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

FORM 10-K

(Mark One)

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2023

OR

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

FOR THE TRANSITION PERIOD FROM TO

COMMISSION FILE NUMBER 001-36485

ARDELYX, INC.
(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

DELAWARE	**26-1303944**
(STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION)	**(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	☒	Accelerated filer	☐
Non-accelerated filer	☐	Small reporting company	☒
		Emerging growth company	☐

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

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

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

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

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

The aggregate market value of the 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, 2023, based on the last reported sales price of the Registrant's common stock on the Nasdaq Global Market of $3.39 per share was $724,838,738.

The number of shares of Registrant's Common Stock outstanding as of February 16, 2024, was 232,686,008.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the Registrant's Definitive Proxy Statement for its 2024 Annual Meeting of Stockholders, which will be filed with the Commission within 120 days of December 31, 2023, the close of the Registrant's 2023 fiscal year, are incorporated by reference into Part III of this Report.

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:

- whether or when XPHOZAH, along with other oral ESRD-related drugs without an injectable or intravenous equivalent, are bundled into the ESRD prospective payment system (ESRD PPS), and the manner in which such introduction into the ESRD PPS may occur, including the length of any applicable Transitional Drug Add-on Payment Adjustment (TDAPA) period; the amount of the add-on payment available during the TDAPA period and whether, and the extent to which, the ESRD PPS base rate is adjusted following any applicable TDAPA period;
- our plans with respect to RDX013 and RDX020;
- 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. 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 are not profitable and have incurred losses since our inception in October 2007, and we expect to continue to incur operating losses in the future as we commercialize IBSRELA and XPHOZAH, incur manufacturing and development costs for tenapanor, and incur research and development costs related to potential new product candidates.
- We will require additional financing for the foreseeable future as we invest in the commercialization of IBSRELA and XPHOZAH in the U.S, and incur research and development cost 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 XPHOZAH, or to delay or limit our pursuit of potential new product candidates.
- We have generated limited revenue from product sales and may never be profitable.
- 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, secure and maintain adequate coverage and reimbursement for XPHOZAH, or generate sufficient revenue from product sales of XPHOZAH.
- In the event no legislative or regulatory action is taken to further delay the inclusion of oral only ESRD related drugs in the ESRD prospective payment system (ESRD PPS), XPHOZAH will become part of the ESRD PPS on January 1, 2025, and will no longer be separately paid for under 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 contract manufacturing organizations (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. Securities and Exchange Commission. 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®, IBSRELA®, and XPHOZAH® 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, 2023
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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®, is approved in the U.S. for the treatment of adults with irritable bowel syndrome with constipation (IBS-C). Tenapanor, branded as XPHOZAH®, was approved by the U.S. Food and Drug Administration (U.S. FDA) on October 17, 2023, to reduce serum phosphorus in adults with chronic kidney disease (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 also have a development stage asset, RDX013 for adult patients with CKD and/or heart failure with hyperkalemia, or elevated serum potassium, and a discovery phase asset, RDX020 for adult patients with metabolic acidosis, a serious electrolyte disorder, in patients with CKD.

Since commencing operations in October 2007, substantially all our efforts have been dedicated to our research and development (R&D) activities, including developing tenapanor and developing our proprietary drug discovery and design platform, as well as commercialization activities, including the marketing and sales of IBSRELA and XPHOZAH. We realized our first product sales of IBSRELA in March 2022 and realized our first product sales of XPHOZAH in November 2023. As of December 31, 2023, we had an accumulated deficit of $846.2 million.

We expect to continue to incur operating losses for the foreseeable future as we invest in the commercialization of IBSRELA and XPHOZAH, incur manufacturing and development cost for tenapanor, and incur R&D cost related to potential new product candidates. To date, we have funded our operations from the sale and issuance of common stock and convertible preferred stock, funds from our collaboration partnerships, which includes license fees, milestones and product supply revenue, funds from our loan agreements with SLR Investment Corp. (SLR), as amended, as well as from sales of IBSRELA and XPHOZAH.

Our Commercial Products

IBSRELA for IBS-C

Our unique discovery platform and deep understanding of the primary mechanism of sodium transport in the intestine resulted in our discovery and development of IBSRELA, a first-in-class, U.S. FDA approved, sodium hydrogen exchange 3 (NHE3) inhibitor for the treatment of IBS-C in adults. IBSRELA acts locally in the gut and is minimally absorbed. IBS-C is a gastrointestinal (GI) disorder characterized by both abdominal pain and altered bowel habits. 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. For our commercial launch of IBSRELA, we designed a market-responsive commercial strategy and built a commercial organization highly experienced in launching 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, 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 patients currently being managed for IBS-C by the approximately 9,000 high-writing healthcare providers who account for approximately 50% of IBS-C prescriptions. Central to our go to market strategy for IBSRELA has been our highly experienced specialty sales force, many with existing relationships across their GI target base, and innovative omnichannel and digital initiatives.

We expect competition for IBSRELA will come largely from the 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.

We have established commercial agreements with Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd. (Fosun Pharma) in China and Knight Therapeutics, Inc. (Knight) in Canada for IBSRELA for IBS-C. Knight is currently marketing IBSRELA in Canada. In October 2023, we announced that Fosun Pharma received approval from the Hong Kong Department of Health for the marketing application for tenapanor for the treatment of IBS-C.

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

On October 17, 2023, XPHOZAH, a first-in-class phosphate absorption inhibitor, received approval from the U.S. FDA to be marketed 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 eighty percent of those patients are being treated with phosphate lowering therapies. On average during 2020 through 2023, approximately seventy percent of patients treated with phosphate binders to treat hyperphosphatemia were unable to consistently maintain phosphorous levels <=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 November 2023. 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, 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. These dynamics enabled a targeted promotional focus on patients currently being managed for hyperphosphatemia by the approximately 8,000 nephrology healthcare providers who write approximately 80% of phosphate lowering therapy prescriptions. Central to our go to market strategy for XPHOZAH is our highly experienced specialty sales force, many with existing relationships across their nephrology target base, and innovative omnichannel digital initiatives.

