board of directors periodically reviews our non-employee director compensation program in consultation with Pearl Meyer and has amended and restated the program from time to time based on recommendations provided by Pearl Meyer. In 2023, our board of directors adopted the Third Amended and Restated Non-Employee Director Compensation Program, or the Director Compensation Program, under which our non-employee directors received compensation during 2024. The Director Compensation Program provides for cash retainers and equity compensation for members of our board of directors who are not employed by us. We do not provide compensation to directors who are employees under the Director Compensation Program. Retainers are paid to our non-employee directors on or about the date of our annual stockholders meeting or, in respect of non-employee directors appointed to our board of directors after the annual stockholders meeting, on the date of appointment but pro-rated to reflect the number of whole or partial months remaining until the next annual stockholders meeting.

Under the Director Compensation Program, our non-employee directors receive an annual retainer of \$50,000. Any non-employee chairperson receives an additional annual cash retainer in the amount of \$35,000. Non-employee directors receive additional annual retainers of \$10,000 for serving on the audit and compliance committee (or \$20,000 for serving as the chair of the audit and compliance committee), \$7,500 for serving on the compensation committee (or \$15,000 for serving as the chair of the compensation committee) and \$5,000 for serving on the nominating and corporate governance committee (or \$10,000 for serving as the chair of the nominating and corporate governance committee).

Under the Director Compensation Program, each newly appointed or elected non-employee director is automatically granted an option to purchase the lesser of 200,000 shares of our common stock or that number of shares that results in the option having an expected grant date fair value of \$300,000 as of the date of appointment or election. In addition, each non-employee director who has been serving on our board of directors for at least six months as of the date of any annual meeting of our stockholders and who will continue to serve as a non-employee director immediately following such meeting automatically is granted an option to purchase the lesser of 100,000 shares of our common stock or that number of shares that results in the option having an expected grant date fair value of \$200,000. Each option has an exercise price per share equal to the closing trading price of our common stock on the date of grant or, if the date of grant is not a trading day, the immediately preceding trading day. Each initial non-employee director stock option vests and becomes exercisable as to 1/36th of the shares underlying the option on each monthly anniversary of the grant date, subject to the non-employee director's continued service on our board of directors through the applicable vesting date. Each annual non-employee director stock option vests and becomes exercisable as to 1/12th of the shares underlying the option on each monthly anniversary of the grant date, subject to accelerated vesting immediately prior to the next annual stockholders meeting, in each case, subject to the non-employee director's continued service on our board of directors through the applicable vesting date.

The Director Compensation Program also provides that all outstanding equity awards that are held by a non-employee director will become fully vested and/or exercisable as of immediately prior to the consummation of a change in control.

The Director Compensation Program includes the opportunity for non-employee directors to elect to receive fully vested stock awards in lieu of cash retainers. The number of shares of our common stock underlying the stock award is calculated by dividing the amount of the cash retainer by the closing trading price of a share of our common stock on the date of our annual meeting of stockholders (or the immediately preceding trading day if the date of our annual meeting of stockholders is not a trading day), rounded to the nearest whole share. For 2024, each of Messrs. Bertrand, Mott and Rodgers elected to receive a stock award in lieu of their respective 2024 annual cash retainers as calculated pursuant to the preceding sentence.

In 2025, our board of directors adopted the Fourth Amended and Restated Non-Employee Director Compensation Program, or the Fourth Amendment, which amends the Director Compensation Program to increase the retainer for any non-employee chairperson to \$37,500; to increase the expected grant date fair value for the equity grant for each newly appointed or elected non-employee director to \$450,000, while retaining the maximum share utilization for any such grant to 200,000; and to increase the expected grant date fair value for the annual equity grant for any non-employee director who has been serving on our board of directors for at least six months as of the date of any annual meeting of our stockholders and who will continue to serve as a non-employee director immediately following such meeting to \$300,000, while retaining the maximum share utilization for each such annual grant to 100,000.



The Fourth Amendment also provides for the initial non-employee director equity grants and the annual non-employee director equity grants to be comprised of a mix of stock options to purchase shares of our common stock and restricted stock units, with the split of stock options and restricted stock units to be determined by the board of directors. The vesting schedule for the stock options granted to non-employee directors remains unchanged from the Director Compensation Plan. Under the Fourth Amendment, subject to the non-employee director's continued service on our board of directors through the applicable vesting date, the restricted stock units comprising part of any initial non-employee director grant will vest as to 1/12th of the shares on each Company designated quarterly restricted stock unit vest date, and the restricted stock units comprising part of any annual non-employee director grant will vest as to 1/4th of the shares on each Company designated quarterly restricted stock unit vest date. Further, under the Fourth Amendment, the board may provide each director with the opportunity to defer the issuance of shares underlying any of the restricted stock units that would otherwise be used to the director in connection with the vesting or grant of the restricted stock units until the earliest of: (i) a fixed date properly elected by the director, (ii) the termination of the director's service, or (iii) a Change in Control (as defined in the Restated Plan).

Members of our board of directors are also reimbursed for reasonable travel and other out-of-pocket expenses.

### 2024 Director Compensation Table

The following table sets forth information for the year ended December 31, 2024 regarding the compensation awarded to, earned by or paid to our non-employee directors.

Name	Fees Earned or Paid in Cash (\$)	Option Awards (\$) <sup>(1)</sup>	Total (\$)
Robert Bazemore . . . . .	\$ 57,500	\$199,997	\$257,497
William Bertrand, Jr., Esq. . . . .	\$ 70,000 <sup>(2)</sup>	\$199,997	\$269,997
Muna Bhanji, R.Ph . . . . .	\$ 57,500	\$199,997	\$257,497
Onaiza Cadoret-Manier . . . . .	\$ 55,000	\$199,997	\$254,997
David Mott . . . . .	\$110,000 <sup>(2)</sup>	\$199,997	\$309,997
Richard Rodgers . . . . .	\$ 77,500 <sup>(2)</sup>	\$199,997	\$277,497

- (1) The amounts reported in the Option Awards column represent the grant date fair value of the stock options granted to the non-employee members of our board of directors during 2024 as computed in accordance with ASC 718. The assumptions used in calculating the grant date fair value of the stock option reported in this column are set forth in Note 13 to the audited financial statements included in our Annual Report on Form 10-K filed on February 20, 2025. The amounts reported in this column exclude the impact of estimated forfeitures related to service-based vesting provisions. Note that amounts reported in this column reflect the accounting cost for these stock options, and do not correspond to the actual economic value that may be received by the directors from the options. In June 2024, each of our non-employee directors was granted an annual option to purchase 40,243 shares of our common stock pursuant to the Director Compensation Program with an exercise price per share of \$6.35.

The following table sets forth for the number of shares of our common stock subject to outstanding options held by each of our non-employee directors as of December 31, 2024:

Name	Shares Subject to Outstanding Option
Robert Bazemore . . . . .	350,775
William Bertrand, Jr., Esq. . . . .	365,775
Muna Bhanji, R.Ph . . . . .	253,167
Onaiza Cadoret-Manier . . . . .	288,135
David Mott <sup>(a)</sup> . . . . .	330,775
Richard Rodgers . . . . .	355,775

- (a) Includes options to purchase 110,000 shares of our common stock that Mr. Mott holds for the benefit of entities associated with New Enterprise Associates.
- (2) Pursuant to the Director Compensation Program, each of Messrs. Bertrand, Mott and Rodgers elected to receive a fully vested stock award in lieu of their respective 2024 annual cash retainers. The fully vested stock awards consisted of 11,023, 17,322 and 12,204 shares of our common stock for Messrs. Bertrand, Mott and Rodgers, respectively. The number of shares of our common stock issued was calculated by dividing the annual retainer otherwise payable in cash at the 2024 Annual Meeting of Stockholders as reported in this column by \$6.35, which was the closing trading price of our common stock on the date of the 2024 Annual Meeting of Stockholders, rounded down to the nearest whole share. The value of the cash fees the non-employee directors would have received had they not elected to receive stock awards is reported in this column.

**PROPOSAL NO. 2**  
**ADVISORY VOTE TO APPROVE NAMED EXECUTIVE OFFICER COMPENSATION**

In accordance with Section 14A of the Securities Exchange Act of 1934, as amended, we are providing stockholders an opportunity to cast a non-binding, advisory vote to approve the compensation of our Named Executive Officers, or NEOs (sometimes referred to as a “Say-on-Pay” vote). Accordingly, you have the opportunity to vote “**FOR**” or “**AGAINST**” or to “**ABSTAIN**” from voting on the following non-binding resolution at the 2025 Annual Meeting:

“Resolved, that the stockholders approve, on an advisory basis, the compensation of the Company’s named executive officers as disclosed in the Company’s proxy statement for the 2025 Annual Meeting of Stockholders pursuant to the compensation disclosure rules of the Securities and Exchange Commission, including the accompanying compensation tables and the related narrative disclosure in the proxy statement.”

In deciding how to vote on this proposal, you are encouraged to review the accompanying compensation tables and the related narrative disclosure. As described in detail in the sections entitled “Compensation Discussion and Analysis” and “Details of our Compensation Program,” our compensation programs are designed to reward, motivate, attract and retain top talent by rewarding performance based upon achievement of pre-approved annual goals and objectives. A portion of each NEO’s compensation is contingent upon overall corporate performance as well as specific performance metrics particular to each NEO’s position and consistent with the NEO’s role on the management team. We believe that our compensation programs align the interests of our NEOs with that of our stockholders and provide motivation for high performance levels from our NEOs.

**Vote Required**

Approval, on a non-binding, advisory basis, of the compensation of our NEOs, as disclosed in this Proxy Statement pursuant to the compensation disclosure rules of the Securities and Exchange Commission, requires the affirmative vote of the majority of votes cast (excluding abstentions and broker non-votes). Abstentions and broker non-votes are not considered votes cast for the foregoing purpose, and will have no effect on the vote for this proposal.

While your vote on this proposal is advisory and will not be binding on the board of directors, the compensation committee, the Company, and the board of directors value the opinions of the stockholders on executive compensation matters and will take into consideration the outcome of the vote when making future executive compensation decisions, to the extent they can determine the cause or causes of any significant negative voting results. Unless the board of directors modifies its determination on the frequency of future Say-on-Pay advisory votes, the next Say-on-Pay advisory vote will be held at the fiscal 2026 annual meeting of stockholders.

**THE BOARD OF DIRECTORS RECOMMENDS A VOTE “FOR” THE APPROVAL OF THE  
COMPENSATION OF THE NAMED EXECUTIVE OFFICERS, AS DISCLOSED IN THIS PROXY  
STATEMENT.**

## EXECUTIVE OFFICERS

The following table sets forth information regarding our executive officers as of March 31, 2025.

Name	Age	Position(s)
Michael Raab .....	60	President, Chief Executive Officer and Director
Justin Renz .....	53	Chief Financial and Operations Officer
Elizabeth Grammer, Esq. ....	61	Chief Legal and Administrative Officer
Laura Williams, M.D., M.P.H. ....	62	Chief Medical Officer <sup>(1)</sup>
Mike Kelliher .....	48	Executive Vice President, Corporate Development and Strategy
Eric Foster .....	50	Chief Commercial Officer

(1) Dr. Williams began the transition into her new role as Chief Patient Officer in early 2025; however, Dr. Williams will continue to serve as Chief Medical Officer until a new Chief Medical Officer has been identified and commenced employment.

The following biographical information is furnished with regard to our executive officers as of April 15, 2025:

Mr. Raab's biographical information is included above under "Class II Nominees for Director."

**Justin Renz** has served as our Chief Financial and Operations Officer since January 2023, and served as our Chief Financial Officer from June 2020 to January 2023. Beginning in 2017, Mr. Renz held various positions of increasing responsibility at Corveio Pharma Corp, a specialty pharmaceutical company, most recently as its President and Chief Financial Officer at the time of its acquisition by Advanz Pharma in May 2020. From 2014 to 2017, Mr. Renz was the Executive Vice President and Chief Financial Officer of Karyopharm Therapeutics, Inc. (Nasdaq: KTPI). Prior to that, from 2006 to 2014, Mr. Renz held a variety of financial positions with Zalicus Pharmaceuticals Ltd., a biopharmaceutical company, including most recently as Executive Vice President and Chief Financial Officer at the time of its acquisition by Epirus Biopharmaceuticals, Inc. in 2014. Mr. Renz received his B.A. in economics and accounting from the College of the Holy Cross, a M.S. in Taxation from Northeastern University and an M.B.A. from Suffolk University.

**Elizabeth Grammer, Esq.**, has served as our Chief Legal and Administrative Officer since January 2020, and formerly served as our General Counsel from May 2014 to January 2020, and as our vice president responsible for legal affairs from December 2012 until May 2014. Ms. Grammer has also served as a director of Sagimet Biosciences, Inc. (Nasdaq: SGMT) since May 2021. From 2006 to December 2012, Ms. Grammer served as an independent outside corporate counsel for public and private biotechnology companies, including Ardelyx from January 2010 until December 2012. From 2001 to 2006, Ms. Grammer served as Vice President and General Counsel of Trine Pharmaceuticals, Inc., a biopharmaceutical company. In addition, Ms. Grammer previously served as independent outside corporate counsel to GelTex Pharmaceuticals, a biopharmaceutical company from 1998 until its acquisition by Genzyme Corporation, a biotechnology company, in 2020. Ms. Grammer received a B.A. from Boston University and a J.D. from Stanford Law School.

**Laura Williams, M.D., M.P.H.**, has served as our Chief Patient Officer since April 2025 and as our Chief Medical Officer since October 2021. Before that, Dr. Williams served as our Senior Vice President, Global Therapeutic Strategies and Patient Advocacy from November 2020 until October 2021. Dr. Williams serves on the board of directors of the National Kidney Foundation in Northern California, Oregon and Washington State (CNOW), as well as on the board of trustees of the American Kidney Fund. Previously, Dr. Williams served as a director of Imara, Inc. from June 2021 until its acquisition by Enliven Therapeutics, Inc (Nasdaq: ELVN) in February 2023. Prior to Ardelyx, Dr. Williams served as Senior Vice President, Head of Clinical Development and Biostatistics at AMAG Pharmaceuticals, a pharmaceutical company, from September 2017 to January 2020, and as Vice President, Clinical Development at Myovant Sciences (NYSE: MYOV) from September 2016 to August 2017. Dr. Williams held roles of increasing responsibility at AbbVie Pharmaceuticals (Nasdaq: ABBV) from January 2013 to July 2016, and at Abbott Laboratories, Inc. (NYSE: ABT) from July 1998 to December 2012. Dr. Williams received a B.S. degree in Pre-Medicine/Pre-Medical Studies and Biochemistry from Mississippi State University, a M.D. from University of Iowa, and a M.P.H. degree in Epidemiology from University of Washington, where she also completed a clinical fellowship in Infectious Diseases. Dr. Williams completed her residency training in Internal Medicine at University of Michigan, where she also served as Chief Medical Resident and Junior Faculty.



**Mike Kelliher** has served as our Executive Vice President, Corporate Development and Strategy since March 2024. From November 2014 to March 2024, Mr. Kelliher worked at Horizon Therapeutics (Nasdaq: NZNP), which was acquired in October 2023 by Amgen (Nasdaq: AMGN). Mr. Kelliher most recently served as Group Vice President, M&A and Business Development at Horizon Therapeutics from January 2022 to March 2024 and Vice President Business Development from April 2016 to December 2021. Prior to his time at Horizon Therapeutics, from 2009 to 2014, Mr. Kelliher held financial roles at Elan Corporation (now Perrigo Company), a public pharmaceutical company. Mr. Kelliher received a Bachelor of Commerce degree from the University College Cork (Ireland).

**Eric Foster** has served as our Chief Commercial Officer since August 2024. Before that, Mr. Foster served as Senior Vice President and U.S. General Manager at Amgen (Nasdaq: AMGN), following the acquisition of Horizon Therapeutics (Nasdaq: HZNP) in October 2023 where he served as Senior Vice President and General Manager of the Gout and Ophthalmology Business Units from October 2022 until October 2023 and Group Vice President and General Manager of the Gout Business Unit from May 2021 until October 2022. Prior to his time at Horizon Therapeutics, from 2010 to 2021, Mr. Foster held roles of increasing responsibility within the sales and marketing organization at GlaxoSmithKline Plc (LSE/NYSE: GSK) across a variety of immunology and rare disease products, including serving as Vice President of Immunology Marketing, Senior Global Marketing Director and Field Sales Vice President. Mr. Foster began his career in sales and market access at Johnson & Johnson (NYSE: JNJ). Mr. Foster holds a Bachelor of Arts in Economics degree from the University of Georgia and a Master of Business Administration from Auburn University.

## COMPENSATION DISCUSSION AND ANALYSIS

The following is a discussion and analysis of the compensation program for our named executive officers, or NEOs. This section covers our philosophy, programs, processes, decisions, and other relevant information for fiscal year 2024.

Our NEOs for fiscal year 2024 were as follows:

Executive	Role
Michael Raab	President, Chief Executive Officer and Director (PEO or CEO)
Justin Renz	Chief Financial and Operations Officer (PFO or CFO)
Elizabeth Grammer	Chief Legal and Administrative Officer
Laura Williams, M.D., M.P.H.	Chief Medical Officer <sup>(1)</sup>
Michael Kelliher	Executive Vice President, Corporate Development and Strategy

(1) Dr. Williams began the transition into her new role as Chief Patient Officer in early 2025; however, Dr. Williams will continue to serve as Chief Medical Officer until a new Chief Medical Officer has been identified and commenced employment.

### Executive Summary

*This section covers our key performance and organizational highlights, the resulting key compensation actions, and our governance best practices.*

We are a patient-focused biopharmaceutical company founded with a mission to discover, develop and commercialize innovative, first-in-class medicines that meet significant unmet medical needs. We operate in a highly competitive environment for talented senior executives that are needed to achieve our mission. As such, we offer competitive compensation to attract and retain these individuals within our overarching philosophy to pay for performance and create shareholder value.

#### 2024 Business Performance and Organizational Highlights

2024 was an exceptional year for our Company, achieving net product sales revenue of \$319.2 million through our two commercial products, IBSRELA® and XPHOZAH®.

<b>\$158.3 million</b> 2024 net product sales revenue of IBSRELA (tenapanor)	<b>\$160.9 million</b> 2024 net product sales revenue of XPHOZAH (tenapanor) in first full year of commercialization
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- **Other business achievements**

- ***Strengthened our balance sheet.*** As of December 31, 2024, we had total cash, cash equivalents and short-term investments of \$250.1 million, compared to \$184.3 million as of December 31, 2023 primarily driven by our strong commercial performance and \$50.0 million of additional proceeds that we drew in October 2024 under our loan agreement with investment affiliates managed by SLR Capital Partners (SLR).
- ***Increased availability of capital.*** In October 2024, we amended our loan agreement with SLR. Pursuant to the amendment, in addition to drawing \$50 million at Secured Overnight Financing Rate (SOFR) plus 4.02%, we also added the opportunity to draw an additional \$50 million at the same interest rate on or before June 30, 2025. In addition, we extended the interest-only period for existing and new tranches under the loan agreement until July 1, 2028.
- ***Growth in total scripts.*** Continued growing demand for IBSRELA and XPHOZAH throughout 2024 was demonstrated by increases in new and refill prescriptions as well as growth in new and repeat writing healthcare providers.
- ***Initiated pediatric study.*** In 2024, we initiated a randomized, double-blind, placebo-controlled study to assess the efficacy, safety and tolerability of IBSRELA in pediatric patients (≥12 and <18 years old) with IBS-C.
- ***Delivered on our commitment to patients.*** In 2024, we reinforced our commitment to patients by advancing our legal and legislative efforts to exclude oral only drugs from the End Stage Renal

Disease Prospective Payment System and the Company continues to take measured steps to help preserve the decision making authority of nephrology healthcare providers in phosphate management under the newly enacted CMS policy.

- **Organizational highlights**

- In March 2024, the Company announced the appointment of veteran biopharma executive Michael Kelliher as Executive Vice President, Corporate Development and Strategy.
- In August 2024, the Company announced the appointment of experienced biopharma executive, Eric Foster, as Chief Commercial Officer.

#### *2024 Compensation Actions*

Our Compensation Committee (the “Committee” for purpose of this Compensation Discussion and Analysis section), or in the case of our CEO compensation, our full board of directors, took several actions related to our NEOs’ 2024 compensation. These actions were informed by our compensation philosophy and objectives, and other factors as detailed in the “Compensation Philosophy and Process” section.

Topic	Key Actions
<b><i>Base Salaries</i></b>	<ul style="list-style-type: none"> <li>• Approved 2024 salaries for our NEOs</li> <li>• The increase in base salary from 2023 averaged 9.5% for our NEOs (excluding Mr. Kelliher who started in March 2024), reflecting (i) a merit increase component, as well as (ii) market adjustments to bring NEOs to within a competitive range of the 50<sup>th</sup> percentile of the market compensation group recommended by Pearl Meyer (the “Market Data”)</li> <li>• Set Mr. Kelliher’s salary at the 50<sup>th</sup> percentile of the Market Data</li> </ul>
<b><i>Cash Performance Incentive Program</i></b>	<ul style="list-style-type: none"> <li>• Approved target bonus levels for each NEO for 2024</li> <li>• Established corporate goals for 2024 across a number of key areas, including financial, regulatory, scientific, operational, and people</li> <li>• Evaluated performance relative to these goals and approved a corporate goal performance score of 92% for 2024</li> </ul>
<b><i>Equity Awards</i></b>	<ul style="list-style-type: none"> <li>• Established a 2024 long-term incentive program, comprised of grants of stock options and restricted stock units (RSUs), each with a four-year vesting schedule</li> <li>• Approved grants to our NEOs within the established program</li> <li>• Set grant amounts based on an average of a targeted long-term incentive value and a targeted long-term incentive award as a percentage of common shares outstanding</li> <li>• Applied this same logic to Mr. Kelliher’s grant upon his hiring</li> </ul>

### *Key Governance Attributes*

Our compensation program is supported by a number of key features, processes, and decisions that reflect good governance and best practice.

What We Do	What We Don't Do
<ul style="list-style-type: none"><li><input checked="" type="checkbox"/> Evaluate compensation against a set of comparable companies</li><li><input checked="" type="checkbox"/> Target our compensation opportunities within established market ranges, typically the 50<sup>th</sup> percentile with flexibility to adjust as business needs dictate</li><li><input checked="" type="checkbox"/> Use multiple incentive plan metrics covering key financial, scientific, operational, strategic, and people goals</li><li><input checked="" type="checkbox"/> Utilize both short- and long-term incentives to balance risk and reward</li><li><input checked="" type="checkbox"/> Allow the Committee full negative discretion to reduce incentives</li><li><input checked="" type="checkbox"/> Maintain a compensation recoupment policy</li><li><input checked="" type="checkbox"/> Engage an independent consultant to advise our Committee</li><li><input checked="" type="checkbox"/> Assess the risk of our compensation program</li></ul>	<ul style="list-style-type: none"><li><input checked="" type="checkbox"/> No guarantees for increases to annual compensation</li><li><input checked="" type="checkbox"/> No single trigger vesting of equity in connection with a change in control unless equity awards are not assumed</li><li><input checked="" type="checkbox"/> No excessive perquisites or executive benefits</li><li><input checked="" type="checkbox"/> No hedging or pledging of company stock</li><li><input checked="" type="checkbox"/> No repricing of outstanding equity awards without stockholder approval</li><li><input checked="" type="checkbox"/> No excise tax gross ups</li></ul>

### **Compensation Philosophy and Process**

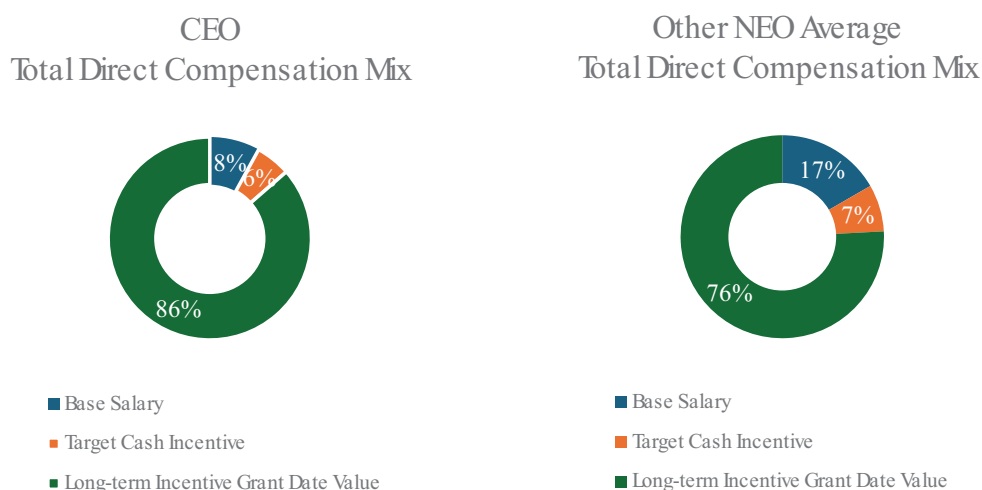
This section covers our key beliefs and objectives regarding the 2024 compensation program, and the process we undertake to evaluate compensation and make decisions.

#### *Compensation Philosophy*

Our compensation program is designed to support our overarching mission as a company; to discover, develop and commercialize innovative, first-in-class medicines that meet significant unmet medical needs. To achieve our mission, it is critical that our compensation program is structured to:

- Attract and retain individuals who can contribute meaningfully to our mission
- Motivate individuals to achieve our business objectives that support our mission
- Measure performance across a number of metrics to drive holistic performance
- Align the interests of our NEOs and shareholders to create value over time

Our compensation philosophy allows for flexibility in establishing compensation levels and pay mix for NEOs. This flexibility is important to ensure our executive compensation program is competitive and that our compensation decisions appropriately reflect the contributions and profile of each of our NEOs. For all NEOs, the mix of target compensation elements is heavily weighted toward variable compensation, including our cash incentive and long-term incentive plans, that are based on a variety of strategic, financial, and operational goals, as well as the Company’s stock price performance. The CEO’s target compensation places a greater emphasis on variable compensation than that of the other NEOs because our CEO’s actions have a greater influence on the performance of the Company as a whole.



As a growth-oriented biopharmaceutical company in a rapidly changing industry, our evaluation of performance cannot always be captured through pre-established objectives. We therefore allow for an appropriate amount of informed judgement in arriving at compensation outcomes for NEOs as well as other employees in our Company. This informed judgement can be negative or positive, and is generally limited to the overall scoring of our corporate objectives at year end. The three-year history of bonus funding levels demonstrates the Committee’s rigor in determining corporate bonus ratings has been appropriate.

Three Year Corporate Bonus Funding History (% of Target)		
2022	2023	2024
85%	92%	92%

The Committee considers the following factors when determining compensation for our NEOs:

Internal Factors	External Factors
<ul style="list-style-type: none"> <li>• Current compensation levels</li> <li>• Company performance</li> <li>• Individual performance</li> <li>• Scope and criticality of NEO’s role</li> <li>• Outstanding equity value</li> <li>• Relative compensation to other NEOs</li> </ul>	<ul style="list-style-type: none"> <li>• Current market conditions</li> <li>• Current business conditions</li> <li>• Labor market supply and demand</li> <li>• Compensation trends</li> <li>• Compensation levels at peer group</li> <li>• Results of our “say-on-pay” vote</li> </ul>

The weighting of these and other relevant factors is determined on an individual basis for each NEO after consideration of the relevant facts and circumstances.

#### *Review of 2024 “Say-on-Pay” Vote*

We currently hold an advisory vote of our NEO compensation each year. We carefully consider the results of this vote from the preceding year. At our 2024 Annual Meeting of Stockholders, approximately 94% of the votes were cast in favor of the compensation of our NEOs, as disclosed in our 2024 Proxy Statement. The Committee

considered the results of the 2024 stockholder advisory vote on executive compensation when determining our 2025 executive compensation and will continue to consider our say-on-pay results, as well as feedback we receive throughout the year when making decisions about our executive compensation program.

#### *Compensation Process*

Each year, the Committee undergoes a comprehensive process to review, evaluate, and make decisions regarding our compensation program. To support these efforts, the Committee engages with Pearl Meyer, its independent compensation consultant, as well as management.

- ***The Role of the Committee.*** Our Committee, appointed by our board of directors, is responsible for, among other things, establishing, implementing and monitoring our compensation philosophy and objectives, overseeing and approving the compensation elements and targets for each of our NEOs, making determinations concerning our incentive programs, administering our Company’s stock-based compensation plans, and approving the benefits offered to NEOs. Compensation decisions for the CEO are subject to review and approval by the full board of directors.
- ***The Role of Management.*** Our CEO annually reviews each NEO’s performance (excluding himself), and recommends salary adjustments and incentive awards with the Committee. Our Chief Legal and Administrative Officer provides data and participates in Committee meetings to provide context and perspective on appropriate matters. Collectively, our CEO and Chief Legal and Administrative Officer also develop, with assistance from other executive officers, and propose corporate objectives for the purpose of our annual cash-based incentives, and may also assist in developing other compensation proposals as may come up from time to time. While our Committee utilizes this information, the ultimate decisions regarding fiscal 2024 executive compensation were made by our Committee and our board of directors.
- ***The Role of the Independent Consultant.*** Pearl Meyer serves as the Committee’s independent consultant and provides information and advice on executive and non-employee director compensation matters to the Committee. Pearl Meyer advises the Committee on all the principal aspects of executive compensation, and attends meetings of the Committee when requested.

#### *Use of Market Data*

When making compensation decisions, our board of directors and compensation committee considered advice and Market Data provided by Pearl Meyer. Pearl Meyer recommended a market compensation group in 2023 that informed 2024 compensation program decisions. The recommended peer group reflected companies with the following characteristics, which were determined to be reflective of our Company’s profile at that time.

<b><i>Company Profile</i></b>	<ul style="list-style-type: none"> <li>• U.S. based</li> <li>• Traded on a major stock exchange</li> <li>• Biotechnology or pharmaceutical company</li> <li>• Commercial stage</li> </ul>
<b><i>Size</i></b>	<ul style="list-style-type: none"> <li>• Market capitalization of \$200 million to \$2,500 million</li> <li>• Revenues of \$40 million to \$400 million</li> <li>• Full time employees of 40 to 500</li> </ul>
<b><i>Other Factors</i></b>	<ul style="list-style-type: none"> <li>• Preference for nephrology or gastroenterology indications</li> <li>• Preference for headquartered in California or Massachusetts</li> </ul>

Based on this criteria, Pearl Meyer recommended, and the Committee approved, the following 20 companies to serve as the peer group for setting 2024 compensation.

- Akebia Therapeutics, Inc.
- Catalyst Pharmaceuticals, Inc.
- Coherus BioSciences, Inc.
- Collegium Pharmaceutical, Inc.
- Deciphera Pharmaceuticals, Inc.
- Eagle Pharmaceuticals, Inc.
- Enanta Pharmaceuticals, Inc.
- EyePoint Pharmaceuticals, Inc.
- Heron Therapeutics, Inc.
- Intercept Pharmaceuticals, Inc.
- Ironwood Pharmaceuticals, Inc.
- Karyopharm Therapeutics Inc.
- MannKind Corporation
- Mirum Pharmaceuticals, Inc.
- Ocular Therapeutix, Inc.
- Rigel Pharmaceuticals, Inc.
- Travere Therapeutics, Inc.
- Vericel Corporation
- Xencor, Inc.
- Xeris Biopharma Holdings, Inc.

In addition to the compensation peer group detailed above, Pearl Meyer also made use of compensation survey data in leveling our NEO compensation to the market. Like the compensation peer group, this survey data was customized to reflect companies that have a similar profile to our Company to ensure the comparisons were appropriate.

The Committee generally references compensation paid by the peer group companies to similarly situated employees at the 50th percentile when evaluating the compensation levels of our NEOs .

### Compensation Program

For fiscal year 2024, our executive compensation program consisted of the following elements, each established as part of our program in order to achieve the compensation objective specified below:

Compensation Element	Compensation Objectives Designed to be Achieved and Key Features
Base Salary	Base salary attracts and retains talented executives, recognizes individual roles and responsibilities and provides stable income.
Cash-Based Incentive Compensation	Directly ties pay to key corporate metrics, which we believe will lead to sustained value for all stakeholders over the long term.
Equity-Based Compensation	Equity-based compensation, provided in the form of stock options and restricted stock units, reinforces the importance of a long-term, ownership orientation, creates alignment with our stockholders, and promotes retention.
Severance and Other Benefits Potentially Payable upon Termination of Employment or Change in Control	Provides our executives security to focus on executing our strategies that support achieving our mission.
Retirement, Health and Welfare Benefits	Provides our executives with security to focus on executing our strategies that support achieving our mission.

### Base Salaries

The base salaries of our NEOs are an important part of their total compensation package, and are intended to reflect their respective positions, duties and responsibilities. Base salary is a visible and stable fixed component of our compensation program. Base salaries for our NEOs were initially established through arms-length negotiation at the time an executive was hired. Generally, the Committee will review our NEO base salaries on an annual basis, and more frequently in such cases as a promotion or change in role.

During fiscal year 2024, the Committee increased the annual base salary for Messrs. Raab and Renz, Ms. Grammer and Dr. Williams by 10%, 10%, 10% and 8%, respectively, following the Committee's evaluation of each NEO's individual performance and its review of Market Data. Mr. Kelliher's annual base salary was established in connection with his commencement of employment with us. In establishing Mr. Kelliher's annual base salary as part of arm's length negotiations with him, the Committee considered the annual base salaries of other NEOs, Mr. Kelliher's experience and Market Data.



The following table sets forth the base salaries of our NEOs for fiscal year 2024:

NEO Fiscal Year 2024 Base Salary	
Michael Raab	\$770,000
Justin Renz	\$517,000
Elizabeth Grammer	\$509,300
Laura Williams, M.D., M.P.H.	\$522,720
Michael Kelliher	\$440,000

### ***Cash-Based Incentive Compensation***

We consider annual cash incentive bonuses to be an important component of our total compensation program and provides incentives necessary to retain and motivate NEOs. For 2024, our NEOs were eligible to receive performance-based cash incentives pursuant to the achievement of certain corporate performance objectives, as well as reflecting on their individual performance (excluding our CEO, who has a bonus opportunity based entirely on corporate performance).

The performance goals for these annual performance cash bonuses were evaluated by our compensation committee and approved by our board of directors. The determination of the bonus amounts paid to our NEOs generally reflects a number of considerations, including the NEO's target bonus opportunity and the performance of the Company against corporate goals, as well as their individual performance.

Each NEO's target bonus opportunity for 2024 performance is expressed as a percentage of base salary and is detailed below.

NEO Fiscal Year 2024 Target Cash Incentive (% of Base Salary)	
Michael Raab	70%
Justin Renz	45%
Elizabeth Grammer	45%
Laura Williams, M.D., M.P.H.	45%
Michael Kelliher	45%

Our board of directors or our Committee has historically reviewed these target percentages annually to ensure they are appropriate and competitive, but does not follow a formula in determining them, though internal parity among NEOs and Market Data have the most impact on each NEO's target percentage. Accordingly, following its review of Market Data, the Committee increased Mr. Raab's target percentage by 10% over the target percentage for fiscal year 2023 and Mr. Renz's, Ms. Grammer's and Dr. Williams' target percentage by 5% over their target percentage for fiscal 2023. Mr. Kelliher's target percentage was established in connection with his commencement of employment in March 2024.

For determining performance bonus amounts for our NEOs for 2024, the Committee established the following percentage allocations for corporate performance and individual performance for each NEO. These allocations are unchanged from the previous year. The Committee believes that the CEO's bonus should be based entirely on corporate performance given the scope and nature of the role as principal executive officer and his responsibility for the Company as a whole. The Committee determined that other NEOs should have a majority of their annual performance cash bonus determined by corporate performance, however some portion should reflect their performance as an individual and functional leader of the Company. The following table provides the breakout of corporate and individual performance, where applicable.

Role	Corporate Performance Allocation	Individual Performance Allocation	Total Allocation
CEO	100%	—	100%
Other NEO	80%	20%	100%

At the beginning of 2024, our Committee and board of directors set our corporate performance goals which covered a broad array of categories that were important to achieving our mission and creating stockholder value.



Each category has an assigned weight, which underscores the relative importance of the goal. Additionally, each category has a number of goals which serve as an evaluation tool for the Committee at year end when assessing Company performance. The Committee has the authority to provide no credit, partial credit, full credit, or more for each category and in total. The scoring of each category reflects the Committee's evaluation, which sums to a total corporate score based on the category weightings.

### ***Discussion of Corporate Objective Goal Scoring***

The Committee reviewed each category of corporate objectives, as well as management's proposed scoring and underlying rationale, in approving the corporate funding total for 2024.

Category	Weighting	Score	Weighted Score
Product Revenue	55.0%	104.5%	57.48%
Regulatory & Government Affairs	15.0%	50.0%	7.5%
Pipeline	7.5%	80.0%	6.0%
Operational	7.5%	85.0%	6.38%
Finance	10.0%	101.5%	10.15%
People & Compliance	5.0%	90.0%	4.5%
<b>Total</b>	<b>100%</b>	<b>—</b>	<b>92.0%*</b>

\* Weighed score does not add to the total due to rounding

### ***Corporate Goals***

- **Product Revenue.** The goals for this category related to our net product sales revenue for IBSRELA and XPHOZAH. While the distribution of net revenue was different than budgeted, the Company achieved combined revenue levels that exceeded the total budgeted net revenue for the year. Specifically, the Company budgeted aggregate net product revenue for IBSRELA and XPHOZAH was \$258.7 million, with IBSRELA net product revenue budgeted at \$174.5 million and XPHOZAH net product revenue budgeted at \$84.2 million.
- **Regulatory and Government Affairs.** The goals for this category related to maintaining and expanding access to patients in support of our mission. Access to our products can be impacted by matters over which we have significant influence, including our distribution strategy and patient assistance programs, but can also be impacted by matters over which our influence is much more limited, such as payor coverage. The Company made significant progress in positively impacting access for our patients and achieved some, but not all of the goals, which resulted in a partial credit score based on the Committee's assessment of the Company's performance in advancing patient access through various actions.
- **Pipeline.** The goals for this category related to activities in support of advancing our pipeline. Among them was hiring a head of corporate development and strategy, as well as conducting a strategic evaluation of our product pipeline and other discovery related items. The Committee determined that the Company achieved some, but not all of these goals, resulting in a partial credit score on this category based on the Committee's evaluation of the progress made towards various pipeline initiatives and the opportunities presented to the board of directors for expansion of IBSRELA and XPHOZAH in new territories.
- **Operational.** These goals related to our manufacturing and supply chain efforts. Specifically managing inventory levels, executing on commercial supply agreements, and manufacturing facility buildouts. The Committee awarded credit to the Company for entering into commercial supply agreements with two manufacturers during 2024, however, partial credit was deducted from this category based on the Committee's evaluation of the management of inventory levels.
- **Financial.** These goals related to managing our operating expenses to ensure appropriate cash levels. The Company exceeded its target goal with respect to budget expense performance. Total operating

expenses were approximately \$311 million for fiscal year 2024 as compared to the annual operating budget of \$326 million. The Committee also assessed the Company's year-end cash balance of approximately \$251 million, using its discretion to score performance, and awarded the Company enhanced credit on this category.

- **People.** These goals related to advancing our organizational capabilities and culture. Specifically, the goals were centered around identification and retention of key talent, development of succession plans, and compliance rates on company-provided training. The Company completed a succession planning exercise and identified and hired key talent. The Company also improved in its achievement of its compliance training goal as compared to fiscal year 2023 but fell short of the target of having 95% of compliance training complete by new hires within 60 days of their start date. Overall, the Committee determined that the Company achieved most, but not all of the underlying goals and awarded partial credit on this category.

#### *Discussion of Individual Goal Scoring*

In addition to the corporate goal scoring, the Committee also evaluated each NEO for their individual performance in consultation with the CEO. Given the collective success of the team during 2024, the CEO recommended, and the Committee approved, that all NEOs would receive an individual score equal to the corporate score.

#### *2024 Cash Incentive Payouts*

NEO	Base Salary	Target Bonus (% of Base Salary)	Target Bonus Amount	Total Bonus Achieved	Total Bonus Achieved as a % of Target Bonus
Michael Raab	\$770,000	70%	\$539,000	\$495,880	92%
Justin Renz	\$517,000	45%	\$232,650	\$214,038	92%
Elizabeth Grammer	\$509,300	45%	\$229,185	\$210,850	92%
Laura Williams, M.D., M.P.H.	\$522,720	45%	\$235,224	\$216,406	92%
Michael Kelliher	\$440,000	45%	\$198,000	\$182,160	92%

In addition to our formal cash incentive program, the Committee may approve discretionary bonuses to be paid to our NEOs from time to time, when it determines it to be appropriate to attract and retain talent, reward performance, or incentivize future results. There were no such bonuses awarded for fiscal year 2024.

#### *Equity-Based Compensation*

The Committee views equity-based compensation as a critical component of our total compensation program. Equity-based compensation creates an ownership culture among our NEOs that provides an incentive to contribute to our mission and align interest of NEOs with those of our stockholders. We do not currently have any formal policy for determining the number of equity-based awards to grant to NEOs, though our Committee does reference the Market Data from our independent consultant when approving annual equity awards, as well as reflects on our philosophy, program objectives, and key factors as described above.

For 2024, the Committee reviewed Market Data that captured both the grant date fair value of long-term incentives provided, as well as the size of long-term incentive grants expressed as a percentage of a company's common shares outstanding at that time. The Committee determined both reference points were important given the volatility of our share price leading up to the grant date, as well as the Committee's desire to balance delivering competitive value and awards that were not excessively dilutive to stockholders or punitive to our NEOs on that basis.

The Committee determined to allocate 50% of each NEO's equity award to time-vesting stock options and 50% to time-vesting Restricted Stock Units (RSUs) applying a 1.28 to 1 ratio for options to RSUs. The Committee reviewed Market Data and considered its desire to balance risk and reward, the volatility of our stock, and the

motivational and retention aspects of the awards in arriving at the decision to grant an equal mix of stock options and RSUs (after applying the 1.28 to 1 ratio of options to RSUs described above). In sizing each equity award, the Committee referenced the 50<sup>th</sup> percentile of the Market Data, as well as internal equity among NEOs.

As such, on January 16, 2024, in connection with our annual compensation review and approvals, the Committee approved the following grants to each of our NEOs other than Mr. Kelliher, who was not yet employed at our Company. Mr. Kelliher received a new hire grant upon commencing employment with us in March 2024, which was structured in the same fashion as the annual grants, while reflecting arm's length negotiations.

NEO	Award Type	Number of Shares Underlying Stock Options	Number of RSUs	Resulting Grant Date Fair Value
Michael Raab	Annual	605,904	475,000	\$8,335,121
Justin Renz	Annual	164,000	127,750	\$2,248,883
Elizabeth Grammer	Annual	164,000	127,750	\$2,248,883
Laura Williams, M.D., M.P.H.	Annual	152,127	118,750	\$2,088,255
Michael Kelliher	New Hire	205,000	160,000	\$2,470,303

Each annual stock option grant disclosed above vests and becomes exercisable in substantially equal monthly installments over four years from the grant date, subject to each holder continuing to provide services to us through such dates. The New Hire stock option grant awarded to Mr. Kelliher also vests and becomes exercisable over four years from the grant date, subject to Mr. Kelliher continuing to provide services to us through such dates but contains a one-year cliff vest of 25% of the award, with vesting thereafter on a monthly ratable basis. The Annual RSU grants vest in substantially equal quarterly installments over four years on each of the Company's designated quarterly RSU vest dates following the grant date, subject to each holder continuing to provide services to us through such dates. Our New Hire RSUs contain a one-year cliff vest of 25% of the award, with vesting thereafter on a quarterly ratable basis.

### ***Retirement Savings and Health and Welfare Benefits***

#### ***Retirement Programs***

We maintain a 401(k) retirement savings plan for our employees, including our NEOs, who satisfy certain eligibility requirements. Our NEOs are eligible to participate in the 401(k) plan on the same terms as other full-time employees. We believe that providing a vehicle for tax-deferred retirement savings through our 401(k) plan adds to the overall desirability of our executive compensation package and further incentivizes our employees, including our NEOs, in accordance with our compensation policies. In 2023, the compensation committee and board of directors approved matching employer contributions under our 401(k) plan for all employees participating in the 401(k) plan, with all contributions to vest immediately, and the Company match to be 0.5% of the first 3% of the employee's contribution.

All of our full-time employees, including our NEOs, are eligible to participate in our health and welfare plans. These health and welfare plans include medical, dental and vision benefits; short-term and long-term disability insurance; and supplemental life and AD&D insurance.

#### ***Perquisites and Other Personal Benefits***

We did not provide any perquisites or personal benefits to our NEOs not otherwise made available to other employees in 2024.

#### ***Employment and Severance Arrangements***

We have entered into an employment agreement with our CEO and an offer letter and a change in control severance agreement with each of our other NEOs. Our CEO's employment agreement and our NEOs' offer letters set forth the terms and conditions of employment of our NEOs, including base salary and standard employee benefit plan participation and, in the case of offer letters, initial equity awards. Our CEO's employment agreement and other NEOs' change in control severance agreements provide for severance benefits and payments upon certain terminations without cause or resignations for good reason. The Committee believes that these types

of arrangements are necessary to attract and retain executive talent and are a customary component of executive compensation. In particular, such arrangements can serve to mitigate a potential disincentive for them when they are evaluating a potential acquisition of the Company and can encourage retention through the conclusion of the transaction. The payments and benefits provided under our CEO's employment agreement and our other NEOs' change in control severance agreements are described in more detail and quantified below under "—Potential Payments Upon Termination or Change in Control."

### ***Other Aspects of our Compensation Program***

#### *Recovery of Erroneously Awarded Compensation Policy*

Our Policy for Recovery of Erroneously Awarded Compensation (the "Clawback Policy") is intended to comply with SEC and Nasdaq listing standards and maintain a culture of focused, diligent, and responsible management that discourages conduct detrimental to our growth. Accordingly, as set forth in the Clawback Policy, we are required to recover certain erroneously paid incentive-based compensation of our current and former executive officers in the event we are required to prepare a qualifying accounting restatement. The Clawback Policy provides that such erroneously paid incentive-based compensation may also be recovered from other compensation payable by us.

#### *Equity Granting Practices*

From time to time, we grant equity awards, including stock options and RSUs, to our employees, including our NEOs. Our typical practice is to grant employee equity awards upon an individual's commencement of employment. We typically grant annual refresh employee equity grants in the first quarter of each fiscal year, which refresh grants are typically approved at a regularly scheduled meeting of the Committee occurring in such quarter. In addition, non-employee directors receive grants of initial and annual equity awards, at the time of a director's initial appointment or election to the board and at the time of each annual meeting of our stockholders, respectively, pursuant to our non-employee director compensation program. We do not otherwise maintain any written policies on the timing of awards of stock options, stock appreciation rights, or similar instruments with option-like features. The Committee considers whether there is any material nonpublic information ("MNPI") about our Company when determining the timing of stock option grants and it does not seek to time the award of stock options in relation to the Company's public disclosure of MNPI. We have not timed the release of MNPI for the purpose of affecting the value of executive compensation.

During fiscal year 2024, we did not grant stock options or similar option-like instruments to our NEOs during the four business days prior to or the one business day following the filing of our periodic reports or the filing or furnishing of a Form 8-K that discloses MNPI.

#### *Insider Trading*

All employees, officers, members of our board of directors and certain consultants of the Company are subject to our Insider Trading Compliance Policy. The policy prohibits the covered individuals from purchasing or selling any of our securities while in possession of material nonpublic information. Our Insider Trading Compliance Policy also prohibits covered individuals, including our NEOs, from (i) making short sales of our securities, (ii) engaging in transactions in puts, calls or other options or derivative instruments related to our securities, (iii) engaging in any hedging or similar transaction designed to decrease the risks associated with holding our securities and (iv) purchasing our securities on margin or pledging our securities as collateral.

#### *Accounting and Tax Considerations*

As a general matter, our Committee reviews and considers the various tax and accounting implications of compensation programs we utilize. We account for equity compensation paid to our employees under the rules of Financial Accounting Standards Board Accounting Standard Codification Topic 718, Compensation—Stock Compensation ("ASC Topic 718"). Accounting standards also require us to record cash compensation as an expense at the time the obligation is accrued.

### *Compensation Risk Assessment*

The Committee carefully considered whether our compensation policies and practices were reasonably likely to have a material adverse effect on the Company. The Committee believes that the mix and design of our compensation plans and policies do not encourage management to assume excessive risks and are not reasonably likely to have a material adverse effect on the Company. The Committee considered several factors in assessing the overall risk of our compensation program:

- ☒ We offer a base salary component of compensation, as well as certain health and welfare benefits, to provide employees fixed compensation and support regardless of performance
- ☒ Our Cash Based Incentive Compensation Program has a range of metrics and outcomes that promote a balanced view of performance and is not binary in application
- ☒ Certain aspects of the Company's Cash Based Incentive Program include qualitative consideration, which restrain the influence of formulae or quantitative factors on excessive risk taking
- ☒ We use multiple incentive plan metrics covering key financial, scientific, operational, strategic, and people goals
- ☒ We set performance goals that we believe are reasonable to achieve
- ☒ The Committee has full discretion to adjust the Cash Based Incentive Compensation funding at the end of year
- ☒ We utilize both short- and long-term incentives to balance risk and reward
- ☒ We grant long-term incentive awards that have a multi-year vesting schedule to promote a long-term view and decision-making
- ☒ We maintain a Clawback Policy

## **REPORT OF THE COMPENSATION COMMITTEE OF THE BOARD OF DIRECTORS**

*The material in this report is not “soliciting material,” is not deemed “filed” with the Securities and Exchange Commission, and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.*

The Compensation Committee has reviewed and discussed the disclosure set forth above under the heading “Compensation Discussion and Analysis” with management and, based on such review and discussions, it has recommended to the board of directors that the “Compensation Discussion and Analysis” be included in this proxy statement and incorporated by reference into our Annual Report on Form 10-K for the fiscal year ended December 31, 2024.

### **Compensation Committee**

David Mott, Chairperson

Robert Bazemore

Muna Bhanji

Richard Rodgers

## EXECUTIVE COMPENSATION TABLES

### 2024 Summary Compensation Table

The following table contains information regarding the compensation earned by each of our named executive officers during the fiscal years ended December 31, 2024, 2023 and 2022.

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards \$( <sup>(1)</sup> )	Option Awards \$( <sup>(1)</sup> )	Non-Equity Incentive Plan Compensation \$( <sup>(2)</sup> )	All other Compensation \$( <sup>(3)</sup> )	Total (\$)
Michael Raab . . . . .	2024	770,000	—	4,170,500	4,164,621	495,880	5,164	9,606,165
President, Chief	2023	700,000	330,000	687,500	2,395,694	—	4,950	4,118,144
Executive Officer and	2022	650,000	300,000 <sup>(4)</sup>	148,500	517,020	331,500	—	1,947,020
Director								
Justin Renz . . . . .	2024	517,000	—	1,121,645	1,127,238	214,038	3,932	2,983,853
Chief Financial and								
Operations Officer								
Elizabeth Grammer . . . . .	2024	509,300	—	1,121,645	1,127,238	210,850	4,273	2,973,306
Chief Legal and	2023	463,300	200,000	214,500	748,121	—	4,950	1,630,871
Administrative Officer								
Laura Williams, M.D., M.P.H. . . .	2024	522,720	—	1,042,625	1,045,630	216,406	—	2,827,381
Chief Medical Officer	2023	483,600	181,210	214,500	748,121	—	—	1,627,431
	2022	465,000	250,000 <sup>(4)</sup>	39,600	141,811	158,800	—	1,055,211
Michael Kelliher <sup>(5)</sup> . . . . .	2024	338,461	—	1,232,000	1,238,303	182,160	—	2,990,924
EVP, Corporate								
Development and								
Strategy								

- (1) The amounts reported in the Stock Awards and Option Awards columns represent the grant date fair value of the restricted stock units and stock options granted to our named executive officers as computed in accordance with ASC 718. The assumptions used in calculating the grant date fair value of the restricted stock units and stock options reported in the Stock Awards and Option Awards columns are set forth in Note 13 to the audited financial statements included in our Annual Report on Form 10-K filed on February 20, 2025. The amounts reported in this column exclude the impact of forfeitures related to service-based vesting conditions. Note that the amounts reported in these columns reflect the accounting cost for these equity awards and do not correspond to the actual economic value that may be received by the named executive officers from the equity awards.
- (2) The amounts reported in the Non-Equity Incentive Plan Compensation column represent annual cash performance-based bonuses earned by our NEOs pursuant to the achievement of certain company performance objectives.
- (3) The amounts reported in the All Other Compensation column represent employer matching contributions under our 401(k) plan.
- (4) The amounts represent discretionary retention bonuses paid to our NEOs in December 2022.
- (5) Mr. Kelliher commenced employment with us on March 25, 2024.



## 2024 Grants of Plan-Based Awards Table

Name	Award Type	Grant Date	Estimated Future Payouts Under Non-Equity Incentive Plan Awards <sup>(1)</sup>		All other stock awards: Number of shares of stock or unit	All other option awards: Number of shares underlying options	Exercise or base price of option award (\$/share)	Grant date fair value of stock and option awards (\$) <sup>(2)</sup>
			Threshold	Target				
Michael Raab . . . . .	Option <sup>(3)</sup>	1/16/2024	—	—	—	605,904	\$8.78	\$4,164,421
	RSU <sup>(4)</sup>	1/16/2024	—	—	475,000	—	—	\$4,170,500
	—	—	\$26,950	\$539,000	—	—	—	—
Justin Renz . . . . .	Option <sup>(3)</sup>	1/16/2024	—	—	—	164,000	\$8.78	\$1,127,238
	RSU <sup>(4)</sup>	1/16/2024	—	—	127,750	—	—	\$1,121,645
	—	—	\$11,633	\$232,650	—	—	—	—
Elizabeth Grammer . . .	Option <sup>(3)</sup>	1/16/2024	—	—	—	164,000	\$8.78	\$1,127,238
	RSU <sup>(4)</sup>	1/16/2024	—	—	127,750	—	—	\$1,121,645
	—	—	\$11,459	\$229,185	—	—	—	—
Laura Williams, . . . . . M.D., M.P.H.	Option <sup>(3)</sup>	1/16/2024	—	—	—	152,127	\$8.78	\$1,045,630
	RSU <sup>(4)</sup>	1/16/2024	—	—	118,750	—	—	\$1,042,625
	—	—	\$11,762	\$235,224	—	—	—	—
Michael Kelliher . . . . .	Option <sup>(5)</sup>	3/25/2024	—	—	—	205,000	\$7.70	\$1,238,303
	RSU <sup>(6)</sup>	3/25/2024	—	—	160,000	—	—	\$1,232,000
	—	—	\$ 9,900	\$198,000	—	—	—	—

- (1) Non-equity incentive plan awards consist of performance-based cash bonuses earned based on achievement of pre-determined performance criteria during fiscal year 2024. There is no maximum payout amount under the non-equity incentive plan. The 2024 cash incentive bonus determinations are described in more detail above under the heading “Cash-Based Incentive Compensation.”
- (2) Amounts represent the aggregate grant date fair value of RSU and stock option awards granted to our named executive officers, computed in accordance with ASC Topic 718 and excluding the effect of estimated forfeitures related to service-based vesting conditions. The assumptions used in the valuation of these awards are set forth in Note 13 to the audited financial statements included in our Annual Report on Form 10-K filed on February 20, 2025.
- (3) Represents annual grants of stock options to our NEOs, except Mr. Kelliher, in 2024. The option awards vest in substantially equal monthly installments over four years from the vesting commencement date, subject to the holder continuing to provide services to us through each such date.
- (4) Represents annual grants of RSU awards to our NEOs, except Mr. Kelliher, in 2024. The awards of restricted stock units vest in substantially equal quarterly installments over four years from the vesting commencement date, on each of February 19; May 19; August 19 and November 19, subject to the holder continuing to provide services to us through each such date.
- (5) Represents the new hire grant of stock options to Mr. Kelliher. The option award vests and becomes exercisable as to 25% of the shares subject to the option on the one year anniversary of the vesting commencement date, and as to 1/48th of the shares subject to the option each month thereafter, subject to the holder continuing to provide services to us through each such date.
- (6) Represents the new hire grant of RSU awards to Mr. Kelliher. The restricted stock unit award vests as to 25% of the restricted stock units subject to the award on May 19, 2025, and as to 1/16th of the shares subject to the restricted stock unit on each February 19; May 19; August 19 and November 19, subject to the holder continuing to provide services to us through each such date.



## Outstanding Equity Awards at Fiscal Year-End 2024

The following table sets forth certain information regarding the exercise of options to purchase shares of our common stock by our NEOs during 2024, and the vesting of RSUs with respect to shares of our common stock that were held by our NEOs during the year ended December 31, 2024.

Name	Vesting Commencement Date	Option Awards <sup>(1)</sup>				Stock Awards <sup>(2)</sup>	
		Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	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 (\$) <sup>(3)</sup>
Michael Raab . . . . .	1/16/2024	138,853	467,051	8.78	1/16/2034	356,248	1,806,177
	1/5/2023	538,583	585,417	2.75	1/5/2033	125,000	633,750
	1/6/2022	330,416	189,584	0.99	1/6/2032	37,500	190,125
	1/5/2021	507,168	10,791	6.35	1/5/2031	—	—
	1/9/2020	557,460	—	7.60	1/9/2030	—	—
	1/17/2019	455,000	—	2.32	1/17/2029	—	—
	7/26/2018	185,000	—	4.30	7/26/2028	—	—
	1/16/2018	390,348	—	7.10	1/16/2028	—	—
	8/9/2017	79,535	—	4.70	8/8/2027	—	—
	1/19/2017	318,141	—	13.90	1/18/2027	—	—
	1/15/2016	301,258	—	10.55	1/14/2026	—	—
	1/6/2015	75,000	—	23.02	1/6/2025	—	—
Justin Renz . . . . .	1/16/2024	37,583	126,417	8.78	1/16/2034	95,810	485,757
	1/5/2023	168,187	182,813	2.75	1/5/2033	39,000	197,730
	1/6/2022	67,916	53,084	0.99	1/6/2032	10,500	53,235
	1/5/2021	143,697	3,058	6.35	1/5/2031	—	—
	6/8/2020	195,017	—	7.35	6/8/2030	—	—
Elizabeth Grammer . . .	1/16/2024	37,583	126,417	8.78	1/16/2034	95,810	485,757
	1/5/2023	58,500	182,813	2.75	1/5/2033	39,000	197,730
	1/6/2022	32,666	53,084	0.99	1/6/2032	10,500	53,235
	1/5/2021	143,697	3,058	6.35	1/5/2031	—	—
	1/9/2020	139,365	—	7.60	1/9/2030	—	—
	1/17/2019	78,000	—	2.32	1/17/2029	—	—
	7/26/2018	54,730	—	4.30	7/26/2028	—	—
	1/16/2018	117,104	—	7.10	1/16/2028	—	—
	8/9/2017	19,884	—	4.70	8/8/2027	—	—
	1/19/2017	79,535	—	13.90	1/18/2027	—	—
	1/15/2016	102,701	—	10.55	1/14/2026	—	—
	1/6/2015	11,450	—	23.02	1/6/2025	—	—
Laura Williams, . . . . . M.D., M.P.H.	1/16/2024	34,862	117,265	8.78	1/16/2034	89,062	—
	1/5/2023	68,187	182,813	2.75	1/5/2033	39,000	—
	1/6/2022	110,000	52,000	0.99	1/6/2032	10,000	—
	11/2/2020	105,000	—	5.19	11/2/2030	—	—
Michael Kelliher . . . . .	3/25/2024 <sup>(4)</sup>	—	205,000	7.70	3/25/2034	160,000	811,200

- (1) Except as otherwise noted, each option vests and becomes exercisable in substantially equal monthly installments over four years from the vesting commencement date, subject to the holder continuing to provide services to us through each such date.
- (2) Except as otherwise noted, each award of restricted stock units vest in substantially equal quarterly installments over four years from the vesting commencement date, on each of February 19; May 19; August 19 and November 19, subject to the holder continuing to provide services to us through each such date.
- (3) Amounts calculated based on the \$5.07 closing trading price of our common stock as of December 31, 2024, the last trading day of fiscal year 2024.
- (4) The option award vests and becomes exercisable as to 25% of the shares subject to the option on the one year anniversary of the vesting commencement date, and as to 1/48th of the shares subject to the option each month thereafter, subject to the holder continuing to provide services to us through each such date, and the restricted stock unit award vests as to 25% of the restricted stock units subject to the award on May 19, 2025, and as to 1/16th of the shares subject to the restricted stock unit on each February 19; May 19; August 19 and November 19, subject to the holder continuing to provide services to us through each such date.