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 other binders in development, including fermagate (Alpharen), an iron-based binder in Phase 3 being developed by Opko Health, Inc., PT20, an iron-based binder in Phase 3 being developed by Shield Therapeutics, AP-301 in Phase 2 being developed by Alebund Pharmaceutical (Hong Kong) Limited, and Oxylanthanum Carbonate (OLC), which has demonstrated pharmacodynamic bioequivalence to Fosrenol. OLC is being developed by Unicycive Therapeutics, which has announced its plans to seek FDA approval via the 505(b)(2) pathway. Additionally, Chugai and Alebund are developing EOS789, an inhibitor of phosphate transporters NaPi-2b, PiT-1, and PiT-2, thus far studied in a phase 1 clinical trial.

In November 2023, XPHOZAH was granted orphan drug designation by the U.S. FDA for the treatment of pediatric hyperphosphatemia.

We have established commercial agreements with Kyowa Kirin, Co. Ltd. (Kyowa Kirin) in Japan, Fosun Pharma in China and Knight in Canada for tenapanor for hyperphosphatemia. In July 2023, we announced that a New Drug Application (NDA) for tenapanor had been accepted for review by China's Center for Drug Evaluation of the National Medical Products Administration (NMPA) for the control of serum phosphorus in adult patients with CKD on hemodialysis. In September 2023, we announced that Kyowa Kirin received approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) for the NDA for tenapanor for the improvement of hyperphosphatemia in adult patients with CKD on dialysis.

Discovery and Developmental Assets

We have a small molecule potassium secretagogue program, RDX013, for the potential treatment of hyperkalemia, or elevated serum potassium. Hyperkalemia is a common problem in patients with heart and kidney disease, particularly in patients taking customary blood pressure medications known as renin-angiotensin-aldosterone system (RAAS) inhibitors. RDX013 is a novel mechanism agent designed to target the underlying biological mechanisms of potassium secretion to lower elevated potassium. We have completed a Phase 2 dose ranging clinical trial evaluating the safety and efficacy of RDX013 for the treatment of hyperkalemia in CKD patients who are not on dialysis. While the results of the study demonstrated an acceptable safety and tolerability profile for RDX013 and supported proof of concept in its ability to lower serum potassium levels, with statistically significant reductions compared to placebo after eight days of treatment, the study did not meet its primary endpoint of significantly reducing serum potassium levels compared to placebo after four weeks of treatment.

We have a discovery program targeting the inhibition of the chloride bicarbonate exchanger for the treatment of metabolic acidosis, a highly prevalent comorbidity in CKD patients that is strongly correlated with disease progression and adverse outcomes. We have identified lead compounds that are potent, selective and proprietary inhibitors of bicarbonate secretion.

We do not currently expect to meaningfully advance either of these two assets until such time as we have determined our available resources can support additional activities after prioritization of the commercialization of IBSRELA and XPHOZAH.

Our Commercial Strategy

We have developed a portfolio of novel products to address unmet medical needs across gastrointestinal and cardiorenal therapeutic areas and intend to commercialize our products in the U.S. 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 ex-U.S. 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 have exclusive rights to tenapanor in the U.S. and we have established 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.

In March 2018, we entered into an exclusive license agreement with Knight (Knight Agreement) for the development, commercialization and distribution of tenapanor in Canada for hyperphosphatemia and IBS-C. In March 2021, Knight announced the commercial availability of IBSRELA for IBS-C in Canada, following its approval by Health Canada in April 2020. Under the terms of the Knight Agreement, Knight paid us a $2.3 million non-refundable, one-time payment in March 2018. We may also be eligible to receive approximately CAD 22.2 million for development and commercialization milestones, or approximately $16.7 million at the currency exchange rate on December 31, 2023, of which $0.7 million has been received and recognized as revenue as of December 31, 2023. We are also eligible to receive royalties throughout the term of the agreement, and a transfer price for manufacturing services.

In November 2017, we entered into an exclusive license agreement with Kyowa Kirin (2017 Kyowa Kirin Agreement) for the development, commercialization and distribution of tenapanor in Japan for cardiorenal indications. Under the terms of the 2017 Kyowa Kirin Agreement, we received a $30.0 million upfront payment from Kyowa Kirin, and we may be entitled to receive up to $55.0 million in total development and regulatory milestones, of which $35.0 million has been received and recognized as revenue as of December 31, 2023. We may also be eligible to receive approximately ¥8.5 billion for commercialization milestones, or approximately $60.3 million at the currency exchange rate on December 31, 2023, as well as reimbursement of costs plus a reasonable overhead for the supply of product and royalties on net sales throughout the term of the agreement. 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 2017 Kyowa Kirin Agreement will be remitted to HealthCare Royalty Partners IV, L.P. pursuant to a Royalty and Sales Milestone Interest Acquisition Agreement.

On April 11, 2022, we entered into a second amendment to the 2017 Kyowa Kirin Agreement (2022 Amendment). Under the terms of the 2022 Amendment, we and Kyowa Kirin agreed to a reduction in the royalty rate payable to us by Kyowa Kirin upon net sales of tenapanor in Japan. The royalty rate was reduced from the 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. As discussed in *Note 8. Deferred Royalty Obligation Related to the Sale of Future Royalties*, the future royalties we may receive under the 2017 Kyowa Kirin Agreement will be remitted to HealthCare Royalty Partners IV, L.P. pursuant to a Royalty and Sales Milestone Interest Acquisition Agreement. As consideration for the reduction in the royalty rate, Kyowa Kirin agreed to pay us up to an additional $40.0 million which has been received and recognized as revenue as of September 2023 as described below.