## Option Exercises and Stock Vested Table

The following table sets forth certain information regarding the exercise of options to purchase shares of our common stock by our NEOs during 2024, and the vesting of RSUs with respect to shares of our common stock that were held by our NEOs during the year ended December 31, 2024.

Name	Option Awards		RSU Awards	
	Number of Shares Acquired on Exercise	Value Realized on Exercise (\$) <sup>(1)</sup>	Number of Shares Acquired on Vesting	Value Realized on Vesting (\$)
Michael Raab	180,000	\$ 897,400	247,526	\$1,709,789
Justin Renz	—	—	70,092	\$ 484,161
Elizabeth Grammer, Esq.	219,937	\$1,601,636	70,092	\$ 484,161
Laura Williams, M.D., M.P.H.	130,000	\$ 669,900	65,020	\$ 449,126
Michael Kelliher	—	—	—	—

(1) The value realized on exercise is based on the difference between the closing market price of our common stock on the date of exercise and the applicable exercise price of those options multiplied by the number of shares underlying the options.

(2) The value realized on vesting is based on the number of shares of our common stock underlying the RSU awards that vested multiplied by the closing market price of our common stock on the vesting date.

## Pension Benefits

We do not maintain any defined benefit pension plans.

## Nonqualified Deferred Compensation

We do not maintain any nonqualified deferred compensation plans.

## Potential Payments Upon Termination or Change in Control

As described above, we have entered into an employment agreement with our CEO and a change in control severance agreement with each of our other NEOs, which provide for the following severance benefits.

Under Mr. Raab's amended and restated employment agreement, in the event Mr. Raab's employment with us is involuntarily terminated for reason other than "cause" or he resigns for "good reason" (each, as defined below), in each case more than three months prior to or more than 12 months after a change in control, then Mr. Raab will receive: (i) continued payment of his annual base salary as in effect immediately prior to such termination for a period of 12 months; (ii) payment of healthcare continuation costs for him and his eligible dependents for up to 12 months following the date of such termination; and (iii) 12 months of accelerated vesting of any outstanding equity awards, with any options remaining exercisable until the earlier of 12 months following the date of termination or the original expiration date. In the event Mr. Raab's employment with us is involuntarily terminated for reason other than cause or he resigns for good reason, in each case within three months prior to and 12 months after a change in control, then Mr. Raab will receive: (i) a lump sum amount equal to 1.5 multiplied by the sum of (a) his base salary as in effect immediately prior to such termination and (b) his target annual bonus for the year of termination; (ii) payment of healthcare continuation costs for him and his eligible dependents for up to 18 months following the date of such termination; and (iii) full accelerated vesting of any outstanding equity awards, with any options remaining exercisable until the earlier of 12 months following the date of termination or the original expiration date. The foregoing severance benefits are subject to Mr. Raab's timely execution and non-revocation of a general release of claims against the Company and its affiliates.

Under each other NEO's change in control severance agreements, in the event the named executive officer's employment with us is involuntarily terminated for reason other than cause or they resign for good reason, in each case more than three months prior to or more than 12 months after a change in control, then they will receive: (i) continued payment of their annual base salary as in effect immediately prior to such termination for a period of nine months; and (ii) payment of healthcare continuation costs for them and their eligible dependents for up to 12 months following the date of such termination. In the event their employment with us is involuntarily terminated for reason other than cause or they resign for good reason, in each case within

three months prior to and 12 months after a change in control, then they will receive: (i) a lump sum amount equal to (a) the sum of their base salary as in effect immediately prior to such termination and (b) their target annual bonus for the year of termination; (ii) payment of healthcare continuation costs for them and their eligible dependents for up to 12 months following the date of such termination; and (iii) full accelerated vesting of any outstanding equity awards, with any options remaining exercisable until the earlier of 12 months following the date of termination or the original expiration date. The foregoing severance benefits are subject to the named executive officer's timely execution and non-revocation of a general release of claims against the Company and its affiliates and continued compliance with their confidential information agreement.

For the purposes of Mr. Raab's amended and restated employment agreement and each of the other NEO's change in control severance agreements, "cause" means (i) the named executive officer's theft, dishonesty or falsification of any employment or company records that is non-trivial in nature; (ii) malicious or reckless disclosure of our confidential or proprietary information or any material breach by the named executive officer of their obligations under their proprietary information and inventions assignment agreement with us; (iii) the conviction of the named executive officer of a felony (excluding motor vehicle violations) or the commission of gross negligence or willful misconduct, where a majority of the non-employee members of the board of directors reasonably determines that such act or misconduct has (A) seriously undermined the ability of the board of directors or management to entrust them with important matters or otherwise work effectively with them, (B) substantially contributed to our loss of significant revenues or business opportunities, or (C) significantly and detrimentally affected the business or reputation of our company or any of our subsidiaries; and/or (iv) the willful failure or refusal by the named executive officer to follow the reasonable and lawful directives of the board of directors, provided such willful failure or refusal continues after their receipt of reasonable notice in writing of such failure or refusal and a reasonable opportunity of not less than 30 days to correct the problem.

For the purposes of Mr. Raab's amended and restated employment agreement and each of the other NEO's change in control severance agreements, "good reason" includes the occurrence of: (i) a material diminution in the NEO's authority, duties, or responsibilities, which substantially reduces the nature or character of their position; (ii) a reduction (or material reduction, in the case of each named executive officer other than Mr. Raab) of their base salary as in effect immediately prior to such reduction; (iii) a relocation of their principal office to a location more than 50 miles from the location of our principal office as of immediately prior to such relocation, except for required travel by them on company business; or (iv) any material breach by us of any provision of the named executive officer's employment agreement or offer letter which we do not cure within 30 days following written notice from the NEO, provided that in order for "good reason" to exist, each of the following conditions must be met: (i) the foregoing good reason conditions must have occurred without the named executive officer's express written consent; (ii) the named executive officer must provide written notice to us of such condition within 30 days of the initial existence of the condition; (iii) the condition specified in such notice must remain uncorrected for 30 days after receipt of such notice; and (iv) the date of the named executive officer's resignation of employment must occur within 60 days after the initial existence of the condition specified in such notice.

The following table provides information concerning the estimated payments and benefits that would be provided in the circumstances described above for each of our NEOs. Except where otherwise noted, payments and benefits are estimated assuming that the triggering event took place on December 31, 2024, and a fair market value of our common stock on December 31, 2024 of \$5.07 per share (determined based on the closing trading price of a share of our common stock on December 31, 2024). There can be no assurance that a triggering event would produce the same or similar results as those estimated below if such event occurs on any other date.

Name	Type of Payment	Covered Termination Unrelated to a Change in Control	Covered Termination in Connection with a Change in Control
<b>Michael Raab</b> .....	<i>Cash Severance Benefits</i>		
	Base Salary	\$ 770,000	\$1,155,000
	Target Bonus	—	\$ 808,500
	<i>Equity Awards</i>		
	RSUs <sup>(1)</sup>	\$1,109,053	\$2,630,052
	Options <sup>(2)</sup>	\$1,365,920	\$2,131,670
	Healthcare Benefits <sup>(3)</sup>	\$ 23,500	\$ 35,250
	<b>Total</b>	<b>\$3,268,473</b>	<b>\$6,760,472</b>
<b>Justin Renz</b> .....	<i>Cash Severance Benefits</i>		
	Base Salary	\$ 387,750	\$ 517,000
	Target Bonus	—	\$ 232,650
	<i>Equity Awards</i>		
	RSUs <sup>(1)</sup>	—	\$ 736,722
	Options <sup>(2)</sup>	—	\$ 640,709
	Healthcare Benefits <sup>(3)</sup>	\$ 33,300	\$ 33,300
	<b>Total</b>	<b>\$ 421,050</b>	<b>\$2,160,381</b>
<b>Elizabeth Grammer</b> .....	<i>Cash Severance Benefits</i>		
	Base Salary	\$ 381,975	\$ 509,300
	Target Bonus	—	\$ 229,185
	<i>Equity Awards</i>		
	RSUs <sup>(1)</sup>	—	\$ 736,722
	Options <sup>(2)</sup>	—	\$ 640,709
	Healthcare Benefits <sup>(3)</sup>	\$ 33,300	\$ 33,300
	<b>Total</b>	<b>\$ 415,275</b>	<b>\$2,149,216</b>
<b>Laura Williams, M.D., M.P.H.</b> .....	<i>Cash Severance Benefits</i>		
	Base Salary	\$ 392,025	\$ 522,720
	Target Bonus	—	\$ 235,224
	<i>Equity Awards</i>		
	RSUs <sup>(1)</sup>	—	\$ 699,974
	Options <sup>(2)</sup>	—	\$ 636,286
	Healthcare Benefits <sup>(3)</sup>	\$ 17,000	\$ 17,000
	<b>Total</b>	<b>\$ 409,025</b>	<b>\$2,111,204</b>
<b>Michael Kelliher</b> .....	<i>Cash Severance Benefits</i>		
	Base Salary	\$ 330,000	\$ 440,000
	Target Bonus	—	\$ 198,000
	<i>Equity Awards</i>		
	RSUs <sup>(1)</sup>	—	\$ 811,200
	Options <sup>(2)</sup>	—	—
	Healthcare Benefits <sup>(3)</sup>	\$ 33,300	\$ 33,300
	<b>Total</b>	<b>\$ 363,300</b>	<b>\$1,482,500</b>

- (1) The value of accelerated vesting for restricted stock units was based on \$5.07 per share, which was the closing trading price of our common stock on December 31, 2024.
- (2) The value of accelerated vesting for stock options was calculated by subtracting the exercise prices of options from \$5.07 per share, which was the closing trading price of our common stock on December 31, 2024. Options with exercise prices in excess of \$5.07 per share were excluded.
- (3) Represents the estimated value of the monthly COBRA premium that would otherwise be payable by the NEO and any eligible dependents multiplied by 12, based on the monthly cost of such benefits to the Company as of December 31, 2024.

In 2025, the Company entered into an amended and restated employment agreement with Mr. Raab (“the Second Amended and Restated Employment Agreement”) as well as amended and restated change in control and severance agreements with each of the other NEOs.

Under Mr. Raab’s Second Amended and Restated Employment Agreement, in the event Mr. Raab’s employment with us is involuntarily terminated for reason other than “cause” or he resigns for “good reason” (each, as defined above), in each case more than three months prior to or more than 12 months after a change in control, then Mr. Raab will receive: (i) continued payment of his annual base salary as in effect immediately prior to such termination for a period of 18 months; (ii) payment of healthcare continuation costs for him and his eligible dependents for up to 18 months following the date of such termination; and (iii) 18 months of accelerated vesting of any outstanding equity awards, with any options remaining exercisable until the earlier of 12 months following the date of termination or the original expiration date. In the event Mr. Raab’s employment with us is involuntarily terminated for reason other than cause or he resigns for good reason, in each case within three months prior to and 12 months after a change in control, then Mr. Raab will receive: (i) a lump sum amount equal to 2.0 multiplied by the sum of (a) his base salary as in effect immediately prior to such termination and (b) his target annual bonus for the year of termination; (ii) payment of healthcare continuation costs for him and his eligible dependents for up to 24 months following the date of such termination; and (iii) full accelerated vesting of any outstanding equity awards, with any options remaining exercisable until the earlier of 12 months following the date of termination or the original expiration date. The foregoing severance benefits are subject to Mr. Raab’s timely execution and non-revocation of a general release of claims against the Company and its affiliates.

Under the amended and restated change in control and severance agreements with each of the other NEOs, in the event the NEO’s employment with us is involuntarily terminated for reason other than cause or they resign for good reason, in each case more than three months prior to or more than 12 months after a change in control, then they will receive: (i) continued payment of their annual base salary as in effect immediately prior to such termination for a period of 12 months; (ii) payment of healthcare continuation costs for them and their eligible dependents for up to 12 months following the date of such termination; and (iii) 3 months of accelerated vesting of any outstanding equity awards for each year the NEO has been employed with the Company (up to 12 months). In the event their employment with us is involuntarily terminated for reason other than cause or they resign for good reason, in each case within three months prior to and 12 months after a change in control, then they will receive: (i) a lump sum amount equal to 1.5 multiplied by (a) the sum of their base salary as in effect immediately prior to such termination and (b) their target annual bonus for the year of termination; (ii) payment of healthcare continuation costs for them and their eligible dependents for up to 18 months following the date of such termination; and (iii) full accelerated vesting of any outstanding equity awards, with any options remaining exercisable until the earlier of 12 months following the date of termination or the original expiration date. The foregoing severance benefits are subject to the named executive officer’s timely execution and non-revocation of a general release of claims against the Company and its affiliates and continued compliance with their confidential information agreement.

## **2024 CEO Pay Ratio**

As required by Section 953(b) of the Dodd-Frank Wall Street Reform and Consumer Protection Act and Item 402(u) of Regulation S-K, we are providing information about the relationship of the annual total compensation of our employees and the annual total compensation of our President and CEO, Mr. Raab. The CEO pay ratio included below is a reasonable estimate calculated in a manner consistent with Item 402(u) of Regulation S-K. In complying with the CEO pay ratio disclosure requirements, companies are permitted to use a variety of assumptions and methodologies. As a result, the CEO pay ratio reported by other companies may not be comparable with the ratio reported below since all results are impacted by the nature of each company’s compensation reward structure and employee demographics and the chosen assumptions and methodologies permitted under the SEC rules.

### ***Ratio***

For the fiscal year that ended December 31, 2024, the estimated median annual total compensation of all our employees (excluding our CEO) was \$239,432 and the 2024 annual total compensation of our CEO, Mr. Raab, was \$9,606,165, as reported in the “Total” column of the 2024 Summary Compensation Table on page 34. Based on the foregoing, the estimated 2024 ratio of the annual total compensation of our CEO to the median of the annual total compensation of all employees is estimated to be approximately 40 to 1.

### ***Identifying the Median Employee and Calculating Total Compensation***

The CEO pay ratio disclosure rules require companies to identify a median employee only once every three years and to calculate total compensation for that median employee each year, provided that there has not been a significant change to the Company's employee population or employee compensation arrangements. For purposes of our 2024 CEO pay ratio calculation, we have used the median employee identified in 2024 through the process described below as this is the first year that the Company is disclosing the CEO pay ratio.

For purposes of identifying the median employee in 2024, we utilized the dollar amount reported in Box 5 of the 2024 Form W-2 Wage and Tax Statement provided for each U.S. employee on the Company's payroll as of December 31, 2024 and annualized the amounts for any employees hired during 2024. This consistently applied compensation measure was chosen because it is a readily available measure for all U.S. employees and we believe it is a reasonable measure of total annual compensation.

## Pay Versus Performance

### Pay Versus Performance Table

The following table sets forth information concerning the compensation provided to our NEOs and certain measures of Company performance in the years ended December 31, 2024, 2023, 2022 and 2021, for services to our Company in all capacities. The Compensation Committee did not consider the pay versus performance disclosure below in making its pay decisions for any of the fiscal years shown.

Year	Summary Compensation Table Total for PEO (\$)	Compensation Actually Paid to PEO (\$) <sup>(1)</sup>	Average Summary Compensation Table Total for Non-PEO NEOs (\$)	Average Compensation Actually Paid to Non-PEO NEOs (\$) <sup>(1)</sup>	Value of Initial Fixed \$100 Investment Based on Total Shareholder Return (“TSR”) (\$) <sup>(2)</sup>	Peer Group TSR (\$) <sup>(3)</sup>	Net Loss (\$ in millions)	Total Revenue (\$ in millions) <sup>(4)</sup>
2024 . . .	9,606,165	4,749,620	2,941,814	1,676,438	78	105	(39)	334
2023 . . .	4,113,194	10,055,709	1,626,676	3,344,278	96	101	(66)	124
2022 . . .	1,947,020	4,047,941	1,049,800	1,913,762	44	103	(67)	52
2021 . . .	4,230,994	39,202	1,700,013	584,783	17	92	(158)	10

- (1) Amounts represent compensation actually paid (“CAP”) to our CEO, Michael Raab, who was our Principal Executive Officer or “PEO” for each of the four years shown, and the average CAP to our remaining NEOs or “Non-PEO NEOs” for the relevant fiscal year, as determined under SEC rules, which includes Justin Renz, Elizabeth Grammer, Esq., Laura Williams, M.D., M.P.H., and Michael Kelliher for 2024, Laura Williams, M.D., M.P.H and Elizabeth Grammer, Esq. for 2023, Laura Williams, M.D., M.P.H. and Susan Rodriguez for 2022 and Justin Renz, Robert Blanks, Elizabeth Grammer, Esq. and David Rosenbaum, Ph.D. for 2021.

Amounts represent the Summary Compensation Table Total Compensation for the applicable fiscal year adjusted as follows:

#### Fiscal Year (“FY”)

	2024	
	PEO (\$)	Average non-PEO NEOs (\$)
2024 Summary Compensation Table Total . . . . .	9,606,165	2,941,814
Deduction for ASC 718 Fair Value as of Grant Date Reported under the Option Awards Columns in the Summary Compensation Table . . . . .	8,335,121	2,264,081
Increase based on ASC 718 Fair Value of Awards Granted during the FY that Remain Unvested as of FY End (“FYE”) . . . . .	2,972,646	919,554
Increase based on ASC 718 Fair Value of Awards Granted during the FY that Vested during the FY as of Vesting Date . . . . .	1,251,140	247,178
Increase/deduction based on ASC 718 Fair Value of Outstanding Unvested Prior FY Awards as of FYE Compared to Valuation as of Prior FYE . . . . .	(1,245,555)	(282,833)
Increase/deduction based on ASC 718 Fair Value of Prior FY Awards that Vested during the FY as of Vesting Date Compared to Valuation as of Prior FYE . . . . .	500,345	114,805
Total Adjustments . . . . .	(4,856,545)	(1,265,377)
Compensation Actually Paid . . . . .	4,749,620	1,676,438

- (2) Cumulative TSR is calculated by dividing the sum of the cumulative amount of dividends for the measurement period, assuming dividend reinvestment, and the difference between our company’s share price at the end and the beginning of the measurement period by our company’s share price at the beginning of the measurement period. No dividends were paid on our common stock in 2021, 2022, 2023 or 2024.
- (3) Represents the weighted peer group TSR, weighted according to the respective companies’ stock market capitalization at the beginning of each period for which a return is indicated. The peer group used for this purpose is the same peer group used in the review of our executive compensation, as disclosed under “Compensation Discussion and Analysis”. Please refer to “Use of Market Data” caption of the “Compensation Discussion and Analysis” for the names of the peer group companies.
- (4) We have selected total revenue as the most important financial measure used by us to link compensation actually paid for 2024 to our performance since it is the financial measure with the largest impact on the cash bonuses we pay our NEOs.

### Tabular List of Financial Performance Measures

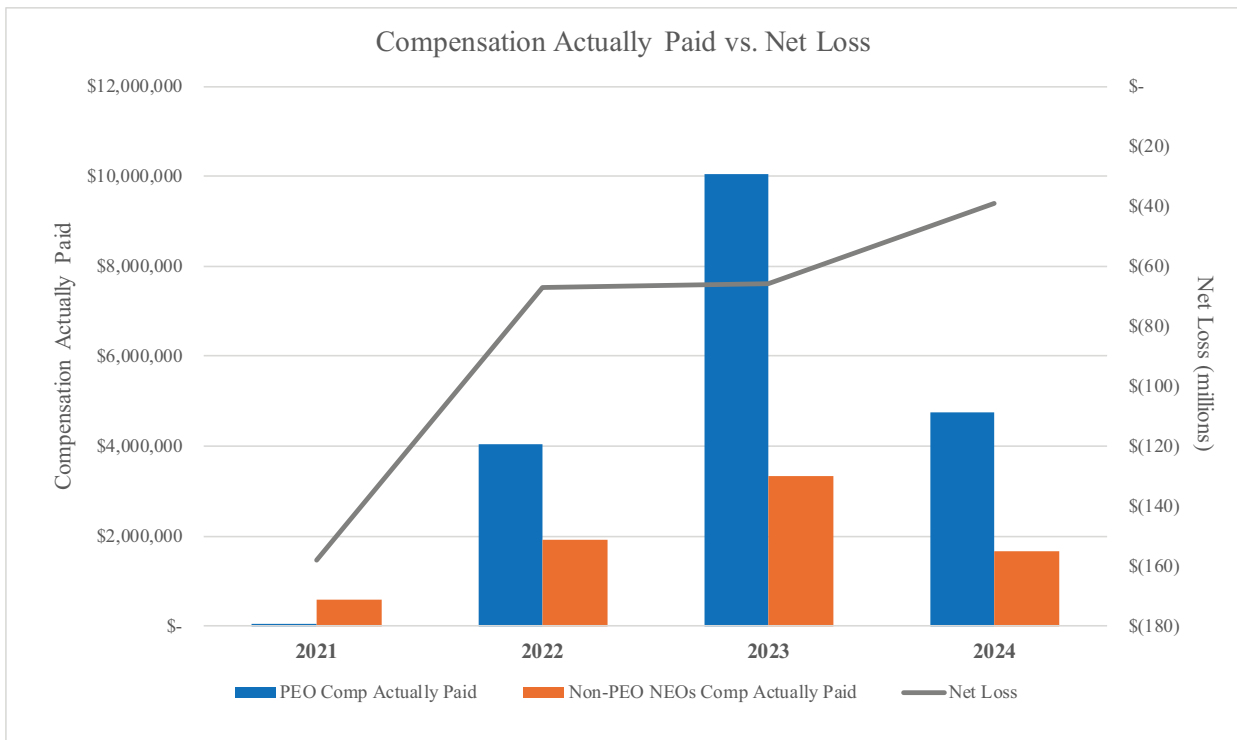
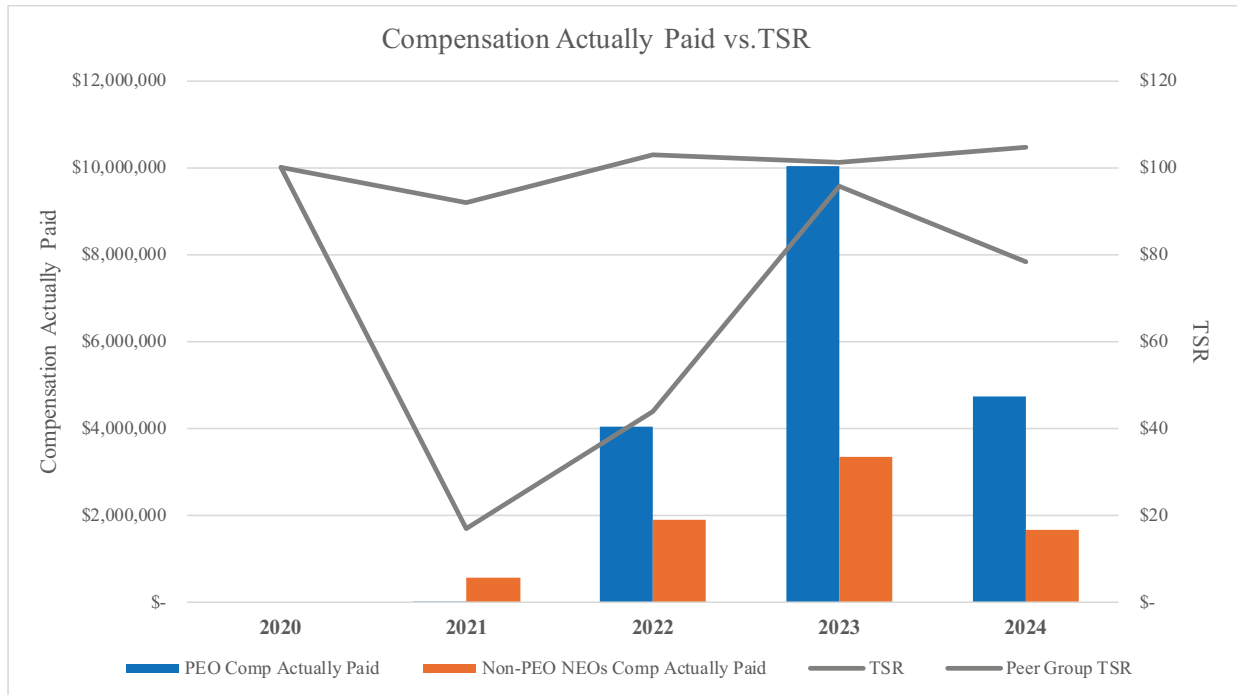
For 2024, the most important financial measures used to link compensation actually paid to our performance are as follows: (i) total revenue; (ii) net loss; and (iii) TSR.

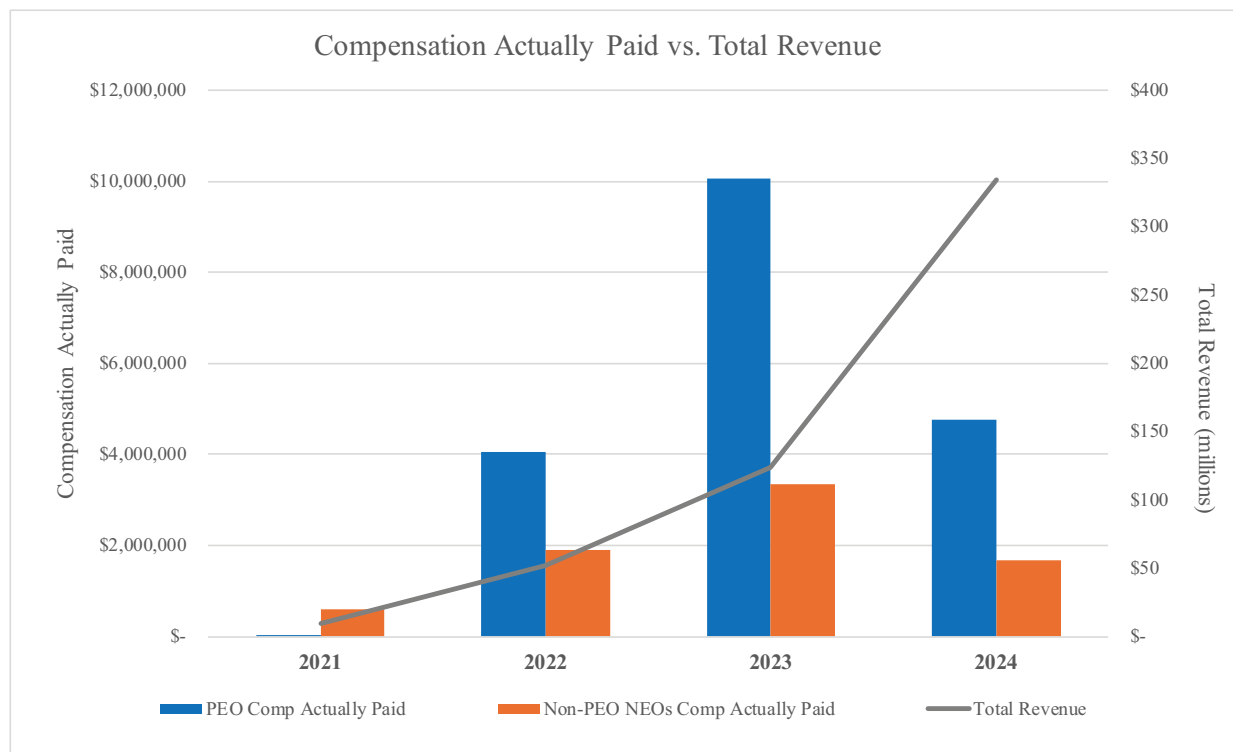


## Narrative Disclosure to Pay Versus Performance Table

### Relationship Between Financial Performance Measures

The graphs below compare the compensation actually paid to our PEO and the average of the compensation actually paid to our remaining NEOs, with (i) our cumulative TSR, and (ii) our net income, in each case, for the fiscal years ended December 31, 2021, 2022, 2023 and 2024.





### Equity Compensation Plan Information

The following table provides certain information as of December 31, 2024, with respect to all of our equity compensation plans in effect on that date:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights (a)	Weighted-Average Exercise Price of Outstanding Options and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity Compensation Plans Approved by Stockholders <sup>(1)</sup>	29,026,116	\$5.7186	21,793,333 <sup>(2)</sup>
Equity Compensation Plans Not Approved by Stockholders <sup>(3)</sup>	7,071,339	\$5.2141	3,948,969
<b>Total</b>	<b>36,097,455</b>		<b>25,742,302</b>

(1) Includes the Restated Plan and the 2014 Employee Stock Purchase Plan. The number of shares of common stock that may be issued pursuant to outstanding awards under the Restated Plan include: (A) 5,644,097 shares subject to outstanding restricted stock units and (B) 23,382,019 shares subject to stock options. The weighted average exercise price shown is for stock options; other outstanding awards had no exercise price.

(2) Includes 3,668,184 shares that were available for future issuances as of December 31, 2024 under the 2014 Employee Stock Purchase Plan (of which 222,734 shares were issued with respect to the purchase period in effect as of December 31, 2024, which purchase period ended on February 29, 2025), which allows eligible employees to purchase shares of common stock with accumulated payroll deductions.

(3) Includes the Ardelyx, Inc. 2016 Employment Commencement Incentive Plan. The number of shares of common stock that may be issued pursuant to outstanding awards under the 2016 Employment Commencement Incentive Plan include: (A) 2,368,767 shares subject to outstanding restricted stock units and (B) 4,702,572 shares subject to stock options. The weighted average exercise price shown is for stock options; other outstanding awards had no exercise price.

### PROPOSAL NO. 3

#### RATIFICATION OF SELECTION OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The audit and compliance committee of our board of directors has selected Ernst & Young LLP, or EY, as our independent registered public accounting firm for the year ending December 31, 2025, and is seeking ratification of such selection by our stockholders at the 2025 Annual Meeting. EY has audited our financial statements since the fiscal year ended December 31, 2014. Representatives of EY are expected to be present in attendance online at the 2025 Annual Meeting. They will have an opportunity to make a statement if they so desire and will be available to respond to appropriate questions.

Neither our Amended and Restated Bylaws nor other governing documents or law require stockholder ratification of the selection of EY as our independent registered public accounting firm. However, the audit and compliance committee is submitting the selection of EY to our stockholders for ratification as a matter of good corporate practice. If our stockholders fail to ratify the selection, the audit and compliance committee will reconsider whether or not to retain EY. Even if the selection is ratified, the audit and compliance committee in its discretion may select a different independent registered public accounting firm at any time during the year if they determine that such a change would be in the best interests of the Company and our stockholders.

The affirmative vote of a majority of the shares cast at the 2025 Annual Meeting will be required to ratify the selection of EY.

#### THE BOARD OF DIRECTORS RECOMMENDS A VOTE “FOR” PROPOSAL NO. 3

#### Independent Registered Public Accounting Firm Fees

For the fiscal years ended December 31, 2024 and 2023, EY billed the approximate fees set forth below. All fees included below were approved by the audit and compliance committee.

	<u>Year Ended December 31,</u>	
	<u>2024</u>	<u>2023</u>
Audit Fees <sup>(1)</sup> .....	\$2,284,700	\$2,190,710
Audit-Related Fees .....	—	—
Tax Fees <sup>(2)</sup> .....	\$ 3,425	\$ 2,936
All Other Fees .....	—	—
Total All Fees .....	<u>\$2,228,125</u>	<u>\$2,193,646</u>

(1) This category consists of fees and expenses for professional services rendered for the integrated audit of our annual financial statements and of our internal controls over financial reporting, reviews of our interim quarterly reports, reporting consultations, and the issuance of consents and comfort letters in connection with regulatory filings or engagements.

(2) This category consists of fees for professional services rendered by EY for tax compliance, tax advice and tax planning.

#### Pre-Approval Policies and Procedures

The audit and compliance committee has adopted a policy for the pre-approval of all audit and non-audit services to be performed for the Company by the independent registered public accounting firm. This policy is set forth in the charter of the audit and compliance committee and available at <http://ir.ardelyx.com/corporate-governance>. The policy provides that before an independent registered public accounting firm is engaged by Ardelyx or its subsidiaries to render audit or non-audit services, the audit and compliance committee must review the terms of the proposed engagement and pre-approve the engagement. Pre-approval of the audit and compliance committee of audit and non-audit services is not required if the engagement for the services is entered into pursuant to the pre-approval policies and procedures established by the audit and compliance committee regarding the Company's engagement of the independent registered public accounting firm, provided the policies and procedures are detailed as to the particular service, the audit and compliance committee is informed of each service provided and such policies and procedures do not include delegation of the audit and compliance committee's responsibilities under the Securities Exchange Act of 1934, as amended, to management. The audit and compliance committee may delegate to one or more members the authority to grant pre-approvals, provided such approvals are presented to the audit and compliance committee at a subsequent meeting. Audit and

compliance committee pre-approval of non-audit services (other than review and attest services) also will not be required if such services fall within available exceptions established by the SEC. The audit and compliance committee has considered the role of EY in providing audit and audit-related services to the Company and has concluded that such services are compatible with EY's role as the Company's independent registered public accounting firm.

## **REPORT OF THE AUDIT AND COMPLIANCE COMMITTEE OF THE BOARD OF DIRECTORS**

*The material in this report is not “soliciting material,” is not deemed “filed” with the Securities and Exchange Commission, and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.*

The primary purpose of the audit and compliance committee is to oversee our accounting and our financial reporting processes on behalf of our board of directors and our compliance with legal and regulatory requirements. The audit and compliance committee’s functions are more fully described in its charter, which is available on our website at <http://ir.ardelyx.com/corporate-governance>.

In fulfilling its oversight responsibilities, the audit and compliance committee reviewed and discussed with management the Company’s audited financial statements for the fiscal year ended December 31, 2024. The audit and compliance committee has discussed with Ernst & Young LLP, or EY, the Company’s independent registered public accounting firm, the matters required to be discussed by the applicable requirements of the Public Company Accounting Oversight Board, or PCAOB, and the Securities and Exchange Commission, or SEC. In addition, the audit and compliance committee has discussed with EY their independence, and received from EY the written disclosures and the letter required by PCAOB Ethics and Independence Rule 3526, “Communication with Audit Committees Concerning Independence.” Finally, the audit and compliance committee discussed with EY, with and without management present, the scope and results of EY’s audit of the financial statements for the fiscal year ended December 31, 2024.

Based on these reviews and discussions, the audit and compliance committee has recommended to our board of directors that such audited financial statements be included in our Annual Report on Form 10-K for the year ended December 31, 2024 for filing with the SEC.

### **Audit and Compliance Committee**

Richard Rodgers, Chairperson

William Bertrand, Jr., Esq.

David Mott

**PROPOSAL NO. 4**  
**APPROVAL OF AMENDMENT TO**  
**THE AMENDED AND RESTATED 2014 EQUITY INCENTIVE AWARD PLAN**

**Introduction**

Our stockholders are being asked to approve an amendment (the “Equity Plan Amendment”) to our Amended and Restated 2014 Equity Incentive Award Plan (the “Restated Plan”) to increase the maximum number of shares of Common Stock that may be delivered pursuant to awards granted under the Restated Plan by 10,000,000 shares of Common Stock.

On June 14, 2024, the Company’s stockholders approved the Restated Plan, which among other changes: (i) increased the shares reserved for issuance by 19,000,000 shares, (ii) increased certain non-employee director compensation limits, (iii) removed certain provisions previously included for tax deductibility purposes, (iv) removed the evergreen provision such that any increase to the total number of shares of common stock that may be issued under the Restated Plan must be approved by our stockholders, and (v) removed the fixed term so that the Restated Plan will continue until terminated by our board of directors or the share reserve thereunder is exhausted.

On April 28, 2025, our board of directors approved the Equity Plan Amendment subject to stockholder approval. The Equity Plan Amendment will become effective as of the date our stockholders approve the Equity Plan Amendment.

**Overview of Proposed Amendment**

We strongly believe that an employee equity compensation program is a necessary and powerful incentive and retention tool that benefits all stockholders. As of April 15, 2025, the total number of shares of our common stock reserved for issuance under the Restated Plan since inception was 58,457,566. As of April 15, 2025, the aggregate number of shares of common stock subject to outstanding awards under the Restated Plan was 38,362,417 and a total of 8,359,043 shares of common stock remained available under the Restated Plan for future issuance. Pursuant to the Equity Plan Amendment, an additional 10,000,000 shares will be reserved for issuance under the Restated Plan over the existing share reserve. There will continue to be no evergreen provision in the Restated Plan.

The Restated Plan also provides that up to 6,500,000 shares subject to outstanding awards under our 2016 Employment Commencement Incentive Plan (the “Inducement Plan”) as of the effective date of the Restated Plan that terminate, expire or lapse without the delivery of shares to the holder thereof or for which shares are repurchased or forfeited may be issued or transferred pursuant to awards under the Restated Plan. No new awards have been made under the Inducement Plan after the effective date of the Restated Plan.

All of the foregoing share numbers may be adjusted for changes in our capitalization and certain corporate transactions, as described below under the heading “Adjustments.”

The Restated Plan is not being amended in any material respect other than to reflect an increase of 10,000,000 shares reserved for issuance described above.

**Equity Incentive Awards Are Critical to Long-Term Stockholder Value Creation**

We believe that the adoption of the Equity Plan Amendment is essential to our success. Equity awards are intended to motivate high levels of performance, align the interests of our directors, employees and consultants with those of our stockholders by giving directors, employees and consultants the perspective of an owner with an equity stake in our company and providing a means of recognizing their contributions to the success of our company. Our board of directors and management believe that equity awards are necessary to remain competitive in our industry and are essential to recruiting and retaining the highly qualified employees who help our company meet its goals.

Our equity incentive program is broad-based. As of April 15, 2025, all of our employees had received grants of equity awards, and all six of our non-employee directors had received grants of equity awards. We do not typically make new grants of equity awards to our consultants. We believe we must continue to offer a competitive equity compensation plan in order to attract, retain and motivate the industry-leading talent imperative to our continued growth and success.

## Outstanding Awards Under Existing Plans

The table below presents information about the number of shares that were subject to various outstanding equity awards under our equity plans, and the shares remaining available for issuance under each such plan, each at April 15, 2025.

As of April 15, 2025, the Restated Plan and the Inducement Plan are the only equity incentive plans under which we can grant awards (other than the shares available for purchase under our 2014 Employee Stock Purchase Plan, or the 2014 ESPP), however, no new awards were made under the Inducement Plan following the effective date of the Restated Plan.

	Number of Shares	As a % of Shares Outstanding <sup>(1)</sup>	Dollar Value <sup>(2)</sup>
<b>Inducement Plan</b>			
Options outstanding . . . . .	4,388,190	1.83%	\$ 20,361,202
Weighted average exercise price of outstanding options . . . . .	\$ 5.36		
Weighted average exercise remaining term of outstanding options . . . . .	7.28		
Restricted stock units outstanding . . . . .	2,096,301	0.88%	\$ 9,726,837
Shares available for future issuance under the Inducement Plan <sup>(3)</sup> . . . . .	3,948,969	1.65%	\$ 18,323,216
<b>Restated Plan</b>			
Options outstanding . . . . .	26,474,147	11.07%	\$122,840,042
Weighted average exercise price of outstanding options . . . . .	\$ 5.62		
Weighted average exercise remaining term of outstanding options . . . . .	7.14		
Restricted stock units outstanding . . . . .	11,888,270	4.97%	\$ 55,161,573
Shares available for future issuance under the 2014 Plan . . . . .	8,359,043	3.49%	\$ 38,785,960
<b>Equity Plan Amendment</b>			
Proposed increase to share reserve under Restated Plan (over existing share reserve under the Restated Plan) . . . . .	10,000,000	4.18%	\$ 46,400,000

(1) Based on 239,255,066 shares of our common stock outstanding as of April 15, 2024.

(2) Based on the closing price of our common stock on April 15, 2024 of \$4.64 per share.

(3) To be effective as of the date the Company's stockholders approve the Equity Plan Amendment, the board of directors has eliminated any remaining reserve under the Inducement Plan.

## Background for the Determination of the Share Reserve under the Equity Plan Amendment

In determining whether to approve the Equity Plan Amendment, and in setting the size of the share reserve increase proposed under the Equity Plan Amendment, our board of directors considered:

- the historical amounts of equity awards granted by our company in the past three years. In 2022, 2023 and 2024, equity awards representing a total of approximately 6,137,663 shares, 8,208,310 shares, and 14,250,725 shares, respectively, were granted under our 2014 Plan, for an annual equity burn rate of 4.7%, 3.5%, and 6.0% respectively. This level of equity awards represents a 3-year average burn rate attributable to our Restated Plan of 4.7% of common shares outstanding. Equity burn rate is calculated by dividing the number of shares subject to equity awards granted during the fiscal year by the number of common shares outstanding at the end of the fiscal year. The equity burn in 2024 was higher than in prior years because of the growth of the Company's employee base associated with its commercialization of its two products which resulted in a larger number of employees receiving annual equity grants in 2024, as well as the Company's continued commercial expansion and hiring in 2024, resulting in a higher number of new hire grants.
- We expect the share authorization under the Restated Plan, as amended by the Equity Plan Amendment, to provide us with enough shares for awards for 2025 and 2026 assuming we continue to grant awards consistent with our current practices and historical usage, as reflected in our historical burn rate, and further dependent on the price of our shares and hiring activity during the next few years, forfeitures of



outstanding awards, and noting that future circumstances may require us to change our current equity grant practices. We cannot predict our future equity grant practices, the future price of our shares or future hiring activity with any degree of certainty at this time, and the share reserve under the Restated Plan, as amended by the Equity Plan Amendment, could last for a shorter or longer time.

- In 2022, 2023 and 2024, our end of year overhang rate (excluding shares available for issuance under our 2014 ESPP) was 11.5%, 9.9%, and 19.8%, respectively. If the Equity Plan Amendment is approved, we expect our overhang rate attributable to the Restated Plan at the end of 2025 will be approximately 24.0%. When modeling overhang including only “in-the-money” options (where options with an exercise price above \$5.00 are considered not “in-the money”), the expected overhang rate attributable to the Restated Plan at the end of 2025 is expected to be approximately 15.9%. Overhang for this purpose is calculated by dividing (1) the sum of the number of shares subject to equity awards outstanding at the end of the fiscal year plus shares remaining available for issuance for future awards at the end of the fiscal year (excluding shares available for issuance under our 2014 ESPP) by (2) the number of shares outstanding at the end of the fiscal year.
- In light of the factors described above, and the fact that the ability to continue to grant equity compensation is vital to our ability to continue to attract and retain employees in the extremely competitive labor markets in which we compete, our board of directors has determined that the size of the share reserve under the Restated Plan is reasonable and appropriate at this time.

#### ***Other Key Features of the Restated Plan (including the Equity Plan Amendment)***

The Restated Plan (including the Equity Plan Amendment) reflects a broad range of compensation and governance best practices, with some of the key features of the Restated Plan as follows:

- *No Increase to Shares Available for Issuance without Stockholder Approval.* Without stockholder approval, the Restated Plan prohibits any alteration or amendment that operates to increase the total number of shares of common stock that may be issued under the Restated Plan (other than adjustments in connection with certain corporate reorganizations and other events).
- *No Repricing of Awards.* Other than pursuant to the provisions of the Restated Plan described below under the headings “Adjustments” and “Corporate Transactions,” the plan administrator may not without the approval of the Company’s stockholders (1) lower the exercise price of an option or SAR after it is granted or (2) cancel an option or SAR when the exercise price exceeds the fair market value of the underlying shares in exchange for cash or another award.
- *Incentive Stock Option Limitation.* The Restated Plan, as amended by the Equity Plan Amendment, contains a limit of 68,457,566 shares that may be issued upon exercise of incentive stock options, or ISOs, following the effective date of the Restated Plan.
- *Limitations on Dividend Payments on Unvested Awards.* Dividends and dividend equivalents may not be paid on awards subject to vesting conditions unless and until such conditions are met. Dividend equivalents may not be paid on stock options or SARs.
- *No In-the-Money Option or Stock Appreciation Right Grants.* The Restated Plan prohibits the grant of options or SARs with an exercise or base price less than 100% of the fair market value of our Common Stock on the date of grant.
- *No Liberal Share Recycling.* The Restated Plan prohibits shares tendered or withheld for the payment of tax obligations on an award or in payment of the exercise price of an option from being added back to the share reserve, in addition to prohibiting other practices considered to be liberal share recycling.
- *Independent Administration.* The compensation committee of our board of directors, which consists of two or more non-employee directors, generally will administer the Restated Plan. The full board of directors will administer the Restated Plan with respect to awards granted to members of the board. The compensation committee may delegate certain of its duties and authorities to a committee of one or more directors or officers of the Company for awards to certain individuals, within specific guidelines and limitations. However, no delegation of authority is permitted with respect to awards made to individuals who (1) are subject to Section 16 of the Exchange Act, or (2) are officers of the Company and have been delegated authority to grant or amend awards under the Restated Plan.

- *No Automatic Change in Control Vesting for Awards.* The Restated Plan does not have automatic accelerated vesting provisions for awards in connection with a change of control (other than in connection with the non-assumption of awards).
- *Limitations on Grants to Directors.* The Restated Plan provides for limitations on grants to non-employee directors such that the sum of the grant date fair value of all equity awards and the maximum amount that may become payable pursuant to all cash-based awards granted to a non-employee director as compensation for services as a non-employee director during any fiscal year of the Company may not exceed \$1,000,000. Prior to the amendment and restatement of the Restated Plan, non-employee directors could be granted awards covering the greater of (a) 100,000 shares or (b) a number of shares such that the maximum aggregate value of the awards to the director in a calendar year is \$400,000.
- *No Fixed Term.* The Restated Plan will not have a fixed term and will continue until terminated by our board of directors or the share reserve thereunder is exhausted.
- *Limitations on Dividend Payments on Unvested Awards.* The Restated Plan provides that dividends and dividend equivalents may not be paid on awards subject to vesting conditions unless and until such conditions are met.
- *Removal of Section 162(m) Provisions.* Section 162(m) of the Internal Revenue Code prior to the Tax Cuts and Jobs Act of 2017 (the “TCJA”), allowed performance-based compensation that met certain requirements to be tax deductible regardless of amount. This qualified performance-based compensation exception was repealed as part of the TCJA. The Restated Plan does not include certain provisions which were otherwise required for awards to qualify as performance-based compensation under the Section 162(m) exception prior to its repeal.

### **Stockholder Approval**

In general, stockholder approval of the Equity Plan Amendment will implement the foregoing share reserve increase while (1) complying with the terms of the Restated Plan regarding amendments, (2) meeting the stockholder approval requirements of Nasdaq, and (3) allowing us to grant ISOs. If the Equity Plan Amendment is not approved by our stockholders, the Equity Plan Amendment will not become effective, the Restated Plan will continue in full force and effect, and the reserve available under the Inducement Plan will not be eliminated.

### **Summary of the Restated Plan**

The principal features of the Restated Plan are summarized below, but the summary is qualified in its entirety by reference to the Restated Plan itself, which is attached as *Annex B* to this proxy statement.

### ***Securities Subject to the Restated Plan***

As of April 15, 2025, the aggregate number of shares of common stock subject to outstanding awards under the Restated Plan was 38,362,417 and a total of 8,359,043 shares of common stock remained available under the Restated Plan for future issuance. Pursuant to the Equity Plan Amendment, subject to stockholder approval of this proposal, the number of shares of our common stock authorized for issuance as of the effective date of the Restated Plan will be increased by 10,000,000 shares.

If any shares subject to an award under the Restated Plan or the Inducement Plan are forfeited, expire or are settled for cash, any shares subject to such award will, to the extent of such forfeiture, expiration or cash settlement, be available for future grants under the Restated Plan. However, the following shares may not be used again for grant under the Restated Plan: (1) shares tendered or withheld to satisfy the exercise price of an option; (2) shares tendered or withheld to satisfy the tax withholding obligations with respect to an award; (3) shares subject to a SAR that are not issued in connection with the stock settlement of the SAR on its exercise; and (4) shares purchased on the open market with the cash proceeds from the exercise of options. If any shares of restricted stock are forfeited by a participant or repurchased by us pursuant to the Restated Plan or the Inducement Plan, such shares shall again be available for future grant or sale under the Restated Plan. The payment of dividend equivalents in cash in conjunction with any outstanding awards shall not be counted against the shares of stock available for issuance under the Restated Plan.

To the extent permitted by applicable law or any exchange rule, and subject to certain other restrictions, shares issued in assumption of, or in substitution for, any outstanding awards or shares available under a pre-existing plan of an entity acquired by the Company or any of its subsidiaries that was approved by stockholders and not adopted in contemplation of such acquisition will not be counted against the shares available for grant under the Restated Plan.

In no event will more than 68,457,455 shares of common stock be issuable pursuant to the exercise of ISOs following the effective date of the Equity Plan Amendment.

### ***Administration***

The Restated Plan, as amended by the Equity Plan Amendment, is administered by the compensation committee of the board of directors. The compensation committee may delegate to a committee of one or more members of the board or one or more of our officers the authority to grant or amend awards to participants other than our senior executives who are subject to Section 16 of the Exchange Act, subject to certain other limitations. Unless otherwise determined by the board of directors, the compensation committee will consist solely of two or more members of the board, each of whom is a “non-employee director” as defined by Rule 16b-3 of the Exchange Act and an “independent director” under the rules of the Nasdaq Stock Market (or other principal securities market on which shares of our common stock are traded).

The compensation committee has general authority to administer the Restated Plan, including the power to determine eligibility, the types and sizes of awards, the price and timing of awards and the acceleration or waiver of any vesting restriction, as well as the authority to delegate such administrative responsibilities. However, the full board of directors will conduct the general administration of the Restated Plan with respect to any awards to non-employee members of the board.

### ***Eligibility***

Options, SARs, restricted stock and other awards under the Restated Plan may be granted to individuals who are then our officers or employees or are the officers or employees of any of our subsidiaries. Such awards may also be granted to our non-employee directors and consultants but only employees may be granted ISOs. As of April 15, 2025, we had six non-employee directors, 437 employees, and 15 consultants, each of whom would have been eligible for awards under the Restated Plan had it been in effect on such date. We do not typically make new grants of equity awards to our consultants. The closing share price per share for our common stock on the Nasdaq Stock Market on April 15, 2025 was \$4.64.

### ***Awards***

The Restated Plan, as amended by the Equity Plan Amendment, provides for the grant of stock options, both incentive stock options and nonqualified stock options, SARs, restricted stock awards, restricted stock units, performance share awards, dividend equivalents, performance bonus awards, and other performance-based awards to eligible individuals. Certain awards under the Restated Plan may constitute or provide for a deferral of compensation, subject to Section 409A of the Code, which may impose additional requirements on the terms and conditions of such awards. All awards under the Restated Plan are or will be set forth in award agreements, which detail the terms and conditions of the awards, including any applicable vesting and payment terms and post-termination exercise limitations. Awards other than cash awards are generally settled in shares of our common stock, but the plan administrator may provide for cash settlement of any award. No determination has been made as to the types or amounts of awards that will be granted to specific individuals pursuant to the Restated Plan, except as set forth below under “New Plan Benefits.” See the “2024 Summary Compensation Table” and “2024 Grants of Plan-Based Awards Table” in this Proxy Statement for information on prior awards to our NEOs identified in those tables.

*Stock Options.* Stock options, including incentive stock options, as defined under Section 422 of the Code, and non-qualified stock options may be granted pursuant to the Restated Plan. The option exercise price of all stock options granted pursuant to the Restated Plan will not be less than 100% of the fair market value of the common stock on the date of grant. Stock options may be exercised as determined by the Compensation Committee, but in no event may a stock option have a term extending beyond ten years after the date of grant. Incentive stock options granted to any person who owns, as of the date of grant, stock possessing more than ten percent of the total combined voting power of all classes of Company stock, however, shall have an exercise price that is not

less than 110% of the fair market value of the common stock on the date of grant and may not have a term extending beyond the fifth anniversary of the date of grant. The aggregate fair market value of the shares with respect to which options intended to be incentive stock options are exercisable for the first time by an employee in any calendar year may not exceed \$100,000, or such other amount as the Code provides.

*Stock Appreciation Rights.* Stock appreciation rights may also be granted under the Restated Plan. Stock appreciation rights typically will provide for payments to the holder based upon increases in the price of our common stock over the exercise price per share, which will be no less than 100% of the fair market value of our common stock on the date of grant. SARs may be exercised as determined by the Compensation Committee, but in no event may a SAR have a term extending beyond ten years after the date of grant. Upon exercise of a SAR, payment may be made in cash or check or other property acceptable to the Compensation Committee.

*Restricted Stock and Restricted Stock Units.* Restricted stock is an award of nontransferable shares of our common stock that remains forfeitable unless and until specified conditions are met and which may be subject to a purchase price. Holders of restricted stock will have voting rights and will have the right to receive dividends; however, dividends may not be paid until the applicable shares of restricted stock vest. RSUs are contractual promises to deliver shares of our common stock in the future, which may also remain forfeitable unless and until specified conditions are met. Delivery of the shares underlying these awards may be deferred under the terms of the award or at the election of the participant if the plan administrator permits such a deferral.

*Dividend Equivalents.* Dividend equivalents represent the right to receive the equivalent value of dividends paid on shares of our common stock and may be granted alone or in tandem with awards. Dividend equivalents are credited as of dividend payments dates during the period between the date an award is granted and the date such award vests, is exercised, is distributed, or expires, as determined by the plan administrator. The Restated Plan requires that any dividend equivalents be paid only to the extent the underlying award vests.

*Performance Awards.* Performance awards include any of the awards that are granted subject to vesting and/or payment based on the attainment of specified performance goals. Performance awards may include any of the awards enumerated in this summary or other incentive awards paid in cash or stock.

The Compensation Committee will determine the methods by which payments by any award holder with respect to any awards may be paid, the form of payment, including, without limitation: (1) cash or check; (2) shares (including in the case of payment of the exercise price of an award, shares issuable pursuant to the exercise of the award) or shares held for such period of time as may be required by the Compensation Committee in order to avoid adverse accounting consequences, in each case, having a fair market value on the date of delivery equal to the aggregate payments required; or (3) other property acceptable to the Compensation Committee (including through the delivery of a notice that the award holder has placed a market sell order with a broker with respect to shares of common stock then issuable upon exercise or vesting of an award and that the broker has been directed to pay a sufficient portion of the net proceeds of the sale to us in satisfaction of the aggregate payments required, provided that payment of such proceeds is then made to us upon settlement of such sale). However, no participant who is a member of the board of directors or an “executive officer” of the Company within the meaning of Section 13(k) of the Exchange Act will be permitted to pay the exercise price of an option in any method that would violate the prohibitions on loans made or arranged by us as set forth in Section 13(k) of the Exchange Act.

### ***Limitations on Awards***

The sum of the grant date fair value of all equity awards and the maximum amount that may become payable pursuant to all cash-based awards that may be granted under the Restated Plan as compensation for services as a non-employee director may not exceed \$1,000,000 in any calendar year.

### ***Tax Withholding***

The Restated Plan permits the plan administrator to allow for the withholding or surrender of shares in satisfaction of tax withholding with respect to awards with a value up to the maximum individual statutory tax rate in the applicable jurisdiction at the time of such withholding (or such other rate as may be required to avoid the liability classification of the applicable award under generally accepted accounting principles in the United States of America).

### ***No Repricing***

In no case (except due to an adjustment to reflect a stock split or similar event or any repricing that may be approved by stockholders) may any adjustment be made to a stock option or a SAR award under the Restated Plan (by amendment, cancellation and re-grant, exchange, or other means) that would constitute a repricing of the per-share exercise or base price of the award.

### ***Transferability***

Generally, awards granted under the Restated Plan will not be transferable by a participant other than by will or the laws of descent and distribution or, subject to the consent of the Compensation Committee, pursuant to a domestic relations order. Generally, stock options and SARs will be exercisable during a participant's lifetime only by him or her, unless it has been disposed of pursuant to a domestic relations order; after the death of a participant, any exercisable portion of an option or SAR may be exercised by his personal representative or by any person empowered to do so under the deceased participant's will or under the then applicable laws of descent and distribution. However, the Compensation Committee has the authority to permit a participant to transfer an award other than an incentive stock option to a permitted transferee, subject to the terms and conditions in the Restated Plan. In no event may an award be transferable for consideration absent stockholder approval.

### ***Forfeiture, Recoupment and Clawback Provisions***

Pursuant to its general authority to determine the terms and conditions applicable to awards under the Restated Plan, the plan administrator has the right to provide, in an award agreement or otherwise, that an award shall be subject to the provisions of the Clawback Policy.

### ***Adjustment Provisions***

Certain transactions with our stockholders not involving our receipt of consideration, such as a stock split, spin-off, stock dividend, or certain recapitalizations may affect the share price of our common stock (which transactions are referred to collectively as "equity restructurings"). In the event that an equity restructuring occurs, the class, number of shares, and exercise or grant price of outstanding awards will be equitably adjusted, and the plan administrator will make such further equitable adjustments as it may deem appropriate to reflect the equity restructuring with respect to the aggregate number and kind of shares that may be issued under the Restated Plan. Other types of transactions may also affect our common stock, such as a dividend or other distribution, reorganization, merger, or other changes in corporate structure. In the event that there is such a transaction, which is not an equity restructuring and the plan administrator determines that an adjustment to the plan and any outstanding awards would be appropriate to prevent any dilution or enlargement of benefits under the Restated Plan, the plan administrator will equitably adjust the Restated Plan as to the class of shares issuable and the maximum number of shares of our stock subject to the Restated Plan, as well as the maximum number of shares that may be issued to an employee during any calendar year, will adjust any outstanding awards as to the class, number of shares, and price per share of our stock in such manner as it may deem equitable and may provide for the cash-out, substitution, assumption or acceleration of outstanding awards.

### ***Effect of Certain Corporate Transactions***

For purposes of the Restated Plan, a "change in control" generally means certain transactions in which a person acquires 50% or more of our total voting power; certain changes in the composition of the board of directors over a two-year period; a merger or consolidation, other than a merger or consolidation that would result in our voting securities outstanding immediately prior thereto continuing to represent at least 50% of the total voting power represented by our voting securities or such surviving entity's voting securities outstanding immediately after such merger or consolidation (or the voting securities of the parent of the entity which survives such merger or consolidation); a sale or disposition of all or substantially all of our assets, subject to certain exceptions; or approval by our stockholders of a plan of complete liquidation. The board of directors, in its sole discretion, may adopt a change-in-control program to determine the vesting schedule, exercisability, and other terms of outstanding awards on or after a change in control.

The board of directors may terminate, amend, or modify the Restated Plan at any time; however, stockholder approval will be obtained for any amendment to increase the number of shares available under the Restated Plan.



In addition, absent stockholder approval, no option or SAR may be amended to reduce the per share exercise price of the shares subject to such option or SAR below the per share exercise price as of the date the option or SAR was granted and, except to the extent permitted by the Restated Plan in connection with certain changes in capital structure, no option, SAR, cash, or other award may be granted in exchange for, or in connection with, the cancellation or surrender of an option or SAR having a higher per share exercise price.

### **Federal Income Tax Consequences**

The following is a general summary under current U.S. law of the material federal income tax consequences with respect to the Restated Plan. This summary deals with the general U.S. tax principles that apply and is provided only for general information. Some kinds of taxes, such as foreign, state, and local income taxes, as well as gift and estate tax considerations, are not discussed. Tax laws are complex and subject to change and may vary depending on individual circumstances and from locality to locality, and the summary does not discuss all aspects of income taxation that may be relevant in light of a holder's personal investment circumstances.

With respect to nonqualified stock options, we are generally entitled to deduct, and the optionee recognizes taxable income in an amount equal to, the difference between the option exercise price and the fair market value of the shares at the time of exercise. A participant receiving incentive stock options will not recognize taxable income upon grant. Additionally, if applicable holding period requirements are met, the participant will not recognize taxable income at the time of exercise. However, the excess of the fair market value of the common stock received over the option price is an item of tax preference income potentially subject to the alternative minimum tax. If stock acquired upon exercise of an incentive stock option is held for a minimum of two years from the date of grant and one year from the date of exercise, the gain or loss (in an amount equal to the difference between the fair market value on the date of sale and the exercise price) upon disposition of the stock will be treated as a long-term capital gain or loss, and we will not be entitled to any deduction. If the holding period requirements are not met, the incentive stock option will be treated as one that does not meet the requirements of the Code for incentive stock options, and the tax consequences described for nonqualified stock options will apply.

The current federal income tax consequences of other awards authorized under the Restated Plan generally follow certain basic patterns: SARs are taxed and deductible in substantially the same manner as nonqualified stock options; nontransferable restricted stock subject to a substantial risk of forfeiture and restricted stock units will result in income recognition equal to the excess of the fair market value over the price paid, if any, only at the time the restrictions applicable to such awards lapse (unless, with respect to an award of restricted stock, the recipient elects to accelerate recognition as of the date of grant); and stock-based performance awards, dividend equivalents, and other types of awards are generally subject to tax at ordinary income rates at the time of payment. In each of the foregoing cases, the Company will generally have a corresponding deduction at the time the participant recognizes income, subject to Section 162(m) with respect to covered employees.

### **New Plan Benefits**

Other than with respect to annual grants of options to our non-employee directors pursuant to the Restated Plan that will be made immediately following the date of the annual meeting, assuming stockholder approval of the Restated Plan, all future grants of awards under the Restated Plan are subject to the discretion of the plan administrator and it is not possible to determine the benefits that will be received in the future by participants in the Restated Plan. The equity awards to be granted to each non-employee director on the date of the annual meeting under the Restated Plan in accordance with the non-employee director compensation policy are described below under “—Director Compensation.”

## Plan Benefits Under the Restated Plan

As of April 15, 2025, each of our named executive officers and the other groups identified below have received the following option and RSU grants under the Restated Plan since its inception that are outstanding:

	Stock Options Granted and Outstanding (#)	Restricted Stock Units/Shares of Restricted Stock Granted and Outstanding (#)
Michael Raab . . . . . <i>President, Chief Executive Officer and Director</i>	5,826,598	1,034,277
Justin Renz . . . . . <i>Chief Financial and Operations Officer</i>	987,774	266,505
Elizabeth Grammer, Esq. . . . . <i>Chief Legal and Administrative Officer</i>	1,434,156	266,505
Laura Williams, M.D., M.P.H. . . . . <i>Chief Medical Officer</i>	827,827	228,465
Michael Kelliher . . . . . <i>Executive Vice President, Corporate Development and Strategy</i>	205,019	136,680
All current executive officers as a group (6 persons) . . . . .	9,716,393	2,249,112
All current directors who are not executive officers as a group (6 persons) . . . . .	1,844,402 <sup>(1)</sup>	—
David Mott, nominee for director . . . . .	330,775 <sup>(1)</sup>	—
Each associate of any directors, executive officers or nominees . . . . .	—	—
Each other person who received or is to receive 5 percent of such options, warrants or rights . . . . .	—	—
All employees who are not executive officers as a group (431 persons) . . . . .	36,662,573	15,649,470

(1) Includes options to purchase 110,000 shares of our common stock that Mr. Mott holds for the benefit of entities associated with New Enterprise Associates.

## Interests of Directors and Executive Officers

Our directors and executive officers (including our named executive officers) have substantial interests in the matters set forth in the Equity Plan Amendment Proposal since equity awards may be granted to them in the future under the Restated Plan (as amended by the Equity Plan Amendment).

## Vote Required

Approval of the Equity Plan Amendment requires the affirmative vote of the majority of votes cast (excluding abstentions and broker non-votes). Abstentions and broker non-votes are not considered votes cast for the foregoing purpose, and will have no effect on the vote for this proposal.

## THE BOARD OF DIRECTORS RECOMMENDS A VOTE “FOR” THE EQUITY PLAN AMENDMENT



## SECURITIES OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information relating to the beneficial ownership of our common stock as of April 15, 2025, by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our outstanding shares of common stock;
- each of our directors and nominees for director;
- each of our named executive officers; and
- all directors and executive officers as a group.

The number of shares beneficially owned by each entity, person, director, nominee or executive officer is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days of April 15, 2025 through the exercise of stock options, warrants or other rights and through the vesting and settlement of RSUs. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock held by that person.

The percentage of shares beneficially owned is computed on the basis of 239,255,066 shares of our common stock outstanding as of April 15, 2025. Shares of our common stock that a person has the right to acquire within 60 days of April 15, 2025 pursuant to the exercise of outstanding stock options, and restricted stock units that are expected to vest and settle on or before June 14, 2025 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all directors and executive officers as a group. Unless otherwise indicated below, the address for each beneficial owner listed is c/o Ardelyx, Inc., at 400 Fifth Ave., Suite 210, Waltham, Massachusetts 02451.

Name and Address of Beneficial Owner	Beneficial Ownership			
	Number of Outstanding Shares Beneficially Owned	Number of Shares Exercisable/Releasable Within 60 Days	Number of Shares Beneficially Owned	Percentage of Beneficial Ownership
<b>5% and Greater Stockholders</b>				
Janus Henderson Group plc <sup>(1)</sup>	24,387,941	—	24,387,941	10.2%
<b>Named Executive Officers and Directors</b>				
Michael Raab <sup>(2)</sup>	544,794	4,164,119	4,708,913	1.9%
Justin Renz	139,324	737,757	877,081	*%
Elizabeth Grammer	33,740	989,122	1,022,862	*%
Laura Williams, M.D., M.P.H.	164,284	432,999	597,283	*%
Michael Kelliher	—	121,147	121,147	*%
David Mott <sup>(3)</sup>	2,015,494	330,775	2,346,269	*%
Robert Bazemore	—	350,775	350,775	*%
William Bertrand, Jr., Esq.	229,766	365,775	595,541	*%
Muna Bhanji, R.Ph	95,802	253,167	348,969	*%
Onaiza Cadoret-Manier	110,150	288,135	398,285	*%
Richard Rodgers	350,524	255,775	606,299	*%
Merdad Parsey, M.D., Ph.D.	—	—	—	*%
All directors and named executive officers as a group (12 persons) <sup>(4)</sup>	3,686,511	8,080,902	11,767,413	4.8%

\* Indicates beneficial ownership of less than 1% of the total outstanding shares of common stock.

(1) Based on a Schedule 13G/A filed with the SEC on February 14, 2025 by Janus Henderson Group plc (“Janus Henderson”). Janus Henderson holds shared voting and dispositive power over 24,387,941 shares and does not hold sole voting or dispositive power over

any shares. Janus Henderson has a 100% ownership stake in Janus Henderson Investors U.S. LLC (“JHIUS”). As a result of its role as investment adviser or sub-adviser to certain fund, individual and/or institutional clients, JHIUS may be deemed to be the beneficial owner of the shares owned by Janus Henderson. However, JHIUS does not have the right to receive any dividends from, or the proceeds from the sale of, the securities held in the by such fund, individual and/or institutional clients and disclaims any ownership associated with such rights. The principal business address of Janus Henderson is 201 Bishopsgate, EC2M 3AE, United Kingdom.

- (2) Consists of (i) 519,430 shares directly owned by Mr. Raab, (ii) 24,364 shares owned directly by Michael G. Raab, trustee of the Michael G. Raab Living Trust dated July 25, 2012, (iii) an aggregate of 1,000 shares owned directly by trusts for the benefit of Mr. Raab’s children, (iv) 4,073,792 shares subject to options that Mr. Raab may acquire within 60 days of April 15, 2025, and (v) 90,327 shares subject to restricted stock units that will vest within 60 days of April 15, 2025.
- (3) Includes (i) 110,000 shares subject to options that Mr. Mott may acquire within 60 days of April 15, 2024 and (ii) 87,566 shares of common stock, each of which are held by Mr. Mott for the benefit of entities associated with New Enterprise Associates . Mr. Mott disclaims beneficial ownership of all such shares and options, except to the extent of his actual pecuniary interest therein.
- (4) Consists of (i) 3,686,511 shares, (ii) 7,864,061 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of April 15, 2025 and (iii) 216,841 restricted stock units that will vest within 60 days of April 15, 2025.

## **DELINQUENT SECTION 16(A) REPORTS**

Section 16(a) of the Securities Exchange Act of 1934, as amended requires the Company’s directors and executive officers, and persons who own more than 10% of a registered class of the Company’s equity securities, to file with the U.S. Securities and Exchange Commission, or SEC, initial reports of ownership and reports of changes in ownership of common stock and other equity securities of the Company. Officers, directors and greater than 10% stockholders are required by SEC regulations to furnish the Company with copies of all Section 16(a) forms they file.

To the Company’s knowledge, based solely on a review of the copies of such reports furnished to the Company and written representations that no other reports were required, during the year ended December 31, 2024, all Section 16(a) filing requirements applicable to our officers, directors and greater than 10% beneficial owners were met, except for late Form 4s due to administrative delays, which were filed on March 15, 2024 for Robert Blanks, May 9, 2024 for Robert Felsch and October 31, 2024 for Michael Raab.

## **ADDITIONAL INFORMATION**

### **Householding of Proxy Materials**

The SEC has adopted rules known as “householding” that permit companies and intermediaries (such as brokers) to deliver one set of proxy materials to multiple stockholders residing at the same address. This process enables us to reduce our printing and distribution costs, and reduce our environmental impact. Householding is available to both registered stockholders and beneficial owners of shares held in street name.

### ***Registered Stockholders***

If you are a registered stockholder and have consented to householding, then we will deliver or mail one set of our proxy materials, as applicable, for all registered stockholders residing at the same address. Your consent will continue unless you revoke it, which you may do at any time by providing notice to the Company’s Corporate Secretary by telephone at (510) 745-1700 or by mail at Ardelyx, Inc., 400 Fifth Avenue, Suite 210, Waltham, MA 02451.

If you are a registered stockholder who has not consented to householding, then we will continue to deliver or mail copies of our proxy materials, as applicable, to each registered stockholder residing at the same address. You may elect to participate in householding and receive only one set of proxy materials for all registered stockholders residing at the same address by providing notice to the Company as described above.

### ***Street Name Holders***

Stockholders who hold their shares through a brokerage may elect to participate in householding, or revoke their consent to participate in householding, by contacting their respective brokers.

## Annual Reports

This proxy statement is accompanied by our 2024 Annual Report to Stockholders, which includes our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, or the 10-K. The 10-K includes our audited financial statements. We have filed the 10-K with the SEC, and it is available free of charge at the SEC's website at [www.sec.gov](http://www.sec.gov) and on our website at [ir.ardelyx.com](http://ir.ardelyx.com). In addition, upon written request to the Company's Corporate Secretary at Ardelyx, Inc., 400 Fifth Avenue, Suite 210, Waltham, MA 02451, we will mail a paper copy of our 10-K, including the financial statements and the financial statement schedules, to you free of charge.

## Other Matters

As of the date of this proxy statement, our board of directors knows of no other matters that will be presented for consideration at the 2025 Annual Meeting other than the matters described in this proxy statement. If other matters are properly brought before the 2025 Annual Meeting, then proxies will be voted in accordance with the recommendation of the board of directors or, in the absence of such a recommendation, in accordance with the best judgment of the proxy holder.

By Order of the Board of Directors:

/s/ Elizabeth Grammer

Elizabeth Grammer, Esq.

Chief Legal and Administrative Officer

Waltham, Massachusetts  
April 30, 2025

**FIRST AMENDMENT TO THE**  
**ARDELYX, INC.**  
**AMENDED AND RESTATED**  
**2014 EQUITY INCENTIVE AWARD PLAN**

This First Amendment (this “Amendment”) to the Amended and Restated 2014 Equity Incentive Award Plan (the “Plan”), is made and adopted by the Board of Directors (the “Board”) of Ardelyx, Inc. (the “Company”), on April 28, 2025 (the “Adoption Date”), effective as of the date that it is approved by the Company’s stockholders; *provided* such date is within twelve (12) months of the Adoption Date (the “Amendment Effective Date”). All capitalized terms used but not otherwise defined herein shall have the respective meanings ascribed to such terms in the Plan.

**RECITALS**

**WHEREAS**, the Company maintains the Plan, which, prior to this Amendment taking effect, provides that the maximum number of shares of Common Stock (the “Shares”) that may be delivered pursuant to awards granted under the Plan is (i) 58,457,566 (ii) any of the 6,500,000 Shares which as of the Effective Date of the Plan were subject to awards granted under the 2016 Employment Commencement Incentive Plan (the “Prior Plan”) that on or after the Effective Date of the Plan terminate, expire or lapse for any reason without delivery of Shares to the holder thereof or for which the Shares are forfeited or repurchased for the original purchase prices thereof.

**WHEREAS**, the Board believes it is in the best interest of the Company to increase the maximum number of shares of Common Stock that may be delivered pursuant to awards granted under the Plan by 10,000,000 shares of Common Stock to provide flexibility to the Company in its ability to motivate, attract, and retain the services of Employees.

**WHEREAS**, pursuant to Section 13.1 of the Plan, the Board may amend the Plan from time to time; provided that any such amendment to increase the number of shares of Common Stock subject to the Plan shall require approval by the Company’s stockholders within twelve (12) months before or after such action by the Board.

**WHEREAS**, the Board has recommended that this Amendment be submitted to the stockholders of the Company for approval within twelve (12) months of the Adoption Date.

**NOW, THEREFORE, BE IT RESOLVED**, that the Plan is hereby amended, as of the Effective Date, as follows:

**AMENDMENT**

1. Amendment to Section 3.1(a). Section 3.1(a) of the Plan is hereby amended and restated in its entirety to read as follows:

“Number of Shares. Subject to Sections 13.1, 13.2 and 3.1(b) hereof, the aggregate number of Shares which may be issued or transferred pursuant to Awards under the Plan is (i) 68,457,566 and (ii) any of the 6,500,000 Shares which were subject to awards under the Prior Plan as of the Effective Date of the Plan that, on or after the Effective Date of the Plan, terminate, expire or lapse for any reason without the delivery of Shares to the holder thereof or for which the Shares are forfeited or repurchased for the original purchase prices thereof (the “Share Limit”). Notwithstanding anything in this Section 3.1 to the contrary, the number of shares of Stock that may be issued or transferred pursuant to Incentive Stock Options under the Plan shall not exceed an aggregate of 68,457,566 Shares, subject to adjustment pursuant to Section 13.2. Notwithstanding the foregoing, Shares added to the Share Limit pursuant to Section 3.1(a)(ii) or Section 3.1(a)(iii) hereof shall be available for issuance as Incentive Stock Options only to the extent that making such Shares available for issuance as Incentive Stock Options would not cause any Incentive Stock Option to cease to qualify as such. Notwithstanding the foregoing, to the extent permitted under Applicable Law, Awards that provide for the delivery of Shares subsequent to the applicable grant date may be granted in excess of the Share Limit if such Awards provide for the forfeiture or cash settlement of such Awards to the extent that insufficient Shares remain under the Share Limit in this Section 3.1 at the time that Shares would otherwise be issued in respect of such Award.”

2. Effectiveness; Approval by Stockholders. This Amendment will be submitted for the approval of the Company's stockholders within twelve (12) months after the Adoption Date. Awards may be granted or awarded prior to such stockholder approval; *provided* that (A) such Awards shall not be exercisable, (B) such Awards shall not vest and (C) the restrictions on such Awards shall not lapse and no shares shall be issued pursuant thereto prior to the Amendment Effective Date; and *provided, further*, that if such approval has not been obtained at the end of said twelve (12) month period, all Awards previously granted or awarded in reliance on this Amendment shall thereupon be canceled and become null and void; however, the Plan shall remain in full force and effect. If stockholder approval of this Amendment is obtained, as of the Amendment Effective Date, this Amendment shall be and is hereby incorporated as part of the Plan.

3. Effect on the Plan. Except as expressly provided herein, all terms and conditions of the Plan shall remain in full force and effect.

ADOPTED BY THE BOARD OF DIRECTORS: April 28, 2025

APPROVED BY THE STOCKHOLDERS: [    ], 2025

**ARDELYX, INC.**  
**AMENDED AND RESTATED 2014 EQUITY INCENTIVE AWARD PLAN**

**ARTICLE 1.**

**PURPOSE**

The purpose of the Ardelyx, Inc. Amended and Restated 2014 Equity Incentive Award Plan (as it may be amended from time to time, the “Plan”) is to promote the success and enhance the value of Ardelyx, Inc. (the “Company”) by linking the individual interests of the members of the Board, Employees, and Consultants to those of the Company’s stockholders and by providing such individuals with an incentive for outstanding performance to generate superior returns to the Company’s stockholders. The Plan is further intended to provide flexibility to the Company in its ability to motivate, attract, and retain the services of members of the Board, Employees, and Consultants upon whose judgment, interest, and special effort the successful conduct of the Company’s operation is largely dependent. The Plan amends and restates the 2014 Equity Incentive Award Plan (the “Original 2014 Plan”) in its entirety, subject to stockholder approval of this Plan at the annual meeting of the Company’s stockholders in 2024. In the event the Company’s stockholders fail to approve the Plan as set forth herein at the annual meeting of the Company’s stockholders in 2024, then this Plan shall be deemed void *ab initio* and the Original 2014 Plan shall continue in effect in accordance with its terms.

**ARTICLE 2.**

**DEFINITIONS AND CONSTRUCTION**

Wherever the following terms are used in the Plan they shall have the meanings specified below, unless the context clearly indicates otherwise. The singular pronoun shall include the plural where the context so indicates.

2.1 “Administrator” shall mean the entity that conducts the general administration of the Plan as provided in Article 12 hereof. With reference to the duties of the Administrator under the Plan which have been delegated to one or more persons pursuant to Section 12.6 hereof, or as to which the Board has assumed, the term “Administrator” shall refer to such person(s) unless the Committee or the Board has revoked such delegation or the Board has terminated the assumption of such duties.

2.2 “Affiliate” shall mean any Parent or Subsidiary.

2.3 “Applicable Accounting Standards” shall mean Generally Accepted Accounting Principles in the United States, International Financial Reporting Standards or such other accounting principles or standards as may apply to the Company’s financial statements under United States federal securities laws from time to time.

2.4 “Applicable Law” shall mean any applicable law, including without limitation, (i) provisions of the Code, the Securities Act, the Exchange Act and any rules or regulations thereunder; (ii) corporate, securities, tax or other laws, statutes, rules, requirements or regulations, whether federal, state, local or foreign; and (iii) rules of any securities exchange or automated quotation system on which the Shares are listed, quoted or traded.

2.5 “Award” shall mean an Option, a Restricted Stock award, a Restricted Stock Unit award, a Performance Award, a Dividend Equivalents award, a Deferred Stock award, a Deferred Stock Unit award, a Stock Payment award or a Stock Appreciation Right, which may be awarded or granted under the Plan (collectively, “Awards”).

2.6 “Award Agreement” shall mean any written notice, agreement, terms and conditions, contract or other instrument or document evidencing an Award, including through electronic medium, which shall contain such terms and conditions with respect to an Award as the Administrator shall determine consistent with the Plan.

2.7 “Board” shall mean the Board of Directors of the Company.

2.8 “Change in Control” shall mean the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

- (a) A transaction or series of transactions (other than an offering of Common Stock to the general public through a registration statement filed with the Securities and Exchange Commission) whereby any

“person” or related “group” of “persons” (as such terms are used in Sections 13(d) and 14(d)(2) of the Exchange Act) (other than the Company, any of its subsidiaries, an employee benefit plan maintained by the Company or any of its subsidiaries or a “person” that, prior to such transaction, directly or indirectly controls, is controlled by, or is under common control with, the Company) directly or indirectly acquires beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of securities of the Company possessing more than 50% of the total combined voting power of the Company’s securities outstanding immediately after such acquisition; or

(b) During any period of two consecutive years, individuals who, at the beginning of such period, constitute the Board together with any new Director(s) (other than a Director designated by a person who shall have entered into an agreement with the Company to effect a transaction described in Section 2.9(a) or 2.9(c)) whose election by the Board or nomination for election by the Company’s stockholders was approved by a vote of at least two-thirds of the Directors then still in office who either were Directors at the beginning of the two-year period or whose election or nomination for election was previously so approved, cease for any reason to constitute a majority thereof; or

(c) The consummation by the Company (whether directly involving the Company or indirectly involving the Company through one or more intermediaries) of (x) a merger, consolidation, reorganization, or business combination or (y) a sale or other disposition of all or substantially all of the Company’s assets in any single transaction or series of related transactions or (z) the acquisition of assets or stock of another entity, in each case other than a transaction:

(i) which results in the Company’s voting securities outstanding immediately before the transaction continuing to represent (either by remaining outstanding or by being converted into voting securities of the Company or the person that, as a result of the transaction, controls, directly or indirectly, the Company or owns, directly or indirectly, all or substantially all of the Company’s assets or otherwise succeeds to the business of the Company (the Company or such person, the “Successor Entity”)) directly or indirectly, at least a majority of the combined voting power of the Successor Entity’s outstanding voting securities immediately after the transaction, and

(ii) after which no person or group beneficially owns voting securities representing 50% or more of the combined voting power of the Successor Entity; provided, however, that no person or group shall be treated for purposes of this Section 2.9(c)(ii) as beneficially owning 50% or more of the combined voting power of the Successor Entity solely as a result of the voting power held in the Company prior to the consummation of the transaction; or

(d) The Company’s stockholders approve a liquidation or dissolution of the Company.

Notwithstanding the foregoing, if a Change in Control constitutes a payment event with respect to any portion of an Award that provides for the deferral of compensation and is subject to Section 409A of the Code, the transaction or event described in subsection (a), (b), (c) or (d) with respect to such Award (or portion thereof) must also constitute a “change in control event,” as defined in Treasury Regulation Section 1.409A-3(i)(5) to the extent required by Section 409A.

The Committee shall have full and final authority, which shall be exercised in its discretion, to determine conclusively whether a Change in Control of the Company has occurred pursuant to the above definition, and the date of the occurrence of such Change in Control and any incidental matters relating thereto; provided that any exercise of authority is in conjunction with a determination of whether a Change in Control is a “change in control event” as defined in Treasury Regulation Section 1.409A-3(i)(5) shall be consistent with such regulation.

2.9 “Code” shall mean the Internal Revenue Code of 1986, as amended from time to time, together with the regulations and official guidance promulgated thereunder, whether issued prior or subsequent to the grant of any Award.

2.10 “Committee” shall mean the Compensation Committee of the Board, a subcommittee of the Compensation Committee of the Board or another committee or subcommittee of the Board, appointed as provided in Section 12.1 hereof.

2.11 “Common Stock” shall mean the common stock of the Company, par value \$0.0001 per share.

2.12 “Company” shall have the meaning set forth in Article 1 hereof.



2.13 “Consultant” shall mean any consultant or advisor engaged to provide services to the Company or any Affiliate who qualifies as a consultant or advisor under the applicable rules of the Securities and Exchange Commission for registration of shares on a Form S-8 Registration Statement or any successor Form thereto.

2.14 “Deferred Stock” shall mean a right to receive Shares awarded under Section 9.4 hereof.

2.15 “Deferred Stock Unit” shall mean a right to receive Shares awarded under Section 9.5 hereof.

2.16 “Director” shall mean a member of the Board, as constituted from time to time.

2.17 “Dividend Equivalent” shall mean a right to receive the equivalent value (in cash or Shares) of dividends paid on Shares, awarded under Section 9.2 hereof.

2.18 “DRO” shall mean a “domestic relations order” as defined by the Code or Title I of the Employee Retirement Income Security Act of 1974, as amended from time to time, or the rules thereunder.

2.19 “Effective Date” shall have the meaning set forth in Section 13.1.

2.20 “Eligible Individual” shall mean any person who is an Employee, a Consultant or a Non-Employee Director, as determined by the Administrator.

2.21 “Employee” shall mean any officer or other employee (as determined in accordance with Section 3401(c) of the Code and the Treasury Regulations thereunder) of the Company or any Affiliate.

2.22 “Equity Restructuring” shall mean a nonreciprocal transaction between the Company and its stockholders, such as a stock dividend, stock split, spin-off, rights offering or recapitalization through a large, nonrecurring cash dividend, that affects the number or kind of Shares (or other securities of the Company) or the share price of Common Stock (or other securities) and causes a change in the per share value of the Common Stock underlying outstanding stock-based Awards.

2.23 “Exchange Act” shall mean the Securities Exchange Act of 1934, as amended from time to time.

2.24 “Fair Market Value” shall mean, as of any given date, the value of a Share determined as follows:

(a) If the Common Stock is (i) listed on any established securities exchange (such as the New York Stock Exchange, the Nasdaq Capital Market, Nasdaq Global Market and the Nasdaq Global Select Market), (ii) listed on any national market system or (iii) listed, quoted or traded on any automated quotation system, its Fair Market Value shall be the closing sales price for a Share as quoted on such exchange or system for such date or, if there is no closing sales price for a Share on the date in question, the closing sales price for a Share on the last preceding date for which such quotation exists, as reported in The Wall Street Journal or such other source as the Administrator deems reliable;

(b) If the Common Stock is not listed on an established securities exchange, national market system or automated quotation system, but the Common Stock is regularly quoted by a recognized securities dealer, its Fair Market Value shall be the mean of the high bid and low asked prices for such date or, if there are no high bid and low asked prices for a Share on such date, the high bid and low asked prices for a Share on the last preceding date for which such information exists, as reported in The Wall Street Journal or such other source as the Administrator deems reliable; or

(c) If the Common Stock is neither listed on an established securities exchange, national market system or automated quotation system nor regularly quoted by a recognized securities dealer, its Fair Market Value shall be established by the Administrator in good faith.

2.25 “Greater Than 10% Stockholder” shall mean an individual then owning (within the meaning of Section 424(d) of the Code) more than ten percent (10%) of the total combined voting power of all classes of stock of the Company or any “parent corporation” or “subsidiary corporation” (as defined in Sections 424(e) and 424(f) of the Code, respectively).

2.26 “Holder” shall mean a person who has been granted an Award.

2.27 “Incentive Stock Option” shall mean an Option that is intended to qualify as an incentive stock option and conforms to the applicable provisions of Section 422 of the Code.

2.28 “Non-Employee Director” shall mean a Director of the Company who is not an Employee.

2.29 “Non-Employee Director Equity Compensation Policy” shall have the meaning set forth in Section 4.6 hereof.

2.30 “Non-Qualified Stock Option” shall mean an Option that is not an Incentive Stock Option or which is designated as an Incentive Stock Option but does not meet the applicable requirements of Section 422 of the Code.

2.31 “Option” shall mean a right to purchase Shares at a specified exercise price, granted under Article 5 hereof. An Option shall be either a Non-Qualified Stock Option or an Incentive Stock Option; provided, however, that Options granted to Non-Employee Directors and Consultants shall only be Non-Qualified Stock Options.

2.32 “Option Term” shall have the meaning set forth in Section 5.4 hereof.

2.33 “Original 2014 Plan” shall have the meaning set forth in Article 1 hereof.

2.34 “Parent” shall mean any entity (other than the Company), whether domestic or foreign, in an unbroken chain of entities ending with the Company if each of the entities other than the Company beneficially owns, at the time of the determination, securities or interests representing more than fifty percent (50%) of the total combined voting power of all classes of securities or interests in one of the other entities in such chain.

2.35 “Performance Award” shall mean a cash bonus award, stock bonus award, performance award or incentive award that is paid in cash, Shares or a combination of both, awarded under Section 9.1 hereof.

2.36 “Performance Stock Unit” shall mean a Performance Award awarded under Section 9.1 hereof which is denominated in units of value including dollar value of shares of Common Stock.

2.37 “Permitted Transferee” shall mean, with respect to a Holder, any “family member” of the Holder, as defined under the General Instructions to Form S-8 Registration Statement under the Securities Act or any successor Form thereto, or any other transferee specifically approved by the Administrator, after taking into account Applicable Law.

2.38 “Plan” shall have the meaning set forth in Article 1 hereof.

2.39 “Prior Plan” shall mean the Ardelyx, Inc. 2016 Employment Commencement Incentive Plan.

2.40 “Program” shall mean any program adopted by the Administrator pursuant to the Plan containing the terms and conditions intended to govern a specified type of Award granted under the Plan and pursuant to which such type of Award may be granted under the Plan.

2.41 “Restricted Stock” shall mean an award of Shares made under Article 7 hereof that is subject to certain restrictions and may be subject to risk of forfeiture or repurchase.

2.42 “Restricted Stock Unit” shall mean a contractual right awarded under Article 8 hereof to receive in the future a Share or the Fair Market Value of a Share in cash.

2.43 “Securities Act” shall mean the Securities Act of 1933, as amended.

2.44 “Shares” shall mean shares of Common Stock.

2.45 “Share Limit” shall have the meaning set forth in Section 3.1(a) hereof.

2.46 “Stock Appreciation Right” shall mean a stock appreciation right granted under Article 10 hereof.

2.47 “Stock Appreciation Right Term” shall have the meaning set forth in Section 10.4 hereof.

2.48 “Stock Payment” shall mean (a) a payment in the form of Shares, or (b) an option or other right to purchase Shares, as part of a bonus, deferred compensation or other arrangement, awarded under Section 9.3 hereof.

2.49 “Subsidiary” shall mean any entity (other than the Company), whether domestic or foreign, in an unbroken chain of entities beginning with the Company if each of the entities other than the last entity in the unbroken chain beneficially owns, at the time of the determination, securities or interests representing more than fifty percent (50%) of the total combined voting power of all classes of securities or interests in one of the other entities in such chain.

2.50 “Substitute Award” shall mean an Award granted under the Plan upon the assumption of, or in substitution for, outstanding equity awards previously granted by a company or other entity in connection with a corporate transaction, such as a merger, combination, consolidation or acquisition of property or stock; provided, however, that in no event shall the term “Substitute Award” be construed to refer to an award made in connection with the cancellation and repricing of an Option or Stock Appreciation Right.

2.51 “Termination of Service” shall mean:

(a) As to a Consultant, the time when the engagement of a Holder as a Consultant to the Company or an Affiliate is terminated for any reason, with or without cause, including, without limitation, by resignation, discharge, death or retirement, but excluding terminations where the Consultant simultaneously commences or remains in employment or service with the Company or any Affiliate.

(b) As to a Non-Employee Director, the time when a Holder who is a Non-Employee Director ceases to be a Director for any reason, including, without limitation, a termination by resignation, failure to be elected, death or retirement, but excluding terminations where the Holder simultaneously commences or remains in employment or service with the Company or any Affiliate.

(c) As to an Employee, the time when the employee-employer relationship between a Holder and the Company or any Affiliate is terminated for any reason, including, without limitation, a termination by resignation, discharge, death, disability or retirement; but excluding terminations where the Holder simultaneously commences or remains in employment or service with the Company or any Affiliate.

The Administrator, in its sole discretion, shall determine the effect of all matters and questions relating to Terminations of Service, including, without limitation, the question of whether a Termination of Service resulted from a discharge for cause and all questions of whether particular leaves of absence constitute a Termination of Service; provided, however, that, with respect to Incentive Stock Options, unless the Administrator otherwise provides in the terms of the Program, the Award Agreement or otherwise, a leave of absence, change in status from an employee to an independent contractor or other change in the employee-employer relationship shall constitute a Termination of Service only if, and to the extent that, such leave of absence, change in status or other change interrupts employment for the purposes of Section 422(a)(2) of the Code and the then applicable regulations and revenue rulings under said Section.

For purposes of the Plan, a Holder’s employee-employer relationship or consultancy relations shall be deemed to be terminated in the event that the Affiliate employing or contracting with such Holder ceases to remain an Affiliate following any merger, sale of stock or other corporate transaction or event (including, without limitation, a spin-off).

### **ARTICLE 3.**

#### **SHARES SUBJECT TO THE PLAN**

##### **3.1 Number of Shares.**

(a) Subject to Sections 13.1, 13.2 and 3.1(b) hereof, the aggregate number of Shares which may be issued or transferred pursuant to Awards under the Plan is (i) 58,457,566 and (ii) any of the 6,500,000 Shares which as of the Effective Date are subject to awards under the Prior Plan that, on or after the Effective Date, terminate, expire or lapse for any reason without the delivery of Shares to the holder thereof or for which the Shares are forfeited or repurchased for the original purchase prices thereof (the “Share Limit”). Notwithstanding anything in this Section 3.1 to the contrary, the number of shares of Stock that may be issued or transferred pursuant to Incentive Stock Options under the Plan shall not exceed an aggregate of 58,457,566 Shares, subject to adjustment pursuant to Section 13.2. Notwithstanding the foregoing, Shares added to the Share Limit pursuant to Section 3.1(a)(ii) or Section 3.1(a)(iii) hereof shall be available for issuance as Incentive Stock Options only to the extent that making such Shares available for issuance as Incentive Stock Options would not cause any Incentive Stock Option to cease to qualify as such. Notwithstanding the foregoing, to the extent permitted under Applicable Law, Awards that provide for the delivery of Shares subsequent to the applicable grant date may be granted in excess of the Share Limit if such Awards provide for the forfeiture or cash settlement of such Awards to the extent that insufficient Shares remain under the Share Limit in this Section 3.1 at the time that Shares would otherwise be issued in respect of such Award.

(b) If any Shares subject to an Award are forfeited or expire or such Award is settled for cash (in whole or in part), the Shares subject to such Award shall, to the extent of such forfeiture, expiration or cash settlement, again be available for future grants of Awards under the Plan and shall be added back to the Share Limit. Any Shares repurchased by the Company pursuant to Section 7.4 hereof at the same price paid by the Holder or a lower price so that such Shares are returned to the Company shall again be available for the grant of an Award pursuant to the Plan and shall be added back to the Share Limit. Notwithstanding anything to the contrary contained herein, the following Shares shall not be added to the Shares authorized for grant under Section 3.1(a) hereof and shall not be available for future grants of Awards: (i) Shares tendered by a Holder or withheld by the Company in payment of the exercise price of an Option; (ii) Shares tendered by the Holder or withheld by the Company to satisfy any tax withholding obligation with respect to an Award; (iii) Shares subject to Stock Appreciation Rights that are not issued in connection with the stock settlement of the Stock Appreciation Rights on exercise thereof; and (iv) Shares purchased on the open market by the Company with the cash proceeds from the exercise of Options. The payment of Dividend Equivalents in cash in conjunction with any outstanding Awards shall not be counted against the Shares available for issuance under the Plan. Notwithstanding the provisions of this Section 3.1(b), no Shares may again be optioned, granted or awarded if such action would cause an Incentive Stock Option to fail to qualify as an incentive stock option under Section 422 of the Code.

(c) Substitute Awards shall not reduce the Shares authorized for grant under the Plan and Shares subject to such Substitute Awards shall not be added back to the Shares available for Awards under the Plan as provided in Section 3.1(b) above. Additionally, in the event that a company acquired by the Company or any Affiliate or with which the Company or any Affiliate combines has shares available under a pre-existing plan approved by its stockholders and not adopted in contemplation of such acquisition or combination, the shares available for grant pursuant to the terms of such pre-existing plan (as adjusted, to the extent appropriate, using the exchange ratio or other adjustment or valuation ratio or formula used in such acquisition or combination to determine the consideration payable to the holders of common stock of the entities party to such acquisition or combination) may be used for Awards under the Plan and shall not reduce the Shares authorized for grant under the Plan (and Shares subject to such Awards shall not be added to the Shares available for Awards under the Plan as provided in Section 3.1(b) above); provided that Awards using such available Shares shall not be made after the date awards or grants could have been made under the terms of the pre-existing plan, absent the acquisition or combination and shall only be made to individuals who were not employed by or providing services to the Company or its Affiliates immediately prior to such acquisition or combination.

3.2 Stock Distributed. Any Shares distributed pursuant to an Award may consist, in whole or in part, of authorized and unissued Common Stock, treasury Common Stock or Common Stock purchased on the open market.

3.3 Limitation on Number of Shares Subject to Awards to Non-Employee Directors. The maximum aggregate value of Awards (with such value determined as of the date of grant under Applicable Accounting Standards) that may be granted to any Non-Employee Director during any calendar year shall be \$1,000,000.

## **ARTICLE 4.**

### **GRANTING OF AWARDS**

4.1 Participation. The Administrator may, from time to time, select from among all Eligible Individuals, those to whom an Award shall be granted and shall determine the nature and amount of each Award, which shall not be inconsistent with the requirements of the Plan. Except as provided in Section 4.6 hereof regarding the grant of Awards pursuant to the Non-Employee Director Equity Compensation Policy, no Eligible Individual shall have any right to be granted an Award pursuant to the Plan.

4.2 Award Agreement. Each Award shall be evidenced by an Award Agreement that sets forth the terms, conditions and limitations for such Award, which may include the term of the Award, the provisions applicable in the event of the Holder's Termination of Service, and the Company's authority to unilaterally or bilaterally amend, modify, suspend, cancel or rescind an Award. Award Agreements evidencing Incentive Stock Options shall contain such terms and conditions as may be necessary to meet the applicable provisions of Section 422 of the Code.

4.3 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan, the Plan, and any Award granted or awarded to any individual who is then subject to Section 16 of the Exchange Act, shall be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including Rule 16b-3 of the Exchange Act and any amendments thereto) that are requirements for the application of such exemptive rule. To the extent permitted by Applicable Law, the Plan and Awards granted or awarded hereunder shall be deemed amended to the extent necessary to conform to such applicable exemptive rule.

4.4 At-Will Employment; Voluntary Participation. Nothing in the Plan or in any Program or Award Agreement hereunder shall confer upon any Holder any right to continue in the employ of, or as a Director or Consultant for, the Company or any Affiliate, or shall interfere with or restrict in any way the rights of the Company and any Affiliate, which rights are hereby expressly reserved, to discharge any Holder at any time for any reason whatsoever, with or without cause, and with or without notice, or to terminate or change all other terms and conditions of employment or engagement, except to the extent expressly provided otherwise in a written agreement between the Holder and the Company or any Affiliate. Participation by each Holder in the Plan shall be voluntary and nothing in the Plan shall be construed as mandating that any Eligible Individual shall participate in the Plan.

4.5 Foreign Holders. Notwithstanding any provision of the Plan to the contrary, in order to comply with the laws in countries other than the United States in which the Company and its Affiliates operate or have Employees, Non-Employee Directors or Consultants, or in order to comply with the requirements of any foreign securities exchange, the Administrator, in its sole discretion, shall have the power and authority to: (a) determine which Affiliates shall be covered by the Plan; (b) determine which Eligible Individuals outside the United States are eligible to participate in the Plan; (c) modify the terms and conditions of any Award granted to Eligible Individuals outside the United States to comply with applicable foreign laws or listing requirements of any such foreign securities exchange; (d) establish subplans and modify exercise procedures and other terms and procedures, to the extent such actions may be necessary or advisable (any such subplans and/or modifications shall be attached to the Plan as appendices); provided, however, that no such subplans and/or modifications shall increase the share limitations contained in Sections 3.1 and 3.3 hereof; and (e) take any action, before or after an Award is made, that it deems advisable to obtain approval or comply with any necessary local governmental regulatory exemptions or approvals or listing requirements of any such foreign securities exchange. Notwithstanding the foregoing, the Administrator may not take any actions hereunder, and no Awards shall be granted, that would violate the Code, the Exchange Act, the Securities Act, any other securities law or governing statute, the rules of the securities exchange or automated quotation system on which the Shares are listed, quoted or traded or any other Applicable Law. For purposes of the Plan, all references to foreign laws, rules, regulations or taxes shall be references to the laws, rules, regulations and taxes of any applicable jurisdiction other than the United States or a political subdivision thereof.

4.6 Non-Employee Director Awards. The Administrator may, in its discretion, provide that Awards granted to Non-Employee Directors shall be granted pursuant to a written non-discretionary formula established by the Administrator (the “Non-Employee Director Equity Compensation Policy”), subject to the limitations of the Plan. The Non-Employee Director Equity Compensation Policy shall set forth the type of Award(s) to be granted to Non-Employee Directors, the number of Shares to be subject to Non-Employee Director Awards, the conditions on which such Awards shall be granted, become exercisable and/or payable and expire, and such other terms and conditions as the Administrator shall determine in its discretion. The Non-Employee Director Equity Compensation Policy may be modified by the Administrator from time to time in its discretion.

4.7 Stand-Alone and Tandem Awards. Awards granted pursuant to the Plan may, in the sole discretion of the Administrator, be granted either alone, in addition to, or in tandem with, any other Award granted pursuant to the Plan. Awards granted in addition to or in tandem with other Awards may be granted either at the same time as or at a different time from the grant of such other Awards.

## **ARTICLE 5.**

### **GRANTING OF OPTIONS**

5.1 Granting of Options to Eligible Individuals. The Administrator is authorized to grant Options to Eligible Individuals from time to time, in its sole discretion, on such terms and conditions as it may determine which shall not be inconsistent with the Plan.



5.2 Qualification of Incentive Stock Options. No Incentive Stock Option shall be granted to any person who is not an Employee of the Company or any subsidiary corporation (as defined in Section 424(f) of the Code) of the Company. No person who qualifies as a Greater Than 10% Stockholder may be granted an Incentive Stock Option unless such Incentive Stock Option conforms to the applicable provisions of Section 422 of the Code. Any Incentive Stock Option granted under the Plan may be modified by the Administrator, with the consent of the Holder, to disqualify such Option from treatment as an “incentive stock option” under Section 422 of the Code. To the extent that the aggregate fair market value of stock with respect to which “incentive stock options” (within the meaning of Section 422 of the Code, but without regard to Section 422(d) of the Code) are exercisable for the first time by a Holder during any calendar year under the Plan, and all other plans of the Company and any subsidiary or parent corporation thereof (each as defined in Section 424(f) and (e) of the Code, respectively), exceeds \$100,000, the Options shall be treated as Non-Qualified Stock Options to the extent required by Section 422 of the Code. The rule set forth in the preceding sentence shall be applied by taking Options and other “incentive stock options” into account in the order in which they were granted and the Fair Market Value of stock shall be determined as of the time the respective options were granted. In addition, to the extent that any Options otherwise fail to qualify as Incentive Stock Options, such Options shall be treated as Nonqualified Stock Options.

5.3 Option Exercise Price. Except as provided in Article 13 hereof, the exercise price per Share subject to each Option shall be set by the Administrator, but shall not be less than one hundred percent (100%) of the Fair Market Value of a Share on the date the Option is granted (or, as to Incentive Stock Options, on the date the Option is modified, extended or renewed for purposes of Section 424(h) of the Code). In addition, in the case of Incentive Stock Options granted to a Greater Than 10% Stockholder, such price shall not be less than one hundred ten percent (110%) of the Fair Market Value of a Share on the date the Option is granted (or the date the Option is modified, extended or renewed for purposes of Section 424(h) of the Code).

5.4 Option Term. The term of each Option (the “Option Term”) shall be set by the Administrator in its sole discretion; provided, however, that the Option Term shall not be more than ten (10) years from the date the Option is granted, or five (5) years from the date an Incentive Stock Option is granted to a Greater Than 10% Stockholder. The Administrator shall determine the time period, including the time period following a Termination of Service, during which the Holder has the right to exercise the vested Options, which time period may not extend beyond the last day of the Option Term. Except as limited by the requirements of Section 409A or Section 422 of the Code and regulations and rulings thereunder, the Administrator may extend the Option Term of any outstanding Option, may extend the time period during which vested Options may be exercised following any Termination of Service of the Holder, and may amend any other term or condition of such Option relating to such a Termination of Service.

5.5 Option Vesting.

(a) The period during which the right to exercise, in whole or in part, an Option vests in the Holder shall be set by the Administrator and the Administrator may determine that an Option may not be exercised in whole or in part for a specified period after it is granted. Such vesting may be based on service with the Company or any Affiliate, any performance criteria, or any other criteria selected by the Administrator. At any time after the grant of an Option, the Administrator may, in its sole discretion and subject to whatever terms and conditions it selects, accelerate the vesting of the Option, including following a Termination of Service; provided, that in no event shall an Option become exercisable following its expiration, termination or forfeiture.

(b) No portion of an Option which is unexercisable at a Holder’s Termination of Service shall thereafter become exercisable, except as may be otherwise provided by the Administrator either in the Program, the Award Agreement or by action of the Administrator following the grant of the Option.

5.6 Substitute Awards. Notwithstanding the foregoing provisions of this Article 5 to the contrary, in the case of an Option that is a Substitute Award, the price per share of the shares subject to such Option may be less than the Fair Market Value per share on the date of grant; provided that the excess of: (a) the aggregate Fair Market Value (as of the date such Substitute Award is granted) of the shares subject to the Substitute Award, over (b) the aggregate exercise price thereof does not exceed the excess of: (x) the aggregate fair market value (as of

the time immediately preceding the transaction giving rise to the Substitute Award, such fair market value to be determined by the Administrator) of the shares of the predecessor entity that were subject to the grant assumed or substituted for by the Company, over (y) the aggregate exercise price of such shares.

5.7 Substitution of Stock Appreciation Rights. The Administrator may provide in the applicable Program or the Award Agreement evidencing the grant of an Option that the Administrator, in its sole discretion, shall have the right to substitute a Stock Appreciation Right for such Option at any time prior to or upon exercise of such Option; provided that such Stock Appreciation Right shall be exercisable with respect to the same number of Shares for which such substituted Option would have been exercisable, and shall also have the same exercise price, vesting schedule and remaining Option Term as the substituted Option.

## **ARTICLE 6.**

### **EXERCISE OF OPTIONS**

6.1 Partial Exercise. An exercisable Option may be exercised in whole or in part. However, an Option shall not be exercisable with respect to fractional Shares and the Administrator may require that, by the terms of the Option, a partial exercise must be with respect to a minimum number of Shares.

6.2 Manner of Exercise. All or a portion of an exercisable Option shall be deemed exercised upon delivery of all of the following to the Secretary of the Company, or such other person or entity designated by the Administrator, or his, her or its office, as applicable:

(a) A written or electronic notice complying with the applicable rules established by the Administrator stating that the Option, or a portion thereof, is exercised. The notice shall be signed by the Holder or other person then entitled to exercise the Option or such portion of the Option;

(b) Such representations and documents as the Administrator, in its sole discretion, deems necessary or advisable to effect compliance with all Applicable Law. The Administrator may, in its sole discretion, also take whatever additional actions it deems appropriate to effect such compliance including, without limitation, placing legends on share certificates and issuing stop-transfer notices to agents and registrars;

(c) In the event that the Option shall be exercised pursuant to Section 11.3 hereof by any person or persons other than the Holder, appropriate proof of the right of such person or persons to exercise the Option, as determined in the sole discretion of the Administrator; and

(d) Full payment of the exercise price and applicable withholding taxes to the stock administrator of the Company for the shares with respect to which the Option, or portion thereof, is exercised, in a manner permitted by Section 11.1 and 11.2 hereof.

6.3 Notification Regarding Disposition. The Holder shall give the Company prompt written or electronic notice of any disposition of Shares acquired by exercise of an Incentive Stock Option which occurs within (a) two (2) years from the date of granting (including the date the Option is modified, extended or renewed for purposes of Section 424(h) of the Code) of such Option to such Holder, or (b) one (1) year after the transfer of such shares to such Holder.

## **ARTICLE 7.**

### **AWARD OF RESTRICTED STOCK**

7.1 Award of Restricted Stock.

(a) The Administrator is authorized to grant Restricted Stock to Eligible Individuals, and shall determine the terms and conditions, including the restrictions applicable to each award of Restricted Stock, which terms and conditions shall not be inconsistent with the Plan, and may impose such conditions on the issuance of such Restricted Stock as it deems appropriate.

(b) The Administrator shall establish the purchase price, if any, and form of payment for Restricted Stock; provided, however, that if a purchase price is charged, such purchase price shall be no less than the par value, if any, of the Shares to be purchased, unless otherwise permitted by Applicable Law. In all cases, legal consideration shall be required for each issuance of Restricted Stock to the extent required by Applicable Law.



7.2 Rights as Stockholders. Subject to Section 7.4 hereof, upon issuance of Restricted Stock, the Holder shall have, unless otherwise provided by the Administrator, all the rights of a stockholder with respect to said Shares, subject to the restrictions in the applicable Program or in each individual Award Agreement, including the right to receive all dividends and other distributions paid or made with respect to the Shares; provided, however, that, in the sole discretion of the Administrator, any extraordinary distributions with respect to the Shares shall be subject to the restrictions set forth in Section 7.3 hereof.

7.3 Restrictions. All shares of Restricted Stock (including any shares received by Holders thereof with respect to shares of Restricted Stock as a result of stock dividends, stock splits or any other form of recapitalization) shall, in the terms of the applicable Program or in each individual Award Agreement, be subject to such restrictions and vesting requirements as the Administrator shall provide. Such restrictions may include, without limitation, restrictions concerning voting rights and transferability and such restrictions may lapse separately or in combination at such times and pursuant to such circumstances or based on such criteria as selected by the Administrator, including, without limitation, criteria based on the Holder's duration of employment, directorship or consultancy with the Company, Company or Affiliate performance, individual performance or other criteria selected by the Administrator. By action taken after the Restricted Stock is issued, the Administrator may, on such terms and conditions as it may determine to be appropriate, accelerate the vesting of such Restricted Stock by removing any or all of the restrictions imposed by the terms of the Program and/or the Award Agreement. Restricted Stock may not be sold or encumbered until all restrictions are terminated or expire. In addition, notwithstanding anything to the contrary herein, with respect to a share of Restricted Stock, dividends which are paid prior to vesting shall only be paid out to the Participant to the extent the share of Restricted Stock vests.

7.4 Repurchase or Forfeiture of Restricted Stock. Except as otherwise determined by the Administrator at the time of the grant of the Award or thereafter, if no price was paid by the Holder for the Restricted Stock, upon a Termination of Service during the applicable restriction period, the Holder's rights in unvested Restricted Stock then subject to restrictions shall lapse, and such Restricted Stock shall be surrendered to the Company and cancelled without consideration. If a price was paid by the Holder for the Restricted Stock, upon a Termination of Service during the applicable restriction period, the Company shall have the right to repurchase from the Holder the unvested Restricted Stock then subject to restrictions at a cash price per share equal to the price paid by the Holder for such Restricted Stock or such other amount as may be specified in the Program or the Award Agreement. Notwithstanding the foregoing, the Administrator in its sole discretion may provide that in the event of certain events, including a Change in Control, the Holder's death, retirement or disability or any other specified Termination of Service or any other event, the Holder's rights in unvested Restricted Stock shall not lapse, such Restricted Stock shall vest and, if applicable, the Company shall not have a right of repurchase.

7.5 Certificates for Restricted Stock. Restricted Stock granted pursuant to the Plan may be evidenced in such manner as the Administrator shall determine. Certificates or book entries evidencing shares of Restricted Stock must include an appropriate legend referring to the terms, conditions, and restrictions applicable to such Restricted Stock. The Company may, in its sole discretion, (a) retain physical possession of any stock certificate evidencing shares of Restricted Stock until the restrictions thereon shall have lapsed and/or (b) require that the stock certificates evidencing shares of Restricted Stock be held in custody by a designated escrow agent (which may but need not be the Company) until the restrictions thereon shall have lapsed, and that the Holder deliver a stock power, endorsed in blank, relating to such Restricted Stock.

7.6 Section 83(b) Election. If a Holder makes an election under Section 83(b) of the Code to be taxed with respect to the Restricted Stock as of the date of transfer of the Restricted Stock rather than as of the date or dates upon which the Holder would otherwise be taxable under Section 83(a) of the Code, the Holder shall be required to deliver a copy of such election to the Company promptly after filing such election with the Internal Revenue Service.

## **ARTICLE 8.**

### **AWARD OF RESTRICTED STOCK UNITS**

8.1 Grant of Restricted Stock Units. The Administrator is authorized to grant Awards of Restricted Stock Units to any Eligible Individual selected by the Administrator in such amounts and subject to such terms and conditions as determined by the Administrator.

8.2 Term. Except as otherwise provided herein, the term of a Restricted Stock Unit award shall be set by the Administrator in its sole discretion.

8.3 Purchase Price. The Administrator shall specify the purchase price, if any, to be paid by the Holder to the Company with respect to any Restricted Stock Unit award; provided, however, that value of the consideration shall not be less than the par value of a Share, unless otherwise permitted by Applicable Law.

8.4 Vesting of Restricted Stock Units. At the time of grant, the Administrator shall specify the date or dates on which the Restricted Stock Units shall become fully vested and nonforfeitable, and may specify such conditions to vesting as it deems appropriate, including, without limitation, vesting based upon the Holder's duration of service to the Company or any Affiliate, Company performance, individual performance or other specific criteria, in each case on a specified date or dates or over any period or periods, as determined by the Administrator.

8.5 Maturity and Payment. At the time of grant, the Administrator shall specify the maturity date applicable to each grant of Restricted Stock Units which shall be no earlier than the vesting date or dates of the Award and may be determined at the election of the Holder (if permitted by the applicable Award Agreement); provided that, except as otherwise determined by the Administrator, set forth in any applicable Award Agreement, and subject to compliance with Section 409A of the Code, in no event shall the maturity date relating to each Restricted Stock Unit occur following the later of (a) the fifteenth (15<sup>th</sup>) day of the third (3<sup>rd</sup>) month following the end of calendar year in which the Restricted Stock Unit vests; or (b) the fifteenth (15<sup>th</sup>) day of the third (3<sup>rd</sup>) month following the end of the Company's fiscal year in which the Restricted Stock Unit vests. On the maturity date, the Company shall, subject to Section 11.4(e) hereof, transfer to the Holder one unrestricted, fully transferable Share for each Restricted Stock Unit scheduled to be paid out on such date and not previously forfeited, or, in the sole discretion of the Administrator, an amount in cash equal to the Fair Market Value of such shares on the maturity date or a combination of cash and Common Stock as determined by the Administrator.

8.6 Payment upon Termination of Service. An Award of Restricted Stock Units shall only be payable while the Holder is an Employee, a Consultant or a member of the Board, as applicable; provided, however, that the Administrator, in its sole and absolute discretion may provide (in an Award Agreement or otherwise) that a Restricted Stock Unit award may be paid subsequent to a Termination of Service in certain events, including a Change in Control, the Holder's death, retirement or disability or any other specified Termination of Service

8.7 No Rights as a Stockholder. Unless otherwise determined by the Administrator, a Holder who is awarded Restricted Stock Units shall possess no incidents of ownership with respect to the Shares represented by such Restricted Stock Units, unless and until the same are transferred to the Holder pursuant to the terms of this Plan and the Award Agreement.

8.8 Dividend Equivalents. Subject to Section 9.2 hereof, the Administrator may, in its sole discretion, provide that Dividend Equivalents shall be earned by a Holder of Restricted Stock Units based on dividends declared on the Common Stock, to be credited as of dividend payment dates during the period between the date an Award of Restricted Stock Units is granted to a Holder and the maturity date of such Award.

## **ARTICLE 9.**

### **AWARD OF PERFORMANCE AWARDS, DIVIDEND EQUIVALENTS, STOCK PAYMENTS, DEFERRED STOCK, DEFERRED STOCK UNITS**

#### **9.1 Performance Awards.**

(a) The Administrator is authorized to grant Performance Awards, including Awards of Performance Stock Units, to any Eligible Individual. The value of Performance Awards, including Performance Stock Units, may be linked to any one or more performance criteria or other specific criteria determined by the Administrator, in each case on a specified date or dates or over any period or periods determined by the Administrator. Performance Awards, including Performance Stock Unit awards may be paid in cash, Shares, or a combination of cash and Shares, as determined by the Administrator.

(b) Without limiting Section 9.1(a) hereof, the Administrator may grant Performance Awards to any Eligible Individual in the form of a cash bonus payable upon the attainment of objective performance goals, or such other criteria, whether or not objective, which are established by the Administrator, in each case on a specified date or dates or over any period or periods determined by the Administrator.

#### 9.2 Dividend Equivalents.

(a) Dividend Equivalents may be granted by the Administrator based on dividends declared on the Common Stock, to be credited as of dividend payment dates during the period between the date an Award is granted to a Holder and the date such Award vests, is exercised, is distributed or expires, as determined by the Administrator. Such Dividend Equivalents shall be converted to cash or additional shares of Common Stock by such formula and at such time and subject to such limitations as may be determined by the Administrator. Notwithstanding anything to the contrary in the Plan, dividends or Dividend Equivalents with respect to an Award that is subject to vesting and that are based on dividends paid prior to the vesting of such Award shall only be paid out to the Holder to the extent that the vesting conditions are subsequently satisfied and the Award vests.

(b) No Dividend Equivalents shall be payable with respect to Options or Stock Appreciation Rights.

9.3 Stock Payments. The Administrator is authorized to make Stock Payments to any Eligible Individual. The number or value of Shares of any Stock Payment shall be determined by the Administrator and may be based upon one or more performance criteria or any other specific criteria, including service to the Company or any Affiliate, determined by the Administrator. Shares underlying a Stock Payment which is subject to a vesting schedule or other conditions or criteria set by the Administrator will not be issued until those conditions have been satisfied. Unless otherwise provided by the Administrator, a Holder of a Stock Payment shall have no rights as a Company stockholder with respect to such Stock Payment until such time as the Stock Payment has vested and the Shares underlying the Award have been issued to the Holder. Stock Payments may, but are not required to, be made in lieu of base salary, bonus, fees or other cash compensation otherwise payable to such Eligible Individual.

9.4 Deferred Stock. The Administrator is authorized to grant Deferred Stock to any Eligible Individual. The number of shares of Deferred Stock shall be determined by the Administrator and may (but is not required to) be based on one or more performance criteria or other specific criteria, including service to the Company or any Affiliate, as the Administrator determines, in each case on a specified date or dates or over any period or periods determined by the Administrator. Shares underlying a Deferred Stock award which is subject to a vesting schedule or other conditions or criteria set by the Administrator will be issued on the vesting date(s) or date(s) that those conditions and criteria have been satisfied, as applicable. Unless otherwise provided by the Administrator, a Holder of Deferred Stock shall have no rights as a Company stockholder with respect to such Deferred Stock until such time as the Award has vested and any other applicable conditions and/or criteria have been satisfied and the Shares underlying the Award have been issued to the Holder.

9.5 Deferred Stock Units. The Administrator is authorized to grant Deferred Stock Units to any Eligible Individual. The number of Deferred Stock Units shall be determined by the Administrator and may (but is not required to) be based on one or more performance criteria or other specific criteria, including service to the Company or any Affiliate, as the Administrator determines, in each case on a specified date or dates or over any period or periods determined by the Administrator. Each Deferred Stock Unit shall entitle the Holder thereof to receive one share of Common Stock on the date the Deferred Stock Unit becomes vested or upon a specified settlement date thereafter (which settlement date may (but is not required to) be the date of the Holder's Termination of Service). Shares underlying a Deferred Stock Unit award which is subject to a vesting schedule or other conditions or criteria set by the Administrator will not be issued until on or following the date that those conditions and criteria have been satisfied. Unless otherwise provided by the Administrator, a Holder of Deferred Stock Units shall have no rights as a Company stockholder with respect to such Deferred Stock Units until such time as the Award has vested and any other applicable conditions and/or criteria have been satisfied and the Shares underlying the Award have been issued to the Holder.

9.6 Term. The term of a Performance Award, Dividend Equivalent award, Stock Payment award, Deferred Stock award and/or Deferred Stock Unit award shall be set by the Administrator in its sole discretion.

9.7 Purchase Price. The Administrator may establish the purchase price of a Performance Award, Shares distributed as a Stock Payment award, shares of Deferred Stock or Shares distributed pursuant to a Deferred Stock Unit award; provided, however, that value of the consideration shall not be less than the par value of a Share, unless otherwise permitted by Applicable Law.

9.8 Termination of Service. A Performance Award, Stock Payment award, Dividend Equivalent award, Deferred Stock award and/or Deferred Stock Unit award is distributable only while the Holder is an Employee, Director or Consultant, as applicable. The Administrator, however, in its sole discretion may provide that the Performance Award, Dividend Equivalent award, Stock Payment award, Deferred Stock award and/or Deferred Stock Unit award may be distributed subsequent to a Termination of Service in certain events, including a Change in Control, the Holder's death, retirement or disability or any other specified Termination of Service.

## **ARTICLE 10.**

### **AWARD OF STOCK APPRECIATION RIGHTS**

#### **10.1 Grant of Stock Appreciation Rights.**

(a) The Administrator is authorized to grant Stock Appreciation Rights to Eligible Individuals from time to time, in its sole discretion, on such terms and conditions as it may determine consistent with the Plan.

(b) A Stock Appreciation Right shall entitle the Holder (or other person entitled to exercise the Stock Appreciation Right pursuant to the Plan) to exercise all or a specified portion of the Stock Appreciation Right (to the extent then exercisable pursuant to its terms) and to receive from the Company an amount determined by multiplying the difference obtained by subtracting the exercise price per Share of the Stock Appreciation Right from the Fair Market Value on the date of exercise of the Stock Appreciation Right by the number of Shares with respect to which the Stock Appreciation Right shall have been exercised, subject to any limitations the Administrator may impose. Except as described in (c) below or in Section 13.2 hereof, the exercise price per Share subject to each Stock Appreciation Right shall be set by the Administrator, but shall not be less than one hundred percent (100%) of the Fair Market Value on the date the Stock Appreciation Right is granted.