In October 2022, we announced that Kyowa Kirin submitted an NDA to the Japanese MHLW for tenapanor for the improvement of hyperphosphatemia in adult patients with CKD on dialysis, which resulted in payment to us from Kyowa Kirin for an aggregate of $35.0 million for milestone payments and payments under the 2022 Amendment.

In September 2023, we announced that Kyowa Kirin received approval from the Japanese MHLW for the NDA for tenapanor for the improvement of hyperphosphatemia in adult patients with chronic kidney disease on dialysis, which resulted in payment to us from Kyowa Kirin for an aggregate of $30.0 million for milestone payments and payments under the 2022 Amendment.

In December 2017, we entered into an exclusive license agreement with Fosun Pharma (Fosun Agreement) for the development and commercialization of tenapanor in China for both hyperphosphatemia and IBS-C. Under the terms of the Fosun Agreement, Fosun paid us a $12.0 million upfront license fee. In July 2023, we announced that an NDA for tenapanor had been accepted for review by China's Center for Drug Evaluation of the NMPA for the control of serum phosphorus in adult patients with chronic kidney disease on hemodialysis. This acceptance triggered a $2.0 million milestone payment to us under the terms of the Fosun Agreement, which we received in the third quarter of 2023.

In October 2023, we announced that the U.S. FDA has approved 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. This triggered an additional $3.0 million milestone payment to us under the terms of the Fosun Agreement, which was received during the first quarter of 2024. Also, in October 2023, we announced that Fosun Pharma received approval from the Hong Kong Department of Health for the marketing application for tenapanor for the treatment of IBS-C. We may be entitled to receive development and commercialization milestones of up to $113.0 million, of which $8.0 million has been recognized as revenue and $5.0 million has been received as of December 31, 2023 and $3.0 million was received in January 2024, as well as 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%.

Corporate Financings

In July 2020, we filed a Form S-3 registration statement, which became effective in August 2020 (2020 Registration Statement), 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 $100.0 million of our common stock that may be issued and sold, from time to time, under an Open Market Sales Agreement with Jefferies LLC (Jefferies), as sales agent, deemed to be "at-the-market offerings" (2020 Open Market Sales Agreement). Pursuant to the 2020 Open Market Sales Agreement, Jefferies, as sales agent, received a commission of up to 3.0% of the gross sales price for shares of common stock sold under the 2020 Open Market Sales Agreement. We sold a cumulative total of 23.3 million shares and received the full gross proceeds of $100.0 million at a weighted average sales price of approximately $4.30 per share under the 2020 Open Market Sales Agreement.

In August 2021, we filed an additional prospectus supplement under the 2020 Registration Statement 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 we were authorized to issue and sell, from time to time, under a sales agreement (2021 Open Market Sales Agreement) we entered into with Jefferies, pursuant to which we, from time to time, sold up to $150.0 million in shares of our common stock through Jefferies. Pursuant to the 2021 Open Market Sales Agreement, Jefferies, as our sales agent, received a commission of up to 3.0% of the gross sales price for shares of common stock sold under the 2021 Open Market Sales Agreement. As of March 2023, we had received the maximum gross proceeds of $150.0 million under the 2021 Open Market Sales Agreement at a weighted average share price of approximately $1.57 per share, which included 15.5 million shares of our common stock for which we received gross proceeds of $51.9 million at a weighted average share price of approximately $3.35 during the quarter ended March 31, 2023.

In January 2023, we filed a Form S-3 registration statement, which became effective in January 2023 (2023 Registration Statement), 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. During the year ended December 31, 2023, we 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 per share.

As of December 31, 2023, we had cash, cash equivalents and short-term investments totaling $184.3 million.

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 U.S. Patent and Trademark Office (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.

Other Program Patents

We have patent applications pending in the U.S. and internationally that cover the compositions and methods of using compounds in our RDX013 program.

Manufacturing

To date, we have relied upon third-party contract manufacturing organizations (CMOs) to manufacture both the active pharmaceutical ingredient 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 active pharmaceutical ingredient 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 Federal Food, Drug, and Cosmetic Act (FFDCA) 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 Good Laboratory Practice (GLP) regulations;

- submission to the U.S. FDA of an Investigational New Drug (IND) application which must become effective before human clinical trials in the U.S. may begin;

- approval by an independent institutional review board, (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 Good Clinical Practice (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 current Good Manufacturing Practice (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 GMP 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 Risk Evaluation and Mitigation Strategy (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 FFDCA 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 Abbreviated New Drug Application (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 a new chemical entity (NCE) that has not been previously approved by the U.S. FDA. A drug is a new chemical entity 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 Centers for Medicare & Medicaid Services (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 Health Insurance Portability and Accountability Act of 1996, or 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 prospective payment system for dialysis treatment. Under the End Stage Renal Disease (ESRD) prospective payment system, 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. The inclusion of oral medications without injectable or intravenous equivalents in the bundled payment was initially delayed until January 1, 2014 and through several subsequent legislative actions was delayed until January 1, 2025. As a result, absent further legislation or regulation on this matter, beginning in 2025, oral ESRD-related drugs without injectable or intravenous equivalents may be included in the ESRD bundle and separate Medicare payment for these drugs will no longer be available, as is the case today under Medicare Part D. While it is too early to project the full impact that bundling may have on XPHOZAH and our business should XPHOZAH be brought into the bundle in 2025, or at any time, 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 Affordable Care Act, a healthcare reform measure (ACA). 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 average manufacturer price;
- 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, under which they must now agree 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. Further, prior to the U.S. Supreme Court ruling, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace from February 15, 2021 through August 15, 2021. The executive order instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.

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 eliminates the statutory Medicaid drug rebate cap beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price.

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 Inflation Reduction Act of 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 (beginning 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 Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations.HHS has issued and will continue to issue guidance implementing the IRA, 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. 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 Medicaid Drug Rebate Program (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. Centers for Medicare & Medicaid Services (CMS), the federal agency that administers the MDRP and Medicare programs. For the MDRP, these data include the average manufacturer price (AMP) and the best price (BP) 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 Public Health Service’s 340B drug pricing program (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 Health Resources and Services Administration (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. Department of Veterans Affairs (VA) Federal Supply Schedule (FSS) pricing program. Under the VA/FSS program, manufacturers must report the Non-Federal Average Manufacturer Price (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, 2023, we had 267 full-time employees, 55 of whom were engaged directly in development and manufacturing, and 212 in marketing, sales and administrative activities. During 2023, our employee base increased by approximately 134, or 101%.

Inclusion and Diversity

Our culture is supported by an unwavering commitment to inclusion and diversity. As of December 31, 2023, approximately 57% of our workforce was female; 50% of our executive leadership team was female and 54% of our employees in managerial roles were female. As of December 31, 2023, minorities represented approximately 31% of our workforce, and 45% 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. We are united by our desire to serve our patients, and we are proud financial sponsors of the California Life Sciences Association Racial and Social Equity Initiative, a first step in a unified effort for the life sciences industry in California to do more for the under-served and under-represented, focusing on the most critical need to address the inequality for Black, Hispanic, Native American and Pacific Islander populations in California.

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 to discuss our core values with potential candidates looking to join our team. We believe that this is an important step in helping 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. In response to the COVID-19 pandemic, we implemented significant changes that we determined were in the best interest of our employees, as well as the communities in which we operate, in compliance with government regulations. This included having the vast majority of our employees work from home. We have reopened our facilities and employees have returned to our facilities. 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.

We file electronically with the Securities and Exchange Commission (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, 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.

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 are not profitable and have incurred significant losses since our inception, and we expect to incur operating losses in the future as we commercialize IBSRELA® and XPHOZAH®, incur manufacturing and development costs for tenapanor, and incur research and development costs related to potential new product candidates.

In March 2022, we commenced the commercialization of our first product, IBSRELA® (tenapanor) for the treatment of irritable bowel syndrome with constipation (IBS-C) in adult patients and have generated approximately $95.6 million in net revenue from product sales through December 31, 2023. In October 2023, we received U.S. Food and Drug Administration (FDA) approval for XPHOZAH® (tenapanor) for the reduction of serum phosphorus in adults with chronic kidney disease (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 November 2023, we commenced the commercialization of XPHOZAH and generated approximately $2.5 million in net revenue from product sales through December 31, 2023.

We are not profitable and 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 other expenses related to our ongoing operations. As of December 31, 2023, we had an accumulated deficit of $846.2 million.

We expect to continue to incur operating losses for the foreseeable future as we commercialize IBSRELA and XPHOZAH, incur manufacturing and development costs for tenapanor, and incur research and development costs related to potential new product candidates.

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 expected 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 (the Code). 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 net operating loss (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 commercialization of IBSRELA and XPHOZAH in the U.S. and incur research and development costs 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 or XPHOZAH, or to delay or limit our pursuit of potential new product candidates

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 and research and development related to potential new product candidates. 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 availability of adequate third-party reimbursement for IBSRELA and XPHOZAH;
- the manufacturing, selling and marketing costs associated with IBSRELA and XPHOZAH;
- whether or when XPHOZAH, along with other oral ESRD-related drugs without an injectable or intravenous equivalent, are bundled into the ESRD prospective payment system (ESRD PPS), the manner in which such introduction into the ESRD PPS may occur, including the length of any applicable TDAPA period and the amount of the add-on payment available during the TDAPA period and whether, and the extent to which, the ESRD PPS base rate is adjusted following any applicable TDAPA period;
- 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 cash requirements for the discovery and/or development of other potential product candidates, including RDX013 and RDX020;
- 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 Investment Corp., 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 XPOHZAH, delay or limit additional clinical trials for tenapanor, or delay or limit our pursuit of potential new product candidates. Additionally, our inability to access capital on a timely basis and on terms that are acceptable to us may force us to 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 or XPHOZAH through the use of alternative structures.

We have generated limited revenue from product sales and may never be profitable.

We began selling IBSRELA in the U.S. in March 2022 and have generated approximately $95.6 million in net revenue from product sales through December 31, 2023. On October 17, 2023, our NDA for XPHOZAH was approved by the U.S. Food and Drug Administration's (U.S. FDA). In November, we commenced the commercialization of XPHOZAH and generated approximately $2.5 million in net revenue from product sales through December 31, 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 ISBRELA 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;
- our ability to obtain and sustain an adequate level of coverage and reimbursement for IBSRELA and XPHOZAH by third-party payors;
- whether or when XPHOZAH, along with other oral ESRD-related drugs without an injectable or intravenous equivalent, are bundled into the ESRD PPS, the manner in which such introduction into the ESRD PPS may occur, including the length of any applicable TDAPA period and the amount of the add-on payment available during the TDAPA period and whether, and the extent to which, the ESRD PPS base rate is adjusted following any applicable TDAPA period;
- 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 get reimbursement at any price. While there is significant uncertainty related to the insurance coverage and reimbursement of newly approved products in general in the U.S., there is additional uncertainty related to insurance coverage and reimbursement for drugs, like XPHOZAH, which is being marketed for the reduction of serum phosphorus in adults with chronic kidney disease (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. Our ability to generate and sustain future revenues from sales of XPHOZAH, will be significantly dependent upon whether and when XPHOZAH, along with other oral end stage renal disease (ESRD)-related drugs without an injectable or intravenous equivalent, are bundled into the ESRD PPS, and the manner in which such introduction into the ESRD PPS may occur. See "*—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*" and "*—In the event no legislative or regulatory action is taken to further delay the inclusion of oral only ESRD related drugs in the ESRD PPS, XPHOZAH will become part of the ESRD PPS on January 1, 2025, and will no longer be separately paid for under 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 the sale of IBSRELA or XPHOZAH. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. 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;
- 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, secure and maintain adequate coverage and reimbursement for XPHOZAH or generate sufficient revenue from product sales of XPHOZAH.