(c) Notwithstanding the foregoing provisions of Section 10.1(b) hereof to the contrary, in the case of a Stock Appreciation Right that is a Substitute Award, the price per Share of the Shares subject to such Stock Appreciation Right may be less than one hundred percent (100%) of the Fair Market Value per share on the date of grant; provided that the excess of: (i) the aggregate Fair Market Value (as of the date such Substitute Award is granted) of the shares subject to the Substitute Award, over (ii) the aggregate exercise price thereof does not exceed the excess of: (x) the aggregate fair market value (as of the time immediately preceding the transaction giving rise to the Substitute Award, such fair market value to be determined by the Administrator) of the shares of the predecessor entity that were subject to the grant assumed or substituted for by the Company, over (y) the aggregate exercise price of such shares.

#### **10.2 Stock Appreciation Right Vesting.**

(a) The period during which the right to exercise, in whole or in part, a Stock Appreciation Right vests in the Holder shall be set by the Administrator and the Administrator may determine that a Stock Appreciation Right may not be exercised in whole or in part for a specified period after it is granted. Such vesting may be based on service with the Company or any Affiliate, any performance criteria or any other criteria selected by the Administrator. At any time after grant of a Stock Appreciation Right, the Administrator may, in its sole discretion and subject to whatever terms and conditions it selects, accelerate the period during which a Stock Appreciation Right vests.

(b) No portion of a Stock Appreciation Right which is unexercisable at Termination of Service shall thereafter become exercisable, except as may be otherwise provided by the Administrator either in the applicable Program or Award Agreement or by action of the Administrator following the grant of the Stock Appreciation Right, including following a Termination of Service; provided, that in no event shall a Stock Appreciation Right become exercisable following its expiration, termination or forfeiture.

10.3 Manner of Exercise. All or a portion of an exercisable Stock Appreciation Right shall be deemed exercised upon delivery of all of the following to the stock administrator of the Company, or such other person or entity designated by the Administrator, or his, her or its office, as applicable:

(a) A written or electronic notice complying with the applicable rules established by the Administrator stating that the Stock Appreciation Right, or a portion thereof, is exercised. The notice shall be signed by the Holder or other person then entitled to exercise the Stock Appreciation Right or such portion of the Stock Appreciation Right;

(b) Such representations and documents as the Administrator, in its sole discretion, deems necessary or advisable to effect compliance with all applicable provisions of the Securities Act and any other federal, state or foreign securities laws or regulations. The Administrator may, in its sole discretion, also take whatever additional actions it deems appropriate to effect such compliance; and

(c) In the event that the Stock Appreciation Right shall be exercised pursuant to this Section 10.3 hereof by any person or persons other than the Holder, appropriate proof of the right of such person or persons to exercise the Stock Appreciation Right.

10.4 Stock Appreciation Right Term. The term of each Stock Appreciation Right (the “Stock Appreciation Right Term”) shall be set by the Administrator in its sole discretion; provided, however, that the term shall not be more than ten (10) years from the date the Stock Appreciation Right is granted. The Administrator shall determine the time period, including the time period following a Termination of Service, during which the Holder has the right to exercise the vested Stock Appreciation Rights, which time period may not extend beyond the expiration date of the Stock Appreciation Right Term. Except as limited by the requirements of Section 409A of the Code and regulations and rulings thereunder or the first sentence of this Section 10.4, the Administrator may extend the Stock Appreciation Right Term of any outstanding Stock Appreciation Right, may extend the time period during which vested Stock Appreciation Rights may be exercised following any Termination of Service of the Holder, and may amend any other term or condition of such Stock Appreciation Right relating to such a Termination of Service.

10.5 Payment. Payment of the amounts payable with respect to Stock Appreciation Rights pursuant to this Article 10 shall be in cash, Shares (based on its Fair Market Value as of the date the Stock Appreciation Right is exercised), or a combination of both, as determined by the Administrator.

## **ARTICLE 11.**

### **ADDITIONAL TERMS OF AWARDS**

11.1 Payment. The Administrator shall determine the methods by which payments by any Holder with respect to any Awards granted under the Plan shall be made, including, without limitation: (a) cash or check, (b) Shares (including, in the case of payment of the exercise price of an Award, Shares issuable pursuant to the exercise of the Award) or Shares held for such period of time as may be required by the Administrator in order to avoid adverse accounting consequences, in each case, having a Fair Market Value on the date of delivery equal to the aggregate payments required, (c) delivery of a written or electronic notice that the Holder has placed a market sell order with a broker with respect to Shares then issuable upon exercise or vesting of an Award, and that the broker has been directed to pay a sufficient portion of the net proceeds of the sale to the Company in satisfaction of the aggregate payments required; provided that payment of such proceeds is then made to the Company upon settlement of such sale, or (d) other form of legal consideration acceptable to the Administrator. The Administrator shall also determine the methods by which Shares shall be delivered or deemed to be delivered to Holders. Notwithstanding any other provision of the Plan to the contrary, no Holder who is a Director or an “executive officer” of the Company within the meaning of Section 13(k) of the Exchange Act shall be permitted to make payment with respect to any Awards granted under the Plan, or continue any extension of credit with respect to such payment, with a loan from the Company or a loan arranged by the Company in violation of Section 13(k) of the Exchange Act.

11.2 Tax Withholding. The Company or any Affiliate shall have the authority and the right to deduct or withhold, or require a Holder to remit to the Company, an amount sufficient to satisfy federal, state, local and foreign taxes (including the Holder’s FICA, employment tax or other social security contribution obligation) required by law to be withheld with respect to any taxable event concerning a Holder arising as a result of the Plan. The Administrator shall determine the methods by which payments by any Holder with respect to the tax



withholding obligations with respect to any Awards granted under the Plan shall be made, which methods may include any of the methods permitted under Section 11.1 above. Without limiting the foregoing, the Administrator, in its sole discretion and in satisfaction of the foregoing requirement, may withhold, or allow a Holder to elect to have the Company withhold, Shares otherwise issuable under an Award (or allow the surrender of Shares). The number of Shares which may be so withheld or surrendered shall be limited to the number of Shares which have a Fair Market Value on the date of withholding or repurchase equal to the aggregate amount of such liabilities based on the minimum statutory withholding rates for federal, state, local and foreign income tax and payroll tax purposes that are applicable to such supplemental taxable income or such higher rate as may be approved by the Administrator (which rates shall in no event exceed the maximum individual statutory tax rate in the applicable jurisdiction at the time of such withholding (or such other rate as may be required to avoid the liability classification of the applicable award under generally accepted accounting principles in the United States of America)); provided, however, that the number of Shares withheld, delivered or returned shall be rounded up to the nearest whole share sufficient to cover the applicable tax withholding obligation to the extent rounding up to the nearest whole share does not result in the liability classification of the applicable Award under generally accepted accounting principles in the United States of America. The Administrator shall determine the fair market value of the Shares, consistent with applicable provisions of the Code, for tax withholding obligations due in connection with a broker-assisted cashless Option or Stock Appreciation Right exercise involving the sale of Shares to pay the Option or Stock Appreciation Right exercise price or any tax withholding obligation.

### 11.3 Transferability of Awards.

(a) Except as otherwise provided in Sections 11.3(b) and 11.3(c) hereof:

(i) No Award under the Plan may be sold, pledged, assigned or transferred in any manner other than by will or the laws of descent and distribution or, subject to the consent of the Administrator, pursuant to a DRO, unless and until such Award has been exercised, or the Shares underlying such Award have been issued, and all restrictions applicable to such Shares have lapsed;

(ii) No Award or interest or right therein shall be liable for the debts, contracts or engagements of the Holder or the Holder's successors in interest or shall be subject to disposition by transfer, alienation, anticipation, pledge, hypothecation, encumbrance, assignment or any other means whether such disposition be voluntary or involuntary or by operation of law by judgment, levy, attachment, garnishment or any other legal or equitable proceedings (including bankruptcy) unless and until such Award has been exercised, or the Shares underlying such Award have been issued, and all restrictions applicable to such Shares have lapsed, and any attempted disposition of an Award prior to the satisfaction of these conditions shall be null and void and of no effect, except to the extent that such disposition is permitted by clause (i) of this provision; and

(iii) During the lifetime of the Holder, only the Holder may exercise an Award (or any portion thereof) granted to such Holder under the Plan, unless it has been disposed of pursuant to a DRO; after the death of the Holder, any exercisable portion of an Award may, prior to the time when such portion becomes unexercisable under the Plan or the applicable Program or Award Agreement, be exercised by the Holder's personal representative or by any person empowered to do so under the deceased Holder's will or under the then applicable laws of descent and distribution.

(b) Notwithstanding Section 11.3(a) hereof, the Administrator, in its sole discretion, may determine to permit a Holder or a Permitted Transferee of such Holder to transfer an Award other than an Incentive Stock Option (unless such Incentive Stock Option is to become a Non-Qualified Stock Option) to any one or more Permitted Transferees, subject to the following terms and conditions: (i) an Award transferred to a Permitted Transferee shall not be assignable or transferable by the Permitted Transferee (other than to another Permitted Transferee of the applicable Holder) other than by will or the laws of descent and distribution; (ii) an Award transferred to a Permitted Transferee shall continue to be subject to all the terms and conditions of the Award as applicable to the original Holder (other than the ability to further transfer the Award); and (iii) the Holder (or transferring Permitted Transferee) and the Permitted Transferee shall execute any and all documents requested by the Administrator, including, without limitation documents to (A) confirm the status of the transferee as a Permitted Transferee, (B) satisfy any requirements for an exemption for the transfer under applicable federal, state and foreign securities laws and (C) evidence the transfer.

(c) Notwithstanding Section 11.3(a) hereof, a Holder may, in the manner determined by the Administrator, designate a beneficiary to exercise the rights of the Holder and to receive any distribution with respect to any Award upon the Holder's death. A beneficiary, legal guardian, legal representative, or other person claiming any rights pursuant to the Plan is subject to all terms and conditions of the Plan and any Program or Award Agreement applicable to the Holder, except to the extent the Plan, the Program and the Award Agreement otherwise provide, and to any additional restrictions deemed necessary or appropriate by the Administrator. If the Holder is married or a domestic partner in a domestic partnership qualified under Applicable Law and resides in a community property state, a designation of a person other than the Holder's spouse or domestic partner, as applicable, as his or her beneficiary with respect to more than fifty percent (50%) of the Holder's interest in the Award shall not be effective without the prior written or electronic consent of the Holder's spouse or domestic partner, as applicable. If no beneficiary has been designated or survives the Holder, payment shall be made to the person entitled thereto pursuant to the Holder's will or the laws of descent and distribution. Subject to the foregoing, a beneficiary designation may be changed or revoked by a Holder at any time; provided that the change or revocation is filed with the Administrator prior to the Holder's death.

#### 11.4 Conditions to Issuance of Shares.

(a) Notwithstanding anything herein to the contrary, the Company shall not be required to issue or deliver any certificates or make any book entries evidencing Shares pursuant to the exercise of any Award, unless and until the Board or the Committee has determined, with advice of counsel, that the issuance of such shares is in compliance with all Applicable Law, and the Shares are covered by an effective registration statement or applicable exemption from registration. In addition to the terms and conditions provided herein, the Board or the Committee may require that a Holder make such reasonable covenants, agreements, and representations as the Board or the Committee, in its discretion, deems advisable in order to comply with Applicable Law.

(b) All Share certificates delivered pursuant to the Plan and all Shares issued pursuant to book entry procedures are subject to any stop-transfer orders and other restrictions as the Administrator deems necessary or advisable to comply with Applicable Law. The Administrator may place legends on any Share certificate or book entry to reference restrictions applicable to the Shares.

(c) The Administrator shall have the right to require any Holder to comply with any timing or other restrictions with respect to the settlement, distribution or exercise of any Award, including a window-period limitation, as may be imposed in the sole discretion of the Administrator.

(d) No fractional Shares shall be issued and the Administrator shall determine, in its sole discretion, whether cash shall be given in lieu of fractional Shares or whether such fractional Shares shall be eliminated by rounding down.

(e) Notwithstanding any other provision of the Plan, unless otherwise determined by the Administrator or required by any Applicable Law, the Company shall not deliver to any Holder certificates evidencing Shares issued in connection with any Award and instead such Shares shall be recorded in the books of the Company (or, as applicable, its transfer agent or stock plan administrator).

11.5 Forfeiture and Claw-Back Provisions. Pursuant to its general authority to determine the terms and conditions applicable to Awards under the Plan, the Administrator shall have the right to provide, in an Award Agreement or otherwise, or to require a Holder to agree by separate written or electronic instrument, that:

(a) (i) Any proceeds, gains or other economic benefit actually or constructively received by the Holder upon any receipt or exercise of the Award, or upon the receipt or resale of any Shares underlying the Award, must be paid to the Company, and (ii) the Award shall terminate and any unexercised portion of the Award (whether or not vested) shall be forfeited, if (x) a Termination of Service occurs prior to a specified date, or within a specified time period following receipt or exercise of the Award, or (y) the Holder at any time, or during a specified time period, engages in any activity in competition with the Company, or which is inimical, contrary or harmful to the interests of the Company, as further defined by the Administrator or (z) the Holder incurs a Termination of Service for "cause" (as such term is defined in the sole discretion of the Administrator, or as set forth in a written agreement relating to such Award between the Company and the Holder); and



(b) All Awards (including any proceeds, gains or other economic benefit actually or constructively received by the Holder upon any receipt or exercise of any Award or upon the receipt or resale of any Shares underlying the Award) shall be subject to the provisions of any claw-back policy implemented by the Company, including, without limitation, any claw-back policy adopted to comply with the requirements of Applicable Law, including, without limitation, the Dodd-Frank Wall Street Reform and Consumer Protection Act and any rules or regulations promulgated thereunder, to the extent set forth in such claw-back policy and/or in the applicable Award Agreement.

11.6 Prohibition on Repricing. Subject to Section 13.2 hereof, the Administrator shall not, without the approval of the stockholders of the Company, (i) authorize the amendment of any outstanding Option or Stock Appreciation Right to reduce its price per share, or (ii) cancel any Option or Stock Appreciation Right in exchange for cash or another Award when the Option or Stock Appreciation Right price per share exceeds the Fair Market Value of the underlying Shares.

11.7 Leave of Absence. Unless the Administrator provides otherwise, vesting of Awards granted hereunder shall be suspended during any unpaid leave of absence. A Holder shall not cease to be considered an Employee, Non-Employee Director or Consultant, as applicable, in the case of any (a) leave of absence approved by the Company, (b) transfer between locations of the Company or between the Company and any of its Affiliates or any successor thereof, or (c) change in status (Employee to Director, Employee to Consultant, etc.), provided that such change does not affect the specific terms applying to the Holder's Award.

## ARTICLE 12.

### ADMINISTRATION

12.1 Administrator. The Committee (or another committee or a subcommittee of the Board or the Compensation Committee of the Board assuming the functions of the Committee under the Plan) shall administer the Plan (except as otherwise permitted herein) and, unless otherwise determined by the Board, shall consist solely of two or more Non-Employee Directors appointed by and holding office at the pleasure of the Board, each of whom is intended to qualify as both a "non-employee director" as defined by Rule 16b-3 of the Exchange Act or any successor rule and an "independent director" under the rules of any securities exchange or automated quotation system on which the Shares are listed, quoted or traded; provided that any action taken by the Committee shall be valid and effective, whether or not members of the Committee at the time of such action are later determined not to have satisfied the requirements for membership set forth in this Section 12.1 or otherwise provided in any charter of the Committee. Except as may otherwise be provided in any charter of the Committee, appointment of Committee members shall be effective upon acceptance of appointment. Committee members may resign at any time by delivering written or electronic notice to the Board. Vacancies in the Committee may only be filled by the Board. Notwithstanding the foregoing, (a) the full Board, acting by a majority of its members in office, shall conduct the general administration of the Plan with respect to Awards granted to Non-Employee Directors and, with respect to such Awards, the terms "Administrator" and "Committee" as used in the Plan shall be deemed to refer to the Board and (b) the Board or Committee may delegate its authority hereunder to the extent permitted by Section 12.6 hereof.

12.2 Duties and Powers of Administrator. It shall be the duty of the Administrator to conduct the general administration of the Plan in accordance with its provisions. The Administrator shall have the power to interpret the Plan, the Program and the Award Agreement, and to adopt such rules for the administration, interpretation and application of the Plan as are not inconsistent therewith, to interpret, amend or revoke any such rules and to amend any Program or Award Agreement; provided that the rights or obligations of the Holder of the Award that is the subject of any such Program or Award Agreement are not affected materially and adversely by such amendment, unless the consent of the Holder is obtained or such amendment is otherwise permitted under Section 13.10 hereof. Any such grant or award under the Plan need not be the same with respect to each Holder. Any such interpretations and rules with respect to Incentive Stock Options shall be consistent with the provisions of Section 422 of the Code. In its sole discretion, the Board may at any time and from time to time exercise any and all rights and duties of the Committee under the Plan except with respect to matters which under Rule 16b-3 under the Exchange Act or any successor rule, or the rules of any securities exchange or automated quotation system on which the Shares are listed, quoted or traded are required to be determined in the sole discretion of the Committee.

12.3 Action by the Committee. Unless otherwise established by the Board or in any charter of the Committee, a majority of the Committee shall constitute a quorum and the acts of a majority of the members present at any meeting at which a quorum is present, and acts approved in writing by all members of the Committee in lieu of a meeting, shall be deemed the acts of the Committee. Each member of the Committee is entitled to, in good faith, rely or act upon any report or other information furnished to that member by any officer or other employee of the Company or any Affiliate, the Company's independent certified public accountants, or any executive compensation consultant or other professional retained by the Company to assist in the administration of the Plan.

12.4 Authority of Administrator. Subject to the Company's Bylaws, the Committee's Charter and any specific designation in the Plan, the Administrator has the exclusive power, authority and sole discretion to:

- (a) Designate Eligible Individuals to receive Awards;
- (b) Determine the type or types of Awards to be granted to each Eligible Individual;
- (c) Determine the number of Awards to be granted and the number of Shares to which an Award will relate;
- (d) Determine the terms and conditions of any Award granted pursuant to the Plan, including, but not limited to, the exercise price, grant price, or purchase price, any performance criteria, any restrictions or limitations on the Award, any schedule for vesting, lapse of forfeiture restrictions or restrictions on the exercisability of an Award, and accelerations or waivers thereof, and any provisions related to non-competition and recapture of gain on an Award, based in each case on such considerations as the Administrator in its sole discretion determines;
- (e) Determine whether, to what extent, and pursuant to what circumstances an Award may be settled in, or the exercise price of an Award may be paid in cash, Shares, other Awards, or other property, or an Award may be canceled, forfeited, or surrendered;
- (f) Prescribe the form of each Award Agreement, which need not be identical for each Holder;
- (g) Decide all other matters that must be determined in connection with an Award;
- (h) Establish, adopt, or revise any rules and regulations as it may deem necessary or advisable to administer the Plan;
- (i) Interpret the terms of, and any matter arising pursuant to, the Plan, any Program or any Award Agreement;
- (j) Make all other decisions and determinations that may be required pursuant to the Plan or as the Administrator deems necessary or advisable to administer the Plan; and
- (k) Accelerate wholly or partially the vesting or lapse of restrictions of any Award or portion thereof at any time after the grant of an Award, subject to whatever terms and conditions it selects and Section 13.2(d) hereof.

12.5 Decisions Binding. The Administrator's interpretation of the Plan, any Awards granted pursuant to the Plan, any Program, any Award Agreement and all decisions and determinations by the Administrator with respect to the Plan are final, binding, and conclusive on all parties.

12.6 Delegation of Authority. To the extent permitted by Applicable Law, the Board or Committee may from time to time delegate to a committee of one or more members of the Board or one or more officers of the Company the authority to grant or amend Awards or to take other administrative actions pursuant to Article 12; provided, however, that in no event shall an officer of the Company be delegated the authority to grant awards to, or amend awards held by, the following individuals: (a) individuals who are subject to Section 16 of the Exchange Act, or (b) officers of the Company (or Directors) to whom authority to grant or amend Awards has been delegated hereunder. Any delegation hereunder shall be subject to the restrictions and limits that the Board or Committee specifies at the time of such delegation, and the Board may at any time rescind the authority so delegated or appoint a new delegatee. At all times, the delegatee appointed under this Section 12.6 hereof shall serve in such capacity at the pleasure of the Board and the Committee.

## ARTICLE 13.

### MISCELLANEOUS PROVISIONS

#### 13.1 Amendment, Suspension or Termination of the Plan.

(a) This Plan shall be effective on the date it is adopted by the Board (the “Effective Date”), provided, that the stockholders of the Company approve the Plan within twelve (12) months following the Effective Date.

(b) Except as otherwise provided in this Section 13.1, the Plan may be wholly or partially amended or otherwise modified, suspended or terminated at any time or from time to time by the Board or the Committee. However, without approval of the Company’s stockholders given within twelve (12) months before or after the action by the Administrator, no action of the Administrator may, except as provided in Section 13.2 hereof, (a) increase the limits imposed in Section 3.1 hereof on the maximum number of shares which may be issued under the Plan, or (b) reduce the price per share of any outstanding Option or Stock Appreciation Right granted under the Plan, or (c) cancel any Option or Stock Appreciation Right in exchange for cash or another Award when the Option or Stock Appreciation Right price per share exceeds the Fair Market Value of the underlying Shares. Except as provided in Section 13.10 hereof, no amendment, suspension or termination of the Plan shall, without the consent of the Holder, materially and adversely affect any rights or obligations under any Award theretofore granted or awarded, unless the Award itself otherwise expressly so provides. No Awards may be granted or awarded during any period of suspension or after termination of the Plan, and in no event may any Incentive Stock Option be granted under the Plan after the tenth (10<sup>th</sup>) anniversary of the Effective Date.

#### 13.2 Changes in Common Stock or Assets of the Company, Acquisition or Liquidation of the Company and Other Corporate Events.

(a) In the event of any stock dividend, stock split, combination or exchange of shares, merger, consolidation or other distribution (other than normal cash dividends) of Company assets to stockholders, or any other change affecting the shares of the Company’s stock or the share price of the Company’s stock other than an Equity Restructuring, the Administrator may make equitable adjustments, if any, to reflect such change with respect to (i) the aggregate number and kind of shares that may be issued under the Plan (including, but not limited to, adjustments of the limitations in Section 3.1 hereof on the maximum number and kind of shares which may be issued under the Plan); (ii) the number and kind of shares of Common Stock (or other securities or property) subject to outstanding Awards; (iii) the number and kind of shares of Common Stock (or other securities or property) for which grants are subsequently to be made to new and continuing Non-Employee Directors pursuant to Section 4.6 hereof; (iv) the terms and conditions of any outstanding Awards (including, without limitation, any applicable performance targets or criteria with respect thereto); and (v) the grant or exercise price per share for any outstanding Awards under the Plan.

(b) In the event of any transaction or event described in Section 13.2(a) hereof or any unusual or nonrecurring transactions or events affecting the Company, any Affiliate of the Company, or the financial statements of the Company or any Affiliate, or of changes in Applicable Law, the Administrator, in its sole discretion, and on such terms and conditions as it deems appropriate, either by the terms of the Award or by action taken prior to the occurrence of such transaction or event and either automatically or upon the Holder’s request, is hereby authorized to take any one or more of the following actions whenever the Administrator determines that such action is appropriate in order to prevent dilution or enlargement of the benefits or potential benefits intended to be made available under the Plan or with respect to any Award under the Plan, to facilitate such transactions or events or to give effect to such changes in laws, regulations or principles:

(i) To provide for either (A) termination of any such Award in exchange for an amount of cash and/or other property, if any, equal to the amount that would have been attained upon the exercise of such Award or realization of the Holder’s rights (and, for the avoidance of doubt, if as of the date of the occurrence of the transaction or event described in this Section 13.2 the Administrator determines in good faith that no amount would have been attained upon the exercise of such Award or realization of the Holder’s rights, then such Award may be terminated by the Company without payment) or (B) the

replacement of such Award with other rights or property selected by the Administrator in its sole discretion having an aggregate value not exceeding the amount that could have been attained upon the exercise of such Award or realization of the Holder's rights had such Award been currently exercisable or payable or fully vested;

(ii) To provide that such Award be assumed by the successor or survivor corporation, or a parent or subsidiary thereof, or shall be substituted for by similar options, rights or awards covering the stock of the successor or survivor corporation, or a parent or subsidiary thereof, with appropriate adjustments as to the number and kind of shares and prices;

(iii) To make adjustments in the number and type of shares of the Company's stock (or other securities or property) subject to outstanding Awards, and in the number and kind of outstanding Restricted Stock or Deferred Stock and/or in the terms and conditions of (including the grant or exercise price), and the criteria included in, outstanding Awards and Awards which may be granted in the future;

(iv) To provide that such Award shall be exercisable or payable or fully vested with respect to all shares covered thereby, notwithstanding anything to the contrary in the Plan or the applicable Program or Award Agreement; and

(v) To provide that the Award cannot vest, be exercised or become payable after such event.

(c) In connection with the occurrence of any Equity Restructuring, and notwithstanding anything to the contrary in Sections 13.2(a) and 13.2(b) hereof:

(i) The number and type of securities subject to each outstanding Award and the exercise price or grant price thereof, if applicable, shall be equitably adjusted; and/or

(ii) The Administrator shall make such equitable adjustments, if any, as the Administrator in its discretion may deem appropriate to reflect such Equity Restructuring with respect to the aggregate number and kind of shares that may be issued under the Plan (including, but not limited to, adjustments of the limitations in Section 3.1 hereof on the maximum number and kind of shares which may be issued under the Plan).

The adjustments provided under this Section 13.2(c) shall be nondiscretionary and shall be final and binding on the affected Holder and the Company.

(d) Change in Control.

(i) Notwithstanding any other provision of the Plan, in the event of a Change in Control, each outstanding Award shall be assumed or an equivalent Award substituted by the successor corporation or a parent or subsidiary of the successor corporation, in each case, as determined by the Administrator.

(ii) In the event that the successor corporation in a Change in Control and its parents and subsidiaries refuse to assume or substitute for any Award in accordance with Section 13.2(d)(i) hereof, each such non-assumed/substituted Award, except for any Performance Awards, shall become fully vested and, as applicable, exercisable and shall be deemed exercised, immediately prior to the consummation of such transaction, and all forfeiture restrictions on any or all such Awards shall lapse at such time. For the avoidance of doubt, the vesting of any Performance Awards not assumed in a Change in Control will not be automatically accelerated pursuant to this Section 13.2(d)(ii) and will instead vest pursuant to the terms and conditions of the applicable Award Agreement upon a Change in Control where the successor corporation and its parents and subsidiaries refuse to assume or substitute for any Award in accordance with Section 13.2(d)(i) hereof. If an Award vests and, as applicable, is exercised in lieu of assumption or substitution in connection with a Change in Control, the Administrator shall notify the Holder of such vesting and any applicable exercise period, and the Award shall terminate upon the Change in Control. For the avoidance of doubt, if the value of an Award that is terminated in connection with this Section 13.2(d)(ii) is zero or negative at the time of such Change in Control, such Award shall be terminated upon the Change in Control without payment of consideration therefor.

(e) The Administrator may, in its sole discretion, include such further provisions and limitations in any Award, agreement or certificate, as it may deem equitable and in the best interests of the Company that are not inconsistent with the provisions of the Plan.

(f) No adjustment or action described in this Section 13.2 or in any other provision of the Plan shall be authorized to the extent that such adjustment or action would cause the Plan to violate Section 422(b)(1) of the Code. Furthermore, no such adjustment or action shall be authorized to the extent such adjustment or action would result in short-swing profits liability under Section 16 of the Exchange Act or violate the exemptive conditions of Rule 16b-3 of the Exchange Act unless the Administrator determines that the Award is not to comply with such exemptive conditions.

(g) The existence of the Plan, the Program, the Award Agreement and the Awards granted hereunder shall not affect or restrict in any way the right or power of the Company or the stockholders of the Company to make or authorize any adjustment, recapitalization, reorganization or other change in the Company's capital structure or its business, any merger or consolidation of the Company, any issue of stock or of options, warrants or rights to purchase stock or of bonds, debentures, preferred or prior preference stocks whose rights are superior to or affect the Common Stock or the rights thereof or which are convertible into or exchangeable for Common Stock, or the dissolution or liquidation of the Company, or any sale or transfer of all or any part of its assets or business, or any other corporate act or proceeding, whether of a similar character or otherwise.

(h) In the event of any pending stock dividend, stock split, combination or exchange of shares, merger, consolidation or other distribution (other than normal cash dividends) of Company assets to stockholders, or any other change affecting the Shares or the share price of the Common Stock including any Equity Restructuring, for reasons of administrative convenience, the Company in its sole discretion may refuse to permit the exercise of any Award during a period of thirty (30) days prior to the consummation of any such transaction.

13.3 Approval of Plan by Stockholders. The Plan will be submitted for the approval of the Company's stockholders within twelve (12) months after the date of the Board's initial adoption of the Plan. Awards may be granted or awarded prior to such stockholder approval; provided that such Awards shall not be exercisable, shall not vest and the restrictions thereon shall not lapse and no Shares shall be issued pursuant thereto prior to the time when the Plan is approved by the stockholders; and provided, further, that if such approval has not been obtained at the end of said twelve (12) month period, all Awards previously granted or awarded under the Plan shall thereupon be canceled and become null and void.

13.4 No Stockholders Rights. Except as otherwise provided herein, a Holder shall have none of the rights of a stockholder with respect to Shares covered by any Award until the Holder becomes the record owner of such Shares.

13.5 Paperless Administration. In the event that the Company establishes, for itself or using the services of a third party, an automated system for the documentation, granting or exercise of Awards, such as a system using an internet website or interactive voice response, then the paperless documentation, granting or exercise of Awards by a Holder may be permitted through the use of such an automated system.

13.6 Effect of Plan upon Other Compensation Plans. The adoption of the Plan shall not affect any other compensation or incentive plans in effect for the Company or any Affiliate. Nothing in the Plan shall be construed to limit the right of the Company or any Affiliate: (a) to establish any other forms of incentives or compensation for Employees, Directors or Consultants of the Company or any Affiliate, or (b) to grant or assume options or other rights or awards otherwise than under the Plan in connection with any proper corporate purpose including without limitation, the grant or assumption of options in connection with the acquisition by purchase, lease, merger, consolidation or otherwise, of the business, stock or assets of any corporation, partnership, limited liability company, firm or association.

13.7 Compliance with Laws. The Plan, the granting and vesting of Awards under the Plan and the issuance and delivery of Shares and the payment of money under the Plan or under Awards granted or awarded hereunder are subject to compliance with all Applicable Law, and to such approvals by any listing, regulatory or governmental authority as may, in the opinion of counsel for the Company, be necessary or advisable in connection therewith. Any securities delivered under the Plan shall be subject to such restrictions, and the person acquiring such securities shall, if requested by the Company, provide such assurances and representations to the



Company as the Company may deem necessary or desirable to assure compliance with all Applicable Law. To the extent permitted by Applicable Law, the Plan and Awards granted or awarded hereunder shall be deemed amended to the extent necessary to conform to such Applicable Law.

13.8 Titles and Headings, References to Sections of the Code or Exchange Act. The titles and headings of the Sections in the Plan are for convenience of reference only and, in the event of any conflict, the text of the Plan, rather than such titles or headings, shall control. References to sections of the Code or the Exchange Act shall include any amendment or successor thereto.

13.9 Governing Law. The Plan and any agreements hereunder shall be administered, interpreted and enforced under the internal laws of the State of Delaware without regard to conflicts of laws thereof or of any other jurisdiction.

13.10 Section 409A. To the extent that the Administrator determines that any Award granted under the Plan is subject to Section 409A of the Code, the Program pursuant to which such Award is granted and the Award Agreement evidencing such Award shall incorporate the terms and conditions required by Section 409A of the Code. To the extent applicable, the Plan, the Program and any Award Agreements shall be interpreted in accordance with Section 409A of the Code and Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued after the Effective Date. Notwithstanding any provision of the Plan to the contrary, in the event that following the Effective Date the Administrator determines that any Award may be subject to Section 409A of the Code and related Department of Treasury guidance (including such Department of Treasury guidance as may be issued after the Effective Date), the Administrator may adopt such amendments to the Plan and the applicable Program and Award Agreement or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, that the Administrator determines are necessary or appropriate to (a) exempt the Award from Section 409A of the Code and/or preserve the intended tax treatment of the benefits provided with respect to the Award, or (b) comply with the requirements of Section 409A of the Code and related Department of Treasury guidance and thereby avoid the application of any penalty taxes under such Section.

13.11 No Rights to Awards. No Eligible Individual or other person shall have any claim to be granted any Award pursuant to the Plan, and neither the Company nor the Administrator is obligated to treat Eligible Individuals, Holders or any other persons uniformly.

13.12 Unfunded Status of Awards. The Plan is intended to be an “unfunded” plan for incentive compensation. With respect to any payments not yet made to a Holder pursuant to an Award, nothing contained in the Plan or any Program or Award Agreement shall give the Holder any rights that are greater than those of a general creditor of the Company or any Affiliate.

13.13 Indemnification. To the extent allowable pursuant to Applicable Law, each member of the Committee or of the Board and any officer or other employee to whom authority to administer any component of the Plan is delegated shall be indemnified and held harmless by the Company from any loss, cost, liability, or expense that may be imposed upon or reasonably incurred by such member in connection with or resulting from any claim, action, suit, or proceeding to which he or she may be a party or in which he or she may be involved by reason of any action or failure to act pursuant to the Plan and against and from any and all amounts paid by him or her in satisfaction of judgment in such action, suit, or proceeding against him or her; provided he or she gives the Company an opportunity, at its own expense, to handle and defend the same before he or she undertakes to handle and defend it on his or her own behalf. The foregoing right of indemnification shall not be exclusive of any other rights of indemnification to which such persons may be entitled pursuant to the Company’s Certificate of Incorporation or Bylaws, as a matter of law, or otherwise, or any power that the Company may have to indemnify them or hold them harmless.

13.14 Relationship to other Benefits. No payment pursuant to the Plan shall be taken into account in determining any benefits under any pension, retirement, savings, profit sharing, group insurance, welfare or other benefit plan of the Company or any Affiliate except to the extent otherwise expressly provided in writing in such other plan or an agreement thereunder.

13.15 Expenses. The expenses of administering the Plan shall be borne by the Company and its Affiliates.

\* \* \* \* \*

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

FORM 10-K

(Mark One)

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2024

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 001-36485



ARDELYX, INC.

(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

DELAWARE  
(STATE OR OTHER JURISDICTION OF  
INCORPORATION OR ORGANIZATION)

26-1303944  
(I.R.S. EMPLOYER  
IDENTIFICATION NO.)

400 FIFTH AVE., SUITE 210, WALTHAM, MASSACHUSETTS 02451  
(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES, INCLUDING ZIP CODE)

(510) 745-1700  
(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	ARDX	The Nasdaq Global Market

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 15(d) of the Act. Yes ☐ No ☒

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

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

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

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

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



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

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

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

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

The aggregate market value of the Registrant's common stock held by non-affiliates of the Registrant as of the last business day of the Registrant's most recently completed second fiscal quarter, June 30, 2024, based on the last reported sales price of the Registrant's common stock on the Nasdaq Global Market of \$7.41 per share was \$1,744,324,359.

The number of shares of Registrant's Common Stock outstanding as of February 14, 2025, was 238,356,222.

#### DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the Registrant's Definitive Proxy Statement for its 2025 Annual Meeting of Stockholders, which will be filed with the Commission within 120 days of December 31, 2024, the close of the Registrant's 2024 fiscal year, are incorporated by reference into Part III of this Report.

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## NOTE REGARDING FORWARD-LOOKING STATEMENTS

Unless the context requires otherwise, in this Annual Report on Form 10-K the terms "Ardelyx," "we," "us," "our" and "the Company" refer to Ardelyx, Inc.

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "continue," "could," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "potential," "positioned," "seek," "should," "target," "will," "would," and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- estimates of our expenses, future revenue, capital requirements, our needs for additional financing and our ability to obtain additional capital; and
- other risks and uncertainties, including those under the caption "Risk Factors."

We have based these forward-looking statements largely on management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate and management's beliefs and assumptions, and these forward-looking statements are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control, that could cause actual outcomes or results to differ materially from those expressed or implied by such forward-looking statements. Factors that could cause actual results or conditions to differ from those anticipated by these and other forward-looking statements include those more fully described in the "Item 1A. Risk Factors" section and elsewhere in this Annual Report on Form 10-K. Except as required by law, we assume no obligation to update any forward-looking statement publicly, or to revise any forward-looking statement to reflect events or developments occurring after the date of this Annual Report on Form 10-K, even if new information becomes available in the future. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in any such forward-looking statement.

## SUMMARY OF PRINCIPAL RISKS ASSOCIATED WITH OUR BUSINESS

The principal risks and uncertainties affecting our business include the following:

- We have incurred losses in each year since our inception, and we expect to continue to incur operating losses in the future as we incur additional expenses related to our ongoing operations and our pursuit of future business opportunities.
- We will require additional financing for the foreseeable future as we invest in the growth of IBSRELA and XPHOZAH in the U.S. and building a pipeline. The inability to access necessary capital when needed on acceptable terms, or at all, could force us to reduce our efforts to commercialize IBSRELA and/or XPHOZAH, or to delay or limit our pursuit of other future business opportunities.
- We have generated limited revenue from product sales and may never be profitable for a full fiscal year.
- We are substantially dependent on the successful commercialization of IBSRELA, and there is no guarantee that we will maintain sufficient market acceptance for IBSRELA, grow market share for IBSRELA, secure and maintain adequate coverage and reimbursement for IBSRELA, or generate sufficient revenue from product sales of IBSRELA.
- There is no guarantee that we will achieve sufficient market acceptance for XPHOZAH, or that we will be able to secure and maintain adequate coverage and reimbursement for XPHOZAH, or generate sufficient revenue from product sales of XPHOZAH.
- XPHOZAH is now included in the ESRD PPS, effective January 1, 2025, which means coverage for XPHOZAH for Medicare beneficiaries is no longer available under Medicare Part D, and as a result the revenue that we may generate on sales of XPHOZAH will be negatively and materially impacted.
- IBSRELA and/or XPHOZAH may cause undesirable side effects or have other properties that could limit the commercial success of the product.
- Third-party payor coverage and reimbursement status of newly commercialized products are uncertain. Failure to obtain or maintain adequate coverage and reimbursement for IBSRELA and XPHOZAH could limit our ability to market those products and decrease our ability to generate revenue.
- We rely completely on third parties, including certain single-source suppliers, to manufacture IBSRELA and XPHOZAH. If they are unable to comply with applicable regulatory requirements, unable to source sufficient raw materials, experience manufacturing or distribution difficulties or are otherwise unable to manufacture sufficient quantities to meet demand, our commercialization of IBSRELA and XPHOZAH may be materially harmed.
- Our future results depend on CMOs, many of whom are our single source manufacturers.
- Our operating activities may be restricted as a result of covenants related to the indebtedness under our loan and security agreement with SLR, as amended, and we may be required to repay the outstanding indebtedness in an event of default, which could have a materially adverse effect on our business.

The summary risk factors described above should be read together with the text of the full risk factors below in the section entitled “Risk Factors” and the other information set forth in this Annual Report on Form 10-K, including our financial statements and the related notes, as well as in other documents that we file with the U.S. SEC. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations, and future growth prospects.

## NOTE REGARDING TRADEMARKS

ARDELYX<sup>®</sup>, IBSRELA<sup>®</sup>, and XPHOZAH<sup>®</sup> are trademarks of Ardelyx. All other trademarks, trade names and service marks appearing in this Annual Report on Form 10-K are the property of their respective owners.

**ARDELYX, INC.**  
**FORM 10-K FOR THE FISCAL YEAR ENDED DECEMBER 31, 2024**  
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## PART I

### ITEM 1. BUSINESS

#### Overview

We are a biopharmaceutical company founded with a mission to discover, develop and commercialize innovative, first-in-class medicines that meet significant unmet medical needs. We developed a unique and innovative platform that enabled the discovery of new biological mechanisms and pathways to develop potent and efficacious therapies that minimize the side effects and drug-drug interactions frequently encountered with traditional, systemically absorbed medicines. The first molecule we discovered and developed was tenapanor, a minimally absorbed, first-in-class, oral, small molecule therapy. Tenapanor, branded as IBSRELA<sup>®</sup>, is approved in the U.S. for the treatment of adults with irritable bowel syndrome with constipation. Tenapanor, branded as XPHOZAH<sup>®</sup>, is approved in the U.S. to reduce serum phosphorus in adults with chronic kidney disease on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy.

Refer to the *Summary of Abbreviated Terms* at the end of this Annual Report on Form 10-K for definitions of terms used throughout the document.

#### Strategy

We are committed to our mission of discovering, developing and commercializing first-in-class medicines that address unmet patient needs. Our principal strategy is to maintain our commercial momentum with our current products while identifying additional assets that leverage our core capabilities, including clinical, developmental and regulatory expertise and commercial excellence while maintaining a solid financial foundation, to support our future growth.

Our priorities include: (i) accelerating IBSRELA growth momentum; (ii) executing our XPHOZAH strategy to grow utilization; (iii) building a pipeline focused on areas of unmet patient need; and (iv) continuing to deliver strong commercial and financial performance.

We expect to continue to incur operating losses for the foreseeable future as we continue to invest in the commercialization of IBSRELA and XPHOZAH, incur manufacturing and development costs for tenapanor, and incur additional expenses related to our ongoing operations and our pursuit of future business opportunities. We have funded our operations primarily from the sale of common stock, product sales, funds from our collaboration partnerships, funds from our loan agreements with SLR, as well as sales of future royalties to HCR. We expect that we will increasingly rely on cash generated from operations to fund our operating plan while maintaining financial flexibility from our ability to source cash from future equity sales and debt financing.

#### Our Commercial Products

##### *IBSRELA for IBS-C*

IBSRELA, our first commercial product, is a first-in-class NHE3 inhibitor approved by the U.S. FDA for the treatment of IBS-C in adults. IBSRELA acts locally in the gut and is minimally absorbed. IBS-C is a gastrointestinal disorder characterized by both altered bowel habits and abdominal pain. IBS-C is associated with significantly impaired quality of life, reduced productivity and substantial economic burden.

We recognized our first sales of IBSRELA in the U.S. in March 2022. Throughout 2024, we continued to build on the commercial success of IBSRELA. We recognized approximately \$158.3 million in net revenue related to sales of IBSRELA in the U.S. during the year ended December 31, 2024, an increase of \$78.2 million compared to the year ended December 31, 2023.

We deploy a market-responsive commercial strategy for IBSRELA and have a commercial organization highly experienced in launching and commercializing novel therapies into specialty areas. The dynamics of the IBS-C market reflect an established patient base, limited number of competitors all confined to a single mechanism of action (secretagogues), concentrated number of prescribers and recognized unmet need. In addition, market research indicated a favorable response to the IBSRELA product profile as a novel mechanism therapy. These dynamics enabled a targeted promotional focus on IBS-C patients currently being managed by high-writing healthcare providers. Central to our go to market strategy for IBSRELA has been our highly experienced specialty sales force, composed of many with existing relationships across their gastrointestinal target base, omnichannel digital initiatives and our patient services programs, including ArdelyxAssist, that support patient access to our therapies.

We believe competition for IBSRELA comes largely from three prescription products indicated for IBS-C: Linzess (linaclotide), Amitiza (lubiprostone) and Trulance (plecanatide). Generic lubiprostone is also available in the U.S. Additionally, over-the-counter products and prescription therapies, not indicated for IBS-C are commonly used to treat the constipation component of IBS-C, alone and in combination with the IBS-C-indicated prescription therapies.

***XPHOZAH to Reduce Serum Phosphorus in Adults with CKD on Dialysis as Add-on Therapy in Patients Who Have an Inadequate Response to Phosphate Binders or Who Are Intolerant of Any Dose of Phosphate Binder Therapy***

XPHOZAH, our second commercial product, was approved by the U.S. FDA in October 2023. XPHOZAH is a first-in-class phosphate absorption inhibitor approved in the U.S. to reduce serum phosphorus in adults with CKD on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy. XPHOZAH has a differentiated mechanism of action and acts locally in the gut to inhibit NHE3. This results in the tightening of the epithelial cell junctions, thereby significantly reducing paracellular uptake of phosphate, the primary pathway of phosphate absorption. It is estimated that there are more than 550,000 adult patients with CKD on dialysis in the U.S. and approximately 80% of those patients are being treated with phosphate lowering therapies. In addition, approximately 70% of patients treated with phosphate binders to treat hyperphosphatemia were unable to consistently maintain phosphorous levels  $\leq 5.5$  mg/dL over a six-month period. XPHOZAH is the first therapy for phosphate management that blocks phosphate absorption at the primary site of uptake.

We recognized our first sales of XPHOZAH in the U.S. in December 2023. We recognized approximately \$160.9 million in net revenue related to sales of XPHOZAH in the U.S. during the year ended December 31, 2024 – the first full year of commercialization of XPHOZAH.

For our commercial launch of XPHOZAH, we designed a market-responsive commercial strategy and built a commercial organization highly experienced and knowledgeable of the nephrology market. The dynamics of the hyperphosphatemia market reflect an established patient base, limited number of competitors all confined to a single mechanism of action (phosphate binders), concentrated number of prescribers and recognized unmet need. In addition, market research indicated a high level of awareness, interest and intent to adopt XPHOZAH upon approval and favorable response to the XPHOZAH product profile as a novel mechanism therapy. Central to our go to market strategy for XPHOZAH has been our highly experienced specialty sales force, many with existing relationships across their nephrology target base, innovative omnichannel digital initiatives and our patient services programs, including ArdelyxAssist, that support patient access to our therapies.

Beginning January 1, 2025, XPHOZAH, along with other oral ESRD related drugs without injectable or intravenous equivalents, are now included in the End-Stage Renal Disease Prospective Payment System, thereby eliminating coverage for XPHOZAH and these other ESRD related drugs under Medicare Part D as of such date. XPHOZAH patients with Medicare Part D accounted for approximately 60% of all XPHOZAH patients in 2024. Our strategy for XPHOZAH remains a targeted promotional focus on nephrology healthcare providers, with a focus on preserving access for patients determined to be appropriate candidates for XPHOZAH by their healthcare provider.

XPHOZAH is indicated to reduce serum phosphorus in adults with CKD on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy. The various types of phosphate binders commercialized in the U.S. include the following: Calcium acetate (several prescription brands including PhosLo and Phoslyra); Lanthanum carbonate (Fosrenol); Sevelamer hydrochloride (Renagel); Sevelamer carbonate (Renvela); Sucroferric oxyhydroxide (Velporo) and Ferric citrate (Auryxia). All of the listed phosphate binders are available as generics in the U.S., with the exception of Velporo and Auryxia. Additionally, over-the-counter calcium carbonate, such as Tums and Caltrate, is also used to bind phosphorus.

In addition to the currently available phosphate binders, we are aware of at least four phosphate binders in development, including AP-301, developed by Alebund Pharmaceutical (Hong Kong) Limited and currently in Phase 3; VS-505, developed by Vidasym and currently in clinical development; TS-172, developed by Taisho Pharmaceuticals and currently in Phase 2; and OLC, developed by Unicycive Therapeutics, which has announced its plans to seek U.S. FDA approval via the 505(b)(2) pathway. OLC has demonstrated pharmacodynamic bioequivalence to Fosrenol. Additionally, Alebund is developing AP-306, an inhibitor of phosphate transporters NaPi-2b, PiT-1, and PiT-2, thus far studied in a Phase 2 clinical trial.

## **Our Commercial Strategy**

We have established a high-quality commercial organization highly experienced in bringing novel products to our customers, including patients, payors and healthcare providers. Our commercial capabilities, including marketing, access, patient services and sales are designed to support our commercialization of IBSRELA and XPHOZAH. We have executed collaborations with established industry leaders to efficiently bring XPHOZAH and IBSRELA to patients in specific territories outside of the U.S.



We continue to evaluate our strategy for the commercialization of IBSRELA and XPHOZAH in other ex-U.S. territories.

## **Collaboration Partners**

We enter into collaboration agreements with third parties for the development and commercialization of tenapanor for certain indications in their respective territories. In exchange for granting the respective licenses, we receive upfront payments upon contract execution, are eligible to receive development and regulatory milestones upon achievement of respective events, and are eligible to receive sales-based royalties and commercial milestones. We also enter into supply agreements with our partners to supply drug substance or finished product for a fee.

We have an exclusive license agreement with Kyowa Kirin for the development, commercialization and distribution of tenapanor in Japan for cardiorenal indications. We supply tenapanor drug substance to satisfy Kyowa Kirin commercial needs. In February 2024, Kyowa Kirin announced the launch of tenapanor, marketed as PHOZEVEL<sup>®</sup>, for CKD patients with hyperphosphatemia in Japan. As discussed in *Note 8. Deferred Royalty Obligation Related To The Sale Of Future Royalties*, the future royalties and commercial milestone payments we may receive under the license, as amended, will be remitted to HCR pursuant to the HCR Agreement.

We have an exclusive license agreement with Fosun Pharma for the development and commercialization of tenapanor in China for both hyperphosphatemia and IBS-C. Fosun Pharma received approval from the Hong Kong Department of Health for the marketing application for tenapanor for the treatment of IBS-C in 2023. A New Drug Application for tenapanor for hyperphosphatemia has been submitted in China with Fosun Pharma.

We have an exclusive license agreement with Knight for the development, commercialization and distribution of tenapanor in Canada for hyperphosphatemia and IBS-C. IBSRELA was launched in Canada in March 2021.

We have an exclusive license agreement with METiS for the development and commercialization of a portfolio of TGR5 agonist compounds that we discovered and developed for all therapeutic areas.

## **Corporate Financings**

In January 2023, we filed a registration statement on Form S-3, which became effective in January 2023, containing (i) a base prospectus for the offering, issuance and sale by us of up to a maximum aggregate offering price of \$250.0 million of our common stock, preferred stock, debt securities, warrants and/or units, from time to time in one or more offerings; and (ii) a prospectus supplement for the offering, issuance and sale by us of up to a maximum aggregate offering price of \$150.0 million of our common stock that may be issued and sold, from time to time, under a sales agreement with Jefferies, deemed to be “at-the-market offerings” (2023 Open Market Sales Agreement). Pursuant to the 2023 Open Market Sales Agreement, Jefferies, as sales agent, may receive a commission of up to 3.0% of the gross sales price for shares of common stock sold under the 2023 Open Market Sales Agreement. As of December 31, 2024, we have completed sales pursuant to the 2023 Open Market Sales Agreement resulting in the issuance of 16.8 million shares of our common stock and receipt of gross proceeds of \$70.0 million at a weighted average sales price of approximately \$4.17.

We have a loan and security agreement (as amended, the 2022 Loan Agreement) with SLR. The 2022 Loan Agreement provides a total of \$200.0 million, of which \$150.0 million has been drawn as of December 31, 2024 to support our ongoing operations and the commercial launches of IBSRELA and XPHOZAH.

As of December 31, 2024, we had cash, cash equivalents and short-term investments totaling \$250.1 million, an increase of \$65.8 million, or 35.7%, from our cash position as of December 31, 2023.

## **Intellectual Property**

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our products, drug candidates, manufacturing and process discoveries and other know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our intellectual property by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology and inventions that are important to the development and operation of our business. We also rely on trade secrets and careful monitoring of our proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

The patent positions of biopharmaceutical companies like us are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued and its scope can be reinterpreted after issuance. Consequently, we do not know whether any of our products or drug candidates will be protectable or remain protected by enforceable patents. We cannot predict whether the patent applications we

are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of our issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties. If third parties prepare and file patent applications in the U.S. that also claim technology or therapeutics to which we have rights, we may have to participate in interference proceedings in the USPTO to determine priority of invention, which would result in substantial costs to us even if the eventual outcome is favorable to us.

The term of individual patents depends upon the legal term of the patents in countries in which they are obtained. In most countries, including the U.S., the patent term is generally 20 years from the earliest date of filing a non-provisional patent application in the applicable country. In the U.S., a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date.

In addition, in the U.S., the Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of a U.S. patent as partial compensation for the patent term lost during the FDA regulatory review process occurring while the patent is in force. A patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent applicable to each regulatory review period may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Similar provisions are available in the European Union and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug.

We may rely, in some circumstances, on trade secrets to protect our technology. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaboration partners, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning the business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during the normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property.

### ***Tenapanor Patents***

Our tenapanor patent portfolio includes five issued U.S. patents, three issued patents in each of Israel and Mexico, two issued patents in each of the European Patent Organization, Japan, Korea, and Hong Kong and one issued patent in each of the following territories: Australia, Brazil, India and China. These issued patents cover the composition and certain methods of using tenapanor, are wholly owned by us, and are predicted, without extension or adjustment, to expire in December 2029. The term of U.S. patent no. 8,541,448, which claims the composition of matter of tenapanor, was extended under the Hatch-Waxman Act to August 1, 2033. The portfolio further includes patents covering the use of tenapanor for controlling serum phosphorus that are wholly owned by us and have been issued in the U.S., Europe, Japan, China, Australia, Gulf Co-op countries, Hong Kong, Israel, Korea, Macao, Mexico, New Zealand, Russia, South Africa and Taiwan and are pending in other countries. These patents are predicted, without extension or adjustment, to expire in April 2034.

Additional U.S. and international patent applications are pending covering additional methods of treatment with tenapanor, and composition of matter and methods of using compounds that we believe may be follow on compounds to tenapanor.

### **Manufacturing**

To date, we have relied upon third-party CMOs to manufacture both the API and final drug product dosage forms of our commercial products, as well as our clinical trial material, and we expect that we will continue to rely upon CMOs for the manufacture of commercial product for IBSRELA, commercial product for XPHOZAH and clinical trial materials. Our license agreements with Knight and Fosun Pharma require us to supply final drug product dosage forms of tenapanor for their use in the development and commercialization of tenapanor in each of their respective territories. We are further obligated to supply API to Kyowa Kirin to support their development and commercialization of tenapanor in Japan. We expect that we will continue to use CMOs to satisfy our supply obligations to our collaboration partners.



## Government Regulation

The FDA and comparable regulatory authorities in state and local jurisdictions and in other countries impose substantial and burdensome requirements upon companies involved in the clinical development, manufacture, marketing and distribution of drugs. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion, distribution, post-approval monitoring and reporting, sampling and export and import of our product candidates.

In the U.S., the FDA regulates drug products under the FDCA and the FDA's implementing regulations. If we fail to comply with applicable U.S. FDA or other requirements at any time during the drug development process, the approval process or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include the U.S. FDA's refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any U.S. FDA enforcement action could have a material adverse effect on us. U.S. FDA approval is required before any new unapproved drug or dosage form, including a new use of a previously approved drug, can be marketed in the U.S.

The process required by the U.S. FDA before a drug may be marketed in the U.S. generally involves:

- completion of extensive preclinical laboratory tests, preclinical animal studies and formulation studies, some performed in accordance with the U.S. FDA's current GLP regulations;
- submission to the U.S. FDA of an IND application which must become effective before human clinical trials in the U.S. may begin;
- approval by an independent IRB or ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with GCP regulations to establish the safety and efficacy of the drug candidate for each proposed indication;
- submission to the U.S. FDA of an NDA;
- satisfactory completion of a U.S. FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMP regulations;
- satisfactory completion of a potential review by an U.S. FDA advisory committee, if applicable; and
- U.S. FDA review and approval of the NDA prior to any commercial marketing, sale or commercial shipment of the drug.

The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for any product candidates that we may seek to advance will be granted on a timely basis, if at all. Nonclinical tests include laboratory evaluation of product chemistry, formulation, stability and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product. The results of preclinical tests, together with manufacturing information, analytical data and a proposed clinical trial protocol and other information, are submitted as part of an IND to the U.S. FDA. Additional preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the U.S. FDA, unless the U.S. FDA, within the 30-day period, raises concerns or questions relating to the IND and places the clinical trial on a clinical hold, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the U.S. FDA must resolve any outstanding concerns before the clinical trial can begin. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be used. Each protocol must be submitted to the U.S. FDA as part of the IND.

An independent IRB or ethics committee for each medical center proposing to conduct a clinical trial must also review and approve a plan for any clinical trial before it can begin at that center and the IRB must monitor the clinical trial until it is completed. The U.S. FDA, the IRB or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive GCP requirements, including the requirements for informed consent.

All clinical research performed in the U.S. in support of an NDA must be submitted in advance by the U.S. FDA under the IND regulations and procedures described above. However, a sponsor who wishes to conduct a clinical trial outside the U.S. may, but need not, obtain U.S. FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the U.S. FDA in support of an NDA so long as the clinical trial is conducted in compliance with GCP and if the U.S. FDA is able to validate the data from the study through an onsite inspection, if necessary. GCP includes review and approval by an independent ethics committee, such as an IRB, and obtaining and documenting the freely given informed consent of each subject before study initiation. If the applicant seeks approval of an NDA solely on the basis of foreign data, the U.S. FDA will only accept such data if they are applicable to the U.S. population and U.S. medical practice, the studies have been performed by clinical investigators of recognized competence, and the data may be considered valid without the need for an on-site inspection by the U.S. FDA, or if the U.S. FDA considers such an inspection to be necessary, the U.S. FDA is able to validate the data through an on-site inspection or through other appropriate means.

### ***Clinical Trials***

The clinical investigation of a new drug is typically conducted in three or four phases, which may overlap or be combined, and generally proceed as follows.

- *Phase 1:* Clinical trials are initially conducted in a limited population of subjects to test the drug candidate for safety, dose tolerance, absorption, metabolism, distribution and excretion in healthy humans or, on occasion, in patients with severe problems or life-threatening diseases to gain an early indication of its effectiveness.
- *Phase 2:* Clinical trials are generally conducted in a limited patient population to evaluate dosage tolerance and appropriate dosage, identify possible adverse effects and safety risks and evaluate preliminarily the efficacy of the drug for specific targeted indications in patients with the disease or condition under study.
- *Phase 3:* Clinical trials are typically conducted when Phase 2 clinical trials demonstrate that a dose range of the product candidate is effective and has an acceptable safety profile. Phase 3 clinical trials are commonly referred to as “pivotal” studies, which typically denotes a study which presents the data that the U.S. FDA or other relevant regulatory agency will use to determine whether or not to approve a drug. Phase 3 clinical trials are generally undertaken with large numbers of patients, such as groups of several hundred to several thousand, to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites.
- *Phase 4:* In some cases, the U.S. FDA may condition approval of an NDA for a product candidate on the sponsor’s agreement to conduct additional clinical trials after NDA approval. In other cases, a sponsor may voluntarily conduct additional clinical trials post approval to gain more information about the drug. Such post approval trials are typically referred to as Phase 4 clinical trials.

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

The U.S. FDA, the IRB or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk.

Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the study.

We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

### ***New Drug Applications***

The results of preclinical studies and of the clinical trials, together with other detailed information, including extensive manufacturing information and information on the composition of the drug, are submitted to the U.S. FDA in the form of an NDA requesting approval to market the drug for one or more specified indications. The U.S. FDA reviews an NDA to determine, among other things, whether a drug is safe and effective for its intended use.

Under the Prescription Drug User Fee Act, the U.S. FDA has a goal of responding to standard review NDAs for new molecular entities within ten months after the 60-day filing review period, or six months after the 60-day filing review period for priority review NDAs. For non-new molecular entities, the U.S. FDA has a goal of responding within ten months of receipt of standard review NDAs and six months of receipt for priority review NDAs. These timeframes are often extended by U.S. FDA requests for additional information or clarification. The U.S. FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The U.S. FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

After the U.S. FDA evaluates the NDA and conducts inspections of manufacturing facilities where the drug product and/or its API will be produced, if deemed necessary, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application is not ready for approval. A Complete Response Letter may require additional clinical data and/or an additional Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Even if such additional information is submitted, the U.S. FDA may ultimately decide that the NDA does not satisfy the criteria for approval. The U.S. FDA could also approve the NDA with a REMS if it is determined that a REMS is necessary to ensure that the drug's benefits outweigh its risks and a REMS to mitigate risks, which could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The U.S. FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase 4 clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. The U.S. FDA has the authority to prevent or limit further marketing of a drug based on the results of these post-market programs. Once the U.S. FDA approves an NDA, or supplement thereto, the U.S. FDA may withdraw the approval if ongoing regulatory requirements are not met or if safety problems are identified after the drug reaches the market.

Drugs may be marketed only for the U.S. FDA approved indications and in accordance with the provisions of the approved labeling. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, the applicant may be required to submit and obtain U.S. FDA approval of a new NDA or NDA supplement, which may require the applicant to develop additional data or conduct additional preclinical studies and clinical trials.