There is no guarantee that we will achieve sufficient market acceptance for XPHOZAH, secure and maintain adequate coverage and reimbursement for XPHOZAH or generate sufficient revenue from product sales of XPHOZAH. The commercial success of XPHOZAH will depend on a number of factors, including the following:

- whether or when XPHOZAH, along with other oral ESRD-related drugs without an injectable or intravenous equivalent, are bundled into the ESRD PPS, the manner in which such introduction into the ESRD PPS may occur, including the length of any applicable TDAPA period and the amount of the add-on payment available during the TDAPA period and whether, and the extent to which, the ESRD PPS base rate is adjusted following any applicable TDAPA period;
- 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 both IBSRELA and 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.

In the event no legislative or regulatory action is taken to further delay the inclusion of oral only ESRD related drugs in the ESRD PPS, XPHOZAH will become part of the ESRD PPS on January 1, 2025, and will no longer be separately paid for under 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 Centers for Medicare & Medicaid Services (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 prospective payment system 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. The inclusion of oral medications without injectable or intravenous equivalents in the bundled payment was initially delayed by CMS until January 1, 2014, and through several subsequent legislative actions has been delayed until January 1, 2025.

Absent further legislation or regulation on this matter, beginning in January 2025, oral ESRD-related drugs without injectable or intravenous equivalents, including XPHOZAH and all other phosphate lowering medications, will be included in the ESRD bundle and separate Medicare payment for these drugs will no longer be available, as is the case today under Medicare Part D. ESRD facilities may nonetheless receive a TDAPA for new renal dialysis drugs and biological products that meet certain criteria for a period of two years. The TDAPA payment is based on 100 percent of average sales price (ASP). If ASP is not available, then the TDAPA is based on 100 percent of wholesale acquisition cost (WAC). If WAC is unavailable, then the payment is based on the drug manufacturer's invoice. There can be no assurances that CMS will determine that XPHOZAH will qualify for TDAPA status. Even if deemed eligible by CMS, revenue for sales of XPHOZAH could be significantly less in the TDAPA period than it would be if XPHOZAH is not bundled into the ESRD PPS. Moreover, in the post-TPDAPA period, CMS currently expects to increase the single bundled payment base rate paid to the dialysis facility for each dialysis treatment to reflect that oral only phosphate lowering drugs will be reimbursed as part of the single bundled payment for Medicare patients. There can be no assurances that any increase in the single bundled payment base rate will be sufficient to adequately reimburse the dialysis facilities for XPOHZAH at a price that is profitable for us. The inclusion of XPHOZAH in the ESRD PPS would affect our ability to optimize the commercialization of XPHOZAH, will negatively and materially impact the revenue that we may generate on sales of XPHOZAH and could materially impact our profitability, results of operations, financial condition, and prospects.

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 Risk Evaluation and Mitigation Strategy (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.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the U.S., the principal decisions about coverage and reimbursement for new drugs are typically made by CMS, an agency within the United States Department of Health and Human Services responsible for administering the Medicare program, as 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. It is difficult to predict what CMS will decide with respect to reimbursement for products such as ours. Additionally, absent legislative or regulatory action, XPHOZAH, along with other oral ESRD related drugs without injectable or intravenous equivalents, will be included in the ESRD PPS beginning on January 1, 2025 at which time separate Medicare payment for these drugs will no longer be available, as is the case today under Medicare Part D. While it is too early to project the full impact that bundling may have on sales of XPHOZAH and on our business, should XPHOZAH be brought into the bundle in 2025, or at any time, we may be unable to sell XPHOZAH to dialysis providers on a profitable basis. See "*—In the event no legislative or regulatory action is taken to further delay the inclusion of oral only ESRD related drugs in the ESRD PPS, XPHOZAH will become part of the ESRD PPS on January 1, 2025, and will no longer be separately paid for under Part D, and as a result the revenue that we may generate on sales of XPHOZAH will be negatively and materially impacted*" above for a more detailed discussion related to the risks that may occur if XPHOZAH is brought into the bundle.

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 contract manufacturing organizations (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 current Good Manufacturing Practice requirements (cGMPs), 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 GMP 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.

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 with SLR (Lender) pursuant to which the Lender agreed to provide us with a loan facility for up to $50.0 million with a maturity date of March 1, 2027, and on August 1, 2022, February 9, 2023 and October 17, 2023, we entered into amendments to the loan and security agreement (collectively, the 2022 Loan Agreement). The loan was funded in the amount of $27.5 million on February 23, 2022 and an additional amount of $22.5 million was drawn on October 19, 2023. We may draw an additional $50.0 million on or before March 15, 2024, and we expect to draw this additional $50.0 million prior to expiry of the option on March 15, 2024. In addition, subject to the Lender approval of its investment committee, we may be able to draw up to an additional $50 million by December 31, 2026. 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.

We are permitted to make interest only payments on the loan facility through December 31, 2026, with principal repayments commencing on January 1, 2027. 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 Lender 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

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. For example, while the results of our Phase 2 clinical trial evaluating RDX013 for the treatment of hyperkalemia demonstrated an acceptable safety and tolerability profile for RDX013 and supported proof of concept in its ability to lower serum potassium levels, with statistically significant reductions compared to placebo after eight days of treatment, the study did not meet its primary endpoint of significantly reducing serum potassium levels compared to placebo after four weeks of treatment. We currently expect that the next step for the program will be to evaluate a new formulation that potentially enhances subject compliance and the efficacy of RDX013 in an additional Phase 2 clinical study at such time as we have determined that our available resources support conducting such an additional clinical study. There can be no assurances that any additional clinical study that we determine to conduct with RDX013 will be successful.

Additionally, if we conduct additional clinical trials with RDX013 or any other product candidates, we could encounter delays in our future development if any clinical trials are suspended or terminated by us, by the institutional review boards 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, including any additional RDX013 clinical trial 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 Contract Research Organizations (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 good clinical practices (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 European Economic Area (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 (EMA), 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.

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 chronic kidney disease (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 fermagate (Alpharen), an iron-based binder in Phase 3 being developed by Opko Health, Inc., PT20, an iron-based binder in Phase 3 being developed by Shield Therapeutics, AP-301, a binder in Phase 3 being developed by Alebund Pharmaceutical (Hong Kong) Limited, and Oxylanthanum Carbonate (OLC), which has demonstrated pharmacodynamic bioequivalence to Fosrenol. OLC is being developed by Unicycive Therapeutics, which has announced its plans to seek U.S. FDA approval via the 505(b)(2) pathway. Additionally, Chugai and Alebund are developing EOS789/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 any commercialization activities in which we may engage 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.

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 XPOHZAH. 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, clinical, medical, manufacturing, and sales and marketing 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., the Health Insurance Portability and Accountability Act of 1996, as amended, and regulations promulgated thereunder (collectively 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 California Consumer Privacy Act (CCPA) went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that has increased the likelihood of, and risk associated with data breach litigation. Further, the California Privacy Rights Act (CPRA) generally went into effect on January 1, 2023 and significantly amends the CCPA. It imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also creates a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. 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, the CPRA 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 Federal Trade Commission (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 Federal Trade Commission 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 European Union General Data Protection Regulation (GDPR) went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the European Economic Area (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 (CJEU) 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 EU-US Data Privacy Framework (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.

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 Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd. (Fosun Pharma) for commercialization of tenapanor for hyperphosphatemia and IBS-C in China and related territories; in Canada with Knight Therapeutics, Inc. (Knight) for commercialization of tenapanor for IBS-C and hyperphosphatemia; and with METiS Therapeutics, Inc. (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.

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.

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;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- 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 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 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 FDA, have had to furlough critical 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, 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 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 and other sales practices, 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 Federal Food, Drug, and Cosmetic Act, 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 prohibitions relating to the promotion of products for unapproved uses, 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 (MA). Before the MA is granted, the EMA 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 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 statutes;
- 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 Affordable Care Act (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 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 Medicaid Drug Rebate Program 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, in which manufacturers must now agree 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.

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 average manuacturer price.

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 Inflation Reduction Act of 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 (beginning 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 Department of Health and Human Services to implement many of these provisions through guidance, as opposed to regulation, for the initial years. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations. HHS has issued and will continue to issue guidance implementing the IRA, 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 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 Medicaid Drug Rebate Program 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.

With the commercial launch of IBSRELA, we participate in the Medicaid Drug Rebate Program (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 average manufacturer price (AMP) and the best price (BP) 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 BP, 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 Public Health Service's 340B drug pricing program (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 Health Resources and Services Administration (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. Department of Veterans Affairs (VA) Federal Supply Schedule (FSS) pricing program. Under the VA/FSS program, we are obligated to report the Non-Federal Average Manufacturer Price (Non-FAM") 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 United States Patent and Trademark Office (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, XPHOZAH, RDX013 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, XPHOZAH, RDX013 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. Further, we have reported that we have completed the data analysis from our Phase 2 clinical trial evaluating the safety and efficacy of RDX013 for the treatment of hyperkalemia, and that we currently expect that the next steps for the RDX013 program will be to evaluate a new formulation that potentially enhances subject compliance and the efficacy of RDX013 in an additional Phase 2 clinical study. We currently expect to delay further development of RDX013 until such time as we have determined that our available resources support conducting such additional formulation work and an additional clinical study. As a result of this delay in our development program for RDX013, the period of time during which we or our collaboration partners could market RDX013 under patent protection could be reduced.

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 noninfringment 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 a new chemical entity (NCE). The U.S. FDA is prohibited during those five years from approving an Abbreviated New Drug Application (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 (PTA) under the American Inventors Protection Act for delays by the United States Patent and Trademark Office 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 (PTE) under the Hatch-Waxman Act and together with PTA 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 European Patent Package (EU Patent Package) regulations were passed with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court (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 European 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.

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 whether XPHOZAH alone or with other oral only medications, will be included in the ESRD PPS, and the time and manner in which such transition is achieved;
- announcements relating to our current or future collaboration partnerships;
- announcements of therapeutic innovations or new products 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 XPOHZAH, 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 will no longer be a "smaller reporting company" in 2024 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 will no longer be a "smaller reporting company," in 2024 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 Securities and Exchange Commission (SEC) or other regulatory authorities, which would require additional financial and management resources.

We are not required to reflect the change in our smaller reporting company status and comply with the increased disclosure obligations until our quarterly report for the quarter ending March 31, 2024, the first quarter in our fiscal year ending December 31, 2024. We will need to reassess, as of June 30, 2024, whether we will continue to qualify as a large accelerated filer for filings beyond the fiscal year ending December 31, 2024.

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 (SVB) was closed by the California Department of Financial Protection and Innovation, which appointed the U.S. Federal Deposit Insurance Corporation (FDIC) 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 growth. Additionally, the terms of our 2022 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. Our cybersecurity program includes a cybersecurity incident response plan as well as key technology and processes required to monitor, alert and escalate in the event of malicious activity.