The testing and approval processes require substantial time, effort and financial resources, and each may take several years to complete. The U.S. FDA may not grant approval on a timely basis, or at all. Even if we believe a clinical trial has demonstrated safety and efficacy of one of our drug candidates for the proposed indication, the results may not be satisfactory to the U.S. FDA. Nonclinical and clinical data may be interpreted by the U.S. FDA in different ways, which could delay, limit or prevent regulatory approval. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals which could delay or preclude us from marketing drugs. The U.S. FDA may limit the indications for use or place other conditions on any approvals that could restrict the commercial application of the drugs. After approval, certain changes to the approved drug, such as adding new indications, manufacturing changes, or additional labeling claims are subject to further U.S. FDA review and approval. Depending on the nature of the change proposed, an NDA supplement must be filed and approved before the change may be implemented.

### ***Other Regulatory Requirements***

Any drugs manufactured or distributed by us or our collaboration partners pursuant to U.S. FDA approvals would be subject to continuing regulation by the U.S. FDA, including recordkeeping requirements and reporting of adverse experiences associated with the drug. Drug manufacturers and their subcontractors are required to register their establishments with the U.S. FDA and certain state agencies and are subject to periodic announced and unannounced inspections by the U.S. FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning or untitled letters, suspension of manufacturing, seizure of product, injunctive action or possible civil penalties. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing U.S. FDA regulatory requirements. If we or our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the U.S. FDA may, among other things, halt our clinical trials, require us to recall a drug from distribution or withdraw approval of the NDA for that drug.

The U.S. FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. A company can make only those claims relating to safety and efficacy that are in the final label or consistent with the final label. Failure to comply with these requirements can result in, among other things, adverse publicity, warning or untitled letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available drugs for uses that are not described in the product's labeling and that differ from those tested by us and approved by the U.S. FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The U.S. FDA does not regulate the behavior of physicians in their choice of treatments. The U.S. FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use.

### ***Hatch-Waxman Act***

Under the Price Competition and Patent Term Restoration Act, or Hatch-Waxman Act, Section 505 of the FDCA describes three types of marketing applications that may be submitted to the U.S. FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A Section 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the U.S. FDA's prior findings of safety and efficacy for an existing product, or published literature, in support of its application. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an ANDA. An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, to a previously approved product. ANDAs are termed "abbreviated" because they are generally not required to include nonclinical (animal) and clinical (human) data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through in vitro, in vivo, or other testing. The generic version must deliver the same amount of active ingredients into a subject's bloodstream in the same amount of time as the innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug. In seeking approval for a drug through an NDA, applicants are required to list with the U.S. FDA each patent with claims that cover the applicant's drug or a method of using the drug. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the U.S. FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an ANDA or 505(b)(2) NDA.

Upon submission of an ANDA or a 505(b)(2) NDA, an applicant must certify to the U.S. FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the U.S. FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through the last type of certification, also known as a Paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired.

If the ANDA or 505(b)(2) NDA applicant has provided a Paragraph IV certification to the U.S. FDA, the applicant must send notice of the Paragraph IV certification to the NDA holder and patent owners once the application has been accepted for filing by the U.S. FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. If the Paragraph IV certification is challenged by an NDA holder or the patent owner(s), the U.S. FDA may not approve that application until the earlier of 30 months from the receipt of the notice of the Paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant's favor or settled, or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a Paragraph IV certification, the NDA holder or patent owner(s) regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation.



The Hatch-Waxman Act establishes periods of regulatory exclusivity for certain approved drug products, during which the U.S. FDA cannot approve (or in some cases accept) an ANDA or 505(b)(2) application that relies on the branded reference drug. For example, the holder of an NDA, including a 505(b)(2) NDA, may obtain five years of exclusivity upon approval of a new drug containing an NCE that has not been previously approved by the U.S. FDA. A drug is an NCE if the U.S. FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the therapeutic activity of the drug substance. During the exclusivity period, the U.S. FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. However, an ANDA or 505(b)(2) NDA may be submitted after four years if it contains a Paragraph IV certification of patent invalidity or non-infringement.

The Hatch-Waxman Act also provides three years of marketing exclusivity to the holder of an NDA (including a 505(b)(2) NDA) for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. This three-year exclusivity period protects against U.S. FDA approval of ANDAs and 505(b)(2) NDAs for the specific condition of the new drug's approval. As a general matter, the three-year exclusivity does not prohibit the U.S. FDA from approving ANDAs or 505(b)(2) NDAs for generic versions of the original, unmodified drug product. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy.

### ***Fraud and Abuse Laws***

In the U.S. the research, manufacturing, distribution, sale and promotion of drug products and medical devices are potentially subject to regulation by various federal, state and local authorities in addition to the U.S. FDA, including the CMS other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice, state Attorneys General, and other state and local government agencies. These laws include but are not limited to, the Anti-Kickback Statute, the federal False Claims Act, the federal Physician Payments Sunshine Act and other state and federal laws and regulations.

The Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce the referral of business, including the purchase, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The term remuneration has been interpreted broadly to include anything of value. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Additionally, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The federal False Claims Act prohibits anyone from knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Although we would not submit claims directly to payors, manufacturers can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, our activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state, and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. If the government were to allege that we were, or convict us of, violating these false claims laws, we could be subject to a substantial fine and may suffer a decline in our stock price. In addition, private individuals have the ability to bring actions under the federal False Claims Act.

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

The federal HIPAA created additional 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 whether the payor is public or private, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute, or the specific intent to violate it, to have committed a violation.

In addition to the laws described above, the Physician Payments Sunshine Act requires certain drug manufacturers to report payments and other transfer of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in significant civil monetary penalties, and additional penalties for knowing failures, for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Manufacturers must submit reports by the 90th day of each subsequent calendar year.

Many states have also adopted laws similar to the federal laws discussed above. Some of these state prohibitions apply to the referral of patients for healthcare services reimbursed by any insurer, not just federal healthcare programs such as Medicare and Medicaid. There has also been a recent trend of increased regulation of payments made to physicians and other healthcare providers. Certain states mandate implementation of compliance programs, impose restrictions on drug manufacturers' marketing practices and/or require the tracking and reporting of pricing and marketing information as well as gifts, compensation and other remuneration to physicians. Many of these laws contain ambiguities as to what is required to comply with such laws, which may affect our sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state and perhaps federal authorities.

Violations of any of such laws or any other governmental regulations that apply may result in penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, reporting obligations and integrity oversight, exclusion from participation in federal and state healthcare programs and imprisonment.

### ***Third-Party Coverage and Reimbursement***

Sales of pharmaceutical products depend in significant part on the availability of coverage and adequate reimbursement by third-party payors, such as state and federal governments, including Medicare and Medicaid, and commercial managed care providers. In the U.S., no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for our product candidates are made on a payor by payor basis. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the U.S. FDA-approved drugs for a particular indication. A decision by a third-party payor not to cover our product candidates could reduce physician utilization of our products once approved and have a material adverse effect on our future sales, results of operations and financial condition. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

There is increased uncertainty related to insurance coverage and reimbursement for certain drugs, like XPHOZAH, which is marketed to reduce serum phosphorus in adults with CKD on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy. In January 2011, CMS implemented a new PPS for dialysis treatment. Under the ESRD PPS, CMS generally makes a single bundled payment to the dialysis facility for each dialysis treatment that covers all items and services routinely required for dialysis treatments furnished to Medicare beneficiaries in Medicare-certified ESRD facilities or at their home, including the cost of certain routine drugs. Beginning January 1, 2025, XPHOZAH, along with other oral ESRD related drugs without injectable or intravenous equivalents, are now included in the ESRD PPS, thereby eliminating coverage for XPHOZAH and these other ESRD related drugs under Medicare Part D as of such date. While it is too early to project the full impact that bundling may have on XPHOZAH and our business, we may be unable to sell XPHOZAH to dialysis providers on a profitable basis.



## ***Healthcare Reform***

In March 2010, Congress passed the Patient Protection and ACA, a healthcare reform measure. The ACA was signed into law and substantially changed the way healthcare is financed by both governmental and private insurers and significantly impacted the pharmaceutical industry.

The ACA contained a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, which have impacted existing government healthcare programs and have resulted in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

Additionally, the ACA:

- increased the minimum level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1% of the AMP;
- required collection of rebates for drugs paid by Medicaid managed care organizations;
- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expanded access to commercial health insurance coverage through new state-based health insurance marketplaces, or exchanges;
- required manufacturers to participate in a coverage gap discount program (which was replaced by a new discount program in 2025, as discussed below), under which they were required to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and
- imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form.

In addition, other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. For example, in August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions to Medicare payments to providers, which went into effect on April 1, 2013, and, due to subsequent legislative amendments, will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. More recently, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminated the statutory Medicaid drug rebate cap beginning January 1, 2024. The rebate was previously capped at 100% of a drug's AMP.

Recently, there has also been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills 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. Most recently, on August 16, 2022, the IRA was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023) and replaces the Part D coverage gap discount program with a new discounting program (which began in 2025). Under the IRA, small molecule drugs and biologics first become eligible for price negotiation seven and eleven years, respectively, after FDA approval. The IRA permits the Secretary of the HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has issued and will continue to issue guidance implementing the IRA. CMS has published the negotiated prices for the initial ten drugs, which will first be effective in 2026, and the list of the subsequent 15 drugs that will be subject to negotiation, although the Medicare drug price negotiation program is currently subject to legal challenges. While the impact of the IRA on the pharmaceutical industry cannot yet be fully determined, it is likely to be significant. Additionally, individual states have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient

reimbursement constraints, discounts, restrictions on certain product access, and to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states. These new laws and the regulations and policies implementing them, as well as other healthcare reform measures that may be adopted in the future, may have a material adverse effect on our industry generally and on our ability to successfully develop and commercialize our products.

### ***Government Price Reporting***

Medicaid is a joint federal and state program for low-income and disabled beneficiaries. Medicare is a federal program covering individuals age 65 and over as well as those with certain disabilities. As a condition of having federal funds being made available for our covered drugs under Medicaid, we have enrolled in the MDRP, which requires us to pay a rebate to state Medicaid programs for each unit of our covered drugs dispensed to a Medicaid beneficiary and paid for by a state Medicaid program. Medicaid drug rebates are based on pricing data that we must report on a monthly and quarterly basis to the U.S. CMS, the federal agency that administers the MDRP and Medicare programs. For the MDRP, these data include the AMP and the best price for each drug. If we become aware that our MDRP price reporting submission for a prior period was incorrect or has changed as a result of recalculation of the pricing data, we must resubmit the corrected data for up to three years after those data originally were due. Manufacturers who fail to provide information timely or are found to have knowingly submitted false information to the government may be subject to civil monetary penalties and other sanctions, including termination from the MDRP.

Federal law requires that a manufacturer that participates in the MDRP also participate in the 340B program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. We participate in the 340B program, which is administered by the HRSA, and requires us to charge statutorily defined covered entities no more than the 340B "ceiling price" for our covered outpatient drugs used in an outpatient setting. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the AMP and rebate amount for the covered outpatient drug as calculated under the MDRP. In general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price calculation and discount requirement. We must report 340B ceiling prices to HRSA on a quarterly basis, and HRSA publishes them to 340B covered entities. HRSA has finalized regulations regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities for 340B-eligible drugs. HRSA has also finalized an administrative dispute resolution process through which 340B covered entities may pursue claims against participating manufacturers for overcharges, and through which manufacturers may pursue claims against 340B covered entities for engaging in unlawful diversion or duplicate discounting of 340B drugs.

In order to be eligible to have drug products paid for with federal funds under Medicaid and purchased by certain federal agencies and grantees, manufacturers must also participate in the U.S. VA FSS pricing program. Under the VA/FSS program, manufacturers must report the Non-FAMP for their covered drugs to the VA and charge certain federal agencies no more than the Federal Ceiling Price, which is calculated based on Non-FAMP using a statutory formula. These four agencies are the VA, the U.S. Department of Defense, the U.S. Coast Guard and the U.S. Public Health Service (including the Indian Health Service). Manufacturers must also pay rebates on products purchased by military personnel and dependents through the TRICARE retail pharmacy program. Manufacturers who fail to provide timely information or are found to have knowingly submitted false information may be subject to civil monetary penalties.

Individual states continue to consider and have enacted legislation to limit the growth of healthcare costs, including the cost of prescription drugs and combination products. A number of states have either implemented or are considering implementation of drug price transparency legislation. Requirements under such laws include advance notice of planned price increases, reporting price increase amounts and factors considered in taking such increases, wholesale acquisition cost information disclosure to prescribers, purchasers, and state agencies, and new product notice and reporting. Such legislation could limit the price or payment for certain drugs, and a number of states are authorized to impose civil monetary penalties or pursue other enforcement mechanisms against manufacturers who fail to comply with drug price transparency requirements, including the untimely, inaccurate or incomplete reporting of drug pricing information.

### ***Data Privacy and Security Laws***

Numerous state, federal and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality and security of personal information, including health-related information. In the U.S., numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. Further, certain foreign laws govern the privacy and security of

personal data, including health-related data. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

### ***Other Regulations***

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

### **Human Capital**

The future success of our company depends on our ability to attract, retain and further develop top talent. Throughout our transition to a commercial organization and expansion of our workforce, we have remained steadfastly committed to our core values, including our goal to develop and maintain an inclusive, diverse and safe workplace with opportunities for our employees to grow and develop in their careers, supported by strong compensation and benefits.

At December 31, 2024, we had 395 full-time employees, 77 of whom were engaged directly in development and manufacturing, 252 in sales and marketing and 66 in general and administrative activities. During 2024, our employee base increased by approximately 128, or 48%.

### ***Inclusion and Diversity***

Our culture is supported by an unwavering commitment to inclusion and diversity. As of December 31, 2024, approximately 61% of our workforce was female; 33% of our executive leadership team was female and 55% of our employees in managerial roles were female. As of December 31, 2024, minorities represented 31% of our workforce, and 37% of our employees in managerial roles were minorities. We strive to foster a culture where mutual respect, inclusive behavior and dignity are core to our individual expectations.

We believe that our success will be significantly impacted by our ability to create and maintain a safe inclusive environment where everyone is empowered to do their best work regardless of race, color, national origin, religion, sex, sexual orientation, gender identity and expression, age or disability.

### ***Core Values***

Fostering and maintaining a strong, healthy culture is a key strategic focus. Our core values reflect who we are and the way our employees interact with one another, our partners and our stockholders. We are dedicated to our core values, recognizing that this dedication will foster an environment where we will be able to realize our vision of advancing patient care. We are Passionate, aware that with integrity and determination, we make a difference for patients. We are Fearless, aware that by challenging convention, we truly innovate. We are Dedicated, aware that working tirelessly together, we are greater than the sum of our parts. We are Inclusive, aware that with respect, grace and humor, we are family. We encourage our employees to live out our core values and believe they help our culture stay strong and unique.

### ***Health, Safety and Wellness***

The health, safety and wellness of our employees is a priority in which we have always invested, and will continue to do so. We continue to offer hybrid and remote working opportunities for our team members employed in areas within the organization where such flexible work options are possible. We will continue to adopt and align our policies to focus on the health, safety and wellness of our employees, and the needs of our business.

### ***Compensation and Benefits***

We recognize that we operate within an industry where there is significant competition for top talent, and we endeavor to provide not only a strong healthy culture, but also important compensation and benefits programs to help meet the needs of our employees. In addition to base compensation, these programs include annual bonuses, stock awards, an Employee Stock Purchase Plan, 401(k) with company match contribution, healthcare and insurance benefits, health savings (funded by the Company) and flexible spending accounts, family leave, family care resources, and flexible work schedules, among many others.

Ensuring fair and equitable pay is integral to our commitment to our employees. Our executive team and board of directors strongly support this commitment. We conduct pay equity reviews annually to help us understand whether our compensation structure is appropriate and to identify what improvements can be made.

## **Corporate Information**

We were founded in October 2007 as a Delaware corporation under the name Nteryx. We changed our name to Ardelyx, Inc. in June 2008. We operate in one business segment, which is the development and commercialization of biopharmaceutical products. Our principal executive offices are located at 400 Fifth Avenue, Suite 210, Waltham, Massachusetts 02415, and our telephone number is (510) 745-1700. Our website address is [www.ardelyx.com](http://www.ardelyx.com).

We file electronically with the SEC our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended. We make available on our website at [www.ardelyx.com](http://www.ardelyx.com), free of charge, copies of these reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that website is [www.sec.gov](http://www.sec.gov).

## **ITEM 1A. RISK FACTORS**

*Our business involves significant risks, some of which are described below. You should carefully consider these risks, as well as other information in this Annual Report on Form 10-K, including our financial statements and the notes thereto and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations, cash flows, the trading price of our common stock and our growth prospects. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.*

### **Risks Related to our Financial Condition and Capital Requirements**

***We have incurred losses in each year since our inception, and we expect to continue to incur operating losses in the future as we incur additional expenses related to our ongoing operations and our pursuit of future business opportunities.***

In March 2022, we commenced the commercialization of our first product, IBSRELA<sup>®</sup> (tenapanor) for the treatment of IBS-C in adult patients. In November 2023, we commenced the commercialization of XPHOZAH<sup>®</sup> (tenapanor) for the reduction of serum phosphorus in adults with CKD on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy.

We have incurred losses in each year since our inception in October 2007, and we do not know whether or when we will become profitable. We continue to incur significant commercialization, development and additional expenses related to our ongoing operations and pursuit of future business opportunities. As of December 31, 2024, we had an accumulated deficit of \$885.3 million.

We expect to continue to incur operating losses for the foreseeable future as we incur expenses related to our ongoing operations and our pursuit of future business opportunities.

There are no assurances that our efforts to meet our operating cash flow requirements will be successful. If our current cash, cash equivalents and short-term investments as well as our plans to meet our operating cash flow requirements are not sufficient to fund necessary expenditures and meet our obligations, our liquidity, financial condition, and business prospects will be materially affected.

Our prior losses, combined with any future losses, have had and will continue to have an adverse effect on our stockholders’ equity and working capital. Further, the net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

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

We have substantial net operating loss and tax credit carryforwards for Federal and California income tax purposes. Such net operating losses and tax credits carryforwards may be reduced as a result of certain intercompany restructuring transactions. In addition, the future utilization of such net operating loss and tax credit carryforwards and credits may be subject to limitations, pursuant to Sections 382 and 383 of the Internal Revenue Code of 1986, as amended. In general, if a corporation undergoes an “ownership change,” generally defined as a cumulative change of more than 50 percentage points (by value) in its



equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. We have experienced ownership changes in the past and may experience additional ownership changes in the future, as a result of subsequent changes in our stock ownership, some of which are outside our control. Accordingly, we may not be able to utilize a material portion of our NOL carryforwards, even if we achieve profitability.

***We will require additional financing for the foreseeable future as we invest in the growth of IBSRELA and XPHOZAH in the U.S. and building a pipeline. The inability to access necessary capital when needed on acceptable terms, or at all, could force us to reduce our efforts to commercialize IBSRELA and/or XPHOZAH, or to delay or limit our pursuit of other future business opportunities.***

We believe that we will continue to expend substantial resources for the foreseeable future, including costs associated with our efforts to commercialize IBSRELA and XPHOZAH; conducting pediatric clinical trials for IBSRELA; manufacturing for IBSRELA and XPHOZAH; investments to build a pipeline; and research and development related to potential new product candidates. The inability to access necessary capital when needed on acceptable terms, or at all, could force us to reduce our efforts to commercialize IBSRELA and/or XPHOZAH or otherwise delay or limit our pursuit of future business opportunities. Our future funding requirements will depend on many factors, including, but not limited to:

- the extent to which we are able to generate product revenue from sales of IBSRELA and XPHOZAH;
- the extent to which access to XPHOZAH is impacted by the elimination of Medicare Part D coverage for XPHOZAH on January 1, 2025, and the extent to which this change will interfere with the shared decision-making between healthcare professionals and their patients, regardless of insurance coverage;
- the extent to which the elimination of separate payment for XPHOZAH for Medicare beneficiaries under Medicare Part D will influence the payment decisions of other payors and the extent to which payment for XPHOZAH will continue to be made as a pharmacy benefit for non-Medicare patients;
- the availability of adequate third-party reimbursement for IBSRELA;
- the manufacturing, selling and marketing costs associated with IBSRELA and XPHOZAH;
- our ability to maintain our existing collaboration partnerships and to establish additional collaboration partnerships, in-license/out-license, joint ventures or other similar arrangements and the financial terms of such agreements;
- the timing, receipt and amount of any milestones that may be received from our collaboration partners in connection with tenapanor, if any;
- the timing, receipt, and amount of royalties we may receive as a result of sales of tenapanor by our collaboration partners in China, and Canada, if any;
- the extent to which IBSRELA and XPHOZAH are commercialized in other ex-U.S. territories;
- the cash requirements necessary to expand our business;
- the cash requirements for the discovery and/or development of other potential product candidates;
- the time and cost necessary to respond to technological and market developments;
- the costs of filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights, including litigation costs and the outcome of such litigation, and costs of defending any claims of infringement brought by others in connection with the development, manufacture or commercialization of tenapanor or any of our product candidates; and
- the payment of interest and principal related to our loan and security agreement entered into with SLR, as amended to date.

Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to limit or reduce our commercialization of IBSRELA or XPHOZAH, delay or limit additional clinical trials for tenapanor, or delay or limit our pursuit of other future business opportunities.

***We have generated limited revenue from product sales and may never be profitable for a full fiscal year.***

We have generated limited revenue from product sales and have incurred significant net losses in each year since inception. We began selling IBSRELA in the U.S. in March 2022 and we began selling XPHOZAH in the U.S. in November 2023. We have no other products approved for sale.

There can be no assurances that we will generate sufficient product revenue from sales of IBSRELA and XPHOZAH to cover our expenses. Our ability to generate product revenue from sales or pursuant to milestone or royalty payments depends heavily on many factors, including but not limited to:

- our ability to successfully commercialize IBSRELA and XPHOZAH and to increase market share for both products;
- maintaining sufficient market acceptance of IBSRELA as a viable treatment option for IBS-C;
- obtaining market acceptance of XPHOZAH;
- the extent to which access to XPHOZAH is impacted by the elimination of Medicare Part D coverage for XPHOZAH on January 1, 2025, and the extent to which this change will interfere with the shared decision-making between healthcare professionals and their patients, regardless of insurance coverage;
- the extent to which the elimination of separate payment for XPHOZAH for Medicare beneficiaries under Medicare Part D will influence the payment decisions of other payors and the extent to which payment for XPHOZAH will continue to be made as a pharmacy benefit for non-Medicare patients;
- our ability to obtain an adequate level of coverage and reimbursement for IBSRELA by third-party payors;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide an adequate (in amount and quality) supply of product to support the market demand for IBSRELA and XPHOZAH;
- addressing any competing technological and market developments;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how, and our ability to develop, manufacture and commercialize our product candidates and products without infringing intellectual property rights of others; and
- attracting, hiring, and retaining qualified personnel.

With respect to our commercialization of IBSRELA and XPHOZAH, our revenue will be dependent, in part, upon the size of the markets in the U.S., the label for which approval was granted, accepted price for the product, and the ability to secure and maintain adequate reimbursement. Beginning January 1, 2025, XPHOZAH, along with other oral ESRD related drugs without injectable or intravenous equivalents, are now included in the ESRD PPS, thereby eliminating coverage for XPHOZAH and these other ESRD related drugs under Medicare Part D as of such date. The inclusion of XPHOZAH in the ESRD PPS creates additional uncertainty as to our ability to generate revenue from sales of XPHOZAH. See “—XPHOZAH is now included in the ESRD PPS, effective January 1, 2025, which means coverage for XPHOZAH for Medicare beneficiaries is no longer available under Medicare Part D, and as a result the revenue that we may generate on sales of XPHOZAH will be negatively and materially impacted” below.

Additionally, if the number of adult patients for IBSRELA and/or XPHOZAH is not as significant as we estimate, coverage and reimbursement for either IBSRELA or XPHOZAH are not available in the manner and to the extent we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of IBSRELA or XPHOZAH. Even if we achieve profitability on a quarterly basis in the future, we may not be able to sustain profitability for a full fiscal year. Our failure to generate adequate revenue from product sales would likely depress our market value and could impair our ability to raise capital, expand our business, discover or develop other product candidates or continue our operations. A decline in the value of our common stock could cause our stockholders to lose all or part of their investment.



## Principal Risks Related to Our Business

***We are substantially dependent on the successful commercialization of IBSRELA, and there is no guarantee that we will maintain sufficient market acceptance for IBSRELA, grow market share for IBSRELA, secure and maintain adequate coverage and reimbursement for IBSRELA, or generate sufficient revenue from product sales of IBSRELA.***

We began selling IBSRELA in the U.S. in March 2022. The overall commercial success of IBSRELA will depend on a number of factors, including the following:

- the ability of the third-party manufacturers we contract with to provide an adequate (in amount and quality) supply of product to support the market demand for IBSRELA;
- our ability to obtain and sustain an adequate level of coverage and reimbursement for IBSRELA by third-party payors;
- the effectiveness of IBSRELA as a treatment for adult patients with IBS-C;
- whether IBSRELA will be subject to price negotiations under the IRA, and the timing and impact of those price negotiations on the revenue from product sales of IBSRELA;
- the size of the treatable patient population;
- our ability to continue to increase the market share of IBSRELA;
- the effectiveness of our sales, market access and marketing efforts;
- whether physicians view IBSRELA as a safe and effective treatment for adult patients with IBS-C, which will impact the adoption of IBSRELA by physicians for the treatment of IBS-C;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of IBSRELA compared to alternative and competing treatments;
- the prevalence and severity of adverse side effects of IBSRELA;
- our potential involvement in lawsuits in connection with enforcing intellectual property rights in and to IBSRELA;
- our potential involvement in third-party interference, opposition, derivation or similar proceedings with respect to our patent rights directed to IBSRELA, and avoiding other challenges to our patent rights and patent infringement claims; and
- a continued acceptable safety and tolerability profile of IBSRELA following approval.

The amount of potential revenue we may achieve from the commercialization of IBSRELA is subject to these and other factors, and may be unpredictable from quarter-to-quarter. If the number of patients in the market for IBSRELA or the price that the market can bear is not as significant as we estimate, or if we are not able to continue to secure and maintain physician and patient acceptance of IBSRELA or adequate coverage and reimbursement for IBSRELA, we may not generate sufficient revenue from sales of IBSRELA. Any failure of IBSRELA to maintain market acceptance, continue to increase market share, obtain and maintain sufficient third-party coverage or reimbursement, or achieve commercial success would adversely affect our results of operations.

***There is no guarantee that we will achieve sufficient market acceptance for XPHOZAH, or that we will be able to secure and maintain adequate coverage and reimbursement for XPHOZAH, or generate sufficient revenue from product sales of XPHOZAH. The inclusion of XPHOZAH in the ESRD PPS creates additional uncertainty as to the commercial opportunity for XPHOZAH.***

We began selling XPHOZAH in the U.S. in November 2023. The overall commercial success of XPHOZAH will depend on a number of factors, including the following:

- the extent to which access to XPHOZAH is impacted by the elimination of Medicare Part D coverage for XPHOZAH on January 1, 2025, and the extent to which this change will interfere with the shared decision-making between healthcare professionals and their patients, regardless of insurance coverage;
- the extent to which the elimination of separate payment for XPHOZAH for Medicare beneficiaries under Medicare Part D will influence the payment decisions of other payors and the extent to which payment for XPHOZAH will continue to be made as a pharmacy benefit for non-Medicare patients;

- the ability of the third-party manufacturers we contract with to provide an adequate (in amount and quality) supply of product to support the market demand for XPHOZAH;
- whether or not the content and breadth of the label that has been approved by the U.S. FDA for XPHOZAH will materially and adversely impact our ability to commercialize the product for the approved indication;
- the prevalence and severity of adverse side effects of XPHOZAH;
- acceptance of XPHOZAH as safe, effective and well-tolerated by patients and the medical community;
- our ability to manage the commercialization of IBSRELA and XPHOZAH and the complex pricing and reimbursement negotiations that may arise with marketing products containing the same active ingredient at different doses for separate indications;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of XPHOZAH compared to alternative and competing treatments;
- obtaining and sustaining an adequate level of coverage and reimbursement for XPHOZAH by third-party payors;
- our potential involvement in lawsuits in connection with enforcing intellectual property rights in and to XPHOZAH;
- our potential involvement in third-party interference, opposition, derivation or similar proceedings with respect to our patent rights, and avoiding other challenges to our patent rights and patent infringement claims; and
- a continued acceptable safety and tolerability profile of XPHOZAH following approval.

There is no guarantee that we will achieve sufficient market acceptance for XPHOZAH, or that we will be able to secure and maintain adequate coverage and reimbursement for XPHOZAH, or generate sufficient revenue from product sales of XPHOZAH. The inclusion of XPHOZAH in the ESRD PPS creates additional uncertainty as to the commercial opportunity for XPHOZAH. See “—XPHOZAH is now included in the ESRD PPS, effective January 1, 2025, which means coverage for XPHOZAH for Medicare beneficiaries is no longer available under Medicare Part D, and as a result the revenue that we may generate on sales of XPHOZAH will be negatively and materially impacted” below.

***XPHOZAH is now included in the ESRD PPS, effective January 1, 2025, which means coverage for XPHOZAH for Medicare beneficiaries is no longer available under Medicare Part D, and as a result the revenue that we may generate on sales of XPHOZAH will be negatively and materially impacted.***

In January 2011, the CMS, an agency within the United States Department of Health and Human Services responsible for administering the Medicare program, implemented the ESRD PPS, a new PPS for dialysis treatment. Under the ESRD PPS, CMS generally makes a single bundled payment to the dialysis facility for each dialysis treatment that covers all items and services routinely required for dialysis treatments furnished to Medicare beneficiaries in Medicare-certified ESRD facilities or at their home, including the cost of certain drugs defined by CMS to be part of the renal dialysis service. CMS included XPHOZAH in the ESRD PPS, effective January 1, 2025, which means coverage for XPHOZAH for Medicare beneficiaries is no longer available under Medicare Part D, and as a result the revenue that we may generate on sales of XPHOZAH will be negatively and materially impacted.

The extent to which the inclusion of XPHOZAH in the ESRD PPS will materially and adversely impact our XPHOZAH business is dependent on the following:

- the extent to which access to XPHOZAH is impacted by the elimination of Medicare Part D coverage for XPHOZAH on January 1, 2025, and the extent to which this change will interfere with the shared decision-making between healthcare professionals and their patients, regardless of insurance coverage; and
- the extent to which the elimination of separate payment for XPHOZAH for Medicare beneficiaries under Medicare Part D will influence the payment decisions of other payors and the extent to which payment for XPHOZAH will continue to be made as a pharmacy benefit for non-Medicare patients.

***IBSRELA and/or XPHOZAH may cause undesirable side effects or have other properties that could limit the commercial success of the product.***

Undesirable side effects caused by IBSRELA and/or XPHOZAH could cause us or regulatory authorities to interrupt, delay or halt the commercialization of the product. Despite marketing approval for IBSRELA and XPHOZAH, the prevalence and/or severity of side effects caused by IBSRELA and/or XPHOZAH could result in a number of potentially significant negative consequences, including:

- regulatory authorities may withdraw their approval of the product or seize the product;
- we or a collaboration partner may be required to recall the product;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof, including the imposition of a REMS which could require creation of a Medication Guide or patient package insert outlining the risks of such side effects for distribution to patients, a communication plan to educate healthcare providers of the drugs' risks, as well as other elements to assure safe use of the product, such as a patient registry and training and certification of prescribers;
- we or a collaboration partner may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of new labeling statements, such as a "black box" warning or a contraindication;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of the foregoing events could prevent us, or a collaboration partner, from achieving or maintaining market acceptance of IBSRELA and/or XPHOZAH, and could result in the loss of significant revenue to us, which would materially and adversely affect our results of operations and business.

***Third-party payor coverage and reimbursement status of newly commercialized products are uncertain. Failure to obtain or maintain adequate coverage and reimbursement for IBSRELA and XPHOZAH could limit our ability to market those products and decrease our ability to generate revenue.***

The pricing, coverage and reimbursement of IBSRELA and XPHOZAH must be adequate to support a commercial infrastructure. The availability and adequacy of coverage and reimbursement by governmental and private payors are essential for most patients to be able to afford treatments. Sales of IBSRELA and XPHOZAH, will depend substantially, both domestically and abroad, on the extent to which the costs of the product will be paid for by health maintenance, managed care, pharmacy benefit, and similar healthcare management organizations, or reimbursed by government authorities, private health insurers, and other third-party payors. If coverage and reimbursement are not available, or are available only to limited levels, we, or our collaboration partners, may not be able to successfully commercialize IBSRELA, or XPHOZAH. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a return on our investment.

In the U.S., CMS decides whether and to what extent a new drug will be covered and reimbursed under Medicare. Private payors tend to follow the coverage reimbursement policies established by CMS to a substantial degree. Beginning January 1, 2025, XPHOZAH, along with other oral ESRD related drugs without injectable or intravenous equivalents, are now included in the ESRD PPS, thereby eliminating coverage for XPHOZAH and these other ESRD related drugs under Medicare Part D as of such date. See "*—XPHOZAH is now included in the ESRD PPS, effective January 1, 2025, which means coverage for XPHOZAH for Medicare beneficiaries is no longer available under Medicare Part D, and as a result the revenue that we may generate on sales of XPHOZAH will be negatively and materially impacted*" above.

Outside the U.S., international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada, Japan, China and other countries has and will continue to put pressure on the pricing and usage of IBSRELA and XPHOZAH, even if regulatory approval is received in such countries. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medicinal products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the U.S., the reimbursement

for our products may be reduced compared with the U.S. and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the U.S. and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, these caps may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of IBSRELA and XPHOZAH, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

***We rely completely on third parties, including certain single-source suppliers, to manufacture IBSRELA and XPHOZAH. If they are unable to comply with applicable regulatory requirements, unable to source sufficient raw materials, experience manufacturing or distribution difficulties or are otherwise unable to manufacture sufficient quantities to meet demand, our commercialization of IBSRELA and XPHOZAH may be materially harmed.***

We do not currently have, nor do we plan to acquire, the infrastructure or capability internally to manufacture IBSRELA or XPHOZAH on a commercial scale, or to manufacture our drug supplies for use in the conduct of our nonclinical and clinical studies. Our success depends upon our ability to enter into new supplier agreements and maintain our relationships with suppliers who are critical and necessary to the production of our drug supply.

The facilities used by our CMOs to manufacture our drug supply are subject to inspection by the U.S. FDA. Our ability to control the manufacturing process of our product candidates is limited to the contractual requirements and obligations we impose on our CMOs. Although they are contractually required to do so, we are completely dependent on our CMOs for compliance with the regulatory requirements, known as cGMP requirements, for manufacture of both active drug substances and finished drug products.

The manufacture of pharmaceutical products requires significant expertise and capital investment. Manufacturers of pharmaceutical products often encounter difficulties in commercial production. These problems may include difficulties with production costs and yields, quality control, including stability of the product and quality assurance testing, and shortages of qualified personnel, as well as compliance with federal, state and foreign regulations and the challenges associated with complex supply chain management. Even if our CMOs do not experience problems and commercial manufacturing is achieved, their maximum or available manufacturing capacities may be insufficient to meet commercial demand. Finding alternative manufacturers or adding additional manufacturers requires a significant amount of time and involves significant expense. New manufacturers would need to develop and implement the necessary production techniques and processes, which along with their facilities, would need to be inspected and approved by the regulatory authorities in each applicable territory. In addition, the raw materials necessary to make API for our products are acquired from a limited number of sources. Any delay or disruption in the availability of these raw materials could result in production disruptions, delays or higher costs with consequent adverse effects on us.

If our CMOs fail to adhere to applicable cGMP or other regulatory requirements, experience delays or disruptions in the availability of raw materials or experience manufacturing or distribution problems, we may suffer significant consequences, including the inability to meet our product requirements for our clinical development programs, and such events could result in product seizures or recalls, loss of product approval, fines and sanctions, reputational damage, shipment delays, inventory shortages, inventory write-offs and other product-related charges and increased manufacturing costs. As a result, or if maximum or available manufacturing capacities are insufficient to meet demand, our development or our commercialization efforts for IBSRELA and/or XPHOZAH may be materially harmed.

***Our future results depend on CMOs, many of whom are our single source manufacturers.***

Many of our CMOs are currently single source manufacturers. While we try to obtain multiple sources whenever possible, similar to other commercial pharmaceutical companies, three stages of our manufacturing process are currently completed by a single source, which exposes us to a number of risks related to our supply chain, including delivery failure and drug shortages. To date, we have no qualified alternative sources for these single source CMOs.

Our manufacturing and commercial supply agreements with our CMOs, including our single source CMOs, contain or are likely to contain pricing provisions that are subject to adjustment based on factors outside of our control, including changes in market prices. Substantial increases in the prices for necessary materials and equipment, whether due to supply chain or logistics issues or due to inflation, would increase our operating costs and could reduce our margins. Any attempts to increase the announced or expected prices of IBSRELA and/or XPHOZAH in response to increased costs could be viewed negatively by the public and could adversely affect our business, prospects, financial condition, and results of operations.



Further, we currently and may in the future rely on foreign CMOs and CROs. Such foreign CMOs and CROs may be subject to U.S. legislation, sanctions, trade restrictions and other foreign regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies.

An inability to continue to source product from any of these CMOs, which could be due to regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a CMO, labor disputes or shortages, unexpected demands, or quality issues, could adversely affect our ability to satisfy demand for our products, which could adversely and materially affect our product sales and operating results, which could significantly harm our business. Furthermore, qualifying alternate suppliers or developing our own manufacturing capability for certain highly customized stages of our manufacturing process may be time consuming and costly. There can be no assurance that our business, financial condition and results of operations will not be materially and adversely affected by supply chain disruptions. Any disruption in the supply chain, whether or not from a single source CMO, could temporarily disrupt production of our drug supply until an alternative supplier is fully qualified by us or until such CMO is able to perform. There can be no assurance that we would be able to successfully retain an alternative CMO on a timely basis, on acceptable terms, or at all. Changes in business conditions, force majeure, governmental changes, and other factors beyond our control or which we do not presently anticipate, could also affect our CMOs' ability to deliver components to us on a timely basis. Any of the foregoing could materially and adversely affect our results of operations, financial condition and prospects.

***Our operating activities may be restricted as a result of covenants related to the indebtedness under our loan and security agreement with SLR, as amended, and we may be required to repay the outstanding indebtedness in an event of default, which could have a materially adverse effect on our business.***

On February 23, 2022, we entered into a loan and security agreement (the 2022 Loan Agreement) with SLR as collateral agent and the lenders listed in the 2022 Loan Agreement (collectively, the 2022 Lenders). The 2022 Loan Agreement was subsequently amended in August 2022 (the First Amendment), February 2023 (the Second Amendment), October 2023 (the Third Amendment) and October 2024 (Fourth Amendment). The loan was funded in the amount of \$27.5 million on February 23, 2022 and additional amounts of \$22.5 million, \$50.0 million and \$50.0 million were drawn on October 19, 2023, March 1, 2024, and October 29, 2024, respectively. In addition, we have the option to draw up to an additional \$50.0 million by June 30, 2025. Until we have repaid all funded indebtedness, the 2022 Loan Agreement subjects us to various customary covenants, including requirements as to financial reporting and insurance and restrictions on our ability to dispose of our business or property, to change our line of business, to liquidate or dissolve, to enter into any change in control transaction, to merge or consolidate with any other entity or to acquire all or substantially all the capital stock or property of another entity, to incur additional indebtedness, to incur liens on our property, to pay any dividends or other distributions on capital stock other than dividends payable solely in capital stock, to redeem capital stock, to enter into licensing agreements, to engage in transactions with affiliates, and to encumber our intellectual property. Our business may be adversely affected by these restrictions on our ability to operate our business.

In addition, we may be required to repay the outstanding indebtedness under the loan facility if an event of default occurs under the 2022 Loan Agreement. An event of default will occur if, among other things, we fail to make payments under the 2022 Loan Agreement; we breach any of our covenants under the 2022 Loan Agreement, subject to specified cure periods with respect to certain breaches; the Lender determines that a material adverse change has occurred; we or our assets become subject to certain legal proceedings, such as bankruptcy proceedings; we are unable to pay our debts as they become due; or we default on contracts with third parties which would permit the Lender to accelerate the maturity of such indebtedness or that could have a material adverse change on us. We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay such indebtedness at the time any such event of default occurs. In this case, we may be required to limit or reduce our activities necessary to commercialize IBSRELA and/or XPHOZAH, or delay or limit clinical trials for tenapanor or other product candidates. The Lenders could also exercise its rights as collateral agent to take possession of and to dispose of the collateral securing the term loans, which collateral includes substantially all of our property (excluding intellectual property, which is subject to a negative pledge). Our business, financial condition and results of operations could be materially adversely affected as a result of any of these events.

### **Additional Risks Related to Our Business and Industry**

***We face substantial competition, and our competitors may discover, develop or commercialize products faster or more successfully than us.***

The biotechnology and pharmaceutical industries are highly competitive, and we face significant competition from companies in the biotechnology, pharmaceutical and other related markets that are researching and marketing products designed to address diseases that we are currently developing products to treat.

Competition for IBSRELA largely comes from three prescription products marketed for certain patients with IBS-C that we are aware of, including Linzess (linaclotide), Amitiza (lubiprostone) and Trulance (plecanatide). Generic lubiprostone is also available in the U.S. Additionally, over-the-counter products not indicated for IBS-C are commonly used to treat the constipation component of IBS-C, alone and in combination with the IBS-C-indicated prescription therapies.

XPHOZAH is indicated to reduce serum phosphorus in adults with CKD on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy. The various types of phosphate binders commercialized in the U.S. include the following: Calcium acetate (several prescription brands including PhosLo and Phoslyra); Lanthanum carbonate (Fosrenol); Sevelamer hydrochloride (Renagel); Sevelamer carbonate (Renvela); Sucroferric oxyhydroxide (Velphoro) and Ferric citrate (Auryxia). All of the listed phosphate binders are available as generics in the U.S., with the exception of Velphoro and Auryxia. Additionally, over-the-counter calcium carbonate, such as Tums and Caltrate, is also used to bind phosphorus.

In addition to the currently available phosphate binders, we are aware of at least four phosphate binders in development, including AP-301, developed by Alebund Pharmaceutical (Hong Kong) Limited and currently in Phase 3; VS-505, developed by Vidasym and currently in clinical development; TS-172, developed by Taisho Pharmaceuticals and currently in Phase 2; and OLC, developed by Unicycive Therapeutics, which has announced its plans to seek U.S. FDA approval via the 505(b)(2) pathway. OLC has demonstrated pharmacodynamic bioequivalence to Fosrenol. Additionally, Alebund is developing AP-306, an inhibitor of phosphate transporters NaPi-2b, PiT-1, and PiT-2, thus far studied in a Phase 2 clinical trial.

It is possible that our competitors' drugs may be less expensive and more effective than our product candidates, or may render our product candidates obsolete. It is also possible that our competitors will commercialize competing drugs or treatments before we or our collaboration partners can launch any products developed from our product candidates. We also may face increased competition in the future as new companies enter into our target markets.

Many of our competitors have materially greater name recognition and financial, manufacturing, marketing, research and drug development resources than we do. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Large pharmaceutical companies in particular have extensive expertise in preclinical and clinical testing and in obtaining regulatory approvals for drugs. In addition, academic institutions, government agencies and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies. These organizations may also establish exclusive collaboration partnerships or licensing relationships with our competitors.

***We may experience difficulties in managing our current activities and growth given our level of managerial, operational, financial and other resources.***

While we have continued to work to optimize our management composition, personnel and systems to support our current activities for future growth, these resources may not be adequate for this purpose. Our need to effectively execute our business strategy requires that we:

- manage our commercialization activities effectively;
- manage our clinical trials effectively;
- manage our internal development efforts effectively while carrying out our contractual obligations to licensors, contractors, collaborators, government agencies and other third parties;
- continue to improve our operational, financial and management controls, reporting systems and procedures; and
- retain and motivate our remaining employees and potentially identify, recruit and integrate additional employees.

If we are unable to maintain or expand our managerial, operational, financial and other resources to the extent required to manage our development and commercialization activities, our business will be materially adversely affected.

***We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.***

We may consider strategic transactions, such as acquisitions of companies, asset purchases, and/or in-licensing of products, product candidates or technologies. In addition, if we are unable to access capital on a timely basis and on terms that are acceptable to us, we may be forced to further restructure certain aspects of our business or identify and complete one or more strategic collaborations or other transactions in order to fund the commercialization of IBSRELA and XPHOZAH, and/or the development of discovery and developmental assets through the use of alternative structures. Additional potential transactions



that we may consider include a variety of different business arrangements, including spin-offs, spin outs, collaboration partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- up-front, milestone and royalty payments, equity investments and financial support of new research and development candidates including increase of personnel, all of which may be substantial;
- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities;
- higher-than-expected acquisition and integration costs;
- write-downs of assets or goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and could have a material adverse effect on our business, results of operations, financial condition and prospects.

***If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of IBSRELA and/or XPHOZAH.***

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and our commercialization of IBSRELA and XPHOZAH. For example, we may be sued if any product we develop and/or commercialize allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would

require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for the product;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- regulatory investigations, product recalls or withdrawals, or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize or co-promote IBSRELA and/or XPHOZAH.

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of any products we develop. Although we maintain product liability insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Moreover, 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.

***If we fail to attract, retain and motivate our executives, senior management and key personnel, our business will suffer.***

Recruiting and retaining qualified scientific, sales and marketing, clinical, medical, business development, manufacturing, finance and administrative personnel is critical to our success. We are highly dependent on our executives, senior management and certain other key employees. The loss of the services of our executives, senior management or other key employees could impede the achievement of our development and commercial objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executives, senior management and other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain marketing approval of and commercialize products. We may be unable to hire, train or motivate these key personnel on acceptable terms given the intense competition among numerous biopharmaceutical companies for similar personnel, particularly in our geographic regions. If we are unable to continue to attract and retain high quality personnel, our ability to grow and pursue our business strategy will be limited.

***Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.***

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal data, such as information that we may collect in connection with clinical trials in the U.S. and abroad. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards or perception of their requirements may have on our business. This evolution may create uncertainty in our business; affect our ability to operate in certain jurisdictions, or to collect, store, transfer use and share personal information; necessitate the acceptance of more onerous obligations in our contracts; result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our operations, financial performance and business.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the U.S., HIPAA imposes, among other

things, certain standards relating to the privacy, security, transmission, and breach reporting of individually identifiable health information. We may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA.

Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, the CCPA requires covered businesses that process the personal information of California residents to, among other things: (i) provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; (ii) receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information; and (iii) enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. Additional compliance investment and potential business process changes may also be required. Similar laws have passed in other states and are continuing to be at the state and federal level, reflecting a trend toward more stringent privacy legislation in the U.S. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA, or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Furthermore, the FTC also has authority to initiate enforcement actions against entities that mislead customers about HIPAA compliance, make deceptive statements about privacy and data sharing in privacy policies, fail to limit third-party use of personal health information, fail to implement policies to protect personal health information or engage in other unfair practices that harm customers or that may violate Section 5(a) of the FTC Act. According to the FTC, failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the FTC Act. The FTC and many state Attorneys General continue to enforce federal and state consumer protection laws against companies for online collection, use, dissemination and security practices that appear to be unfair or deceptive, including on websites, to regulate the presentation of website content. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities.

We are also or may become subject to rapidly evolving data protection laws, rules and regulations in foreign jurisdictions. For example, in Europe, the GDPR went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the EEA. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the U.S. and the efficacy and longevity of current transfer mechanisms between the EEA, and the United States remains uncertain. Case law from the Court of Justice of the European Union states that reliance on the standard contractual clauses - a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism - alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. On July 10, 2023, the European Commission adopted its Adequacy Decision in relation to the new DPF, rendering the DPF effective as a GDPR transfer mechanism to U.S. entities self-certified under the DPF. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue. In particular, we expect the DPF Adequacy Decision to be challenged and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As a result, we may have to make certain operational changes and we will have to implement revised standard contractual clauses and other relevant documentation for existing data transfers within required time frames.

Relatedly, following the United Kingdom's withdrawal from the EEA and the European Union, and the expiry of the transition period, companies have had to comply with both the GDPR and the GDPR as incorporated into United Kingdom national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover. On October 12, 2023, the UK Extension to the DPF came into effect (as approved by the UK Government), as a data transfer mechanism from the United Kingdom to U.S. entities self-certified under the DPF. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

In addition, we use AI Technologies in our business. The regulatory framework for AI Technologies is rapidly evolving as many federal, state, and foreign government bodies and agencies have introduced or are currently considering additional laws and regulations. Additionally, existing laws and regulations may be interpreted in ways that would affect the operation of AI Technologies. As a result, implementation standards and enforcement practices are likely to remain uncertain for the

foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or market perception of their requirements may have on our business and may not always be able to anticipate how to respond to these laws or regulations.

It is possible that new laws and regulations will be adopted in the United States and in other non-U.S. jurisdictions, or that existing laws and regulations, including competition and antitrust laws, may be interpreted in ways that would limit our ability to use AI Technologies for our business, or require us to change the way we use AI Technologies in a manner that negatively affects the performance of our products, services, and business and the way in which we use AI Technologies. We may need to expand resources to adjust our products or services in certain jurisdictions if the laws, regulations, or decisions are not consistent across jurisdictions. Further, the cost to comply with such laws, regulations, or decisions and/or guidance interpreting existing laws, could be significant and would increase our operating expenses (such as by imposing additional reporting obligations regarding our use of AI Technologies). Such an increase in operating expenses, as well as any actual or perceived failure to comply with such laws and regulations, could adversely affect our business, financial condition and results of operations.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, CROs, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations.

***We and our collaborators, CROs and other contractors and consultants depend on information technology systems, and any failure of these systems could harm our business. Security breaches, loss of data, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, results of operations and financial condition.***

We and our collaborators, CROs, and other contractors and consultants collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we and our collaborators, CROs and other contractors and consultants collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information, clinical trial data and personal information (collectively, Confidential Information). It is critical that we and our collaborators, CROs and other contractors and consultants do so in a secure manner to maintain the confidentiality and integrity of such Confidential Information. We have established physical, electronic and organizational measures designed to safeguard and secure our systems to prevent a data compromise, and rely on commercially available systems, software, tools, and monitoring to provide security for our information technology systems and the processing, transmission and storage of Confidential Information. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our Confidential Information.

Our information technology systems and infrastructure, and those of our current and any future collaborators, CROs, contractors and consultants and other third parties on which we rely, are vulnerable to attack, damage and interruption from computer viruses, malware (e.g., ransomware), natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, phishing attacks and other social engineering schemes, attachments to emails, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization.

The risk of a security breach or disruption or data loss, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access Confidential Information increases the risk of data security breaches, which could lead to the loss of Confidential Information or other intellectual property. We may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our



business and our competitive position. There can also be no assurance that our and our collaborators', CROs', CMOs, contractors', consultants' and other service providers' cybersecurity risk management program and processes, including policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems, networks and Confidential Information.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. We do not believe that we have experienced any significant system failure, accident or security breach to date, but if such an event were to occur and cause interruptions in our operations, it could result in a material disruption to our business. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal and state privacy and security laws, if applicable. Moreover, if a computer security breach affects our systems or those of our collaborators, CROs or other contractors, or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged. Any adverse impact to the availability, integrity or confidentiality of our or third-party systems or Confidential Information can result in legal claims or proceedings (such as class actions), regulatory investigations and enforcement actions, fines and penalties, negative reputational impacts that cause us to lose existing or future customers, and/or significant incident response, system restoration or remediation and future compliance costs, which could materially adversely affect our business, results of operations and financial condition.

***If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, our ability to operate our business and investors' views of us and could have a material adverse effect on the price of our common stock.***

Our failure to implement and maintain effective internal controls over financial reporting could result in errors in our financial statements that could result in a restatement of our financial statements and cause us to fail to meet our reporting obligations. If we cannot in the future favorably assess the effectiveness of our internal controls over financial reporting, investor confidence in the reliability of our financial reports may be adversely affected, which could have a material adverse effect on the trading price of our common stock.

***We have formed in the past, and may form in the future, collaboration partnerships, joint ventures and/or licensing arrangements, and we may not realize the benefits of such collaborations.***

We have current collaboration partnerships for the commercialization of tenapanor in certain foreign countries, and we may form additional collaboration partnerships, create joint ventures or enter into additional licensing arrangements with third parties in the U.S. and abroad that we believe will complement or augment our existing business. In particular, we have formed collaboration partnerships with Kyowa Kirin for commercialization of tenapanor for hyperphosphatemia in Japan; with Fosun Pharma for commercialization of tenapanor for hyperphosphatemia and IBS-C in China and related territories; in Canada with Knight for commercialization of tenapanor for IBS-C and hyperphosphatemia; and with METiS for the development and commercialization of a portfolio of TGR5 agonist compounds for all therapeutic areas. We face significant competition in seeking appropriate collaboration partners, and the process to identify an appropriate partner and negotiate appropriate terms is time-consuming and complex. Any delays in identifying suitable additional collaboration partners and entering into agreements to develop our product candidates could also delay the commercialization of our product candidates, which may reduce their competitiveness even if they reach the market. There is no guarantee that our current collaboration partnerships or any such arrangements we enter into in the future will be successful, or that any collaboration partner will commit sufficient resources to the development, regulatory approval, and commercialization effort for such products, or that such alliances will result in us achieving revenues that justify such transactions.

***Clinical drug development involves a lengthy and expensive process with an uncertain outcome.***

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical studies to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain.

In the conduct of additional clinical trials, we could encounter delays in our development if any clinical trials are suspended or terminated by us, by the IRBs of the institutions in which the trial is being conducted, or by the U.S. FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the U.S. FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

In addition, identifying and qualifying patients to participate in any clinical trials is critical to the success of the clinical trials. The timing of any future clinical trials that we may determine to conduct, will depend, in part, on the speed at which we

can recruit patients to participate in testing our product candidates. Patients may be unwilling to participate in our clinical studies because of concerns about adverse events observed with the current standard of care, competitor products and/or other investigational agents, in each case for the same indications and/or similar patient populations. In addition, patients currently receiving treatment with the current standard of care or a competitor product may be reluctant to participate in a clinical trial with an investigational drug, or our inclusion and exclusion criteria for our clinical trials may present challenges in identifying acceptable patients. As a result, the timeline for recruiting patients and conducting clinical trials may be delayed. These delays could result in increased costs, delays in advancing our development of the program or termination of the clinical studies altogether. Any of these occurrences may significantly harm our business, financial condition and prospects.

***We will rely on third parties to conduct all of our nonclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for additional products or commercialize our product candidates.***

We do not have the ability to independently conduct nonclinical studies or clinical trials. We rely on medical institutions, clinical investigators, contract laboratories, and other third parties, such as CROs, to conduct clinical trials on our product candidates. The third parties with whom we contract for execution of the clinical trials play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, these third parties are not our employees, and except for contractual duties and obligations, we control only certain aspects of their activities and have limited ability to control the amount or timing of resources that they devote to our programs. Although we rely, and will continue to rely, on these third parties to conduct our nonclinical studies and our clinical trials, we remain responsible for ensuring that each of our studies and clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on third parties does not relieve us of our regulatory responsibilities. We, and these third parties are required to comply with current GLPs for nonclinical studies and GCPs for clinical studies. GLPs and GCPs are regulations and guidelines enforced by the U.S. FDA, the Competent Authorities of the Member States of the EEA and comparable foreign regulatory authorities for all of our products in nonclinical and clinical development, respectively. Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our third-party contractors fail to comply with applicable regulatory requirements, including GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the U.S. FDA, the European Medicines Agency or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. There can be no assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which could add additional costs and could delay the regulatory approval process.

***Our CMOs manufacture tenapanor API outside of the U.S., our collaboration partners outside of the U.S. have sought and obtained and may continue to seek and obtain approval to commercialize tenapanor outside of the U.S., and as a result a variety of risks associated with international operations could materially adversely affect our business.***

Our collaboration partners have sought and obtained and may continue to seek and obtain marketing approval for tenapanor outside the U.S. Furthermore, we may seek and obtain marketing approval for IBSRELA or XPHOZAH in other territories outside of the U.S. Additionally, we have contractual agreements with CMOs involving the manufacture of tenapanor API outside of the U.S., and may otherwise engage in business outside of the U.S., including entering into additional contractual agreements with third parties. We are subject to additional risks related to entering these international business markets and relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- differing U.S. and foreign drug import and export rules;
- reduced protection for intellectual property rights in foreign countries;
- changes in laws or policies governing the terms of foreign trade, and in particular increased trade restrictions, tariffs or taxes on imports or exports from or to countries where we manufacture or, sell, or our partners sell, our products to may affect the prices of and demand for our products;
- different reimbursement systems, and different competitive drugs;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;



- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- potential liability resulting from development work conducted by these distributors; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters.

***Our business involves the use of hazardous materials and we and third-parties with whom we contract must comply with environmental laws and regulations, which can be expensive and restrict how we do business.***

We and manufacturers and suppliers with whom we may contract are subject to laws and regulations governing the use, manufacture, storage, handling, and disposal of hazardous materials, including the components of our tenapanor and our product candidates. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, and business operations, and could result in environmental damage requiring costly clean-up and resulting in liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. We cannot guarantee that the safety procedures utilized by third-party manufacturers and suppliers with whom we may contract will comply with the standards prescribed by laws and regulations or will eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

***We 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.***

We currently occupy a leased facility located in the San Francisco Bay Area, which in the past has experienced severe earthquakes. We do not carry earthquake insurance. 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 leased facilities, including our California facility, that damaged critical infrastructure supporting access to systems such as our enterprise financial systems or manufacturing resource planning and enterprise quality systems, or that otherwise disrupted operations, it may be difficult or time consuming to restore some business of our business functions. The disaster recovery and business continuity plans we have in place currently are not holistic in coverage and may prove inadequate 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, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

## **Risks Related to Government Regulation**

***Despite having received regulatory approval for IBSRELA and XPHOZAH, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, IBSRELA and XPHOZAH could be subject to other restrictions and market withdrawal, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.***

Even after a drug is approved by the U.S. FDA or foreign regulatory authorities, the manufacturing processes, labeling, packaging, distribution, pharmacovigilance, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCP regulations for any clinical trials that we conduct post-approval. As such, we and our third-party CMOs will be subject to continual review and periodic inspections to assess compliance with regulatory requirements. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control. Regulatory authorities may also impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-marketing studies. Furthermore, any new legislation addressing drug safety issues could result in delays or increased costs to assure compliance.

We will also be required to report certain adverse reactions and production problems, if any, to the U.S. FDA, and to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products for indications or uses for which they do not have U.S. FDA approval.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- warning or untitled letters or fines;
- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls;
- injunctions or the imposition of civil or criminal penalties;
- suspension or revocation of existing regulatory approvals;
- suspension of any of our ongoing clinical trials;
- refusal to approve pending applications or supplements to approved applications submitted by us;
- restrictions on our or our CMOs' operations; or
- product seizure or detention, or refusal to permit the import or export of products.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize IBSRELA and XPHOZAH. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

In addition, the U.S. FDA's policies may change, and additional government regulations may be enacted. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the U.S. or abroad.

***Disruptions at the U.S. FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise review and process regulatory submissions in a timely manner, which could negatively impact our business.***

The ability of the U.S. FDA to review and process regulatory submissions can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, policy changes, and other events that may otherwise affect the U.S. FDA's ability to perform routine functions. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the U.S. FDA, have had to furlough critical U.S. FDA employees and stop critical activities.

Disruptions at the U.S. FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs, or if global health concerns prevent the U.S. FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the U.S. FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

***We and our CMOs are subject to significant regulation with respect to manufacturing IBSRELA and XPHOZAH. The manufacturing facilities on which we rely may not continue to meet regulatory requirements or may not be able to meet supply demands.***

All entities involved in the preparation of product for commercial sale, or product candidates for clinical trials, including our existing CMOs are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical studies must be manufactured in accordance with cGMP regulations. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our products or product candidates that may not be detectable in final product testing. We or our CMOs must supply all necessary documentation in support of an NDA or comparable regulatory filing on a timely basis and must adhere to cGMP regulations enforced by the U.S. FDA and other regulatory agencies through their facilities inspection programs. The facilities and quality systems of some, or all, of our CMOs must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the manufacture of our product or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we oversee the CMOs, we cannot control the manufacturing process of, and are completely dependent on, our CMOs for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever. In addition, we have no control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our CMOs. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time consuming for us or a third party to implement, and that may include the temporary or permanent suspension of a clinical study or commercial sales or the temporary or permanent suspension of production or closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If we or any of our third-party manufacturers fail to maintain regulatory compliance, the U.S. FDA or other applicable regulatory authority can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product, withdrawal of an approval, or suspension of production. As a result, our business, financial condition, and results of operations may be materially harmed.