We design, assess and benchmark our program based on the National Institute of Standards and Technology Cybersecurity Framework (NIST CSF).

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.

Our cybersecurity program includes:

- risk assessments designed to help identify material cybersecurity risks to our critical systems, information, products, services, and our broader enterprise IT environment;
- 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 controls;
- cybersecurity awareness training of our employees, 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.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or 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 Factor— Our information technology systems, or those of our CROs or other contractors or consultants we may utilize, may fail, suffer disruptions or suffer security breaches, which could result in a material disruption of our product development programs."

Cybersecurity Governance

Our board considers cybersecurity risk as part of its risk oversight function and has delegated to the Audit and Compliance Committee (Committee) oversight of cybersecurity and other information technology risks. The Committee oversees 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 regular reports from management on our cybersecurity posture. In addition, management updates the Committee, as necessary, regarding any material cybersecurity incidents, as well as any incidents with lesser impact potential.

The Committee reports to the full Board regarding its activities, including those related to cybersecurity. The Board also receives periodic briefings from management on our cybersecurity program. The Board members receive presentations on cybersecurity topics from our IT Senior Director, internal security staff or external experts as part of the Board's continuing education on topics that impact public companies.

Our management team, including our Chief Legal Officer, Chief Financial Officer and IT Senior Director, has over a combined 50 years of risk management experience, including our IT Senior Director who has over 15 years of experience overseeing cybersecurity and risk management. 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 supervises 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

Our headquarters is currently located in Waltham, Massachusetts and consists of 17,111 square feet of leased office space under a lease agreement that expires in June 2026. In addition, we lease 72,500 square feet of office and laboratory space in Fremont, California under a lease agreement that expires in March 2025 and 4,768 square feet of office space in Milwaukee, Wisconsin under a lease agreement that expires in February 2026. Prior to October 2021, our headquarters were co-located in Fremont, California and Waltham, Massachusetts.

ITEM 3. LEGAL PROCEEDINGS

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, 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 an amended complaint on September 29, 2022. Defendants filed a motion to dismiss the amended complaint on December 2, 2022. In January and February 2023, in lieu of filing a response to defendant's motion to dismiss, plaintiffs filed a motion seeking leave to further amend their complaint and defendants filed an opposition to the motion for leave to further amend the complaint. On April 6, 2023, the court granted plaintiff's motion for leave to further amend the complaint. With the second amended complaint, 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 August 22, 2023, the court cancelled the hearing scheduled for September 14, 2023 on the motion to dismiss the amended complaint and indicated its decisions to instead rule on the filed briefs. We believe the plaintiff's claims are without merit and we have not recorded any accrual for a contingent liability associated with these legal proceedings.

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. We believe the plaintiff's claims are without merit and we have not recorded any accrual for a contingent liability associated with these legal proceedings.

From time to time, we may be involved in legal proceedings arising in the ordinary course of business. As of December 31, 2023, there is no litigation pending that would reasonably be expected to have a material adverse effect on our results of operations and financial condition, and no contingent liabilities were accrued as of December 31, 2023.

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

On June 19, 2014, our common stock commenced trading on The Nasdaq Global Market under the symbol "ARDX". Prior to that date, there was no public trading market for our common stock. As of December 31, 2023, there were 25 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", "Company", "we", "us", and "our" refer to Ardelyx, Inc.

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®, is approved in the U.S. for the treatment of adults with irritable bowel syndrome with constipation (IBS-C). Tenapanor, branded as XPHOZAH®, was approved by the U.S. Food and Drug Administration (U.S. FDA) on October 17, 2023, to reduce serum phosphorus in adults with chronic kidney disease (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 also have a development stage asset, RDX013 for adult patients with CKD and/or heart failure with hyperkalemia, or elevated serum potassium, and a discovery phase asset, RDX020 for adult patients with metabolic acidosis, a serious electrolyte disorder, in patients with CKD.

Since commencing operations in October 2007, substantially all our efforts have been dedicated to our research and development (R&D) activities, including developing tenapanor and developing our proprietary drug discovery and design platform, as well as commercialization activities, including the marketing and sales of IBSRELA and XPHOZAH. We realized our first product sales of IBSRELA in March 2022 and realized our first product sales of XPHOZAH in November 2023. As of December 31, 2023, we had an accumulated deficit of $846.2 million.

We expect to continue to incur operating losses for the foreseeable future as we invest in the commercialization of IBSRELA and XPHOZAH, incur manufacturing and development cost for tenapanor, and incur R&D costs related to potential new product candidates. To date, we have funded our operations from the sale and issuance of common stock and convertible preferred stock, funds from our collaboration partnerships, which includes license fees, milestones and product supply revenue, funds from our loan agreement with SLR Investment Corp. (SLR), as amended on August 1, 2022, February 9, 2023 and October 17, 2023 (collectively, the 2022 Loan Agreement), as well as from sales of IBSRELA and XPHOZAH.

Our Commercial Products

IBSRELA for IBS-C

Our unique discovery platform and deep understanding of the primary mechanism of sodium transport in the intestine resulted in our discovery and development of IBSRELA, a first-in-class, U.S. FDA approved, sodium hydrogen exchange 3 (NHE3) inhibitor for the treatment of IBS-C in adults. IBSRELA acts locally in the gut and is minimally absorbed. IBS-C is a gastrointestinal (GI) disorder characterized by both abdominal pain and altered bowel habits. 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. For our commercial launch of IBSRELA, we designed a market-responsive commercial strategy and built a commercial organization highly experienced in launching 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, 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 patients currently being managed for IBS-C by the approximately 9,000 high-writing healthcare providers who account for approximately 50% of IBS-C prescriptions. Central to our go to market strategy for IBSRELA has been our highly experienced specialty sales force, many with existing relationships across their GI target base, and omnichannel digital initiatives.