Additionally, if supply from one approved manufacturer is interrupted, an alternative manufacturer would need to be qualified through an NDA, a supplemental NDA or equivalent foreign regulatory filing, which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause us to incur higher costs and could cause the delay or termination of clinical studies, regulatory submissions, required approvals, or commercialization of our product candidates. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical studies may be delayed, or we could lose potential revenue.

***If we fail to comply or are found to have failed to comply with U.S. FDA and other regulations related to the promotion of our products for unapproved uses, other sales practices, as well as the design and implementation of our patient assistance programs, we could be subject to criminal penalties, substantial fines or other sanctions and damage awards.***

The regulations relating to the promotion of products for unapproved uses and the design and implementation of patient assistance programs are complex and subject to substantial interpretation by the U.S. FDA and other government agencies. With respect to the commercialization of IBSRELA and/or XPHOZAH, we will be restricted from marketing the product outside of its approved labeling, also referred to as off-label promotion. However, physicians may nevertheless prescribe an approved product to their patients in a manner that is inconsistent with the approved label, which is an off-label use. We have implemented compliance and training programs designed to ensure that our sales and marketing practices comply with applicable regulations regarding off-label promotion. Notwithstanding these programs, the U.S. FDA or other government agencies may allege or find that our practices constitute prohibited promotion of our product candidates for unapproved uses. We also cannot be sure that our employees will comply with company policies and applicable regulations regarding the promotion of products for unapproved uses.

Over the past several years, a significant number of pharmaceutical and biotechnology companies have been the target of inquiries and investigations by various federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses, other sales practices, as well as the design and implementation of patient assistance programs, including the Department of Justice and various U.S. Attorneys' Offices, the Office of Inspector General of the Department of Health and Human Services, the U.S. FDA, the FTC and various state Attorneys General offices. These investigations have alleged violations of various federal and state laws and regulations, including claims asserting antitrust violations, violations of the FFDCA, the False Claims Act, the Prescription Drug Marketing Act, anti-kickback laws, and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. Many of these investigations originate as "qui tam" actions under the False Claims Act. Under the False Claims Act, any individual can bring a claim on behalf of the government alleging that a person or entity has presented a false claim, or caused a false claim to be submitted, to the government for payment. The person bringing a qui tam suit is entitled to a share of any recovery or settlement. Qui tam suits, also commonly referred to as "whistleblower suits," are often brought by current or former employees. In a qui tam suit, the government must decide whether to intervene and prosecute the case. If it declines, the individual may pursue the case alone.

If the U.S. FDA or any other governmental agency initiates an enforcement action against us or if we are the subject of a qui tam suit and it is determined that we violated U.S. FDA or other regulations relating to the promotion of our products and/or the design and implementation of our patient assistance programs, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects and reputation.

***IBSRELA and/or XPHOZAH may cause or contribute to adverse medical events that we are required to report to regulatory agencies and if we fail to do so we could be subject to sanctions that would materially harm our business.***

We are required to report certain information about adverse medical events if our products may have caused or contributed to those adverse events. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events we become aware of within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the U.S. FDA or a foreign regulatory agency could take action, including criminal prosecution, the imposition of civil monetary penalties, seizure of our products or delay in approval or clearance of future products.

***Our employees, independent contractors, principal investigators, CROs, collaboration partners, consultants, CMOs and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.***

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, collaboration partners, consultants, CMOs and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or unauthorized activities that violate any of the following: U.S. FDA regulations, including those laws that require the reporting of true, complete and accurate financial and other information to the U.S. FDA; manufacturing standards; or federal and state healthcare fraud and abuse laws and regulations. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. These activities also include the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other 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 comply with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. 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 civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.



***Failure to obtain regulatory approvals in foreign jurisdictions would prevent us from marketing our products internationally.***

In order to market any product in the EEA (which is composed of the 27 Member States of the European Union plus Norway, Iceland and Liechtenstein), and many other foreign jurisdictions, separate regulatory approvals are required. In the EEA, medicinal products can only be commercialized after obtaining a Marketing Authorization. Before the Marketing Authorization is granted, the European Medicines Agency or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

The approval procedures vary among countries and can involve additional clinical testing, and the time required to obtain approval may differ from that required to obtain U.S. FDA approval. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the U.S. FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the U.S. FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. The foreign regulatory approval process may include all of the risks associated with obtaining U.S. FDA approval. We may not be able to file for regulatory approvals or to do so on a timely basis, and even if we do file, we may not receive necessary approvals to commercialize our products in any market.

***We and our collaboration partners are subject to healthcare laws, regulation and enforcement; our failure or the failure of any such collaboration partners to comply with these laws could have a material adverse effect on our results of operations and financial conditions.***

We and our collaboration partners are subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. The laws that may affect our ability to operate as a commercial organization include:

- the federal Anti-Kickback Statute, 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. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation;
- federal false claims laws, including the False Claims Act, 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 payors that are false or fraudulent. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the federal Civil Monetary Penalties law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation;
- the federal Physician Payments Sunshine Act requirements under the ACA, which requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to CMS information related to payments and other transfers of value to physicians, (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives), and teaching hospitals, and ownership and investment interests held by physicians (as defined by the statute) and their immediate family members;
- 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 payor, including commercial insurers;
- state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources;

- state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or pricing information and marketing expenditures; and
- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to market our products and adversely impact our financial results.

***Legislative or regulatory healthcare reforms in the U.S. may make it more difficult and costly for us to obtain regulatory clearance or approval of our product candidates and to produce, market and distribute our products after clearance or approval is obtained.***

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture, and marketing of regulated products or the reimbursement thereof. In addition, U.S. FDA regulations and guidance are often revised or reinterpreted by the U.S. FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our product candidates. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

- additional clinical trials to be conducted prior to obtaining approval;
- changes to manufacturing methods;
- recall, replacement, or discontinuance of one or more of our products; and
- additional record keeping.

Each of these would likely entail substantial time and cost and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any future products would harm our business, financial condition and results of operations.

In addition, the full impact of recent healthcare reform and other changes in the healthcare industry and in healthcare spending is currently unknown, and may adversely affect our business model. In the U.S., the ACA was enacted in 2010 with a goal of reducing the cost of healthcare and substantially changing the way healthcare is financed by both government and private insurers. Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. The ACA, among other things, increased the minimum Medicaid rebates owed by manufacturers under the MDRP and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program, which was replaced by a new manufacturer discount program on January 1, 2025 (as discussed below), in which manufacturers were required to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Moreover, beginning January 1, 2025, XPHOZAH, along with other oral ESRD related drugs without injectable or intravenous equivalents, are now included in the ESRD PPS, thereby eliminating coverage under Medicare Part D as of such date. See “—XPHOZAH is now included in the ESRD PPS, effective January 1, 2025, which means coverage for XPHOZAH for Medicare beneficiaries is no longer available under Medicare Part D, and as a result the revenue that we may generate on sales of XPHOZAH will be negatively and materially impacted” above.



Other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. These new laws, among other things, included aggregate reductions of Medicare payments to providers that will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional action is taken by Congress, additional specific reductions in Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and an increase in the statute of limitations period for the government to recover overpayments to providers from three to five years. More recently, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminated the statutory Medicaid drug rebate cap beginning January 1, 2024. The rebate was previously capped at 100% of a drug's AMP.

Recently, there has also been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills 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. On August 16, 2022, the IRA was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare which will start to take effect in 2026, imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023), and replaces the Part D coverage gap discount program with a new discounting program (which began on January 1, 2025). Under the IRA, small molecule drugs and biologics first become eligible for price negotiation seven and eleven years, respectively, after U.S. FDA approval. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. CMS has published the negotiated prices for the initial ten drugs, which will first be effective in 2026, and the list of the subsequent 15 drugs that will be subject to negotiation. Each year thereafter, more Part B and Part D products will become subject to the HHS price negotiation program, although the program is currently subject to legal challenges. While the impact of the IRA on the pharmaceutical industry cannot yet be fully determined, it is likely to be significant. Additionally, individual states have become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and to encourage importation from other countries and bulk purchasing.

We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect the demand for any drug products for which we may obtain regulatory approval, our ability to set a price that we believe is fair for our products, our ability to obtain coverage and reimbursement approval for a product, our ability to generate revenues and achieve or maintain profitability, and the level of taxes that we are required to pay.

***If we fail to comply with our reporting and payment obligations under the MDRP or other governmental pricing programs in the U.S., we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, results of operations and financial condition.***

We participate in the MDRP and other federal and state government pricing programs in the U.S., and we may participate in additional government pricing programs in the future. These programs generally require manufacturers to pay rebates or otherwise provide discounts to government payors in connection with drugs that are dispensed to beneficiaries of these programs. Medicaid drug rebates are based on pricing data that we will be obligated to report on a monthly and quarterly basis to CMS, the federal agency that administers the MDRP and Medicare programs. For the MDRP, these data include the AMP and the best price for each drug. If we become aware that our MDRP price reporting submission for a prior period was incorrect or has changed as a result of recalculation of the pricing data, we must resubmit the corrected data for up to three years after those data originally were due. In addition, there is increased focus by the Office of Inspector General within the U.S. Department of Health and Human Services on the methodologies used by manufacturers to calculate AMP, and best price, to assess manufacturer compliance with MDRP reporting requirements. If we fail to provide information timely or are found to have knowingly submitted false information to the government, we may be subject to civil monetary penalties and other sanctions, including termination from the MDRP, which would result in payment not being available for our covered drugs under Medicaid. Failure to make necessary disclosures and/or to identify overpayments could result in allegations against us under the Federal False Claims Act and other laws and regulations.

Federal law requires that a manufacturer that participates in the MDRP also participate in the 340B program in order for federal funds to be available for the manufacturer's drugs under Medicaid. We participate in the 340B program, which is administered by the HRSA, and requires us to charge statutorily defined covered entities no more than the 340B "ceiling price" for our covered drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the AMP and rebate amount for the covered drug as calculated under the MDRP. In general, products subject to Medicaid price reporting and rebate liability are

also subject to the 340B ceiling price calculation and discount requirement. We are obligated to report 340B ceiling prices to HRSA on a quarterly basis, and HRSA publishes them to 340B covered entities. HRSA has finalized regulations regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities for 340B-eligible drugs. HRSA has also finalized an administrative dispute resolution process through which 340B covered entities may pursue claims against participating manufacturers for overcharges, and through which manufacturers may pursue claims against 340B covered entities for engaging in unlawful diversion or duplicate discounting of 340B drugs.

In order to be eligible to have drug products paid for with federal funds under Medicaid and purchased by certain federal agencies and grantees, we also participate in the U.S. VA/FSS pricing program. Under the VA/FSS program, we are obligated to report the Non-FAMP for our covered drugs to the VA and charge certain federal agencies no more than the Federal Ceiling Price, which is calculated based on Non-FAMP using a statutory formula. These four agencies are the VA, the U.S. Department of Defense, the U.S. Coast Guard and the U.S. Public Health Service (including the Indian Health Service). We are also required to pay rebates on products purchased by military personnel and dependents through the TRICARE retail pharmacy program. If we fail to provide timely information or are found to have knowingly submitted false information, we may be subject to civil monetary penalties.

Individual states continue to consider and have enacted legislation to limit the growth of healthcare costs, including the cost of prescription drugs and combination products. A number of states have either implemented or are considering implementation of drug price transparency legislation that may prevent or limit our ability to take price increases at certain rates or frequencies. Requirements under such laws include advance notice of planned price increases, reporting price increase amounts and factors considered in taking such increases, wholesale acquisition cost information disclosure to prescribers, purchasers, and state agencies, and new product notice and reporting. Such legislation could limit the price or payment for IBSRELA and, if launched, XPHOZAH, and a number of states are authorized to impose civil monetary penalties or pursue other enforcement mechanisms against manufacturers who fail to comply with drug price transparency requirements, including the untimely, inaccurate, or incomplete reporting of drug pricing information. If we are found to have violated state law requirements, we may become subject to penalties or other enforcement mechanisms, which could have a material adverse effect on our business.

Pricing and rebate calculations are complex, vary among products and programs, and are often subject to interpretation by us, governmental or regulatory agencies, and the courts. The terms, scope and complexity of these government pricing programs change frequently, as do interpretations of applicable requirements for pricing and rebate calculations. Responding to current and future changes may increase our costs and the complexity of compliance will be time consuming. Any required refunds to the U.S. government or responding to a government investigation or enforcement action would be expensive and time consuming and could have a material adverse effect on our business, results of operations and financial condition. Price recalculations under the MDRP also may affect the ceiling price at which we are required to offer products under the 340B program. Civil monetary penalties can be applied if we are found to have knowingly submitted any false price or product information to the government, if we fail to submit the required price data on a timely basis, or if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. In the event that CMS were to terminate our Medicaid rebate agreement, no federal payments would be available under Medicaid or Medicare for IBSRELA or, if launched, XPHOZAH. We cannot offer any assurances that our submissions will not be found to be incomplete or incorrect.

## **Risks Related to Intellectual Property**

### ***Our success will depend on our ability to obtain, maintain and protect our intellectual property rights.***

Our success and ability to compete depend in part on our ability to obtain, maintain and enforce issued patents, trademarks and other intellectual property rights and proprietary technology in the U.S. and elsewhere. If we cannot adequately obtain, maintain and enforce our intellectual property rights and proprietary technology, competitors may be able to use our technologies or the goodwill we have acquired in the marketplace and erode or negate any competitive advantage we may have and our ability to compete, which could harm our business and ability to achieve profitability and/or cause us to incur significant expenses.

We rely on a combination of contractual provisions, confidentiality procedures and patent, trademark, copyright, trade secret and other intellectual property laws to protect the proprietary aspects of our products, product candidates, brands, technologies, trade secrets, know-how and data. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property rights and proprietary information. Our success will depend, in part, on preserving our trade secrets, maintaining the security of our data and know-how and obtaining, maintaining and enforcing other intellectual property rights. We may not be able to obtain, maintain and/or enforce our intellectual property or other proprietary rights necessary to our business or in a form that provides us with a competitive advantage.

Failure to obtain, maintain and/or enforce intellectual property rights necessary to our business and failure to protect, monitor and control the use of our intellectual property rights could negatively impact our ability to compete and cause us to incur significant expenses. The intellectual property laws and other statutory and contractual arrangements in the U.S. and other jurisdictions we depend upon may not provide sufficient protection in the future to prevent the infringement, use, violation, or misappropriation of our patents, trademarks, data, technology, and other intellectual property rights and products by others; and may not provide an adequate remedy if our intellectual property rights are infringed, misappropriated, or otherwise violated by others.

We rely in part on our portfolio of issued and pending patent applications in the U.S. and other countries to protect our intellectual property and competitive position. However, it is also possible that we may fail to identify patentable aspects of inventions made in the course of our development, manufacture and commercialization activities before it is too late to obtain patent protection on them. If we fail to timely file for patent protection in any jurisdiction, we may be precluded from doing so at a later date. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, suppliers, consultants, advisors, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in any of our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Moreover, should we become a licensee of a third party's patents or patent applications, depending on the terms of any future in-licenses to which we may become a party, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain or enforce the patents, covering technology in-licensed from third parties. Therefore, these patents and patent applications may not be prosecuted, maintained and/or enforced in a manner consistent with the best interests of our business. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The patent positions of companies, including our patent position, may involve complex legal and factual questions that have been the subject of much litigation in recent years, and, therefore, the scope of any patent claims that we have or may obtain cannot be predicted with certainty. Accordingly, we cannot provide any assurances about which of our patent applications will issue, the breadth of any resulting patent, whether any of the issued patents will be found to be infringed, invalid or unenforceable or will be threatened or challenged by third parties, that any of our issued patents have, or that any of our currently pending or future patent applications that mature into issued patents will include, claims with a scope sufficient to protect our products and services. Our pending and future patent applications may not result in the issuance of patents or, if issued, may not issue in a form that will be advantageous to us. The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. We cannot offer any assurances that the breadth of our granted patents will be sufficient to stop a competitor from developing, manufacturing and commercializing a product or technologies in a non-infringing manner that would be competitive with one or more of our products or technologies, or otherwise provide us with any competitive advantage. Furthermore, any successful challenge to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for our commercial success. Further, there can be no assurance that we will have adequate resources to enforce our patents.

Patents have a limited lifespan. In the U.S., the natural expiration of a utility patent is generally 20 years from the earliest effective non-provisional filing date. Though an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products or services. Patents, if issued, may be challenged, deemed unenforceable, invalidated, narrowed or circumvented. Proceedings challenging our patents or patent applications could result in either loss of the patent, or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. Any successful challenge to our patents and patent applications could deprive us of exclusive rights necessary for our commercial success. In addition, defending such challenges in such proceedings may be costly. Thus, any patents that we may own may not provide the anticipated level of, or any, protection against competitors. Furthermore, an adverse decision may result in a third party receiving a patent right sought by us, which in turn could affect our ability to develop, manufacture or commercialize our products or technologies.

Some of our patents and patent applications may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products, services and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- Any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect our products or product candidates;
- Any of our pending patent applications will issue as patents;
- We were the first to make the inventions covered by each of our patents and pending patent applications;
- We were the first to file patent applications for these inventions;
- Others will not develop, manufacture and/or commercialize similar or alternative products or technologies that do not infringe our patents;
- Any of our challenged patents will ultimately be found to be valid and enforceable;
- Any patents issued to us will provide a basis for an exclusive market for our commercially viable products or technologies will provide us with any competitive advantages or will not be challenged by third parties;
- We will develop additional proprietary technologies or products that are separately patentable; or
- Our commercial activities or products will not infringe upon the patents of others.

***We may become subject to third-party claims alleging infringement, misappropriation or violation of such third parties' patents or other intellectual property rights and/or third-party claims seeking to invalidate our patents, which would be costly, time consuming and, if successfully asserted against us, delay or prevent the development, manufacture or commercialization of our products or product candidates.***

Our commercial success depends, in part, on our ability to develop, manufacture or commercialize our products and product candidates without infringing, misappropriating or otherwise violating the intellectual property rights of third parties. There have been many lawsuits and other proceedings asserting infringement or misappropriation of patents and other intellectual property rights in the pharmaceutical and biotechnology industries, and companies in the industry have used intellectual property litigation to gain a competitive advantage. While we take steps to ensure that we do not infringe upon, misappropriate or otherwise violate the intellectual property rights of others, there can be no assurances that we will not be subject to claims alleging that the manufacture, use or sale of IBSRELA or XPHOZAH or of any other product candidates infringes existing or future third-party patents, or that such claims, if any, will not be successful. Because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of IBSRELA or XPHOZAH or other product candidates. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may thus have no deterrent effect. We may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of IBSRELA or XPHOZAH or our other product candidates.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights. These proceedings could cause us to pay substantial damages, including treble damages and attorney's fees if we are found to be willfully infringing a third party's patents. We may be required to indemnify future collaboration partners against such claims. We are not aware of any threatened or pending claims related to these matters, but in the future, litigation may be necessary to defend against such claims. If a patent infringement suit were brought against us, we could be forced to stop or delay development, manufacturing or sales of the product or product candidate that is the subject of the suit. As a result of patent infringement claims, or in order to avoid potential claims, we may choose to seek, or be required to seek, a license from the third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, we may be unable to maintain such licenses and the rights may be nonexclusive, which would give our competitors access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or forced to redesign it if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms, or unable to maintain such licenses when granted. Even if we are successful in defending against such claims, such litigation can be expensive and time consuming to litigate and would divert management's attention from our core business. Any of these events could harm our business significantly.



We also could be ordered to pay substantial damages, including treble damages and attorney's fees if we are found to be willfully infringing a third party's patents or other intellectual property right. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third party patents are valid and enforceable, and infringed by the use of our products and/or technologies, which could have a negative impact on the commercial success of our current and any future products or technologies. If we were to challenge the validity of any such third party U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. We will have similar burdens to overcome in foreign courts in order to successfully challenge a third party claim of patent infringement. Even if we are successful in defending against such claims, such litigation can be expensive and time consuming to litigate and would divert management's attention from our core business. Any of these events could harm our business significantly.

In addition to infringement claims against us, third parties may also raise similar claims before administrative bodies in the U.S. or abroad. Such mechanisms include reexamination, post grant review, inter parties review, derivation or opposition proceedings before the USPTO or other jurisdictional body relating to our intellectual property rights or the intellectual property rights of others. If third parties prepare and file patent applications in the U.S. that also claim technology similar or identical to ours, we may have to participate in interference or derivation proceedings in the USPTO to determine which party is entitled to a patent on the disputed invention. We may also become involved in similar opposition proceedings in the European Patent Office or similar offices in other jurisdictions regarding our intellectual property rights with respect to our products and technology. Since patent applications are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. Such administrative proceedings could result in revocation of or amendment to our patents in such a way that they no longer cover our products or product candidates. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity and/or unenforceability, we may lose at least part, and perhaps all, of the patent protection on our products or technologies. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

***If we are not able to successfully enforce our intellectual property rights, the commercial value of IBSRELA and XPHOZAH or other product candidates may be adversely affected and we may not be able to compete effectively in our market.***

The enforceability of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions, the answers to which can be uncertain. The patent applications that we own or license may fail to result in issued patents in the U.S. or in foreign countries. Additionally, our research and development efforts may result in product candidates for which patent protection is limited or not available. Even if patents do issue, third parties may challenge the validity, enforceability, scope or infringement thereof, which may result in such patents being narrowed, invalidated, held unenforceable or not infringed. For example, U.S. patents can be challenged by any person before the new USPTO Patent Trial and Appeals Board at any time before one year after that person is served an infringement complaint based on the patents. Patents granted by the European Patent Office may be similarly opposed by any person within nine months from the publication of the grant. Similar proceedings are available in other jurisdictions, and in the U.S., Europe and other jurisdictions third parties can raise questions of validity with a patent office even before a patent has granted. Furthermore, even if unchallenged, our patents and patent applications may not prevent others from designing around our patent claims. For example, a third party may develop a competitive product that provides therapeutic benefits similar to one or more of our product candidates but has a sufficiently different composition to fall outside the scope of our patent protection. If the breadth or strength of protection provided by the patents and patent applications we hold or pursue with respect to IBSRELA and XPHOZAH or any future product candidates is successfully challenged, then our ability to commercialize such product could be negatively affected, and we may face unexpected competition that could have a material adverse impact on our business.

Even where laws provide intellectual property and/or regulatory protection, costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and the outcome of such litigation would be uncertain. If we or one of our collaboration partners were to initiate legal proceedings against a third party to enforce a patent covering a product or product candidate, the defendant could counterclaim that our patent is invalid, unenforceable and/or not infringed. In patent litigation in the U.S. and other jurisdictions, defendant counterclaims alleging invalidity, unenforceability and/or noninfringement are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including novelty, nonobviousness and enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity, unenforceability and noninfringement is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of

invalidity, unenforceability or non-infringement of our intellectual property related to a product or a product candidate, we could lose part, and possibly all, of the patent protection on such product or product candidate. Such a loss of patent protection could have a material adverse impact on our business. Moreover, our competitors could counterclaim that we infringe their intellectual property and may attempt to prevent us from commercializing a product.

Although the composition and use of IBSRELA are currently claimed by four (4) issued patents that are listed in the U.S. FDA's Orange Book, we cannot assure that we will be successful in defending against third parties asserting that any of our patents are invalid, unenforceable or not infringed by the third parties' products, or in competing against third parties seeking to introduce generic versions of IBSRELA or any of our future products.

In the U.S., the Hatch-Waxman Act provides non-patent regulatory exclusivity for five years from the date of the first U.S. FDA approval of a drug containing an NCE. The U.S. FDA is prohibited during those five years from approving an ANDA that references the NDA that has been granted NCE exclusivity. However, if any patents are listed in the U.S. FDA Orange Book for such NCE-containing drug, a generic manufacturer may file an ANDA that references a NDA product with granted NCE exclusivity after four years from the first NDA approval date provided it is accompanied by a Paragraph IV certification asserting that each Orange Book listed patent is invalid, unenforceable, or that the generic product does not infringe the Orange Book listed patents. The Hatch-Waxman Act does not prevent a third party from filing, or the U.S. FDA from approving, another full NDA (i.e., not an ANDA) for an already-approved drug where the third party has conducted its own pre-clinical and clinical trials to independently demonstrate safety and effectiveness without reliance on the original NDA data.

In cases where NCE exclusivity has been granted for an NDA, as in the case of IBSRELA, if an ANDA sponsor has provided a Paragraph IV certification to the U.S. FDA when filing an ANDA, the ANDA sponsor must also send a notice thereof to the NCE NDA owner. The NCE NDA owner may then initiate a patent infringement lawsuit in response to the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the NCE NDA owner's receipt of a notice of the Paragraph IV certification automatically prevents the U.S. FDA from approving the ANDA until the earlier of 30 months after the NCE NDA owner's receipt of the Paragraph IV certification notice or a final decision in the infringement case in favor of the ANDA sponsor. There can be no assurances that an ANDA that references our IBSRELA NDA and includes a Paragraph IV certification will not be filed, or that we will be successful in enforcing our Orange Book listed patents against such ANDA sponsor.

We also rely on trade secret protection and confidentiality agreements to protect proprietary know-how that may not be patentable, processes for which patents may be difficult to obtain and/or enforce and any other elements of our drug discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology, to assign their inventions to us, and endeavor to execute confidentiality agreements with all such parties, we cannot be certain that we have executed such agreements with all parties who may have helped to develop our intellectual property or who had access to our proprietary information, nor can we be certain that our agreements will not be breached by such consultants, advisors or third parties, or by our former employees. The breach of such agreements by individuals or entities who were actively involved in the discovery and design of our products or potential drug candidates, or in the development of our discovery and design platform could require us to pursue legal action to protect our trade secrets and confidential information, which could be expensive, and the outcome of which would be unpredictable. If we are not successful in prohibiting the continued breach of such agreements, our business could be negatively impacted. We cannot guarantee that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques.

Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the U.S. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S. and abroad. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.



***Although we have obtained patent term extension in the U.S. under the Hatch-Waxman Act, extending the term of exclusivity for tenapanor, if we do not obtain patent term extension in foreign countries under similar legislation, our business may be materially harmed. Furthermore, we have obtained patent term adjustment in the U.S. under the American Inventors Protection Act extending the patent term for certain patents covering tenapanor.***

U.S. Patent No. 8,541,448 covering tenapanor was subject to patent term adjustment under the American Inventors Protection Act for delays by the USPTO in granting the patent. Additionally, following the approval by the U.S. FDA for our NDA to market tenapanor for IBS-C, this patent was granted patent term extension under the Hatch-Waxman Act and together with patent term adjustment provides us with exclusivity for tenapanor and uses thereof until August 1, 2033. The Hatch-Waxman Act allows a maximum of one patent to be extended per U.S. FDA approved product. Extension and/or adjustment of patent term (collectively, Patent Restoration) also may be available in certain foreign countries upon regulatory approval of our product candidates. Despite seeking Patent Restoration for tenapanor in all countries where it is available, it may not be granted in any foreign country because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of patent protection subject to Patent Restoration, as well as the scope of patent protection during any such Patent Restoration, afforded by the governmental authority could be less than we request or could change due to changes to applicable Patent Restoration laws or regulations or interpretations thereof.

If we are unable to obtain Patent Term Restoration in any particular country, or the term of any such extension is less than we request, or is changed due to changes in applicable laws or regulations or interpretations thereof, the period during which we will have exclusive rights to our product in such country could be shortened and our competitors may obtain approval of competing products following our non-extended/adjusted patent expiration, and our revenue could be reduced, possibly materially.

The USPTO and various foreign patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions to maintain patent applications and issued patents. Noncompliance with these requirements can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

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

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the U.S. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties.

Europe's new Unified Patent Court may, in particular, present uncertainties for our ability to protect and enforce our patent rights against competitors in Europe. In 2012, the EU Patent Package regulations were passed with the goal of providing a single pan-European Unitary Patent and a new UPC, for litigation involving European patents. Implementation of the EU Patent Package entered into force on June 1, 2023. Under the UPC, all European patents, including those issued prior to ratification of the EU Patent Package, will by default automatically fall under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents and allow for the possibility of a competitor to obtain pan-European injunctions. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by the UPC. Under the EU Patent Package as currently proposed, we will have the right to opt our patents out of the UPC over the first seven years of the court's existence, but doing so may preclude us from realizing the benefits of the new unified court.

In addition, geo-political actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, the United States and foreign government actions related to Russia's conflict in Ukraine may limit or prevent filing, prosecution, and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees from the United States without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the U.S. and foreign countries may affect our ability to obtain and enforce adequate intellectual property protection for our technology.

***If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed.***

We consider proprietary trade secrets, confidential know-how and unpatented know-how to be important to our business. We seek to protect our confidential proprietary information, in part, by entering into confidentiality agreements and invention assignment agreements with parties who have access to them, including our employees, consultants, scientific advisors, contractors, CROs, contract manufacturers, collaborators and other third parties, that are designed to protect our proprietary information. However, we cannot be certain that such agreements have been entered into with all relevant parties that may have or have had access to our trade secrets or proprietary technology, and we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets and other confidential proprietary technology, or independently develop substantially equivalent information and techniques. For example, any of these parties with whom we have entered into such confidentiality or invention assignment agreements may breach the agreements and disclose our proprietary information, including trade secrets, and we may not be able to obtain adequate remedies for such breaches. We also seek to preserve the integrity and confidentiality of our confidential proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know, whether the steps we have taken to protect our intellectual property will be effective.

Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. We may not be able to obtain adequate remedies in the event of such unauthorized use. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Trade secrets will also over time be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel skilled in the art from company to company or academic institutions to industry scientific positions. Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors and consultants to publish data potentially relating to our trade secrets and proprietary information, our agreements may contain certain limited publication rights. In addition, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are incorporated (inadvertently or not) into the technology of others, or are disclosed or used in violation of these agreements. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of such information may be greatly reduced and our competitive position, business, financial condition, results of operations and prospects would be harmed.

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

Our current or future registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive, cancelled or determined to be infringing on other marks. We may not be able to protect or

preserve our rights to these trademarks and trade names or may be forced to stop using those names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Although these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our competitive position, business, financial condition, results of operations and prospects.

Moreover, any name we have proposed to use with our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

***We may be subject to claims that we or our employees have misappropriated the intellectual property, including know-how or trade secrets, of a third party, or claiming ownership of what we regard as our own intellectual property.***

Many of our employees, consultants and contractors were previously employed at or engaged by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants and contractors, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees, consultants and contractors do not use the intellectual property and other proprietary information or know-how or trade secrets of others in their work for us, and do not perform work for us that is in conflict with their obligations to another employer or any other entity, we may be subject to claims that we or these employees, consultants and contractors have used or disclosed such intellectual property, including know-how, trade secrets or other proprietary information. In addition, an employee, advisor or consultant who performs work for us may have obligations to a third party that are in conflict with their obligations to us, and as a result such third party may claim an ownership interest in the intellectual property arising out of work performed for us. We are not aware of any threatened or pending claims related to these matters, but in the future litigation may be necessary to defend against such claims. If we fail to defend any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, or access to consultants and contractors. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

## Risks Related to Our Common Stock

*Our stock price may continue to be volatile and our stockholders may not be able to resell shares of our common stock at or above the price they paid.*

The trading price of our common stock is highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed in this “Risk Factors” section and others such as:

- the success or lack of success with regards to our commercialization of IBSRELA and XPHOZAH;
- results of regulatory inspections of our facilities or those of our CMOs, or specific label restrictions or patient populations for XPHOZAH’s use, or changes or delays in the regulatory review process;
- announcements regarding coverage and reimbursement for XPHOZAH alone or with other oral ESRD related drugs without injectable or intravenous equivalents;
- announcements relating to our current or future collaboration partnerships;
- announcements of therapeutic innovations or new products or strategic transactions by us or our competitors;
- adverse actions taken by regulatory agencies with respect to our product label, our clinical trials, manufacturing supply chain or sales and marketing activities;
- changes or developments in laws or regulations applicable to our approved products or our product candidates;
- the success of our testing and clinical trials;
- failure to meet any of our projected timelines or goals with regard to the commercialization of IBSRELA and XPHOZAH, or the clinical development and commercialization of any of our product candidates;
- the success of our efforts to acquire or license or discover additional product candidates;
- any intellectual property infringement actions in which we may become involved;
- the success of our efforts to obtain adequate intellectual property protection for our product candidates;
- announcements concerning our competitors or the pharmaceutical industry in general;
- achievement of expected product sales and profitability;
- manufacture, supply or distribution shortages;
- actual or anticipated fluctuations in our operating results;
- U.S. FDA or other U.S. or foreign regulatory actions affecting us or our industry or other healthcare reform measures in the U.S.;
- changes in financial estimates or recommendations by securities analysts;
- trading volume of our common stock;
- sales of our common stock by us, our executive officers and directors or our stockholders in the future;
- sales of debt securities and sales or licensing of assets;
- general economic and market conditions and overall fluctuations in the U.S. equity markets; and
- the loss of any of our key scientific or management personnel.

In addition, the stock markets in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that may have been unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the

lawsuit and the attention of our management would be diverted from the operation of our business, which could seriously harm our financial position. Any adverse determination in litigation could also subject us to significant liabilities.

***If we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.***

We may from time to time issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders will experience additional dilution and, as a result, our stock price may decline.

***We are no longer a “smaller reporting company” and as a result we are or will be subject to certain enhanced disclosure requirements which will require us to incur significant expenses and expend time and resources.***

We are no longer a “smaller reporting company,” and, as a result, we are or will be required to comply with various disclosure and compliance requirements that did not previously apply to us. Compliance with these additional requirements increases our legal and financial compliance costs and causes management and other personnel to divert attention from operational and other business matters to these additional public company reporting requirements. In addition, if we are not able to comply with changing requirements in a timely manner, the market price of our stock could decline and we could be subject to delisting proceedings by the Nasdaq Global Market, or sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

## **General Risk Factors**

***We incur significant costs as a result of operating as a public company, and our management will devote substantial time to new compliance initiatives. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002, which could result in sanctions or other penalties that would harm our business.***

We incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Securities Exchange Act of 1934, as amended (Exchange Act) and regulations regarding corporate governance practices. The listing requirements of The Nasdaq Global Market require that we satisfy certain corporate governance requirements relating to director independence, distributing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements. Moreover, the reporting requirements, rules and regulations will increase our legal and financial compliance costs and will make some activities more time consuming and costly. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors’ and officers’ insurance, on acceptable terms.

We are subject to Section 404 of The Sarbanes-Oxley Act of 2002 (Section 404) and the related rules of the SEC which generally require, among other things, our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Our compliance with Section 404 requires that we incur substantial expense and expend significant management efforts.

During the course of our review and testing of our internal controls, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we are required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from The Nasdaq Global Market or other adverse consequences that would materially harm our business.



***We may be adversely affected by the global economic environment.***

Our ability to attract and retain collaboration partners or customers, invest in and grow our business and meet our financial obligations depends on our operating and financial performance, which, in turn, is subject to numerous factors, including the prevailing economic conditions and financial, business and other factors beyond our control, such as the rate of unemployment, the number of uninsured persons in the U.S., presidential elections, other political influences and inflationary pressures. Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets, including the current inflationary environment and rising interest rates. Adverse developments that affect financial institutions, transactional counterparties, or other third parties, or concerns or rumors about these events, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed the U.S. Federal Deposit Insurance Corporation as receiver. Similarly, other institutions have been and may continue to be swept into receivership. We currently have no borrowing or deposit exposure to directly impacted institutions and have not experienced an adverse impact to our liquidity or to our business operations, financial condition, or results of operations as a result of these recent events. However, uncertainty may remain over liquidity concerns in the broader financial services industry, and there may be unpredictable impacts to our business and our industry. We cannot anticipate all the ways in which the global economic climate and global financial market conditions could adversely impact our business in the future.

We are exposed to risks associated with reduced profitability and the potential financial instability of our collaboration partners or customers, many of which may be adversely affected by volatile conditions in the financial markets. For example, unemployment and underemployment, and the resultant loss of insurance, may decrease the demand for healthcare services and pharmaceuticals. If fewer patients are seeking medical care because they do not have insurance coverage, our collaboration partners or customers may experience reductions in revenues, profitability and/or cash flow that could lead them to reduce their support of our programs or financing activities. If collaboration partners or customers are not successful in generating sufficient revenue or are precluded from securing financing, they may not be able to pay, or may delay payment of, accounts receivable that are owed to us. In addition, volatility in the financial markets could cause significant fluctuations in the interest rate and currency markets. We currently do not hedge for these risks. The foregoing events, in turn, could adversely affect our financial condition and liquidity. In addition, if economic challenges in the U.S. result in widespread and prolonged unemployment, either regionally or on a national basis, or if certain provisions of the Patient Protection and ACA, as amended by the Health Care and Education Reconciliation Act, collectively known as the ACA, are repealed, a substantial number of people may become uninsured or underinsured. To the extent economic challenges result in fewer individuals pursuing or being able to afford our product candidates once commercialized, our business, results of operations, financial condition and cash flows could be adversely affected.

***Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.***

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could significantly reduce the value of our shares to a potential acquirer or delay or prevent changes in control or changes in our management without the consent of our board of directors. The provisions in our charter documents include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the required approval of at least two-thirds of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;

- the required approval of at least two-thirds of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

In addition, these provisions would apply even if we were to receive an offer that some stockholders may consider beneficial.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

***Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.***

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such a person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnities, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.
- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

***We do not currently intend to pay dividends on our common stock, and, consequently, our stockholders' ability to achieve a return on their investment will depend on appreciation in the price of our common stock.***

We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our future business opportunities. Additionally, the terms of our Loan Agreement could restrict our ability to pay dividends. Therefore, our stockholders are not likely to receive any dividends on our common stock for the foreseeable future. Since we do not intend to pay dividends, our stockholders' ability to receive a return on their investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders have purchased it.

#### **ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

#### **ITEM 1C. CYBERSECURITY**

##### **Cybersecurity Risk Management and Strategy**

We have developed and implemented a cybersecurity program intended to manage risk, and protect the confidentiality, integrity, and availability of our critical systems and information.

We design, assess and benchmark our program based on the National Institute of Standards and Technology Cybersecurity Framework.

Our cybersecurity risk management program is integrated into our overall enterprise risk management program, and shares common methodologies, reporting channels and governance processes that apply across the enterprise risk management program, in areas such as legal, compliance, strategic, operational and financial risk.

Key elements of our cybersecurity program include but are not limited to the following:

- risk assessments designed to help identify material risks from cybersecurity threats to our critical systems and information;
- a security team principally responsible for managing (1) our cybersecurity risk assessment processes, (2) our security controls and (3) our response to cybersecurity incidents;
- the use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of our security processes;
- cybersecurity awareness training of our employees, including incident response personnel and senior management;
- a cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents; and
- a third-party risk management process for service providers, suppliers and vendors that have access to our critical systems and information based on our assessment of their criticality to our operations and respective risk profile.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected us, including our operations, business strategy, results of operations, or financial condition. We face risks from cybersecurity threats that, if realized are reasonably likely to materially affect us, including our operations, business strategy, results of operations or financial condition. For more information, see the section titled “Risk Factors— *We and our collaborators, CROs and other contractors and consultants depend on information technology systems, and any failure of these systems could harm our business. Security breaches, loss of data, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, results of operations and financial condition.*”

##### **Cybersecurity Governance**

Our board of directors considers cybersecurity risk as part of its risk oversight function and has delegated to the Audit and Compliance Committee (Committee) oversight of cybersecurity risks, including oversight of management's implementation of our cybersecurity risk management program, maintains a strategic role in coordinating cyber risk initiatives and policies, and confirming their efficacy.

The Committee receives annual reports from management on our cybersecurity posture. In addition, management updates the Committee where it deems appropriate regarding any cybersecurity incidents it considers to be significant or potentially significant.

The Committee reports to the full board of directors regarding its activities, including those related to cybersecurity. The board of directors also receives periodic briefings from management on our cybersecurity program. The board members receive presentations on cybersecurity topics from our Chief Information Officer, internal security staff or external experts as part of the board of directors' continuing education on topics that impact public companies.

Our Chief Information Officer has over 20 years of experience in overseeing cybersecurity and risk management. In addition, our Chief Legal and Administrative Officer has over 25 years of risk management experience and our Chief Financial and Operations Officer has over 20 years of experience in overseeing risk management and cybersecurity. This team is responsible for assessing and managing our material risks from cybersecurity threats and has primary responsibility for our overall cybersecurity risk management program and supervises both our internal cybersecurity personnel and our retained external cybersecurity consultants. Our management team's experience includes experience running cybersecurity programs at similarly situated commercial biotechnology organizations and navigating the associated risk landscape.

Our management team takes steps to stay informed about and monitor efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include briefings from internal security personnel, threat intelligence and other information obtained from governmental, public or private sources, including external consultants engaged by us and alerts and reports produced by security tools deployed in the IT environment.

## **ITEM 2. PROPERTIES**

We do not own any real estate or other physical properties materially important to our operations. Our Waltham, Massachusetts headquarters is leased for three suites, two of which expire on July 31, 2026, and one expires on April 30, 2027. In addition, we have lease agreements to lease office space and/or laboratory space in Fremont, California, Milwaukee, Wisconsin and Newark, California which expire in March 2025, February 2029 and May 2028, respectively.

## **ITEM 3. LEGAL PROCEEDINGS**

See information under the "Legal Proceedings and Claims" caption in *Note 19. Commitments And Contingencies* which we incorporated here by reference.

## **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

#### Common Stock

As of December 31, 2024, there were 24 holders of record of our common stock.

#### Dividends

We have never declared or paid cash dividends on our capital stock. We currently intend to retain any future earnings to finance the growth and development of our business.

#### Securities Authorized for Issuance under Equity Compensation Plans

The information required by this item regarding executive compensation will be incorporated by reference to the information set forth in the sections titled "Executive Compensation" in our Proxy Statement.

#### Recent Sales of Unregistered Securities

None.

#### Use of Proceeds

Not applicable.

#### Issuer Purchases of Equity Securities

Not applicable.

### ITEM 6. [RESERVED]

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

*You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our financial statements and related notes included elsewhere in this report. This discussion and other parts of this report contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations and intentions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this report entitled "Risk Factors." These forward-looking statements speak only as of the date hereof. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason. Unless the context requires otherwise, the terms "Ardelyx," "we," "us," "our" and "the Company" refer to Ardelyx, Inc.*

#### EXECUTIVE SUMMARY AND FINANCIAL HIGHLIGHTS

We are a biopharmaceutical company founded with a mission to discover, develop and commercialize innovative, first-in-class medicines that meet significant unmet medical needs. We developed a unique and innovative platform that enabled the discovery of new biological mechanisms and pathways to develop potent and efficacious therapies that minimize the side effects and drug-drug interactions frequently encountered with traditional, systemically absorbed medicines. The first molecule we discovered and developed was tenapanor, a minimally absorbed, first-in-class, oral, small molecule therapy. Tenapanor, branded as IBSRELA<sup>®</sup>, is approved in the U.S. for the treatment of adults with IBS-C. Tenapanor, branded as XPHOZAH<sup>®</sup>, is approved in the U.S. to reduce serum phosphorus in adults with CKD on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy.



Below is a summary of our product sales, net by product for the years ended December 31 and total cash, cash equivalents and short-term investments as of December 31:

<i>(in thousands)</i>	<b>2024</b>	<b>2023</b>
IBSRELA product sales, net	\$ 158,286	\$ 80,062
XPHOZAH product sales, net	160,910	2,464
Total product sales, net	<u>\$ 319,196</u>	<u>\$ 82,526</u>
Cash, cash equivalents and short-term investments	\$ 250,100	\$ 184,299

IBSRELA and XPHOZAH product sales have continually grown since their respective commercial launches. IBSRELA net sales growth was attributed to patient demand for this first-in-class therapy as well as increased product awareness achieved through the IBSRELA field-based team. XPHOZAH's commercial launch has been met with a strong response from the prescribing community and net sales continued to increase during 2024, the first full year of commercialization. As of January 1, 2025, we no longer receive reimbursement for XPHOZAH from Medicare Part D following the decision by the Centers of Medicare and Medicaid Services to eliminate Medicare Part D reimbursement to transition oral only therapies, including XPHOZAH, into the End Stage Renal Disease Prospective Payment System. Patient access to XPHOZAH remains through a prescription written by a qualifying healthcare provider through our ArdelyxAssist specialty pharmacy partner. Patients who do not have affordable access will be evaluated for eligibility to receive XPHOZAH fulfilled by our Ardelyx patient assistance program.

The increase in our cash, cash equivalents and short-term investment was attributed to higher product sales, net and incremental borrowings. During 2024, we amended the 2022 Loan Agreement with SLR and drew an additional \$100.0 million in debt as discussed in *Note 9. Borrowing*. We expect that we will increasingly rely on cash generated from operations to fund our operating plan. We believe our existing cash, cash equivalents and short-term investments, and cash generated from operations will be sufficient to satisfy our anticipated cash needs for operations for at least the next few years. Our access to additional capital, including our ability to source cash from future equity sales and debt financing, provides us financial flexibility to execute our principal strategy as discussed below.

## Strategy

We are committed to our mission of discovering, developing and commercializing first-in-class medicines that address unmet patient needs. Our principal strategy is to maintain our commercial momentum with our current products while identifying additional assets that leverage our core capabilities, including clinical, developmental and regulatory expertise and commercial excellence while maintaining a solid financial foundation, to support our future growth.

Our priorities include: (i) accelerating IBSRELA growth momentum; (ii) executing our XPHOZAH strategy to grow utilization; (iii) building a pipeline focused on areas of unmet patient need; and (iv) continuing to deliver strong commercial and financial performance.

## RECENT ACCOUNTING PRONOUNCEMENTS

A summary of recent accounting pronouncements that we have adopted or may expect to adopt is included in *Note 2. Summary Of Significant Accounting Policies* in the notes to our financial statements, included in Part II, Item 8, of this Annual Report on Form 10-K.

## CRITICAL ACCOUNTING POLICIES AND ESTIMATES

A detailed discussion of our significant accounting policies can be found in *Note 2. Summary Of Significant Accounting Policies*, in the notes to our financial statements, included in Part II, Item 8, of this Annual Report on Form 10-K. The preparation of financial statements requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of revenues and expenses. Our critical accounting policies are those that significantly affect our financial condition and results of operations and require the most difficult, subjective or complex judgments, often because of the need to make estimates about the effect of matters that are inherently uncertain.

While we believe that our estimates, assumptions and judgments are reasonable, they are based on information available when the estimate or assumption was made. Actual results may differ significantly. Additionally, changes in our assumptions, estimates or assessments due to unforeseen events or otherwise could have a material impact on our financial position or results of operations.

## *Revenue Recognition*

The application of ASC 606 *Revenue from Contracts with Customers* substantially impacts our reported results, particularly product sales, net, which requires certain estimates in determining the transaction price. Total revenues are recognized following a five-step model: (i) identify the customer contract; (ii) identify the contract's performance obligations; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations; and (v) recognize revenue when or as a performance obligation is satisfied.

### *Product Sales, Net*

GTN adjustments are primarily a function of sales volume, payor mix, contractual or legislative discounts and rebates. The transaction price for product sales, net is reduced for estimates of variable consideration related to GTN adjustments for discounts and chargebacks, rebates, wholesaler and GPO fees, copay assistance and returns. Except for certain wholesaler and GPO fees and discounts, which are based on contracts, these adjustments involve estimation and judgment. The GTN adjustments for rebates, copay assistance and chargebacks are impacted by our estimate of payor mix, which requires significant judgment. We consider legal interpretations of applicable laws and regulations, historical experience, current contract prices under applicable programs, unbilled claims, processing time lags and inventory levels in the distribution channel in determining our estimates. Estimates are assessed each period and adjusted as required to revise information or actual experience.

#### Discounts and chargebacks:

Our U.S. business participates in programs with government entities, the most significant of which are the U.S. Department of Defense and the U.S. Department of Veterans Affairs, and other parties, including covered entities under the 340B program, whereby pricing on products is extended below wholesaler list price to participating entities. These entities purchase products through wholesalers at the lower program price and the wholesalers then charge us the difference between their acquisition cost and the lower program price. Accounts receivable is reduced for the estimated amount of unprocessed chargeback claims attributable to a sale (typically within a two to four week time lag).

Our Customers may also receive prompt pay discounts for payment within a specified period, generally approximating two percent of the invoiced sales price. Our payment terms are generally 30 to 60 days. We expect discounts to be earned when offered and we deduct the full amount of these discounts from product sales when revenue is recognized.

Accounts receivable is reduced for the estimated amount of fees and cash discount at the time of sale and the discount is typically taken by the customer within contractual terms.

#### Rebates, wholesaler and GPO fees:

Our U.S. business participates in state government Medicaid and Medicare programs and other qualifying Federal and state government programs requiring discounts and rebates to participating state and local government entities. All discounts and rebates provided through these programs are included in our Medicaid and Medicare rebate accruals. Medicaid rebates have also been extended to drugs used in managed Medicaid plans. The estimated amount of unpaid or unbilled rebates and discounts is presented as a liability. Settlement of Medicare and Medicaid accruals can lag for multiple quarters due to extensive time delays between recording an accrual and subsequent receipt of an invoice. Due to this lag, adjustments can incorporate revision of several prior quarters. Through December 31, 2024, we paid a 70% discount to CMS when the Medicare Part D beneficiaries were in the coverage gap. Beginning in 2025, as part of the Medicare Part D redesign within the IRA, there is a \$2,000 cap for out-of-pocket costs for Medicare Beneficiaries and manufacturers are responsible for 10% of costs up to the cap and 20% after the cap is reached.

Wholesaler and GPO administrative fees are a significant portion of our GTN adjustments, however, since they are based on contracts, they require inherently less estimation.

#### Copay assistance and returns:

Patients who have commercial insurance may receive copay assistance when product is dispensed by pharmacies to patients. We estimate the amount of copay assistance provided to eligible patients based on the terms of the program and redemption information provided by third-party claims processing organizations. We also estimate the amount of copay assistance that we will provide to patients associated with product we have sold but has not yet been dispensed to commercial patients, which requires significant estimation and judgment. Our estimates are recorded in accrued expenses and other current liabilities on the balance sheets.

Considering the timing of our respective product launches, and limited experiences with returns, we are primarily reliant on historical sales returns of similar products, such as those within the same product line, similar therapeutic area, similar distribution model, estimated levels of inventory in the distribution channel and projected demand. We increasingly rely on our products' actual returns history and other factors, including levels of our inventory in the distribution channel and estimated shelf life, to estimate our returns. Our estimates are recorded in accrued expenses and other current liabilities on the balance sheets.

#### Use of Information from External Sources:

Information from external sources is used to estimate GTN adjustments. Our estimate of inventory at the wholesalers is based on the historical inventory experience, as well as our analysis of third-party information, including written and oral information obtained from certain wholesalers with respect to their inventory levels and sell-through to customers and our internal information. The inventory information received from wholesalers is a product of their recordkeeping process and excludes inventory held by intermediaries to whom they sell, such as retailers and hospitals. We also use information from external sources to identify prescription trends, patient demand and average selling prices. Our estimates are subject to inherent limitations of estimates that rely on third-party information, as certain third-party information was itself in the form of estimates and reflect other limitations including lags between the date as of which third-party information is generated and the date on which we receive third-party information.

## RESULTS OF OPERATIONS

### Revenue

Our revenue to date has been generated primarily through a combination of product sales and payments in connection with license, research and development collaborative agreements with our various collaboration partners. In the future, we may generate revenue from a combination of our own product sales and payments in connection with our current or future collaborative partnerships, including license fees, other upfront payments, milestone payments, royalties and payments for drug product and/or drug substance. We expect that any revenue we generate will fluctuate in future periods as a result of many factors as described in Part I, Item 1A, "Risk Factors," of this Annual Report on Form 10-K.

Below is a summary of our total revenues:

(\$ in thousands)	Year Ended December 31,			Change 2024 vs. 2023		Change 2023 vs. 2022	
	2024	2023	2022	\$	%	\$	%
Product sales, net	\$ 319,196	\$ 82,526	\$ 15,600	\$ 236,670	287 %	\$ 66,926	429 %
Product supply revenue	11,649	6,121	1,527	5,528	90 %	4,594	301 %
Licensing revenue	78	35,809	35,031	(35,731)	(100)%	778	2 %
Non-cash royalty revenue related to the sale of future royalties	2,692	—	—	2,692	(a)	—	(a)
Total revenues	<u>\$ 333,615</u>	<u>\$ 124,456</u>	<u>\$ 52,158</u>	<u>\$ 209,159</u>	168 %	<u>\$ 72,298</u>	139 %

(a) Percent change is not meaningful.

Below is a summary of our product sales, net by product:

(in thousands)	Year Ended December 31,		
	2024	2023	2022
Product sales, net			
IBSRELA	\$ 158,286	\$ 80,062	\$ 15,600
XPHOZAH	160,910	2,464	—
Total product sales, net	<u>\$ 319,196</u>	<u>\$ 82,526</u>	<u>\$ 15,600</u>

*Product sales, net:*

The increase in IBSRELA product sales, net in 2024 and 2023 was due to higher demand since its commercial launch in March 2022, reflecting continued increase in awareness and prescriber experience. In addition, the increase in 2024 was attributable to the completion of our field-base team expansion.

The increase in XPHOZAH product sales, net in 2024 and 2023 was due to higher demand since its commercial launch in November 2023. As of January 1, 2025, we no longer receive reimbursement for XPHOZAH from Medicare Part D following the decision by the Centers of Medicare and Medicaid Services to eliminate Medicare Part D reimbursement to transition oral only therapies, including XPHOZAH, into the End Stage Renal Disease Prospective Payment System. Patient access to XPHOZAH remains through a prescription written by a qualifying healthcare provider through our ArdelyxAssist specialty pharmacy partner. Patients who do not have affordable access will be evaluated for eligibility to receive XPHOZAH fulfilled by our Ardelyx patient assistance program.

*Product supply revenue:*

The increase in product supply revenue in 2024 and 2023 was due to product supply shipments to our collaboration partners, primarily Kyowa Kirin, under our respective commercial supply agreements in support of non-US launches.

*Licensing revenue:*

Licensing revenue is primarily impacted by the timing of regulatory and commercial milestone achievements from our out-licensing partners, as well as sales-based royalties received from Knight. The 2023 licensing revenue included \$30.0 million in payments received under the Kyowa Kirin Agreement, following Kyowa Kirin's submission to the Japanese MHLW for the NDA for tenapanor in the improvement of hyperphosphatemia in adult patients with CKD on dialysis; and a \$5.0 million payment under the Fosun Agreement, following the NDA acceptance by China's Center for Drug Evaluation of the NMPA for tenapanor in the control of serum phosphorus in adult patients with CKD on hemodialysis and the U.S. FDA approval of XPHOZAH to reduce serum phosphorus in adults with CKD on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy.

*Non-cash royalty revenue:*

Non-cash royalty revenue in 2024 was attributable to royalties from Kyowa Kirin for sales of PHOZEVEL in Japan since its launch in February 2024, which we remitted to HCR upon receipt in accordance with the HCR Agreement.

**GTN Adjustments**

We recognize product sales net of GTN adjustments that are further described in *Note 6. Revenue* and the "Critical Accounting Policies and Estimates" caption in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations." Reconciliation of gross product sales to product sales, net by GTN adjustment category is as follows:

(\$ in thousands)	Year Ended December 31,		
	2024	2023	2022
Gross product sales	\$ 429,053	\$ 113,861	\$ 21,648
GTN adjustments	(109,857)	(31,335)	(6,048)
Product sales, net	<u>\$ 319,196</u>	<u>\$ 82,526</u>	<u>\$ 15,600</u>
GTN adjustment percentage	25.6 %	27.5 %	27.9 %

GTN adjustments are primarily a function of sales volume, payor mix, contractual or legislative discounts and rebates. Adjustments to provisions for product sales made in prior periods due to changes in estimates were not significant for any of the years presented. The decrease in GTN adjustment percentage in 2024 was primarily due to a higher percentage of sales which had a more favorable GTN rate. The reduction was mainly due to lower sales subjected to copay assistance and contractual chargebacks which had higher GTN adjustment percentages. We expect GTN adjustment percentages to increase in the future due to unfavorable payor mix shifts associated with loss of XPHOZAH Medicare Part D reimbursement beginning January 1, 2025.

The activities and ending reserve balances for each significant category of GTN adjustments on product sales, net, which constitute variable consideration, were as follows:

<i>(in thousands)</i>	<b>Discounts and chargebacks</b>	<b>Rebates, wholesaler and GPO fees</b>	<b>Copay assistance and returns</b>	<b>Total</b>
Balance as of December 31, 2022	\$ 142	\$ 1,444	\$ 1,258	\$ 2,844
Provisions	5,341	15,365	10,629	31,335
Credits/payments	(5,005)	(12,575)	(7,971)	(25,551)
Balance as of December 31, 2023	478	4,234	3,916	8,628
Provisions	15,099	65,833	28,925	109,857
Credits/payments	(13,934)	(55,592)	(21,671)	(91,197)
Balance as of December 31, 2024	<u>\$ 1,643</u>	<u>\$ 14,475</u>	<u>\$ 11,170</u>	<u>\$ 27,288</u>

Adjustments to prior period provisions recorded in the current period were not material.

## Expenses

Below is a summary of our cost of goods sold, operating expenses, interest expense, non-cash interest expense related to the sale of future royalties and other income, net:

<i>(\$ in thousands)</i>	<b>Year Ended December 31,</b>			<b>Change 2024 vs. 2023</b>		<b>Change 2023 vs. 2022</b>	
	<b>2024</b>	<b>2023</b>	<b>2022</b>	<b>\$</b>	<b>%</b>	<b>\$</b>	<b>%</b>
Cost of product sales	\$ 6,851	\$ 2,323	\$ 566	\$ 4,528	195 %	\$ 1,757	310 %
Other cost of revenue	43,705	15,472	3,551	28,233	182 %	11,921	336 %
Total cost of goods sold	<u>\$ 50,556</u>	<u>\$ 17,795</u>	<u>\$ 4,117</u>	<u>\$ 32,761</u>	184 %	<u>\$ 13,678</u>	332 %
Research and development	\$ 52,317	\$ 35,536	\$ 35,201	\$ 16,781	47 %	\$ 335	1 %
Selling, general and administrative	258,692	134,401	76,599	124,291	92 %	57,802	75 %
Total operating expenses	<u>\$ 311,009</u>	<u>\$ 169,937</u>	<u>\$ 111,800</u>	<u>\$ 141,072</u>	83 %	<u>\$ 58,137</u>	52 %
Interest expense	\$ (13,006)	\$ (4,950)	\$ (3,400)	\$ (8,056)	163 %	\$ (1,550)	46 %
Non-cash interest expense related to the sale of future royalties	(7,088)	(3,924)	(1,673)	(3,164)	81 %	(2,251)	135 %
Other income, net	9,174	6,630	1,633	2,544	38 %	4,997	306 %

## Cost of Goods Sold

Cost of product sales consists of the cost of commercial goods sold to our Customers and includes the cost of materials, third-party contract manufacturing, third-party packaging services, freight, labor costs for personnel involved in the manufacturing process and indirect overhead costs. Other cost of revenue consists of the cost of materials sold to our international partners under product supply agreements, certain costs related to capacity expansion at current and future CMOs, as well as payments due to AstraZeneca based on sales of tenapanor. See the “AstraZeneca” caption in *Note 7. Collaboration And Licensing Agreements* for further detail.

### Cost of product sales:

The increase in cost of product sales in 2024 and 2023 was due to higher product sales. A portion of the costs of IBSRELA and XPHOZAH units recognized as revenue during the years ended December 31, 2024 and 2023 were expensed as research and development expenses in periods prior to the commencement of capitalization of inventory costs for each respective product as discussed in *Note 2. Summary Of Significant Accounting Policies*. The cost associated with inventory sold but previously expensed as research and development was \$6.3 million, \$4.4 million and \$1.9 million in 2024, 2023 and 2022, respectively. The value of inventory on hand as of December 31, 2024 and 2023 that was previously expensed as research and development was approximately \$15.6 million and \$21.8 million, respectively.



### *Other cost of revenue:*

The increase in other cost of revenue in 2024 and 2023 was primarily due to higher AstraZeneca royalties, driven by higher product sales, net of tenapanor. In 2023, AstraZeneca royalties attributed to licensing revenue had a greater impact on the obligation than royalties from product sales, net. Other cost of revenue related to the AstraZeneca Termination Agreement was \$34.7 million, \$12.4 million and \$3.6 million in 2024, 2023 and 2022, respectively. The remaining future royalty obligation to AstraZeneca was \$12.1 million as of December 31, 2024. In addition, the increase in other cost of revenue was due to higher product supply revenue and costs associated with that revenue.

### **Research and Development**

Research and development activities include research and early discovery, preclinical and clinical development, drug formulation and medical support to marketed products. External R&D expenses include research and development expenses incurred under agreements with outside consultants, third-party CROs and investigative sites where a substantial portion of our clinical studies are conducted, and with CMOs where our clinical supplies are produced; employee-related expenses, which include salaries, bonuses, benefits, travel and stock-based compensation; expenses associated with supplies and materials consumed in connection with our research operations; and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation and amortization expense, information technology expense and other supplies.

Below is a summary of our research and development expenses:

(\$ in thousands)	Year Ended December 31,			Change 2024 vs. 2023		Change 2023 vs. 2022	
	2024	2023	2022	\$	%	\$	%
External R&D and other expenses	\$ 20,723	\$ 15,213	\$ 17,011	\$ 5,510	36 %	\$ (1,798)	(11)%
Employee-related expenses	27,541	17,391	15,065	10,150	58 %	2,326	15 %
Facilities, equipment, depreciation and other expenses	4,053	2,932	3,125	1,121	38 %	(193)	(6)%
Total research and development expenses	<u>\$ 52,317</u>	<u>\$ 35,536</u>	<u>\$ 35,201</u>	<u>\$ 16,781</u>	47 %	<u>\$ 335</u>	1 %

The increase in R&D expenses in 2024, including other R&D expenses, primarily reflected increased medical engagement with scientific communities in the areas of gastroenterology and nephrology related to our marketed products. The increase in external R&D expenses was also attributable to clinical trial and pharmacovigilance activities. The increase in employee-related R&D expenses was the result of increases in headcount and personnel costs, including an increase in stock-based compensation expenses totaling \$6.0 million and \$0.4 million in 2024 and 2023, respectively.

R&D expenses in 2023 remained relatively stable as compared to 2022, however, the focus of 2023 activities primarily shifted towards medical and pharmacovigilance efforts supporting our marketed products. Whereas, in 2022, activities focused more on clinical activities in preparation for the respective regulatory approvals.

### **Selling, General and Administrative**

Selling, general and administrative expenses relate to sales and marketing, finance, human resources, legal and other administrative activities, including information technology investments. Selling, general and administrative expenses consist primarily of personnel costs, outside professional services, marketing, advertising and legal expenses, facilities costs not otherwise allocated to research and development and other general and administrative costs.

The increase in selling, general and administrative expenses in 2024 and 2023 was primarily due to increased commercialization and administrative costs to support net sales growth of IBSRELA and XPHOZAH and to support our strategy. The increases consisted of external spending for disease awareness initiatives, patient affordability, access support and related patient awareness, as well as increased commercial infrastructure and increased legal fees incurred related to the Company's lawsuit against CMS in 2024. The increase was also attributable to increases in headcount and related personnel costs, including an increase in stock-based compensation expense totaling \$17.8 million and \$2.4 million in 2024 and 2023, respectively.

## Interest Expense

Interest expense represents the interest associated with our loan agreements.

The increase in interest expense in 2024 and 2023 was due to a higher loan balance resulting from the term loan draws in each respective year: \$50.0 million for the Term D Loan in October 2024, \$50.0 million for the Term C Loan in March 2024, and \$22.5 million for the Term B Loan in October 2023.

## Non-Cash Interest Expense Related to the Sale of Future Royalties

Non-cash interest expense related to the sale of future royalties represents the imputed interest expense on our deferred royalty obligation related to the sale of future royalties using the effective interest method. Non-cash interest expense is impacted by the outstanding balance of the deferred royalty obligation, which increases from milestone payments received from HCR under the sale of future royalties agreement and imputed interest accrued on the outstanding deferred royalty obligation, and decreases as royalties received from Kyowa Kirin related to the sale of tenapanor for cardiorenal indications in Japan are subsequently remitted to HCR. Refer to *Note 8. Deferred Royalty Obligation Related To The Sale Of Future Royalties* for further detail.

The increase in non-cash interest expense related to the sale of future royalties in 2024 and 2023 was due to the increasing outstanding balance of the deferred royalty obligation attributed to the upfront milestones received from HCR, including the \$10.0 million upfront payment received in June 2022 and the \$5.0 million milestone payment received in October 2023 as a result of Kyowa Kirin's receipt of regulatory approval to market tenapanor for hyperphosphatemia in Japan in February 2024 and imputed interest accrued on the outstanding balance. In 2024, we began to receive royalties from Kyowa Kirin which were remitted to HCR, thereby reducing the outstanding deferred royalty obligation.

## Other Income, Net

Other income, net consists of interest income earned on our cash, cash equivalents and short-term investments, the periodic revaluation of the exit fees related to our loan agreements, as well as currency exchange gains and losses.

The increase in other income, net in 2024 and 2023 primarily reflected higher income on our investments, resulting from both higher interest rates and larger investment balances throughout the periods.

## Provision for Income Taxes

Our provision for income taxes includes current and deferred tax, including foreign withholding taxes paid on payments received from certain collaboration partners. Deferred income tax balances reflect the effects of temporary differences between the carrying amounts of assets and liabilities and their income tax bases, as well as from net operating loss and tax credit carryforwards. Our deferred tax assets continue to be fully offset by a valuation allowance, including deferred tax assets related to our net operating loss and tax credit carryforwards, which may be subject to annual limitations as a result of ownership changes that may have occurred or could occur in the future.

Refer to *Note 2. Summary Of Significant Accounting Policies* for further discussion of our significant accounting policies.

## LIQUIDITY AND CAPITAL RESOURCES

Below is a summary of our cash, cash equivalents and short-term investments:

(\$ in thousands)	December 31,		Change 2024 vs. 2023	
	2024	2023	\$	%
Cash and cash equivalents	\$ 64,932	\$ 21,470	\$ 43,462	202 %
Short-term investments	185,168	162,829	22,339	14 %
Total liquid funds	<u>\$ 250,100</u>	<u>\$ 184,299</u>	<u>\$ 65,801</u>	<u>36 %</u>

We regularly assess our cash position and our working capital needs to execute our strategy. Our primary uses of cash to date have been to fund research and development expenditures related to our development of tenapanor and to support the commercialization of our marketed products. We have funded our operations primarily from the sale of common stock, product sales, funds from our collaboration partnerships, funds from our loan agreements with SLR, as well as sales of future royalties to HCR. We expect that we will increasingly rely on cash generated from operations to fund our operating plan while maintaining financial flexibility from our ability to source cash from future equity sales and debt financing.

Under a registration statement filed in 2020, we had the ability to sell up to \$150.0 million of our common stock through Jefferies, as our sales agent. As of March 2023, we had received the maximum gross proceeds of \$150.0 million at a weighted average share price of approximately \$1.57.

In January 2023, we filed a registration statement on Form S-3, which became effective in January 2023, containing (i) a base prospectus for the offering, issuance and sale by us of up to a maximum aggregate offering price of \$250.0 million of our common stock, preferred stock, debt securities, warrants and/or units, from time to time in one or more offerings; and (ii) a prospectus supplement for the offering, issuance and sale by us of up to a maximum aggregate offering price of \$150.0 million of our common stock that may be issued and sold, from time to time, under a sales agreement with Jefferies, deemed to be “at-the-market offerings” (2023 Open Market Sales Agreement). Pursuant to the 2023 Open Market Sales Agreement, Jefferies, as sales agent, may receive a commission of up to 3.0% of the gross sales price for shares of common stock sold under the 2023 Open Market Sales Agreement. As of December 31, 2024, we have completed sales pursuant to the 2023 Open Market Sales Agreement resulting in the issuance of 16.8 million shares of our common stock and receipt of gross proceeds of \$70.0 million at a weighted average sales price of approximately \$4.17.

We have a loan and security agreement (as amended, the 2022 Loan Agreement) with SLR. The 2022 Loan Agreement provides a total of \$200.0 million, of which \$150.0 million has been drawn as of December 31, 2024 to support our ongoing operations and the commercial launches of IBSRELA and XPHOZAH. The borrowings under the 2022 Loan Agreement bear interest at SOFR plus a spread based on our public debt rating. We classify outstanding borrowings under the 2022 Loan Agreement as long-term based on the maturity date of the loan. All the term loans mature on July 1, 2028. See *Note 9. Borrowing* for further discussion.

We believe our available cash, cash equivalents and short-term investments as of December 31, 2024 will be sufficient to fund our planned operations for at least a period of one year from the issuance of these financial statements. We have based this estimate on assumptions that may prove to be wrong and we could utilize our available capital resources sooner than we currently expect. In particular, our operating plan may change and we may require significant additional capital to fund our operations. There are no assurances that our efforts to meet our operating cash flow requirements will be successful. If our current cash, cash equivalents and short-term investments as well as our plans to meet our operating cash flow requirements are not sufficient to fund necessary expenditures and meet our obligations following the issuance of these financial statements, our liquidity, financial condition and business prospects will be materially affected.

Our future funding requirements will depend on many factors as described in Part I, Item 1A, “Risk Factors,” of this Annual Report on Form 10-K.

## CASH FLOW ACTIVITIES

The following table summarizes our cash flows activities:

(\$ in thousands)	Year Ended December 31,			Change 2024 vs. 2023		Change 2023 vs. 2022	
	2024	2023	2022	\$	%	\$	%
Net cash used in operating activities	\$ (44,809)	\$ (89,717)	\$ (70,044)	\$ 44,908	(50)%	\$ (19,673)	28 %
Net cash (used in) provided by investing activities	(18,318)	(131,248)	18,415	112,930	(86)%	(149,663)	(813)%
Net cash provided by financing activities	106,589	146,295	75,341	(39,706)	(27)%	70,954	94 %
Net increase (decrease) in cash and cash equivalents	<u>\$ 43,462</u>	<u>\$ (74,670)</u>	<u>\$ 23,712</u>	<u>\$ 118,132</u>	(158)%	<u>\$ (98,382)</u>	(415)%

### *Cash Flows from Operating Activities*

Net cash used in operating activities decreased in 2024 compared to 2023, primarily due to cash generated from higher product sales, net, partially offset by working capital cash uses to support our commercial growth. Net working capital cash outflows were driven primarily by increases in customer credit and inventory purchases, which were partially offset by increases in accounts payable and accruals.

Net cash used in operating activities increased in 2023 compared to 2022, primarily due to working capital cash uses to support our commercial launches, partially offset by cash generated from higher product sales, net from such launches. Net working capital cash outflows were driven primarily by increases in customer credit, upfront payments to CMOs for the commercial manufacturing of IBSRELA and XPHOZAH and increased prepaid selling and marketing spending.

### ***Cash Flows from Investing Activities***

Net cash used in investing activities for 2024 and 2023 was primarily impacted by the timing of our investment maturities and purchases. In 2023, net investment purchases were significantly higher when compared to other reported periods. To a lesser extent, the 2024 cash used for investing activities included property, plant and equipment purchases associated with our new leased facility and build outs of existing facilities.

### ***Cash Flows from Financing Activities***

Net cash provided by financing activities decreased in 2024 compared to 2023, primarily due to \$99.5 million net proceeds from the Term C Loan and Term D Loan and proceeds from the issuance of common stock under our equity incentive and stock purchase plans in 2024 which were less than \$119.2 million received in 2023 from the issuance of common stock pursuant to at the market offerings. We have not received any proceeds under the 2021 Open Market Sales Agreement in 2024.

Net cash provided by financing activities increased in 2023 compared to 2022, primarily due to higher net proceeds from issuance of our common stock pursuant to the at the market offerings of \$47.6 million, as well as net proceeds received of \$22.4 million from drawing the Term B Loan as compared to net expenditure of \$6.1 million in 2022 in conjunction with entering into the 2022 Loan Agreement and repaying the principal outstanding under the 2018 Loan. This increase was partially offset by lower net proceeds from the sale of future royalties to HCR of \$5.0 million.

### **SMALLER REPORTING COMPANY AND LARGE ACCELERATED FILER STATUS**

As a non-accelerated filer, we were not required to obtain an opinion of our independent auditors with respect to our internal controls over financial reporting for the year ended December 31, 2022. On June 30, 2023, our public float exceeded \$700.0 million and therefore since January 1, 2024, we are considered a large accelerated filer. This Annual Report on Form 10-K includes an opinion of Ernst & Young LLP, our independent auditors with respect to our internal control over financial reporting as of December 31, 2024.

### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

#### ***Interest Rate Risk***

We are subject to market risks, including interest rate fluctuation exposure through our investments, in the ordinary course of our business. The goals of our investment policy are the preservation of capital, fulfillment of liquidity needs and fiduciary control of cash. To achieve our goal of maximizing income without assuming significant market risk, we maintain our excess cash and cash equivalents in money market funds and short-term debt securities. Because of the short-term maturities of our cash equivalents, we do not believe that a decrease in interest rates would have any material negative impact on the fair value of our cash equivalents.

As of December 31, 2024, we had cash, cash equivalents and short-term investments of \$250.1 million, which consisted of bank deposits and money market funds, as well as high quality fixed income instruments including commercial paper, U.S. government-sponsored agency bonds, U.S. treasury securities, corporate bonds, Yankee bonds and asset-backed securities. The credit rating of our short-term investments must be rated A-1/P-1, or better by Standard and Poor's and Moody's Investors Service. Asset-backed securities must be rated AAA/Aaa. Money Market funds must be rated AAA/Aaa. Such interest-earning instruments carry a degree of interest rate risk. However, because our investments are high quality and short-term in duration, we believe that our exposure to interest rate risk is not significant and that a 10% movement in market interest rates would not have a significant impact on the total value of our portfolio, as noted above. We do not enter into investments for trading or speculative purposes.

We are subject to interest rate fluctuation exposure through our borrowings under the 2022 Loan Agreement, which bear interest at SOFR plus a spread based on our public debt rating. A hypothetical increase in one-month CME Term SOFR of 100 basis points above the current one-month CME Term SOFR rate would have increased our interest expense by approximately \$1.0 million for the year ended December 31, 2024. As of December 31, 2024, we had an aggregate principal amount of \$150.0 million outstanding pursuant to our 2022 Loan Agreement.

#### ***Foreign Currency Risk***

The majority of our transactions are denominated in U.S. dollars. However, we do have certain transactions that are denominated in currencies other than the U.S. dollar, primarily Swiss francs, Japanese yen and the Euro, and we therefore are subject to foreign exchange risk. The fluctuation in the value of the U.S. dollar against other currencies affects the reported amounts of expenses, non-cash royalty revenue related to the sale of future royalties, assets and liabilities associated with a limited number of manufacturing activities.

We do not use derivative financial instruments for speculative trading purposes, nor do we hedge foreign currency exchange rate exposure in a manner that entirely offsets the earnings effects of changes in foreign currency exchange rates. The counterparties to our forward foreign currency exchange contracts are creditworthy commercial banks, which minimizes the risk of counterparty nonperformance.

As of December 31, 2024, we had no open forward foreign currency exchange contracts.



## **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

### **ARDELYX, INC. INDEX TO FINANCIAL STATEMENTS**

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## **Report of Independent Registered Public Accounting Firm**

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

### **Opinion on the Financial Statements**

We have audited the accompanying balance sheets of Ardelyx, Inc. (the “Company”) as of December 31, 2024 and 2023, the related statements of operations and comprehensive loss, stockholders’ equity, and cash flows for each of the three years in the period ended December 31, 2024, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024, 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, 2024, 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 February 20, 2025 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 Matter**

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

*Description of the Matter*

***Estimates of Reserves for Variable Consideration Impacted by Estimated Payor Mix***

As described in Notes 2 and 6 to the financial statements, the transaction price for product sales, net is reduced for estimates of variable consideration related to gross-to-net (“GTN”) adjustments for discounts and chargebacks, rebates, wholesaler and group purchasing organization (“GPO”) fees, copay assistance and returns. Except for certain wholesaler and GPO fees and discounts, which are based on contracts, these adjustments involve estimation and judgment. The GTN adjustments for rebates, copay assistance and chargebacks are impacted by our estimate of payor mix, which requires significant judgment. The Company’s total estimate of reserves for variable consideration was \$27.3 million as of December 31, 2024. During 2024, the Company recorded \$109.9 million in total reductions to gross product sales for variable consideration.

Auditing the Company’s estimates of reserves for variable consideration relating to rebates, copay assistance and chargebacks was especially challenging as it involved evaluation of management’s subjective judgments with respect to payor mix that considers various data sources. The Company has a limited history upon which to base its assumptions, and changes in these assumptions could have a material impact on the reserves recorded for variable consideration.

*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 Company’s process to determine the reserves for variable consideration that are impacted by the payor mix. For example, we tested controls over management’s review of the completeness and accuracy of the data used to determine the estimate.

To test the Company’s estimates of reserves for variable consideration relating to rebates, copay assistance and chargebacks, our audit procedures included, among others, evaluating the methodologies and assumptions used and testing the accuracy and completeness of the underlying data used in the Company’s payor mix analysis and the related reserves. We compared the assumptions used by management to third-party industry data and evaluated trends in the data. We also evaluated the reasonableness of changes in estimated reserves during the year and assessed the accuracy of the Company’s estimates against actual results. We also performed sensitivity analyses to determine the effect of changes in management’s payor mix assumptions on the reserves recorded for variable consideration impacted by the payor mix. Further, we evaluated the appropriateness of classification and disclosure of the Company’s reserves for variable consideration in the financial statements.

/s/ Ernst & Young LLP

We have served as the Company’s auditor since 2009.

Boston, MA

February 20, 2025

**ARDELYX, INC.**  
**BALANCE SHEETS**  
(in thousands, except share and per share amounts)

	<b>December 31,</b>	
	<b>2024</b>	<b>2023</b>
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 64,932	\$ 21,470
Short-term investments	185,168	162,829
Accounts receivable	57,705	22,031
Inventory	21,173	12,448
Prepaid commercial manufacturing	16,378	18,925
Prepaid expenses and other current assets	11,096	8,408
Total current assets	356,452	246,111
Property and equipment, net	1,495	1,009
Inventory, non-current	70,011	37,039
Prepaid commercial manufacturing, non-current	—	4,235
Right-of-use assets	2,380	5,589
Other assets	5,416	3,596
Total assets	<u>\$ 435,754</u>	<u>\$ 297,579</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities		
Accounts payable	\$ 16,000	\$ 11,138
Accrued compensation and benefits	14,940	12,597
Current portion of operating lease liability	1,562	4,435
Deferred revenue	10,686	7,182
Accrued expenses and other current liabilities	34,642	15,041
Total current liabilities	77,830	50,393
Operating lease liability, net of current portion	1,023	1,725
Long-term debt	150,853	49,822
Deferred revenue, non-current	7,232	8,644
Deferred royalty obligation related to the sale of future royalties	25,527	20,179
Total liabilities	262,465	130,763
Commitments and contingencies (Note 19)		
Stockholders' equity		
Common stock, \$0.0001 par value; 500,000,000 shares authorized; 238,015,825 and 232,453,190 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively.	24	23
Additional paid-in capital	1,058,548	1,012,773
Accumulated deficit	(885,340)	(846,204)
Accumulated other comprehensive income	57	224
Total stockholders' equity	173,289	166,816
Total liabilities and stockholders' equity	<u>\$ 435,754</u>	<u>\$ 297,579</u>

The accompanying notes are an integral part of these financial statements.

**ARDELYX, INC.**  
**STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**  
(in thousands, except share and per share amounts)

	Year Ended December 31,		
	2024	2023	2022
Revenues			
Product sales, net	\$ 319,196	\$ 82,526	\$ 15,600
Product supply revenue	11,649	6,121	1,527
Licensing revenue	78	35,809	35,031
Non-cash royalty revenue related to the sale of future royalties	2,692	—	—
Total revenues	333,615	124,456	52,158
Cost of goods sold			
Cost of product sales	6,851	2,323	566
Other cost of revenue	43,705	15,472	3,551
Total cost of goods sold	50,556	17,795	4,117
Operating expenses			
Research and development	52,317	35,536	35,201
Selling, general and administrative	258,692	134,401	76,599
Total operating expenses	311,009	169,937	111,800
Loss from operations	(27,950)	(63,276)	(63,759)
Interest expense	(13,006)	(4,950)	(3,400)
Non-cash interest expense related to the sale of future royalties	(7,088)	(3,924)	(1,673)
Other income, net	9,174	6,630	1,633
Loss before provision for income taxes	(38,870)	(65,520)	(67,199)
Provision for income taxes	266	547	8
Net loss	<u>\$ (39,136)</u>	<u>\$ (66,067)</u>	<u>\$ (67,207)</u>
Net loss per share of common stock - basic and diluted	<u>\$ (0.17)</u>	<u>\$ (0.30)</u>	<u>\$ (0.42)</u>
Shares used in computing net loss per share - basic and diluted	<u>235,232,927</u>	<u>219,331,253</u>	<u>158,690,083</u>
<b>Comprehensive loss</b>			
Net loss	\$ (39,136)	\$ (66,067)	\$ (67,207)
Unrealized (losses) gains on available-for-sale securities	(167)	278	(48)
Comprehensive loss	<u>\$ (39,303)</u>	<u>\$ (65,789)</u>	<u>\$ (67,255)</u>

The accompanying notes are an integral part of these financial statements.



**ARDELYX, INC.**  
**STATEMENTS OF STOCKHOLDERS' EQUITY**  
(in thousands, except share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive (Loss) Income	Total Stockholder' Equity
	Shares	Amount				
<b>Balance as of December 31, 2021</b>	130,182,535	\$ 13	\$ 795,540	\$ (712,930)	\$ (6)	\$ 82,617
Issuance of common stock under employee stock purchase plan	308,356	—	195	—	—	195
Issuance of common stock for services	711,675	—	390	—	—	390
Issuance of common stock upon exercise of options	14,080	—	7	—	—	7
Issuance of common stock upon vesting of restricted stock units	3,243,828	—	—	—	—	—
Issuance of common stock in at-the-market offering	64,114,542	7	71,618	—	—	71,625
Stock-based compensation	—	—	10,750	—	—	10,750
Unrealized losses on available-for-sale securities	—	—	—	—	(48)	(48)
Net loss	—	—	—	(67,207)	—	(67,207)
<b>Balance as of December 31, 2022</b>	198,575,016	\$ 20	\$ 878,500	\$ (780,137)	\$ (54)	\$ 98,329
Issuance of common stock under employee stock purchase plan	435,708	—	808	—	—	808
Issuance of common stock for services	86,095	—	337	—	—	337
Issuance of common stock upon exercise of options	225,988	—	365	—	—	365
Issuance of common stock upon vesting of restricted stock units	855,642	—	—	—	—	—
Issuance of common stock in at-the-market offering	32,274,741	3	119,233	—	—	119,236
Stock-based compensation	—	—	13,530	—	—	13,530
Unrealized gains on available-for-sale securities	—	—	—	—	278	278
Net loss	—	—	—	(66,067)	—	(66,067)
<b>Balance as of December 31, 2023</b>	232,453,190	\$ 23	\$ 1,012,773	\$ (846,204)	\$ 224	\$ 166,816
Issuance of common stock under employee stock purchase plan	479,609	—	2,227	—	—	2,227
Issuance of common stock for services	40,549	—	257	—	—	257
Issuance of common stock upon exercise of options	2,654,370	1	5,910	—	—	5,911
Issuance of common stock upon vesting of restricted stock units	2,388,107	—	—	—	—	—
Stock-based compensation	—	—	37,381	—	—	37,381
Unrealized losses on available-for-sale securities	—	—	—	—	(167)	(167)
Net loss	—	—	—	(39,136)	—	(39,136)
<b>Balance as of December 31, 2024</b>	238,015,825	\$ 24	\$ 1,058,548	\$ (885,340)	\$ 57	\$ 173,289

The accompanying notes are an integral part of these financial statements.

**ARDELYX, INC.**  
**STATEMENTS OF CASH FLOWS**  
(in thousands)

	Year Ended December 31,		
	2024	2023	2022
<b>Operating activities</b>			
Net loss	\$ (39,136)	\$ (66,067)	\$ (67,207)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization expense	2,063	1,292	1,144
Non-cash lease expense	4,008	3,624	3,457
Stock-based compensation	37,381	13,530	10,750
Non-cash interest expense	7,400	4,220	1,962
Non-cash royalty revenue related to the sale of future royalties	(2,692)	—	—
Gain on sale of equipment	—	—	(1,260)
Other, net	(4,664)	(2,930)	685
Changes in operating assets and liabilities			
Accounts receivable	(35,674)	(14,298)	(7,231)
Inventory	(41,697)	(21,141)	(28,346)
Prepaid commercial manufacturing	6,782	(9,593)	(4,161)
Prepaid expenses and other assets	(4,543)	(6,035)	2,299
Accounts payable	4,862	279	6,582
Accrued compensation and benefits	2,343	5,049	2,126
Operating lease liabilities	(4,588)	(3,928)	(3,491)
Accrued and other liabilities	21,254	3,691	4,138
Deferred revenue	2,092	2,590	8,509
Net cash used in operating activities	(44,809)	(89,717)	(70,044)
<b>Investing activities</b>			
Proceeds from maturities and redemptions of investments	177,854	84,321	67,000
Purchases of investments	(195,161)	(215,225)	(50,328)
Proceeds from sale of property and equipment	—	—	1,798
Purchases of property and equipment	(1,011)	(344)	(55)
Net cash (used in) provided by investing activities	(18,318)	(131,248)	18,415
<b>Financing activities</b>			
Proceeds from issuance of common stock in at the market offering, net of issuance costs	—	119,236	71,625
Proceeds from 2022 Loan Agreement, net of issuance costs	99,451	22,386	26,971
Proceeds from the sale of future royalties, net of issuance costs	—	5,000	9,581
Proceeds from issuance of common stock under equity incentive and stock purchase plans	8,138	1,173	202
Payment of the exit fees	(1,000)	(1,500)	—
Payments for the 2018 Loan, net of costs	—	—	(33,038)
Net cash provided by financing activities	106,589	146,295	75,341
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>43,462</b>	<b>(74,670)</b>	<b>23,712</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>21,470</b>	<b>96,140</b>	<b>72,428</b>
<b>Cash and cash equivalents at end of period</b>	<b>\$ 64,932</b>	<b>\$ 21,470</b>	<b>\$ 96,140</b>
<b>Supplementary disclosure of cash flow information</b>			
Cash paid for interest	\$ 11,408	\$ 4,240	\$ 2,901
Cash paid for income taxes	\$ 266	\$ 51	\$ 6
<b>Supplementary disclosure of non-cash activities</b>			
Right-of-use assets obtained in exchange for lease obligations	\$ 1,010	\$ 339	\$ —
Issuance of common stock for services	\$ 257	\$ 337	\$ 390
Issuance of derivative in connection with issuance of loan payable	\$ —	\$ —	\$ 375

The accompanying notes are an integral part of these financial statements.

## ARDELYX, INC.

### NOTES TO FINANCIAL STATEMENTS

#### NOTE 1. NATURE OF OPERATIONS

We are a biopharmaceutical company founded with a mission to discover, develop and commercialize innovative, first-in-class medicines that meet significant unmet medical needs. We developed a unique and innovative platform that enabled the discovery of new biological mechanisms and pathways to develop potent and efficacious therapies that minimize the side effects and drug-drug interactions frequently encountered with traditional, systemically absorbed medicines. The first molecule we discovered and developed was tenapanor, a minimally absorbed, first-in-class, oral, small molecule therapy. Tenapanor, branded as IBSRELA<sup>®</sup>, is approved in the U.S. for the treatment of adults with IBS-C. Tenapanor, branded as XPHOZAH<sup>®</sup>, is approved in the U.S. to reduce serum phosphorus in adults with CKD on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy.

We operate in one business segment, which is the development and commercialization of biopharmaceutical products. Refer to *Note 17. Segment Reporting* for further segment reporting information.

#### NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

##### *Basis of Presentation*

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP). Certain prior year amounts have been reclassified to conform to the current year presentation.

Refer to the *Summary of Abbreviated Terms* at the end of this Annual Report on Form 10-K for definitions of terms used throughout the document.

##### *Use of Estimates*

The preparation of financial statements requires management to make estimates, judgments and assumptions. The most significant assumptions are estimates used in our revenue gross-to-net accruals and other assumptions. Management bases its estimates on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable under the circumstances. Actual results could materially differ from those estimates.

##### *Cash and Cash Equivalents*

Cash and cash equivalents consist of highly liquid investments purchased with an original maturity date of 90 days or less and are recognized at cost, which approximates fair value.

##### *Short-Term Investments*

Short-term investments consist of debt securities classified as available-for-sale and have maturities greater than 90 days, but less than one year, from the date of acquisition. Short-term investments are carried at fair value based upon quoted market prices or other observable market data. Unrealized (losses) gains on available-for-sale securities are included in accumulated other comprehensive income on our balance sheets. The cost of available-for-sale securities sold is based on the specific-identification method.

Marketable debt securities are reviewed for impairment by determining whether the decline in their market value below carrying value is other-than-temporary. This assessment considers the intent and ability to retain the investment for a period of time sufficient for an anticipated recovery in market value, the duration and extent that the market value has been below cost, and the investee's financial condition. Other-than-temporary impairments and credit losses are recorded in the statements of operations and comprehensive loss.

##### *Concentration of Credit Risk*

Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash, cash equivalents, short-term investments and accounts receivable. We are exposed to credit risks in the event of default by the counterparties to the extent of the amount recorded in our balance sheets. Cash, cash equivalents and short-term investments are invested through banks and other financial institutions in the U.S.

## ***Foreign Currency***

Our business is conducted in U.S. dollars; however, a portion of our expense and capital activities are transacted in foreign currencies which are subject to exchange rate fluctuations that can affect cash or earnings. Foreign currency transactions are translated into the functional currency using exchange rates prevailing at the dates of the transactions. At the end of each reporting period, monetary assets and liabilities that are denominated in foreign currencies are translated at the rates prevailing at that date. All gains and losses on these foreign currency transactions are recorded in other income, net in our statements of operations and comprehensive loss.

## ***Property and Equipment***

Expenditures for property and equipment are capitalized at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets, ranging from three to five years for laboratory equipment and office equipment and furniture. Leasehold improvements are amortized over the lesser of the estimated useful lives or the related remaining lease term.

## ***Impairment of Long-Lived Assets***

The carrying values of long-lived assets, including property and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the asset may not be recoverable. An impairment loss is recognized when the total of estimated future undiscounted cash flows, expected to result from the use of the asset and its eventual disposition, are less than the asset's carrying amount. Impairment, if any, would be assessed using discounted cash flows or other appropriate measures of fair value.

## ***Income Taxes***

The asset and liability method of accounting is used for income taxes. Deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that a portion or all of a deferred tax asset will not be realized.

## ***Accounts Receivable***

Accounts receivable are stated at amortized cost less allowance for credit losses. The allowance for credit losses reflects our best estimate of future losses over the contractual life of outstanding accounts receivable and is determined on the basis of historical experience, specific allowances for known troubled accounts, other currently available information including customer financial condition and both current and forecasted economic conditions. To date, we have determined that an allowance for doubtful accounts is not required. As of December 31, 2024, our accounts receivable balance was comprised of \$56.7 million from commercial customers and \$1.0 million from our collaboration partners. As of December 31, 2023, our accounts receivable balance was comprised of \$17.1 million from commercial customers and \$4.9 million from our collaboration partners.

## ***Inventory***

Inventory costs incurred are capitalized after regulatory approval, or if based on management's judgment, future commercialization is considered probable and future economic benefit is expected to be realized. We began to capitalize inventory costs associated with IBSRELA during the fourth quarter of 2021, when our intent to commercialize IBSRELA was established and we commenced preparation for the launch of IBSRELA. We began to capitalize inventory costs associated with XPHOZAH during the fourth quarter of 2023, following approval by the U.S. FDA to market XPHOZAH in the U.S. Inventory costs incurred prior to regulatory approval were expensed as research and development.

Inventories are stated at the lower of cost or estimated net realizable value with cost determined under the specific identification method. A portion of inventory that represents product that is not expected to be sold or used within the next 12 months is classified as non-current assets on our balance sheets.

## ***Revenue Recognition***

The application of ASC 606 *Revenue from Contracts with Customers* substantially impacts our reported results, particularly product sales, net, which requires certain estimates in determining the transaction price. Total revenues are recognized following a five-step model: (i) identify the customer contract; (ii) identify the contract's performance obligations; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations; and (v) recognize revenue when or as a performance obligation is satisfied.

### *Product Sales, Net Recognition*

The transaction price for product sales, net is reduced for estimates of variable consideration related to GTN adjustments for discounts and chargebacks, rebates, wholesaler and GPO fees, copay assistance and returns. Except for certain wholesaler and GPO fees and discounts, which are based on contracts, these adjustments involve estimation and judgment. The GTN adjustments for rebates, copay assistance and chargebacks are impacted by our estimate of payor mix, which requires significant judgment. We consider legal interpretations of applicable laws and regulations, historical experience, current contract prices under applicable programs, unbilled claims, processing time lags and inventory levels in the distribution channel in determining our estimates.

Estimates are assessed each period and adjusted as required to revise information or actual experience. Changes in estimates recorded through December 31, 2024 have not been material.

### *Licensing Revenue Recognition*

Licensing revenue and product supply revenue result from our collaboration and licensing agreements as discussed in *Note 7. Collaboration And Licensing Agreements*. Goods and services in these agreements may include the grant of licenses for use of our intellectual property and manufacturing services. Significant judgment is required to determine whether promised goods and services represent distinct performance obligations, which are identified and separated when the other party can benefit from the rights, goods or services either on their own or together with other readily available resources and when the rights, goods or services are not highly interdependent or interrelated.

Transaction prices for these arrangements may include non-refundable, up-front license fees; research, development, regulatory and commercial milestone payments; payments for manufacturing supply services; and future royalties on net sales of licensed products. Variable consideration is included in the transaction price only to the extent significant reversal of cumulative revenue recognized is not probable of occurring when the uncertainty associated with the variable consideration is subsequently resolved. Significant judgment is required in estimating variable consideration for each performance obligation identified in the contract. This judgment involves assessing factors outside of our influence, including market conditions, development timelines, likelihood of regulatory success, reimbursement rates for personnel costs, forecasted revenues, potential limitations on the selling price of the product, discount rates, lack of relevant past experience and a large number and broad range of possible amounts. The most likely amount method is used to estimate contingent development, regulatory and sales-based milestones because the ultimate outcomes are binary in nature. The expected value method is used to estimate royalties because a broad range of potential outcomes exists, except in instances where the royalties relate to a license. For arrangements with multiple separable performance obligations, the transaction price assigned to each distinct performance obligation is reflective on the relative stand-alone selling price and recognized at a point in time upon the transfer of control.

Collaboration agreements typically include: (i) licensing intellectual property to a third party with no further performance obligations and (ii) arrangements that include both a license and an additional performance obligation to supply product upon the request of the third party. Out-licensing arrangements that contain a single performance obligation are satisfied upon execution of the agreement, when development and commercialization rights are transferred to a third party. Upfront fees are immediately recognized as licensing revenue. Contingent development and regulatory milestones are assessed each period for likelihood of achievement, however, they are typically constrained and recognized when uncertainty is subsequently resolved for the full amount of the milestone and included in licensing revenue. Licensing revenue also includes sales-based milestones and royalties, which are recognized when the milestone is achieved or when the subsequent sales occur.

Certain collaboration agreements also include contingent performance obligations to supply commercial product to the third party upon its request. The license and supply obligations are accounted for as separate distinct performance obligations as the third party can benefit from the license either on its own or together with the other supply resources readily available to it and the other obligations in the contract. Consideration for the supply obligation is based upon stipulated cost-plus margin contractual terms which represent a standalone selling price. The supply consideration is recognized as product supply revenue at a point in time upon transfer of control of the product to the third party. After considering the stand-alone selling price of these supply arrangements, the upfront fees, contingent development, regulatory and sales-based milestones and royalties are allocated to the license.

When two or more contracts are entered into with the same customer at or near the same time, we evaluate the contracts to determine whether the contracts should be accounted for as a single arrangement. Contract modifications due to the addition of distinct promised goods or services with price increases consistent with stand-alone selling prices are accounted for as a separate contract. Contract modifications that are not considered a separate contract and containing remaining goods or services distinct from the goods or services transferred on or before the date of the contract modification are accounted for as a termination of the existing contract and the subsequent creation of a new contract. Contract modifications not considered a

separate contract and containing remaining goods or services not distinct are accounted for as an add-on to the existing contract and as an adjustment to revenue on a cumulative catch-up basis.

### ***Accrued Expenses***

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses, which involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with our service providers and make adjustments if necessary.

Service fee accruals are estimated based on the period over which each component of service will be performed, with vendor input if appropriate. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrued or prepaid expense balance, accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing differ from the actual status and timing of services performed, we may report amounts that are too high or too low in any particular period.

### ***Retirement Savings Plan***

We offer retirement saving plans through our 401(k) plan, which is available to all full-time employees. In June 2023, we expanded the benefit with the inclusion of a company matching contribution. We contribute to tax-qualified retirement plans for the benefit of employees who meet certain eligibility requirements and choose to participate in the plans. Participating employees specify the percentage of salary they wish to contribute from their compensation, and we make matching contributions. We recognized compensation costs from our contributions of \$1.1 million and \$0.2 million in 2024 and 2023, respectively.

### ***Stock-Based Compensation***

Stock-based compensation expense is recognized for all stock-based payment awards made to employees, non-employees and directors based on estimated fair values. The grant date fair value of the awards is determined using the Black-Scholes option-pricing model. Stock-based compensation expense is recognized on a straight-line basis over the requisite service period and is reduced for estimated forfeitures at the date of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

### ***Non-cash Interest Expense on Deferred Royalty Obligation***

Non-cash interest expense related to the sale of future royalties represents imputed interest expense on our deferred royalty obligation related to the sale of future royalties using the effective interest method.

### ***Leases***

Operating leases are included in right-of-use assets, current portion of operating lease liability, and operating lease liability, net of current portion on our balance sheets. Right-of-use assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the present value of lease payments, we use our incremental borrowing rate based on information available at the lease commencement date. Operating lease right-of-use assets also include any lease payments made and exclude lease incentives. Our lease terms may include options to extend or terminate a lease when it is reasonably certain that we will exercise any such option. Lease expense is recognized on a straight-line basis over the expected lease term. We have elected not to separate lease and non-lease components, such as common area maintenance charges, and instead account for these as a single lease component.

### ***Net Loss per Share***

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period, without consideration of potential shares of common stock. Diluted net loss per common share in the periods presented is the same as basic net loss per common share because the effects of potentially dilutive securities are antidilutive due to net losses recognized for each period presented.



## Recent Accounting Pronouncements

### New Accounting Pronouncements - Recently Adopted

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280) - Improvements to Reportable Segment Disclosures*. This Update requires publicly traded entities to provide enhanced disclosures about significant segment expenses regularly reviewed by the chief operating decision maker, including publicly traded entities with a single reportable segment. The amendments in this update were effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. We adopted the ASU in the fourth quarter of 2024 and determined that its adoption did not have a material impact on our financial statements. Refer to *Note 17. Segment Reporting* for additional information.

### Recent Accounting Pronouncements Not Yet Adopted

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740) - Improvements to Income Tax Disclosures*, an amendment which modifies the measurement and recognition of credit losses for most financial assets and certain other instruments. The amendments in this Update provide more transparency about income tax information through improvements to income tax disclosures primarily related to the rate reconciliation and income taxes paid information. For public business entities, the amendments in this Update are effective for annual periods beginning after December 15, 2024. Early adoption is permitted on a prospective basis for annual financial statements that have not yet been issued or made available for issuance. Management is currently assessing the impact of this standard on our financial statements.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement (Topic 220) - Reporting Comprehensive Income - Expense Disaggregation Disclosures, Disaggregation of Income Statement Expenses*, which requires public companies to disclose, in interim and reporting periods, additional information about certain expenses in the financial statements. ASU No. 2024-03 is effective for annual periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted and is effective on either a prospective basis or retrospective basis. Management is currently assessing the impact of this standard on our financial statements.

## NOTE 3. CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS

Securities classified as cash, cash equivalents and short-term investments as of December 31, 2024 and 2023 were as follows:

(in thousands)	December 31, 2024			
	Amortized Cost	Gross Unrealized		Fair Value
		Gains	Losses	
Cash and cash equivalents				
Cash	\$ 16,282	\$ —	\$ —	\$ 16,282
Money market funds	48,650	—	—	48,650
Total cash and cash equivalents	64,932	—	—	64,932
Short-term investments				
U.S. treasury securities	\$ 79,720	\$ 58	\$ (5)	\$ 79,773
U.S. government-sponsored agency bonds	45,960	29	(27)	45,962
Commercial paper	37,061	19	(15)	37,065
Corporate bonds	17,415	4	(6)	17,413
Asset-backed securities	2,983	2	—	2,985
Yankee bonds	1,972	—	(2)	1,970
Total short-term investments	185,111	112	(55)	185,168
Total cash, cash equivalents and investments	\$ 250,043	\$ 112	\$ (55)	\$ 250,100

**December 31, 2023**

<i>(in thousands)</i>	<b>Amortized Cost</b>	<b>Gross Unrealized</b>		<b>Fair Value</b>
		<b>Gains</b>	<b>Losses</b>	
Cash and cash equivalents				
Cash	\$ 2,829	\$ —	\$ —	\$ 2,829
Money market funds	18,641	—	—	18,641
Total cash and cash equivalents	21,470	—	—	21,470
Short-term investments				
U.S. government-sponsored agency bonds	\$ 101,892	\$ 235	\$ (34)	\$ 102,093
Commercial paper	49,630	41	(17)	49,654
Asset-backed securities	8,628	2	(5)	8,625
U.S. treasury securities	2,455	2	—	2,457
Total short-term investments	162,605	280	(56)	162,829
Total cash, cash equivalents and investments	\$ 184,075	\$ 280	\$ (56)	\$ 184,299

Realized gains or losses have not been significant and are included in other income, net, in our statements of operations and comprehensive loss.

Unrealized losses in 2024 and 2023 were not material. We determined that none of our available-for-sale securities were other-than-temporarily impaired as of December 31, 2024 and 2023, and no investment was in a continuous unrealized loss position for more than one year. Therefore, we believe that it is more likely than not that the investments will be held until maturity or a forecasted recovery of fair value.

Based on our procedures under the expected credit loss model, including an assessment of unrealized losses in our portfolio, we concluded that any unrealized losses on our marketable securities were not attributable to credit and, therefore, we have not recorded an allowance for credit losses as of December 31, 2024 and 2023.

#### **NOTE 4. FAIR VALUE MEASUREMENTS**

Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The three-level hierarchy for the inputs to valuation techniques is briefly summarized as follows:

- Level 1 – Valuations are based on quoted prices in active markets for identical assets or liabilities and readily accessible by us at the reporting date.
- Level 2 – Valuations based on inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 – Valuations based on unobservable inputs for which there is little or no market data, which require us to develop our own assumptions.

The following table sets forth the fair value of our financial assets and liabilities that are measured or disclosed on a recurring basis by level within the fair value hierarchy:

(in thousands)	December 31, 2024				December 31, 2023			
	Total Fair Value	Level 1	Level 2	Level 3	Total Fair Value	Level 1	Level 2	Level 3
<b>Assets</b>								
Money market funds	\$ 48,650	\$ 48,650	\$ —	\$ —	\$ 18,641	\$ 18,641	\$ —	\$ —
U.S. government-sponsored agency bonds	45,962	—	45,962	—	102,093	—	102,093	—
U.S. treasury securities	79,773	—	79,773	—	2,457	—	2,457	—
Commercial paper	37,065	—	37,065	—	49,654	—	49,654	—
Corporate bonds	17,413	—	17,413	—	—	—	—	—
Asset-backed securities	2,985	—	2,985	—	8,625	—	8,625	—
Yankee bonds	1,970	—	1,970	—	—	—	—	—
<b>Total</b>	<b>\$ 233,818</b>	<b>\$ 48,650</b>	<b>\$ 185,168</b>	<b>\$ —</b>	<b>\$ 181,470</b>	<b>\$ 18,641</b>	<b>\$ 162,829</b>	<b>\$ —</b>
<b>Liabilities</b>								
Derivative liabilities for exit fee	\$ —	\$ —	\$ —	\$ —	\$ 675	\$ —	\$ —	\$ 675
<b>Total</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 675</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 675</b>

The 2022 Exit Fee valuation as of December 31, 2023 as defined and discussed in *Note 10. Derivative Liabilities*, was classified as Level 3. During 2024, the conditions for payment of the 2022 Exit Fee were met and the \$1.0 million contract amount was fully valued and settled accordingly.

### ***Fair Value of Debt***

The principal outstanding under our term loan is subject to a variable interest rate and therefore, we believe the carrying amount of the term loan approximates fair value. See *Note 9. Borrowing* for a description of the Level 2 inputs used to estimate the fair value of the liability.

The carrying value of the deferred royalty obligation related to the sale of future royalties approximates its fair value as of December 31, 2024 and is based on our current estimate of future royalties and commercialization milestones expected to be paid to us by Kyowa Kirin over the life of the agreement. See *Note 8. Deferred Royalty Obligation Related To The Sale Of Future Royalties* for a description of the Level 3 inputs used to estimate the fair value of the liability.

## **NOTE 5. INVENTORY**

Inventory consisted of the following:

(in thousands)	December 31,	
	2024	2023
Raw materials	\$ 30,792	\$ 22,920
Work in process	58,685	24,582
Finished goods	1,707	1,985
<b>Total</b>	<b>\$ 91,184</b>	<b>\$ 49,487</b>
<b>Reported as</b>		
Inventory	\$ 21,173	\$ 12,448
Inventory, non-current	70,011	37,039
<b>Total</b>	<b>\$ 91,184</b>	<b>\$ 49,487</b>

Prepaid commercial manufacturing with third-party CMOs not included in inventory was \$16.4 million and \$23.2 million at December 31, 2024 and 2023, respectively. There were no prepayments expected to be converted into inventory after 12 months at December 31, 2024, compared to \$4.2 million at December 31, 2023.

## NOTE 6. REVENUE

Disaggregation of total revenues by nature is as follows:

(in thousands)	Year Ended December 31,		
	2024	2023	2022
Product sales, net	\$ 319,196	\$ 82,526	\$ 15,600
Product supply revenue	11,649	6,121	1,527
Licensing revenue	78	35,809	35,031
Non-cash royalty revenue related to the sale of future royalties	2,692	—	—
Total revenues	<u>\$ 333,615</u>	<u>\$ 124,456</u>	<u>\$ 52,158</u>

### *Product Sales, Net*

Total product sales, net was as follows:

(in thousands)	Year Ended December 31,		
	2024	2023	2022
Product sales, net			
IBSRELA	\$ 158,286	\$ 80,062	\$ 15,600
XPHOZAH	160,910	2,464	—
Total product sales, net	<u>\$ 319,196</u>	<u>\$ 82,526</u>	<u>\$ 15,600</u>

Product sales, net approximated 95.7%, 66.3% and 29.9% of total revenues in 2024, 2023 and 2022, respectively. Products are primarily sold to wholesalers, GPOs and specialty pharmacies, and to a lesser extent, directly to retailers, hospitals, clinics and government agencies. Customer orders are generally fulfilled within a few days from receipt. Contractual performance obligations are fulfilled once control of product is transferred to our customer, which occurs when our customer receives the product and obtains legal title. At this point, our customers are able to direct the use of and obtain substantially all of the remaining benefits of the product.

### *GTN Adjustments*

Wholesalers, GPOs and specialty pharmacies are initially invoiced at contract list prices. Wholesalers and GPOs may also receive prompt pay discounts for payment within a specified period, generally approximating two percent of the invoiced sales price. Our payment terms are generally 30 to 60 days. At the time of recognition, revenue is reduced from contract list price for estimates of variable consideration related to GTN adjustments for chargebacks and cash discounts, rebates, wholesaler and GPO fees, and copay assistance and returns. These GTN adjustments are attributed to governmental programs such as Medicare, Medicaid and the 340B program, which involve various pricing implications, including mandatory discounts and discounts when Medicare Part D beneficiaries are in the coverage gap. Chargebacks and specialty pharmacies fees are reflected as reductions to receivables and are typically settled within contractual terms through credits to our customers. All other GTN adjustments are reflected as a liability and settled through cash payments to our customer or government payor program, typically over various time periods that may span for multiple quarters. Significant judgment is required to estimate certain of our GTN adjustments, considering factors such as legal interpretations of applicable laws and regulations, historical experience, payor mix (e.g., Medicare or Medicaid), current contract prices under applicable programs, unbilled claims, processing time lags and inventory levels in the distribution channel.

The activities and ending reserve balances for each significant category of GTN adjustments on product sales, net, which constitute variable consideration, were as follows:

<i>(in thousands)</i>	<b>Discounts and chargebacks</b>	<b>Rebates, wholesaler and GPO fees</b>	<b>Copay assistance and returns</b>	<b>Total</b>
Balance as of December 31, 2022	\$ 142	\$ 1,444	\$ 1,258	\$ 2,844
Provisions	5,341	15,365	10,629	31,335
Credits/payments	(5,005)	(12,575)	(7,971)	(25,551)
Balance as of December 31, 2023	478	4,234	3,916	8,628
Provisions	15,099	65,833	28,925	109,857
Credits/payments	(13,934)	(55,592)	(21,671)	(91,197)
Balance as of December 31, 2024	<u>\$ 1,643</u>	<u>\$ 14,475</u>	<u>\$ 11,170</u>	<u>\$ 27,288</u>

Adjustments to prior period provisions recorded in the current period were not material.

### ***Geographic Information and Concentrations***

Revenues are attributed to geographical areas based on the location at which we earned revenue for product sales of IBSRELA and XPHOZAH or the domicile of our collaboration partners. A summary of our revenues by geographic area is as follows:

<i>(in thousands)</i>	<b>Year Ended December 31,</b>		
	<b>2024</b>	<b>2023</b>	<b>2022</b>
United States <sup>(1)</sup>	\$ 319,196	\$ 83,276	\$ 15,600
International			
Asia Pacific <sup>(2)</sup>	14,341	41,121	36,527
North America <sup>(3)</sup>	78	59	31
Total revenues	<u>\$ 333,615</u>	<u>\$ 124,456</u>	<u>\$ 52,158</u>

<sup>(1)</sup> Revenues from the United States are primarily comprised of amounts earned from sales of IBSRELA and XPHOZAH, as well as the upfront license fee from the METiS Agreement.

<sup>(2)</sup> Revenues from Asia Pacific are primarily comprised of amounts earned in accordance with the Kyowa Kirin Agreement and the Fosun Agreement.

<sup>(3)</sup> Revenues from North America are comprised of amounts earned from Canada in accordance with the Knight Agreement.

Gross product sales from Customers and revenues from collaboration partners, each accounting for more than 10% of total revenues, were as follows:

	<b>Year Ended December 31,</b>		
	<b>2024</b>	<b>2023</b>	<b>2022</b>
Customers			
BioRidge Pharma, LLC	75.4 %	24.0 %	3.2 %
Cencora	16.4 %	19.1 %	11.1 %
Cardinal Health	14.5 %	19.8 %	9.6 %
McKesson Corporation	14.1 %	15.7 %	8.9 %
Collaboration partners			
Kyowa Kirin	4.3 %	29.0 %	70.0 %

### **NOTE 7. COLLABORATION AND LICENSING AGREEMENTS**

We out-licensed to external partners the development of tenapanor and commercialization of tenapanor through agreements with Kyowa Kirin in Japan, Fosun Pharma in China and Knight in Canada for the development and commercialization of tenapanor for certain indications in their respective territories. We recognize revenue from such arrangements as licensing revenue, product supply revenue or non-cash royalty revenue related to the sale of future royalties. Our significant accounting policies for such revenue streams are as follows:

*Licensing revenue* includes:

- upfront license fees, as well as developmental, regulatory and commercialization milestone payments. We assess upfront and milestone payments using the most likely amount method, including variable payments only when it is probable that no significant revenue reversal will occur. Upfront license fees are recognized upon receipt. Milestones tied to external factors, such as regulatory approvals, are considered probable when those accomplishments are achieved.
- sales-based royalties, other than non-cash royalty revenue related to the sale of future royalties as discussed below, are recognized when sales occur or when related performance obligations are met.

*Product supply revenue* includes drug substance or drug supply revenue received from our out-licensing agreements. Product supply revenue is recognized when control of goods is transferred upon delivery. Advanced payments from partners for drug substance are recognized as deferred revenue until delivery.

*Non-cash royalty revenue related to the sale of future royalties* includes royalties earned and received under the Kyowa Kirin Agreement, which are remitted to HCR upon receipt, pursuant to the HCR Agreement as discussed in *Note 8. Deferred Royalty Obligation Related To The Sale Of Future Royalties*.

The following table summarizes total revenue by collaboration partner:

(in thousands)	Year Ended December 31,		
	2024	2023	2022
Licensing revenue			
Kyowa Kirin	\$ —	\$ 30,000	\$ 35,000
Fosun Pharma	—	5,000	—
METiS	—	750	—
Knight	78	59	31
Total licensing revenue	\$ 78	\$ 35,809	\$ 35,031
Product supply revenue			
Kyowa Kirin	11,649	6,092	1,518
Fosun Pharma	—	29	9
Total supply revenue	\$ 11,649	\$ 6,121	\$ 1,527
Non-cash royalty revenue related to the sale of future royalties			
Kyowa Kirin	\$ 2,692	\$ —	\$ —

### ***Kyowa Kirin***

We granted Kyowa Kirin an exclusive license (Kyowa Kirin Agreement) to develop and commercialize certain NHE3 inhibitors including tenapanor in Japan for the treatment of cardiorenal diseases and conditions, excluding cancer, in exchange for future royalties defined below, an upfront license fee of \$30.0 million, and potential future development and regulatory milestones up to \$55.0 million, of which \$35.0 million has been received and recognized as revenue to date, as well as approximately ¥8.5 billion for commercialization milestones, or approximately \$54.0 million at the currency exchange rate on December 31, 2024. In addition, we are eligible to receive royalties on net sales of tenapanor in Japan throughout the term of the agreement. Under a Commercial Supply Agreement, we supply tenapanor drug substance that will be used to satisfy Kyowa Kirin's commercial needs which includes advanced payments for reimbursement of costs plus a reasonable overhead for the supply of product. In February 2024, Kyowa Kirin announced the launch of tenapanor, marketed as PHOZEVEL<sup>®</sup>, for patients with CKD with hyperphosphatemia in Japan.

The Kyowa Kirin Agreement was amended to reduce the royalty rate Kyowa Kirin would pay on tenapanor sales in Japan from high teens to low double digits for a two-year period of time following the first commercial sale in Japan, and then to mid-single digits for the remainder of the royalty term (2022 Amendment). As consideration for reduction in the royalty rate, Kyowa Kirin agreed to pay us up to an additional \$40.0 million payable in two tranches, with the first payment due following Kyowa Kirin's filing with the Japanese MHLW of its application for marketing approval for tenapanor and the second payment due following Kyowa Kirin's receipt of regulatory approval to market tenapanor for hyperphosphatemia in Japan, both of which occurred as of September 30, 2023. As discussed in *Note 8. Deferred Royalty Obligation Related To The Sale Of Future Royalties*, future royalties and commercial milestone payments we may receive under the license, as amended, will be remitted to HCR pursuant to the HCR Agreement.



The following table presents changes in our current and non-current deferred revenue balances, which are all attributable to Kyowa Kirin:

(in thousands)	2024		2023	
	Current	Non-Current	Current	Non-Current
Balance at January 1,	\$ 7,182	\$ 8,644	\$ 4,211	\$ 9,025
Prepaid product supply	3,716	8,212	1,547	5,629
Product supply delivered	(9,836)	—	(4,586)	—
Reclassify amounts to be recognized in the next twelve months	9,624	(9,624)	6,010	(6,010)
Balance at December 31,	<u>\$ 10,686</u>	<u>\$ 7,232</u>	<u>\$ 7,182</u>	<u>\$ 8,644</u>

### ***Fosun Pharma***

We have an exclusive license agreement with Fosun Pharma (Fosun Agreement) for the development, commercialization and distribution of tenapanor in China for both hyperphosphatemia and IBS-C. The Fosun Agreement granted exclusive license rights to Fosun Pharma in exchange for an upfront license fee of \$12.0 million, recognized upon execution of the agreement, and potential regulatory milestone payments up to \$113.0 million, of which \$8.0 million has been received and recognized to date. In addition, we are eligible to receive reimbursement of cost plus a reasonable overhead for the supply of product and tiered royalties on net sales ranging from the mid-teens to 20%.

### ***Knight***

We have an exclusive license agreement with Knight (Knight Agreement) for the development, commercialization and distribution of tenapanor in Canada for hyperphosphatemia and IBS-C. The Knight Agreement granted exclusive license rights to Knight in exchange for an upfront license fee of \$2.3 million, recognized upon execution, and potential regulatory and commercialization milestones up to CAD 22.2 million, or approximately \$15.4 million at the currency exchange rate on December 31, 2024, of which \$0.7 million has been received and recognized to date. In addition, we are eligible to receive royalties ranging from the mid-single digits to the low twenties throughout the term of the agreement and a transfer price for manufacturing supply services.

### ***METiS***

We have an exclusive license agreement with METiS Therapeutics Inc., (METiS Agreement) for the development and commercialization of a portfolio of TGR5 agonist compounds that we discovered and developed for all therapeutic areas in exchange for an upfront license fee of \$0.8 million, recognized upon execution in 2023. In addition, we may be eligible to receive development and commercialization milestone payments worth up to \$243.0 million. We are also eligible to receive royalties ranging within the mid-single digits throughout the term of the agreement.

### ***AstraZeneca***

In June 2015, we entered into a termination agreement with AstraZeneca (AstraZeneca Termination Agreement) pursuant to which we have agreed to pay AstraZeneca (i) future royalties at a royalty rate of 10% of net sales of tenapanor or other NHE3 products by us or our licensees, and (ii) 20% of non-royalty revenue received from a new collaboration partner should we elect to license, or otherwise provide rights to develop and commercialize tenapanor or other NHE3 products, up to a maximum of \$75.0 million in aggregate for (i) and (ii). Royalty expense recognized under this agreement as other cost of revenue on our statements of operations and comprehensive loss was \$34.7 million, \$12.4 million and \$3.6 million in 2024, 2023 and 2022, respectively. As of December 31, 2024, we have recognized \$62.3 million of the total \$75.0 million outstanding royalty obligation.

## **NOTE 8. DEFERRED ROYALTY OBLIGATION RELATED TO THE SALE OF FUTURE ROYALTIES**

In June 2022, we and HCR entered into the HCR Agreement in which HCR agreed to pay up to \$20.0 million in exchange for royalty payments and commercial milestone payments that we may receive under our Kyowa Kirin License Agreement. See *Note 7. Collaboration And Licensing Agreements* for further detail. The \$20.0 million is payable as follows:

- \$10.0 million upfront upon agreement execution, received in June 2022;
- \$5.0 million upon Kyowa Kirin's receipt of regulatory approval to market tenapanor for hyperphosphatemia in Japan, received in October 2023; and

- \$5.0 million in the event net sales by Kyowa Kirin in Japan exceed a certain annual target level by the end of 2025.

The HCR Agreement is effective until terminated by the mutual agreement of the parties and contains customary representations and warranties and customary affirmative and negative covenants.

Payments received from HCR are recorded as a deferred royalty obligation on our balance sheets. Due to our ongoing manufacturing obligations under the Kyowa Kirin Agreement, we account for the proceeds as imputed debt and therefore recognize royalties earned under the Kyowa Kirin Agreement as non-cash royalty revenue. In conjunction with the HCR Agreement, we incurred approximately \$0.4 million in transaction costs, which, along with the deferred royalty obligation, are being amortized as non-cash interest expense over the estimated life of the HCR Agreement using the effective interest method, which is based on the imputed interest rate derived from estimated amounts and timing of future royalty payments to be received from Kyowa Kirin. The deferred royalty obligation will be effectively repaid over the life of the HCR Agreement as we remit royalties paid to us from Kyowa Kirin, recorded as non-cash royalty revenue related to the sale of future royalties, to HCR. We periodically assess the estimated royalty payments from Kyowa Kirin and, to the extent that the amount or timing of such payments is materially different than our original estimates, we prospectively adjust the imputed interest rate and the related amortization of the deferred royalty obligation.

A summary of financial information related to the HCR Agreement is as follows:

(\$ in thousands)	Year Ended December 31,		
	2024	2023	2022
Non-cash interest expense related to the sale of future royalties	\$ (7,088)	\$ (3,924)	\$ (1,673)
Effective interest rate	31.0 %	34.7 %	34.4 %

(in thousands)	2024	2023	2022
Beginning deferred royalty obligation	\$ 20,179	\$ 11,254	\$ —
Upfront payment, net of transaction costs	—	—	9,581
Regulatory approval milestone	—	5,000	—
Non-cash interest expense related to sale of future royalties	7,088	3,924	1,673
Royalty distributed to HCR	(1,740)	—	—
Other	—	1	—
Ending deferred royalty obligation	<u>\$ 25,527</u>	<u>\$ 20,179</u>	<u>\$ 11,254</u>

## NOTE 9. BORROWING

Long-term borrowing was as follows:

(in thousands)	December 31,		Interest rate
	2024	2023	
Principal			
Term A Loan	\$ 27,500	\$ 27,500	7.95% + 0.022% + SOFR (subject to a floor of 1.0%)
Term B Loan	22,500	22,500	7.95% + 0.022% + SOFR (subject to a floor of 1.0%)
Term C Loan	50,000	—	4.25% + 0.022% + SOFR (subject to a floor of 4.7%)
Term D Loan	50,000	—	4.00% + 0.022% + SOFR (subject to a floor of 4.7%)
Total principal	<u>\$ 150,000</u>	<u>\$ 50,000</u>	
Adjustments to principal value			
Unamortized discount and debt issuance costs	(1,136)	(912)	
Accreted value of final fee	1,989	734	
Total long-term debt	<u>150,853</u>	<u>49,822</u>	
Less: Current portion of long-term debt	—	—	
Long-term debt, net of current portion	<u>\$ 150,853</u>	<u>\$ 49,822</u>	

On February 23, 2022 (Closing Date), we entered into a loan and security agreement with SLR (2022 Loan Agreement) as collateral agent (Agent) and the lenders listed in the 2022 Loan Agreement (collectively, the 2022 Lenders), which was subsequently amended in August 2022 (the First Amendment) and February 2023 (the Second Amendment). The 2022 Loan Agreement, as amended, provided for a senior secured loan facility (the Term A Loan) funded on the Closing Date and Term B Loan borrowable on or prior to December 20, 2023; provided that (i) we received approval by the U.S. FDA for our NDA for

XPHOZAH by November 30, 2023, and (ii) we achieved certain product revenue milestone targets described in the 2022 Loan Agreement. We met the requirements to borrow Term B Loan and subsequently drew it in October 2023.

In October 2023, we entered into a Third Amendment (the Third Amendment) with the 2022 Lenders. The Third Amendment provided us with the option to draw the Term C Loan by March 15, 2024, contingent upon having drawn the Term B Loan; and provided us with the option to draw the Term D Loan of uncommitted capital by December 31, 2026, subject to approval by the Agent's investment committee. We provided the Agent with notice of our decision to draw the Term C Loan in February 2024 and received the proceeds in March 2024.

In October 2024, we entered into a Fourth Amendment (the Fourth Amendment) with the 2022 Lenders. The Fourth Amendment, among other things, provided for the immediate draw of the Term D Loan on the closing date of the Fourth Amendment and provides us with the option to draw an additional \$50.0 million of committed capital by June 30, 2025 (the Term E Loan and together with the Term A, B, C and D Loans, the Five Loans). The interest rate for the Term E Loan will be 4.00% plus a SOFR value equal to 0.022% plus the 1-month CME Term SOFR reference rate as published by the CME Term SOFR Administrator on the CME Term SOFR Administrator's Website, subject to a SOFR floor of 4.7%. We drew the Term D Loan in October 2024.

Under the Fourth Amendment, the maturity date for the Five Loans was extended to July 1, 2028 (the Maturity Date) and the period under which we are permitted to make interest-only payments on the Five Loans was extended to the Maturity Date.

We paid fees of \$0.2 million, \$0.1 million, \$0.3 million and \$0.3 million on each funding date of the Term A, Term B, Term C and Term D Loans, respectively. In addition, we will be obligated to pay 0.5% of the aggregate original principal amount of the Term E Loan commitment, which shall be due on the earliest of (1) the funding of the Term E Loan, (2) June 30, 2025, or (3) the prepayment, refinancing, substitution or replacement of any of the Five Loans on or prior to the date immediately preceding June 30, 2025.

We are obligated to pay a final fee equal to 4.95% of the aggregate original principal amount of the Five Loans, to the extent such loans are funded, upon the earliest to occur of the maturity date, the acceleration of the Five Loans, and the prepayment, refinancing, substitution, or replacement of the Five Loans. The total unaccrued final fee was \$5.4 million and \$1.7 million at December 31, 2024 and December 31, 2023, respectively.

We may voluntarily prepay all amounts outstanding under the Five Loans, subject to a prepayment premium of 2% of the outstanding principal amount of the Five Loans if prepaid through and including October 17, 2025 or 1% of the outstanding principal amount of the Five Loans if prepaid after October 17, 2025 and prior to the maturity date. The Five Loans are secured by substantially all of our assets, except for our intellectual property and certain other customary exclusions. Additionally, as discussed in *Note 10. Derivative Liabilities*, in connection with the Term A and Term B Loans (Original Loans), we paid an exit fee in the amount of \$1.0 million in October 2024.

The 2022 Loan Agreement, as amended, contains customary representations and warranties that place restrictions on disposition of assets, granting liens, occurring additional debt and other matters, as well as customary events of default. We have agreed to not allow our cash, cash equivalents and available-for-sale investments to be less than the eighty percent (80%) of the outstanding balance of the Five Loans for any period in which our net revenue from the sale of any products, calculated on a trailing six (6) month basis and tested monthly, is less than sixty percent (60%) of the outstanding balance of the Five Loans. We have concluded that the provisions that could cause acceleration of the principal repayment are remote as of December 31, 2024.

As of December 31, 2024, our total future payment obligation related to the outstanding balance of the Five Loans, excluding interest payments, was \$157.4 million, which is due on July 1, 2028.

## **NOTE 10. DERIVATIVE LIABILITIES**

### ***2018 Exit Fee***

In October 2023, we received approval from the U.S. FDA for XPHOZAH to reduce serum phosphorus in adults with CKD on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy. In connection with a previous loan agreement (2018 Loan), we became obligated to pay an exit fee of \$1.5 million, which was paid in 2023.

### ***2022 Exit Fee***

The 2022 Loan Agreement obligated us to pay an exit fee in the amount of 2% of the Original Loans funded (2022 Exit Fee) upon (i) any change of control transaction or (ii) our achievement of net revenue from the sale of any products equal to or

greater than \$100.0 million, measured on a six (6) months basis (Revenue Milestone), tested monthly at the end of each month. The 2022 Exit Fee was accounted for as a freestanding derivative and recorded at fair value. The estimated fair value of the 2022 Exit Fee of \$0.7 million was recorded as a derivative liability and included in accrued expenses and other current liabilities at December 31, 2023. The Revenue Milestone was achieved in the second quarter of 2024, resulting in a \$1.0 million payment in October 2024 to settle the obligation. The Term C and Term D Loans do not contain an exit fee obligation.

The fair value of the derivative liability was determined using a discounted cash flow analysis and was classified as a Level 3 measurement within the fair value hierarchy since our valuation utilized significant unobservable inputs prior to June 30, 2024. Specifically, the key assumptions included in the calculation of the estimated fair value of the 2022 Exit Fee derivative liability included: (i) our estimates of both the probability and timing of achieving the Revenue Milestone and (ii) the probability and timing of funding the Term B Loan, which was dependent upon (a) approval by the U.S. FDA for our NDA for the control of serum phosphorus in adult patients with CKD on dialysis by November 30, 2023, and (b) achievement of certain product revenue milestone targets. As of December 31, 2023, uncertainty around all of the noted valuation estimates had been removed, as the Term B Loan had been funded, the U.S. FDA had approved our NDA for the control of serum phosphorus in adult patients with CKD on dialysis prior to November 30, 2023, and we had achieved the Revenue Milestone.

Changes in the fair value of recurring measurements are presented as other income, net in our statements of operations and comprehensive loss and were as follows:

<i>(in thousands)</i>	<b>2024</b>	<b>2023</b>
January 1,	\$ 675	\$ 1,656
Changes in estimated fair value		
2018 Exit Fee	—	292
2022 Exit Fee	325	227
2018 Exit Fee payment	—	(1,500)
2022 Exit Fee payment	(1,000)	—
Fair value of exit fee derivative liabilities at December 31,	<u>\$ —</u>	<u>\$ 675</u>

#### **NOTE 11. LEASES**

Our lease obligation is comprised of operating leases for our offices and research facilities with remaining lease terms ranging from two months to four years and each containing customary rent escalation clauses. Our leases contain one renewal, at our option, which is generally for a five-year period. We have not included these renewal periods in the calculation of the right-of-use asset and lease liability since it is uncertain whether we will exercise the renewal option.

Our leased offices and research facilities in Fremont, California expired on February 10, 2025 and our sub-lease agreement for office space at that facility, entered into with Chronus Health in 2023 expired on February 1, 2025.

The following table provides additional details of our facility leases presented in our balance sheets:

Facilities	December 31,	
	2024	2023
Right-of-use assets	\$ 2,380	\$ 5,589
Current portion of lease liabilities	1,562	4,435
Operating lease liability, net of current portion	1,023	1,725
Total lease liabilities	\$ 2,585	\$ 6,160
Weighted-average remaining term (in years)	1.8	1.6
Weighted-average discount rate	6.5 %	6.8 %

The lease costs, which are included in operating expenses in our statements of operations and comprehensive loss, were as follows:

	Year Ended December 31,		
	2024	2023	2022
Operating lease expense	\$ 4,699	\$ 3,857	\$ 4,257
Cash paid for operating leases	\$ 4,931	\$ 4,481	\$ 4,292

The following table summarizes our undiscounted cash payment obligations for our operating lease liabilities as of December 31, 2024:

	Operating Leases
2025	\$ 1,660
2026	702
2027	238
2028	124
Thereafter	21
Total undiscounted operating lease payments	2,745
Imputed interest expenses	(160)
Total operating lease liabilities	2,585
Less: Current portion of operating lease liability	(1,562)
Operating lease liability, net of current portion	\$ 1,023

## NOTE 12. STOCKHOLDERS' EQUITY

Under a registration statement filed in 2020, we had the ability to sell up to \$150.0 million of our common stock through Jefferies, as our sales agent. As of March 2023, we had received the maximum gross proceeds of \$150.0 million at a weighted average share price of approximately \$1.57.

In January 2023, we filed a registration statement on Form S-3, which became effective in January 2023, containing (i) a base prospectus for the offering, issuance and sale by us of up to a maximum aggregate offering price of \$250.0 million of our common stock, preferred stock, debt securities, warrants and/or units, from time to time in one or more offerings; and (ii) a prospectus supplement for the offering, issuance and sale by us of up to a maximum aggregate offering price of \$150.0 million of our common stock that may be issued and sold, from time to time, under a sales agreement with Jefferies, deemed to be "at-the-market offerings" (2023 Open Market Sales Agreement). Pursuant to the 2023 Open Market Sales Agreement, Jefferies, as sales agent, may receive a commission of up to 3.0% of the gross sales price for shares of common stock sold under the 2023 Open Market Sales Agreement. As of December 31, 2024, we have completed sales pursuant to the 2023 Open Market Sales Agreement resulting in the issuance of 16.8 million shares of our common stock and receipt of gross proceeds of \$70.0 million at a weighted average sales price of approximately \$4.17.

## NOTE 13. EQUITY INCENTIVE PLANS

### 2008 Plan

The 2008 Stock Incentive Plan (2008 Plan), which governed the granting of stock options, stock purchase rights and other equity awards, was terminated in June 2014 for future awards. When the 2014 Equity Incentive Award Plan (2014 Plan) was approved by the board of directors and stockholders on June 18, 2014, all remaining shares available for future award under the 2008 Plan were transferred to the 2014 Plan, as discussed below.

### 2014 Plan

The 2014 Equity Incentive Plan (2014 Plan), effective on June 18, 2014, provided for the stock-based compensation awards, including stock options, stock appreciation rights, restricted stock, service-based RSUs, performance-based RSUs, deferred stock, deferred stock units, dividend equivalents, stock payments and performance awards. The 2014 Plan initially reserved 1.5 million shares, including the 35 thousand shares remaining for future awards under the 2008 Plan, with up to 1.2 million additional shares which could be added from forfeited or lapsed awards from the 2008 Plan. The 2014 Plan allowed for an annual increase in the number of shares available for issuance on the first day of each year through 2024, equal to the lesser of four percent (4.0%) of our outstanding common stock on the last day of the immediately preceding year or a smaller amount determined by the board of directors (2014 Plan evergreen provision).

On June 14, 2024, stockholders approved the Amended and Restated 2014 Equity Incentive Award Plan (2014 A&R Plan). The key provisions pursuant to the 2014 A&R Plan include: (1) 19.0 million shares were added to the total existing share reserve; (2) the 2014 Plan evergreen provision was removed such that any increase to the total number of shares that may be issued must be approved by our stockholders; and (3) the limit of shares that may be issued upon exercise of incentive stock options was increased from 10.7 million to 58.5 million shares. In addition to increases resulting from repurchases, forfeitures, expirations and cancellations of awards under the 2008 Plan, shares reserved for issuance under the 2014 A&R Plan will be increased by the number of shares subject to awards granted under the Inducement Plan, as discussed below, that are repurchased, forfeited, expire or are cancelled on or after June 14, 2024. As a result, no new awards will be made under the Inducement Plan after June 14, 2024. As of December 31, 2024, approximately 18.1 million shares of our common stock were available for future issuance under the 2014 A&R Plan.

### 2016 Plan

In November 2016, our board of directors approved the 2016 Employment Commencement Incentive Plan (Inducement Plan) under which 1.0 million shares were reserved. In January 2021, January 2022, December 2022 and January 2024, 0.5 million, 2.0 million, 3.0 million and 5.8 million shares, respectively, were added to the Inducement Plan. As of December 31, 2024, 8.8 million shares of our common stock were subject to inducement grants that were issued pursuant to the Inducement Plan. As of December 31, 2024, approximately 3.9 million shares of our common stock were available for future issuance under the 2016 Plan.

### Stock Options

A summary of our stock option activity and related information during the year ended December 31, 2024 is as follows:

	Options Issued and Outstanding		Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
	Number of Shares (in thousands)	Weighted-Average Exercise Price per Share		
Balance at December 31, 2023	22,168	\$ 4.20		
Options granted	9,674	\$ 7.95		
Options exercised	(2,654)	\$ 2.24		
Options canceled	(1,103)	\$ 5.35		
Balance at December 31, 2024	28,085	\$ 5.63	7.1	\$ 31,830
Vested and expected to vest at December 31, 2024	28,085	\$ 5.63	7.1	\$ 31,830
Exercisable at December 31, 2024	14,968	\$ 5.52	5.7	\$ 19,161

The aggregate intrinsic value represents the difference between the total pre-tax value (i.e., the difference between our stock price and the exercise price) of stock options outstanding as of December 31, 2024, based on our common stock closing price of \$5.07 per share, which would have been received by the option holders if all their in-the-money options had been exercised as of that date.



The intrinsic value of options exercised during the years ended December 31, 2024, 2023 and 2022 was \$19.6 million, \$1.1 million and \$30 thousand, respectively. The total fair value of options vested during the years ended December 31, 2024, 2023 and 2022 was \$61.0 million, \$24.9 million and \$7.0 million, respectively.

The weighted-average grant-date estimated fair value of options granted during the years ended December 31, 2024, 2023 and 2022 was \$6.22, \$2.36 and \$0.63 per share, respectively. The estimated grant date fair value of employee stock options was calculated using the Black-Scholes option-pricing model, based on the following weighted-average assumptions:

	Year Ended December 31,		
	2024	2023	2022
Expected term (in years)	5.4	5.1	4.9
Expected volatility	100.8 %	97.6 %	92.1 %
Risk-free interest rate	4.0 %	3.8 %	2.2 %
Dividend yield	— %	— %	— %

**Expected Term**—We estimate the expected term of our options based upon historical exercises and post-vesting termination behavior.

**Expected Volatility**—We use the historic volatility of our own stock over the retrospective period corresponding to the expected remaining term of the options, or the period since our shares were first quoted on The Nasdaq Global Market, if that is shorter, to compute our expected stock price volatility.

**Risk-Free Interest Rate**—The risk-free interest rate assumption is based on the zero-coupon U.S. treasury instruments on the date of grant with a maturity date consistent with the expected term of our stock option grants.

**Dividend Yield**—To date, we have not declared or paid any cash dividends and do not have any plans to do so in the future. Therefore, we use an expected dividend yield of zero.

### **Restricted Stock Units**

A summary of our RSUs activity and related information for the year ended December 31, 2024 is as follows:

	Number of RSUs (in thousands)	Weighted-Average Grant Date Fair Value Per Share
Non-vested restricted stock units at December 31, 2023	3,646	\$ 3.09
Granted	7,382	\$ 7.94
Vested	(2,430)	\$ 5.65
Forfeited	(585)	\$ 5.68
Non-vested restricted stock units at December 31, 2024	8,013	\$ 6.59

The total estimated fair value of RSUs vested during the years ended December 31, 2024, 2023 and 2022 was \$16.4 million, \$3.5 million and \$2.6 million, respectively.

### **Issuance of Common Stock for Services**

During the years ended December 31, 2024, 2023 and 2022, we issued approximately 41 thousand, 0.1 million and 0.7 million shares, respectively, of common stock to members of the board of directors who elected to receive stock in lieu of their cash fees under our Non-Employee Director Compensation Program. The shares issued during the years ended December 31, 2024, 2023 and 2022 were valued at \$0.3 million, \$0.3 million and \$0.4 million, respectively, based on the fair value of the common stock on the date of grant.

### **Employee Stock Purchase Plan**

The 2014 ESPP, effective on June 18, 2014, initially reserved approximately 0.2 million shares of common stock for our eligible employees to purchase shares of our common stock at a discount. If approved by the administrator of the ESPP, on the first day of each calendar year through 2024, the number of shares in the reserve increased by an amount equal to the lesser of (i) one percent (1.0%) of the shares of common stock outstanding on the last day of the immediately preceding fiscal year and

(ii) such number of shares of common stock as determined by the board of directors (2014 ESPP evergreen provision); provided, however, no more than 2.2 million shares of our common stock could be issued under the ESPP.

On June 14, 2024, stockholders approved the Amended and Restated 2014 ESPP (A&R ESPP). The key provisions pursuant to the A&R ESPP include: (1) 3.0 million shares were added to the total existing share reserve and (2) the 2014 ESPP evergreen provision was eliminated and no evergreen increases will be made after June 14, 2024.

During the years ended December 31, 2024, 2023 and 2022, we issued approximately 0.5 million, 0.4 million and 0.3 million shares, respectively, at an average share price of \$4.64, \$1.85 and \$0.63, respectively, pursuant to the ESPP. As of December 31, 2024, approximately 3.7 million shares of our common stock were available for future issuance under the A&R ESPP.

The following table illustrates the weighted-average assumptions for the Black-Scholes option-pricing model used in determining the fair value of ESPP purchase rights granted to our employees:

	Year Ended December 31,		
	2024	2023	2022
Expected term (in years)	0.5	0.5	0.5
Expected volatility	82.8 %	86.0 %	97.2 %
Risk-free interest rate	5.0 %	5.3 %	1.9 %
Dividend yield	— %	— %	— %

### ***Stock-based Compensation Expense***

Stock-based compensation expense recognized for stock options, RSUs and our ESPP is recorded as operating expenses in our statements of operations and comprehensive loss, as follows:

<i>(in thousands)</i>	Year Ended December 31,		
	2024	2023	2022
Selling, general and administrative	\$ 27,791	\$ 9,952	\$ 7,525
Research and development	9,590	3,578	3,225
Total	<u>\$ 37,381</u>	<u>\$ 13,530</u>	<u>\$ 10,750</u>

A summary of our total unrecognized stock-based compensation expense, net of estimated forfeitures, as of December 31, 2024 is as follows:

	December 31, 2024	
	Unrecognized Compensation Expense (in thousands)	Average Remaining Vesting Period (in years)
Stock option grants	\$ 55,610	2.71
RSU grants	\$ 49,930	2.96
ESPP	\$ 162	0.1

### **NOTE 14. PROPERTY AND EQUIPMENT, NET**

Property and equipment consisted of the following:

<i>(in thousands)</i>	December 31,	
	2024	2023
Laboratory equipment	\$ 46	\$ 46
Office equipment and furniture	2,923	2,433
Leasehold improvements	9,144	8,731
Property and equipment, gross	12,113	11,210
Less: Accumulated depreciation	(10,618)	(10,201)
Total property and equipment, net	<u>\$ 1,495</u>	<u>\$ 1,009</u>

We recognized depreciation expense in the amount of \$0.5 million, \$0.6 million and \$0.7 million in 2024, 2023 and 2022, respectively.

#### NOTE 15. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consisted of the following:

<i>(in thousands)</i>	December 31,	
	2024	2023
Accrued payments due to AstraZeneca	\$ 12,077	\$ 3,680
Accrued gross to net revenue liabilities	10,112	3,258
Accrued sales and marketing expenses	3,696	3,223
Other	8,757	4,880
Total accrued expenses and other current liabilities	<u>\$ 34,642</u>	<u>\$ 15,041</u>

#### NOTE 16. INCOME TAXES

The components of our provision for income taxes were as follows:

<i>(in thousands)</i>	Year Ended December 31,		
	2024	2023	2022
Current			
State	\$ 266	\$ 47	\$ 8
Foreign	—	500	—
Total current	266	547	8
Deferred			
Federal	—	—	—
Total deferred	—	—	—
Provision for income taxes	<u>\$ 266</u>	<u>\$ 547</u>	<u>\$ 8</u>

A reconciliation of the statutory federal income tax rate to our effective tax rate is as follows:

	Year Ended December 31,		
	2024	2023	2022
Income tax at the federal statutory rate	21.0 %	21.0 %	21.0 %
State taxes, net of federal benefit	4.0	3.4	1.9
Tax credits	0.6	1.7	1.5
Stock based compensation	5.2	0.1	(2.3)
Foreign withholding tax	—	(0.8)	—
Executive compensation disallowed under IRC Sec 162(m)	(5.8)	(1.9)	(1.6)
Other	(0.6)	—	(0.8)
Change in valuation allowance	(25.0)	(24.3)	(19.7)
Effective tax rate	<u>(0.6)%</u>	<u>(0.8)%</u>	<u>— %</u>

Deferred income tax balances reflect the effects of temporary differences between the carrying amounts of assets and liabilities and their income tax bases, as well as from net operating loss and tax credit carryforwards. Significant components of our deferred tax assets were as follows:

<i>(in thousands)</i>	December 31,	
	2024	2023
Deferred tax assets		
Amortization and depreciation	\$ 64,237	\$ 64,919
Net operating loss carryforwards	103,643	98,702
Tax credits	15,529	15,375
Stock-based compensation	11,226	6,946
Deferred royalty obligation	6,409	4,907
Other	8,122	6,707
Deferred tax assets	209,166	197,556
Valuation allowance	(208,568)	(196,197)
Deferred tax assets net of valuation allowance	598	1,359
Deferred tax liabilities		
Right-of-use asset	(598)	(1,359)
Deferred tax liabilities	(598)	(1,359)
Net deferred taxes	\$ —	\$ —

Realization of deferred tax assets is dependent on future taxable income, if any, the timing and the amount of which are uncertain. We assess the available positive and negative evidence to estimate whether sufficient future taxable income will be generated to permit use of the existing deferred tax assets. A significant component of objective negative evidence evaluated was our cumulative loss incurred over the three-year period ended December 31, 2024. Such objective evidence limits the ability to consider other subjective evidence, such as our projections for future growth. On the basis of this evaluation, as of December 31, 2024, 2023 and 2022, a full valuation allowance has been recorded against our deferred tax assets. The valuation allowance increased by \$12.4 million in 2024 primarily attributable to net operating loss carryforwards and stock-based compensation. The amount of the deferred tax assets considered realizable could be adjusted if estimates of future taxable income during the carryforward period are reduced or increased, or if objective negative evidence, such as cumulative losses, are no longer present. In such cases, additional weight may be given to subjective evidence, such as our projections for growth.

As of December 31, 2024, we had net operating loss carryforwards for federal income tax purposes of approximately \$495.0 million, of which approximately \$344.8 million can be carried forward indefinitely and the remaining net operating losses begin to expire in 2030, if not utilized. We had approximately \$17.8 million of federal research and development tax credit carryforwards and approximately \$1.7 million of foreign tax credit carryforwards that begin to expire in 2027, if not utilized.

In addition, we had net operating loss carryforwards for California income tax purposes of approximately \$94.7 million that begin to expire in 2030, if not utilized, and state research and development tax credit carryforwards of approximately \$9.2 million that do not expire. We had approximately \$0.1 million of minimum tax credit carryovers for California income tax purposes that do not expire. We had other state net operating losses of approximately \$64.0 million that begin to expire in 2031.

The future utilization of net operating loss and tax credit carryforwards may be subject to an annual limitation, pursuant to Internal Revenue Code Sections 382 and 383, as a result of ownership changes that may have occurred previously or that could occur in the future. Due to the existence of the valuation allowance, limitations under Section 382 and 383 will not impact our effective tax rate.

Effective January 1, 2022, research and development expenses are required to be capitalized and amortized for U.S. tax purposes. The mandatory capitalization requirement did not have a material impact on our deferred tax assets and did not result in a cash tax liability as we have historically elected to capitalize research and development expenses for tax purposes.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

(in thousands)	December 31,		
	2024	2023	2022
Balance at beginning of year	\$ 23,625	\$ 24,075	\$ 24,426
Additions based on tax positions related to current year	105	262	460
Additions based on tax positions related to prior year	—	99	—
Subtractions based on tax positions related to prior year	(811)	(811)	(811)
Balance at end of year	<u>\$ 22,919</u>	<u>\$ 23,625</u>	<u>\$ 24,075</u>

We recognize a tax benefit from an uncertain tax position when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits. Income tax positions must meet a more likely than not recognition at the effective date to be recognized. None of our unrecognized tax benefits would impact the effective tax rate if recognized, because the benefit would be offset by an increase in the valuation allowance.

We have elected to include interest and penalties as a component of tax expense. During the years ended December 31, 2024, 2023 and 2022, we did not recognize accrued interest and penalties related to unrecognized tax benefits. Although the timing and outcome of an income tax audit is highly uncertain, we do not anticipate that the amount of existing unrecognized tax benefits will significantly change during the next 12 months.

We file a U.S. federal income tax return and income tax returns in various state and local jurisdictions. Due to our net operating loss and tax credit carryforwards, the income tax returns remain open to U.S. federal and state tax examinations. We are not currently under examination in any tax jurisdiction.

#### NOTE 17. SEGMENT REPORTING

We operate in a single reportable segment with a mission to discover, develop and commercialize innovative, first-in-class medicines that meet significant unmet medical needs. A centralized research and development organization, supply chain organization and commercial organization are all responsible for the discovery, development, manufacturing, supply and sale of our products. Our business is also supported by centralized corporate functions. We currently operate primarily in the U.S. and earn revenues from sales of IBSRELA and XPHOZAH, both branded products derived from tenapanor, a molecule developed from our unique and innovative platform. Licensing agreements with international partners are utilized for development and commercialization activities outside the U.S. Currently, we maintain such agreements for certain indications of tenapanor in Japan (Kyowa Kirin), China (Fosun Pharma) and Canada (Knight). Refer to *Note 7. Collaboration And Licensing Agreements* for further detail. We recognize other revenue in the form of product supply revenue and licensing revenue under the Kyowa Kirin and Knight agreements. Revenue streams associated with the Kyowa Kirin Agreement are subject to a separate agreement where such future royalties and commercial milestones were sold to a third-party. Refer to *Note 8. Deferred Royalty Obligation Related To The Sale Of Future Royalties* for further information.

Our Chief Executive Officer (CEO) is our Chief Operating Decision Maker (CODM), responsible for allocating resources and assessing Company performance using aggregated financial information. Utilizing aggregated financial information enables the CODM to determine the most appropriate resource allocation across the commercial organization, research and development projects or other initiatives consistent with our long-term corporate wide strategic goals. The CODM primarily uses aggregated net loss as reported on the statements of operations and comprehensive loss to measure segment loss, supplemented by certain additional significant expense details reflected in the table below.

Detailed information regarding our single operating segment's significant revenues, expenses and operating loss are as follows:

<i>(in thousands)</i>	Year Ended December 31,		
	2024	2023	2022
<b>Revenues</b>			
Product sales, net	\$ 319,196	\$ 82,526	\$ 15,600
Other revenues <sup>(1)</sup>	14,419	41,930	36,558
Total revenues	333,615	124,456	52,158
<b>Less:</b>			
Cost of product sales	6,851	2,323	566
Other cost of revenue	43,705	15,472	3,551
Total cost of goods sold	50,556	17,795	4,117
Research and development <sup>(2)</sup>	39,480	29,231	28,777
Selling expenses <sup>(2)</sup>	162,957	80,028	10,750
General and administrative expenses <sup>(2)</sup>	52,916	34,020	34,895
Stock-based compensation	37,381	13,530	25,144
Other segment expenses <sup>(3)</sup>	18,275	13,128	12,234
Total operating expenses	311,009	169,937	111,800
Segment and consolidated loss from operations	(27,950)	(63,276)	(63,759)
Other reconciliation items <sup>(4)</sup>	(11,186)	(2,791)	(3,448)
Segment and consolidated net loss	<u>\$ (39,136)</u>	<u>\$ (66,067)</u>	<u>\$ (67,207)</u>

<sup>(1)</sup> "Other revenues" includes revenues from our collaboration partnerships, including license fees, milestone payments, product supply revenue and non-cash royalty revenue related to the sale of future royalties.

<sup>(2)</sup> Research and development, selling and general administrative expenses herein do not include certain allocated items, such as stock-based compensation expenses.

<sup>(3)</sup> "Other segment expenses" primarily consists of allocated facilities, information technology, and employee costs of approximately \$16.9 million, \$12.3 million and \$11.4 million in 2024, 2023 and 2022, respectively.

<sup>(4)</sup> "Other reconciliation items" includes interest expense, non-cash interest expense related to the sale of future royalties, provision for income taxes and other income, net.

## NOTE 18. NET LOSS PER SHARE

Basic net loss per share is calculated by dividing net loss by the weighted-average number of common shares outstanding during the period and excludes any dilutive effects of stock-based awards and warrants. Diluted net loss per common share is computed giving effect to all potential dilutive common shares, including common stock issuable upon exercise of stock options, and unvested restricted common stock and stock units. As we had net losses for the years ended December 31, 2024, 2023 and 2022, all potential common shares were determined to be anti-dilutive.

The following table sets forth the computation of net loss per common share:

<i>(in thousands, except per share amounts)</i>	Year Ended December 31,		
	2024	2023	2022
<b>Numerator:</b>			
Net loss	\$ (39,136)	\$ (66,067)	\$ (67,207)
<b>Denominator:</b>			
Weighted average common shares outstanding - basic and diluted	235,233	219,331	158,690
Net loss per share of common stock - basic and diluted	<u>\$ (0.17)</u>	<u>\$ (0.30)</u>	<u>\$ (0.42)</u>



The total numbers of securities that could potentially dilute net income per share in the future that were not considered in the diluted net loss per share calculations because the effect would have been anti-dilutive were as follows:

(in thousands)	Year Ended December 31,		
	2024	2023	2022
Options to purchase common stock	27,800	20,877	13,522
Restricted stock units	7,883	3,086	2,694
ESPP shares issuable	230	249	166
Total	35,913	24,212	16,382

The number of potential common shares that would have been included in diluted income per share had it not been for the anti-dilutive effect caused by the net loss, computed by converting these securities using the treasury stock method during the years ended December 31, 2024, 2023 and 2022, was approximately 9.2 million, 6.3 million and 0.6 million, respectively.

## NOTE 19. COMMITMENTS AND CONTINGENCIES

### *Guarantees and Indemnifications*

We indemnify each of our officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at our request in such capacity, as permitted under Delaware law and in accordance with our certificate of incorporation and bylaws. The term of the indemnification period lasts as long as an officer or director may be subject to any proceeding arising out of acts or omissions of such officer or director in such capacity.

The maximum amount of potential future indemnification is unlimited; however, we currently hold director and officer liability insurance, which allows the transfer of risk associated with our exposure and may enable us to recover a portion of any future amounts paid. We believe that the fair value of these indemnification obligations is minimal. Accordingly, we have not recognized any liabilities relating to these obligations for any period presented.

### *Legal Proceedings and Claims*

On July 30 and August 12, 2021, two putative securities class action lawsuits were commenced in the U.S. District Court for the Northern District of California naming as defendants Ardelyx and two current officers captioned *Strezsak v. Ardelyx, Inc., et al.*, Case No. 4:21-cv-05868-HSG, and *Siegel v. Ardelyx, Inc., et al.*, Case No. 5:21-cv-06228-HSG (together, the Securities Class Actions). The complaints allege that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the Exchange Act), as amended, and Rule 10b-5 thereunder, by making false and misleading statements and omissions of material fact related to tenapanor. The plaintiffs seek damages and interest, and an award of costs, including attorneys' fees. On July 19, 2022, the court consolidated the two putative class actions and appointed a lead plaintiff and lead counsel. The lead plaintiff filed a second amended complaint under which the plaintiffs seek to represent all persons who purchased or otherwise acquired Ardelyx securities between March 6, 2020 and July 19, 2021. Defendants filed a motion to dismiss the amended complaint on June 2, 2023. On March 22, 2024, the court granted defendants' motion to dismiss. The court provided plaintiffs a third opportunity to amend and plaintiffs filed a third amended complaint on April 19, 2024. Defendants filed a motion to dismiss the third amended complaint on June 3, 2024. The case was dismissed with prejudice on September 12, 2024. On October 9, 2024, plaintiff appealed the District Court's dismissal of the case to the Ninth Circuit. We believe the plaintiffs' claims are without merit.

On December 7, 2021 and March 29, 2022, two verified shareholders derivative lawsuits were filed in the U.S. District Court for the Northern District of California purportedly on behalf of Ardelyx against certain of Ardelyx's executive officers and members of our board of directors, captioned *Go v. Raab, et al.*, Case No. 4:21-cv-09455-HSG, and *Morris v. Raab, et al.*, Case No. 4:22-cv-01988-JSC. The complaints allege that the defendants' violations of Section 14(a) of the Securities Exchange Act of 1934, as amended, breaches of fiduciary duties, unjust enrichment, abuse of control, gross mismanagement, and waste of corporate assets for personally making and/or causing Ardelyx to make materially false and misleading statements regarding the Company's business, operations and prospects. The complaint seeks contribution under Sections 10(b) and 21D of the Securities Exchange Act of 1934 from two executive officers. On January 19, and April 27, 2022, the court granted the parties' stipulation to stay the Go and Morris actions, respectively, until resolution of the anticipated motion(s) to dismiss in the Securities Class Actions. On October 25, 2022, the parties filed a stipulation to consolidate and stay the Go and Morris actions, and on October 27, 2022, the court consolidated the Go and Morris action and stayed the consolidated action pending resolution of the anticipated motion(s) to dismiss in the Securities Class Action. The consolidated case remains stayed pending resolution of the appeal in the Securities Class Action. We believe the plaintiffs' claims are without merit.

On July 17, 2024, in partnership with the AAKP and the NMQF, we filed a lawsuit in the U.S. District Court for the District of Columbia against the CMS, claiming that CMS has violated its statutory and regulatory authority under the MIPPA, which established the ESRD PPS bundled payment system for dialysis services in 2008. Specifically, the lawsuit claims that CMS's plan to move XPHOZAH, along with all oral-only drugs, into the ESRD PPS is inconsistent with MIPPA's statutory provision, and contradicts CMS's own regulations. XPHOZAH and other oral-only drugs, which are currently available to patients under Medicare Part D, are not administered by dialysis providers and cannot be taken during the delivery of maintenance dialysis. The Company, AAKP and NMQF are seeking relief under the Administrative Procedure Act to enjoin CMS from proceeding with its plan to include XPHOZAH in the ESRD PPS and eliminate coverage under Medicare Part D beginning on January 1, 2025. On November 8, 2024, the U.S. District Court for the District of Columbia granted defendants' Motion to Dismiss and denied plaintiffs Motion for Preliminary Injunction, or in the Alternative, for Expedited Summary Judgment. Following the District Court's denial of plaintiffs' Motion to Alter or Amend the Judgment, or in the Alternative, for an Injunction Pending Appeal, plaintiffs filed an Emergency Motion for an Administrative Stay and Injunction Pending Appeal, which was denied by the United States Court of Appeals for the District of Columbia Circuit. Appellants filed a brief in the appeal on February 4, 2025, and Appellee's brief is due March 6, 2025. Final briefs in the appeal are currently expected to be filed on April 10, 2025.

On August 16, 2024, a complaint was filed against us in the U.S. District Court of Massachusetts, captioned *Yarborough v. Ardelyx, Inc., et al.*, No. 24-cv-12119 (D. Mass.). The complaint names the Company, Mike Raab, and Justin Renz as defendants and alleges violations of Sections 10(b) and 20(a) the Exchange Act and Rule 10b-5 promulgated thereunder, related to our announcement on July 2, 2024 that it had chosen not to file an application for Transitional Drug Add-on Payment Adjustment for XPHOZAH (the "Yarborough Action"). The plaintiffs seek damages and interest, and an award of costs, including attorneys' fees. Two shareholders filed motions to be appointed lead plaintiff in the Yarborough Action on October 15, 2024. The Court appointed Tate Wood as lead plaintiff on October 30, 2024. Lead Plaintiff filed an amended complaint on January 13, 2025, alleging violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder related to our announcement on July 2, 2024 regarding TDAPA. Lead Plaintiff purports to bring claims on behalf of all those who acquired Ardelyx common stock between February 23, 2024 and July 1, 2024. Defendants' motion to dismiss the amended complaint is due March 14, 2025. We believe the plaintiff's claims are without merit.

On September 6 and 13, 2024, certain Ardelyx shareholders filed two verified derivative complaints purportedly on behalf of the Company in the United States District Court for the District of Massachusetts alleging violations of Sections 10(b) and/or 14(a) of the Exchange Act, breaches of fiduciary duty, unjust enrichment, waste, and aiding and abetting breaches of fiduciary duty against certain members of our board of directors and management based on substantially the same factual allegations in the Yarborough Action. The complaints seek unspecified damages and corporate governance reforms, as well as costs and attorneys' fees. On September 25, 2024, the Court consolidated the two derivative actions into the case *In re Ardelyx, Inc. Stockholder Derivative Litigation*, Case No. 1:24-cv-12302-LTS (D. Mass.). On November 7, 2024, the Court stayed the consolidated derivative action pending resolution of any and all motion(s) to dismiss in the Yarborough Action. We believe the plaintiffs' claims are without merit.

From time to time, we may be involved in legal proceedings arising in the ordinary course of business. As of December 31, 2024, there is no litigation pending that would reasonably be expected to have a material adverse effect on our results of operations and financial condition.

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

None.

## **ITEM 9A. CONTROLS AND PROCEDURES**

### ***Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures***

As of December 31, 2024, management, with the participation of our CEO and Chief Financial and Operations Officer (CFOO), performed 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) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including the CEO and the CFOO, to allow timely decisions regarding required disclosures.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit

relationship of possible controls and procedures. Based on this evaluation, our CEO and CFOO concluded that, as of December 31, 2024, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

### ***Management's Annual Report on Internal Control Over Financial Reporting***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed by, or under the supervision of, our CEO and CFOO, and effected by our board of directors, management and other personnel, 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 and includes those policies and procedures that:

- Pertain to the maintenance of records that accurately and fairly reflect in reasonable detail the transactions and dispositions of the assets of our company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- Provide reasonable assurances regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material adverse effect on our financial statements.

Our management assessed our internal control over financial reporting as of December 31, 2024, the end of the period covered by this Annual Report on Form 10-K. Management based its assessment on criteria established in "Internal Control—Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on management's assessment of our internal control over financial reporting, management concluded that, as of December 31, 2024, our internal control over financial reporting was effective.

### ***Changes in Internal Control over Financial Reporting***

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### **Attestation Report of Independent Registered Public Accounting Firm**

Our independent registered public accounting firm, Ernst & Young LLP, has audited our Financial Statements included in Item 8 of this Annual Report on Form 10-K and have issued a report on our internal control over financial reporting as of December 31, 2024. Their report on the audit of internal control over financial reporting appears below.

### **Report of Independent Registered Public Accounting Firm**

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

### **Opinion on Internal Control Over Financial Reporting**

We have audited Ardelyx, Inc.'s internal control over financial reporting as of December 31, 2024, 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, Ardelyx, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2024, 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 balance sheets of Ardelyx, Inc. as of December 31, 2024 and 2023, the related statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2024, and the related notes, and our report dated February 20, 2025 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 Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are

required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

### Definition and Limitations of Internal Control Over Financial Reporting

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

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

/s/ Ernst & Young LLP

Boston, Massachusetts

February 20, 2025

## ITEM 9B. OTHER INFORMATION

### Trading Plans

During the three months ended December 31, 2024, our Section 16 officers and directors adopted or terminated contracts, instructions or written plans for the purchase or sale of our securities as noted below:

Name and Title of Director or Officer	Action	Date	Trading Arrangement		Total Shares Available to be Sold	Expiration Date
			Rule 10b5-1*	Non-Rule 10b5-1**		
Robert Blanks, Chief Regulatory Officer	Termination	December 20, 2024	X		339,500	June 21, 2024
* Intended to satisfy the affirmative defense conditions of Rule 10b5-1(c)						
** Not intended to satisfy the affirmative defense conditions of Rule 10b5-1(c)						

## ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not Applicable.

## PART III

### Items 10, 11, 12, 13, 14.

As described below, we incorporate by reference in this Annual Report on Form 10-K certain information appearing in the Proxy Statement that we will furnish to our stockholders for our 2025 Annual Meeting of Stockholders.

	<b>Incorporated by reference to our Proxy Statement</b>
<b>Item 10. Directors, Executive Officers, and Corporate Governance.</b>	“Executive Officers,” “Election of Directors,” “Corporate Governance,” and “Section 16(a) Beneficial Ownership Reporting Compliance” sections. We have included information regarding our Code Business Conduct and Ethics and our Insider Trading Policy below.
<b>Item 11. Executive Compensation.</b>	“Executive Compensation” section.
<b>Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.</b>	“Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” sections.
<b>Item 13. Certain Relationships and Related Transactions, and Director Independence.</b>	“Certain Relationships and Related Party Transactions” and “Election of Directors” sections.
<b>Item 14. Principal Accountant Fees and Services.</b>	“Principal Accountant Fees and Services” section.

### Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that applies to our officers, directors and employees which is available on our website at [www.ardelyx.com](http://www.ardelyx.com). The Code of Business Conduct and Ethics is intended to qualify as a “code of ethics” within the meaning of Section 406 of the Sarbanes-Oxley Act of 2002 and Item 406 of Regulation S-K. If we make any amendment to, or waiver from, a provision of our Code of Conduct that we are required to disclose under SEC rules, we intend to satisfy that disclosure requirement by posting such information to our website at [www.ardelyx.com](http://www.ardelyx.com). The contents of our websites are not intended to be incorporated by reference into this Form 10-K or in any other report or document we file with the SEC, and any references to our websites are intended to be inactive textual references only.

### Insider Trading Policy and Procedures

We have an insider trading compliance policy and procedures governing the purchase, sale and other dispositions of our securities that applies to all of our personnel, including directors, officers, employees and other covered persons. We believe that our insider trading compliance policy and procedures are reasonably designed to promote compliance with insider trading laws, rules and regulations, and listing standards applicable to us. A copy of our Trading Policy is filed as Exhibit 19.1 to this Form 10-K.

## **PART IV**

### **ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

(a) The following documents are filed as part of this report:

1. Financial Statements

See Index to Financial Statements at Item 8 herein.

2. Financial Statement Schedules

All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

3. Exhibits

See the Exhibit Index immediately following this page.

### **ITEM 16. FORM 10-K SUMMARY**

None.



## Exhibit Index

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation	8-K	6/24/2014	3.1	
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation	8-K	6/20/2023	3.1	
3.3	Amended and Restated Bylaws	8-K	6/24/2014	3.2	
4.1	Reference is made to Exhibits 3.1 and 3.2				
4.2	Form of Common Stock Certificate	S-1/A	6/18/2014	4.2	
4.3	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934	10-K	3/8/2021	4.4	
10.1(a)	Termination Agreement, dated June 2, 2015, by and between AstraZeneca AB and Ardelyx, Inc.	10-Q	8/12/2015	10.1	
10.1(b)	Amendment No. 1 to Termination Agreement and to Manufacturing and Supply Agreement, dated November 2, 2015 by and between AstraZeneca AB and Ardelyx, Inc.	10-K	3/4/2016	10.1(d)	
10.2(a)	Lease, dated August 8, 2008, by and between 34175 Ardenwood Venture, LLC and Ardelyx, Inc.	S-1	5/19/2014	10.4(a)	
10.2(b)	First Amendment to Lease, dated December 20, 2012, by and between 34175 Ardenwood Venture, LLC and Ardelyx, Inc.	S-1	5/19/2014	10.4(b)	
10.2(c)	Second Amendment to Lease, dated September 5, 2014, by and between Ardelyx, Inc. and 34175 Ardenwood Venture, LLC	8-K	9/9/2014	10.1	
10.2(d)	Third Amendment to Lease, dated April 28, 2016, by and between Ardelyx, Inc. and 34175 Ardenwood Venture, LLC	10-Q	8/8/2016	10.3	
10.2(e)	Fourth Amendment to Lease, dated May 25, 2021, by and between Ardelyx, Inc. and 34175 Ardenwood Venture, LLC	10-K	3/2/2023	10.2(e)	
10.2(f)	Fifth Amendment to Lease, dated May 25, 2021, by and between Ardelyx, Inc. and 34175 Ardenwood Venture, LLC	8-K	6/1/2021	10.1	
10.2(g)	Sixth Amendment to Lease, dated May 25, 2021, by and between Ardelyx, Inc. and 34175 Ardenwood Venture, LLC.	8-K	10/9/2024	10.2	
10.3(a)	Lease Agreement, dated December 30, 2020, by and between Ardelyx, Inc. and Prospect Fifth Ave, LLC.	10-K	3/8/2021	10.31	
10.3(b)	Amendment Number 2 to Lease Agreement by and between Ardelyx, Inc, and Prospect Fifth Avenue, LLC.	10-Q	5/2/2024	10.3(b)	
10.3(c)	Amendment Number 3 to Lease Agreement by and between Ardelyx, Inc, and Prospect Fifth Avenue, LLC.	10-Q	5/2/2024	10.3(c)	
10.4	Lease Agreement, dated October 3, 2024, by and between Ardelyx, Inc. and BMR-Pacific Research Center LP.	8-K	10/9/2024	10.1	
10.5#	Ardelyx, Inc. Amended and Restated 2014 Equity Incentive Award Plan.	10-Q	8/1/2024	10.1	
10.6#	Ardelyx, Inc. Amended and Restated 2014 Employee Stock Purchase Plan.	10-Q	8/1/2024	10.2	
10.7(a)#	Ardelyx, Inc. 2008 Stock Incentive Plan, as amended	S-1	5/19/2014	10.5(a)	
10.7(b)#	Form of Stock Option Grant Notice and Stock Option Agreement under the 2008 Stock Incentive Plan, as amended	S-1	5/19/2014	10.5(b)	
10.7(c)#	Form of Restricted Stock Purchase Grant Notice and Restricted Stock Purchase Agreement under the 2008 Stock Incentive Plan,	S-1	5/19/2014	10.5(c)	
10.8(a)#	Ardelyx, Inc. Amended and Restated 2014 Equity Incentive Award Plan	10-Q	8/1/2024	10.1	
10.8(b)#	Form of Stock Option Grant Notice and Stock Option Agreement under the 2014 Equity Incentive Award Plan	S-1/A	6/9/2014	10.6(b)	
10.8(c)#	Form of Restricted Stock Award Agreement and Restricted Stock Unit Award Grant Notice under the 2014 Equity Incentive Award	S-1/A	6/9/2014	10.6(c)	

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.9#	Ardelyx, Inc. Amended and Restated 2014 Employee Stock Purchase Plan	10-Q	8/1/2024	10.2	
10.10(a)#	Ardelyx, Inc. 2016 Employment Commencement Incentive Plan	10-K	2/22/2024	10.7(a)	
10.10(b)#	Form of Stock Option Grant Notice and Stock Option Agreement under the 2016 Employment Commencement Incentive Plan	S-8	11/10/2016	99.2	
10.10(c)#	Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the 2016 Employment Commencement Incentive Plan	S-8	11/10/2016	99.3	
10.10(d)#	Form of Restricted Stock Award Grant Notice and Restricted Stock Award Agreement under the 2016 Employment Commencement Incentive Plan	S-8	11/10/2016	99.4	
10.11	Registration Rights Agreement by and among Ardelyx, Inc. and the investors signatory thereto, dated June 2, 2015	S-3	7/13/2015	99.1	
10.12	Registration Rights Agreement by and among Ardelyx, Inc. and the investors signatory thereto, dated July 14, 2016	10-Q	8/8/2016	10.2	
10.13#	Form of Indemnification Agreement for directors and officers	S-1/A	6/9/2014	10.7	
10.14#	Amended and Restated Executive Employment Agreement, dated June 6, 2014, by and between Ardelyx, Inc. and Michael Raab	S-1/A	6/9/2014	10.8	
10.15#	Offer Letter, dated December 28, 2009, by and between Ardelyx, Inc. and David Rosenbaum, Ph.D.	S-1/A	6/9/2014	10.13	
10.16(a)#	Second Amended and Restated Change in Control and Severance Agreement by and between Ardelyx, Inc. and David P. Rosenbaum, Ph.D.	10-Q	5/8/2018	10.1	
10.16(b)#	Amendment Number One to Second Amended and Restated Change in Control Severance Agreement and Retention Agreement dated December 1, 2021 between Ardelyx, Inc. and	10-K	2/28/2022	10.20	
10.17#	Offer Letter, dated November 21, 2012, by and between Ardelyx, Inc. and Elizabeth Grammer, Esq.	S-1/A	6/9/2014	10.14	
10.18#	Second Amended and Restated Change in Control and Severance Agreement by and between Ardelyx, Inc. and Elizabeth Grammer.	10-Q	5/8/2018	10.0	
10.19#	Offer Letter, dated April 27, 2020, by and between Ardelyx, Inc. and Susan Rodriguez	10-Q	8/6/2020	10.1	
10.20#	Change in Control Severance Agreement dated June 2, 2020, by and between Ardelyx, Inc. and Susan Rodriguez	10-Q	8/6/2020	10.2	
10.21#	Offer Letter, dated June 2, 2020, by and between Ardelyx, Inc. and Justin Renz	10-Q	8/6/2020	10.3	
10.22#	Change in Control Severance Agreement, dated June 8, 2020, by and between Ardelyx, Inc. and Justin Renz	10-Q	8/6/2020	10.4	
10.23(a)#	Second Amended and Restated Non-Employee Director Compensation Program	10-Q	8/4/2022	10.3	
10.23(b)#	Third Amended and Restated Non-Employee Director Compensation Program	10-K	2/22/2024	10.20(b)	
10.24#	Offer Letter, dated February 13, 2024 by and between Ardelyx, Inc. and Michael Kelliher.	10-Q	5/2/2024	10.29	
10.25#	Offer Letter, dated July 25, 2024 by and between Ardelyx, Inc. and Eric Foster.	10-Q	10/31/2024	10.6	
10.26†	Commercial Supply Agreement, dated August 7, 2024 and effective as of July 23, 2024, by and between Ardelyx, Inc. and Catalent.	8-K	8/12/2024	10.1	
10.27†	Commercial Supply Agreement, dated October 25, 2024, by and among Ardelyx, Inc., Hovione Farmaciência, S.A. and Hovione, LLC.	10-Q	10/31/2024	10.2	

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.28(a)††	License Agreement, dated November 27, 2017, by and between Kyowa Hakko Kirin Co., Ltd. and Ardelyx, Inc.	10-K	3/14/2018	10.35	
10.28(b)	Amendment Number 1 to License Agreement, dated as of November 27, 2017, by and among Ardelyx, Inc., and Kyowa Kirin Co., Ltd.	10-K	3/2/2023	10.21(b)	
10.28(c)††	Amendment Number 2 to License Agreement, dated as of April 11, 2022, by and among Ardelyx, Inc., and Kyowa Kirin Co., Ltd.	8-K	4/11/2022	99.1	
10.29††	License Agreement, dated December 11, 2017, by and between Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd. and Ardelyx, Inc.	10-K	3/14/2018	10.36	
10.30††	Royalty and Sales Milestone Interest Acquisition Agreement dated June 29, 2022, by and between Ardelyx, Inc. and Healthcare Royalty Partners IV, L.P.	10-Q	8/4/2022	10.1	
10.31(a)	Loan and Security Agreement dated February 23, 2022, by and between Ardelyx, Inc. and SLR Investment Corp.	10-Q	5/5/2022	10.1	
10.31(b)	First Amendment to the Loan and Security Agreement dated August 1, 2022, by and between Ardelyx, Inc. and SLR	10-Q	8/4/2022	10.2	
10.31(c)	Second Amendment to the Loan and Security Agreement dated February 9, 2023, by and between Ardelyx, Inc. and SLR Investment Corp.	10-K	3/2/2023	10.24(c)	
10.31(d)	Third Amendment to the Loan and Security Agreement dated October 17, 2023, by and between Ardelyx, Inc. and SLR Investment Corp.	8-K	10/18/2023	10.1	
10.31(e)	Fourth Amendment to the Loan and Security Agreement dated October 29, 2024, by and between Ardelyx, Inc. and SLR Investment Corp.	10-Q	10/31/2024	10.5	
10.32	Exit Fee Agreement dated February 23, 2022, by and between Ardelyx, Inc. and SLR Investment Corp.	10-Q	5/5/2022	10.2	
10.33	Exit Fee Agreement, dated May 16, 2018, by and between the Company and Solar Capital Ltd. and Western Alliance Bank	10-Q	8/7/2018	10.2	
10.34(a)††	Manufacturing Services Agreement, dated May 18, 2020, between Ardelyx, Inc. and Patheon Pharmaceuticals Inc.	10-Q	8/6/2020	10.5	
10.34(b)††	First Amendment to the Manufacturing Services Agreement dated February 27, 2023, between Ardelyx, Inc. and Patheon Pharmaceuticals Inc.	10-K	3/2/2023	10.27(b)	
10.35	Open Market Sales Agreement, dated January 18, 2023 between Ardelyx, Inc. and Jefferies LLC.	S-3	1/19/2023	1.2	
19.1	Ardelyx, Inc. Insider Trading Compliance Policy and Procedures			—	X
23.1	Consent of Independent Registered Public Accounting Firm			—	X
31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended			—	X
31.2	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended			—	X
32.1	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C §1350			—	X
97.1	Policy for Recovery of Erroneously Awarded Compensation	10-K	2/22/2024	97.1	
101.SCH	Inline XBRL Taxonomy Extension Schema Document			—	X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase			—	X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase			—	X

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Incorporated by Reference</b>			<b>Filed Herewith</b>
		<b>Form</b>	<b>Date</b>	<b>Number</b>	
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document			—	X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase			—	X

† Confidential treatment granted as to portions of this Exhibit. The confidential portions of this Exhibit have been omitted and are marked by asterisks.

†† Certain portions of this exhibit have been redacted pursuant to Item 601(b)(10) of Regulation S-K. A copy of the omitted portions will be furnished supplementally to the Securities and Exchange Commission upon request.

# Indicates management contract or compensatory plan.

## 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.

**Ardelyx, Inc.**

Date: February 20, 2025

By: /s/ Joseph Reilly

**Joseph Reilly**  
**Senior Vice President and Chief Accounting Officer**  
**(Principal Accounting Officer)**

## POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Michael Raab, Justin Renz, and Joseph Reilly, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file 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, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or 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 dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
_____ /s/ Michael Raab Michael Raab	President, Chief Executive Officer and Director <i>(Principal Executive Officer)</i>	February 20, 2025
_____ /s/ Justin Renz Justin Renz	Chief Financial and Operations Officer <i>(Principal Financial Officer)</i>	February 20, 2025
_____ /s/ Joseph Reilly Joseph Reilly	Chief Accounting Officer <i>(Principal Accounting Officer)</i>	February 20, 2025
_____ /s/ David Mott David Mott	Chairman of the Board of Directors	February 20, 2025
_____ /s/ Robert Bazemore Robert Bazemore	Director	February 20, 2025
_____ /s/ William Bertrand, Jr. William Bertrand, Jr., J.D.	Director	February 20, 2025
_____ /s/ Muna Bhanji Muna Bhanji, R.Ph	Director	February 20, 2025
_____ /s/ Onaiza Cadoret-Manier Onaiza Cadoret-Manier	Director	February 20, 2025
_____ /s/ Richard Rodgers Richard Rodgers	Director	February 20, 2025



## SUMMARY OF ABBREVIATED TERMS

Throughout this 2024 Form 10-K, we have used terms which are defined below:

340B Program	Public Health Service's 340B Drug Pricing Program	HCR Agreement	Royalty and Sales Milestone Interest Acquisition Agreement
AAKP	American Association of Kidney Patients	HHS	Department of Health and Human Services
ACA	Affordable Care Act	HIPAA	Health Insurance Portability and Accountability Act of 1996, as amended, and regulations promulgated thereunder
AI Technologies	Artificial intelligence, machine learning and certain automated decision-making technologies	HRSA	Health Resources and Services Administration
AMP	average manufacturer price	IBS-C	irritable bowel syndrome with constipation
ANDA	abbreviated New Drug Application	IND	Investigational New Drug
API	active pharmaceutical ingredient	IRA	Inflation Reduction Act of 2022
AstraZeneca	AstraZeneca AB	IRB	institutional review board
ASU	Accounting Standards Update	Jefferies	Jefferies, LLC
CCPA	California Consumer Privacy Act, as amended by the California Privacy Rights Act	Kyowa Kirin	Kyowa Kirin Co., Ltd.
cGMP	current Good Manufacturing Practice	Knight	Knight Therapeutics, Inc.
CKD	chronic kidney disease	MDRP	Medicaid Drug Rebate Program
CME	Chicago Mercantile Exchange	METiS	METiS Therapeutics, Inc.
CMO	contract manufacturing organization	MHLW	Ministry of Health, Labour and Welfare
CMS	Centers for Medicare & Medicaid Services	MIPPA	Medicare Improvements for Patients and Providers Act
CRO	contract research organization	OLC	Oxylanthanum Carbonate
Customers	collectively, major wholesalers, specialty pharmacies and GPOs (IBSRELA) and specialty wholesaler (XPHOZAH)	NCE	new chemical entity
DPF	EU-US Data Privacy Framework	NDA	New Drug Application
EEA	European Economic Area	NH3	sodium hydrogen exchange 3
ESPP	Employee Stock Purchase Plan	NMPA	National Medical Products Administration
ESRD	End-Stage Renal Disease	NOL	net operating loss
ESRD PPS	End-Stage Renal Disease Prospective Payment System	NMQF	National Minority Quality Forum
EU Patent Package	European Patent Package	Non-FAMP	Non-Federal Average Manufacturer Price
FASB	Financial Accounting Standards Board	R&D	research and development
FDA	Food and Drug Administration	REMS	Risk Evaluation and Mitigation Strategy
FFDCA	Federal Food, Drug, and Cosmetic Act	RSU	restricted stock units
Fosun Pharma	Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd.	SLR	SLR Investment Corp.
FSS	Federal Supply Schedule	SEC	Securities and Exchange Commission
FTC	Federal Trade Commission	SOFR	Secured Overnight Financing Rate
GCP	Good Clinical Practice	TDAPA	Transitional Drug Add-on Payment Adjustment
GDPR	European Union General Data Protection Regulation	UPC	European Unified Patent Court
GLP	Good Laboratory Practice	U.S.	United States
GPO	group purchasing organization	USPTO	U.S. Patent and Trademark Office
GTN	gross-to-net	VA	Department of Veterans Affairs
HCR	HealthCare Royalty Partners IV, L.P.		