We expect competition for IBSRELA will come largely from the 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.

We have established commercial agreements with Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd. (Fosun Pharma) in China and Knight Therapeutics, Inc. (Knight) in Canada for IBSRELA for IBS-C. Knight is currently marketing IBSRELA in Canada. In October 2023, we announced that Fosun Pharma received approval from the Hong Kong Department of Health for the marketing application for tenapanor for the treatment of irritable bowel syndrome with constipation (IBS-C).

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

On October 17, 2023, XPHOZAH, a first-in-class phosphate absorption inhibitor, received approval from the U.S. FDA to market XPHOZAH in the U.S. to reduce serum phosphorus in adults with chronic kidney disease (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 eighty percent of those patients are being treated with phosphate lowering therapies. On average during 2020 through 2023, approximately seventy percent of patients treated with phosphate binders to treat hyperphosphatemia were unable to consistently maintain phosphorous levels <=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 November 2023. 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, 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. These dynamics enabled a targeted promotional focus on patients currently being managed for hyperphosphatemia by the approximately 8,000 nephrology healthcare providers who write approximately 80% of phosphate lowering therapy prescriptions. Central to our go to market strategy for XPHOZAH is our highly experienced specialty sales force, many with existing relationships across their nephrology target base, and innovative omnichannel digital initiatives.

XPHOZAH is indicated to reduce serum phosphorus in adults with chronic kidney disease (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 other binders in development, including fermagate (Alpharen), an iron-based binder in Phase 3 being developed by Opko Health, Inc., PT20, an iron-based binder in Phase 3 being developed by Shield Therapeutics, AP-301 in Phase 2 being developed by Alebund Pharmaceutical (Hong Kong) Limited, and Oxylanthanum Carbonate (OLC), which has demonstrated pharmacodynamic bioequivalence to Fosrenol. OLC is being developed by Unicycive Therapeutics, which has announced its plans to seek U.S. FDA approval via the 505(b)(2) pathway. Additionally, Chugai and Alebund are developing EOS789, an inhibitor of phosphate transporters NaPi-2b, PiT-1, and PiT-2, thus far studied in a phase 1 clinical trial.

In November 2023, XPHOZAH was granted orphan drug designation by the U.S. FDA for the treatment of pediatric hyperphosphatemia.

We have established commercial agreements with Kyowa Kirin, Co. Ltd. (Kyowa Kirin) in Japan, Fosun Pharma in China and Knight in Canada for tenapanor for hyperphosphatemia. In July 2023, we announced that a New Drug Application (NDA) for tenapanor had been accepted for review by China's Center for Drug Evaluation of the National Medical Products Administration (NMPA) for the control of serum phosphorus in adult patients with CKD on hemodialysis. In September 2023, we announced that Kyowa Kirin received approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) for the NDA for tenapanor for the improvement of hyperphosphatemia in adult patients with CKD on dialysis.

Discovery and Developmental Assets

We have a small molecule potassium secretagogue program, RDX013, for the potential treatment of hyperkalemia, or elevated serum potassium. Hyperkalemia is a common problem in patients with heart and kidney disease, particularly in patients taking customary blood pressure medications known as renin-angiotensin-aldosterone system (RAAS) inhibitors. RDX013 is a novel mechanism agent designed to target the underlying biological mechanisms of potassium secretion to lower elevated potassium. We have completed a Phase 2 dose ranging clinical trial evaluating the safety and efficacy of RDX013 for the treatment of hyperkalemia in CKD patients who are not on dialysis. While the results of the study demonstrated an acceptable safety and tolerability profile for RDX013 and supported proof of concept in its ability to lower serum potassium levels, with statistically significant reductions compared to placebo after eight days of treatment, the study did not meet its primary endpoint of significantly reducing serum potassium levels compared to placebo after four weeks of treatment.

We have a discovery program targeting the inhibition of the chloride bicarbonate exchanger for the treatment of metabolic acidosis, a highly prevalent comorbidity in CKD patients that is strongly correlated with disease progression and adverse outcomes. We have identified lead compounds that are potent, selective and proprietary inhibitors of bicarbonate secretion.

We do not currently expect to meaningfully advance either of these two assets until such time as we have determined our available resources can support additional activities after prioritization of the commercialization of IBSRELA and XPHOZAH.

Collaboration Partners

We have exclusive rights to tenapanor in the U.S. and we have established 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.

In March 2018, we entered into an exclusive license agreement with Knight (Knight Agreement) for the development, commercialization and distribution of tenapanor in Canada for hyperphosphatemia and IBS-C. In March 2021, Knight announced the commercial availability of IBSRELA in Canada, following its approval by Health Canada in April 2020. Under the terms of the Knight Agreement, Knight paid us a $2.3 million non-refundable, one-time payment in March 2018. We may also be eligible to receive approximately CAD 22.2 million for development and commercialization milestones, or approximately $16.7 million at the currency exchange rate on December 31, 2023, of which $0.7 million has been received and recognized as revenue as of December 31, 2023. We are also eligible to receive royalties throughout the term of the agreement, and a transfer price for manufacturing services.

In November 2017, we entered into an exclusive license agreement with Kyowa Kirin (2017 Kyowa Kirin Agreement) for the development, commercialization and distribution of tenapanor in Japan for cardiorenal indications. Under the terms of the 2017 Kyowa Kirin Agreement, we received a $30.0 million upfront payment from Kyowa Kirin, and we may be entitled to receive up to $55.0 million in total development and regulatory milestones, of which $35.0 million has been recognized as revenue and received as of December 31, 2023. We may also be eligible to receive approximately ¥8.5 billion for commercialization milestones, or approximately $60.3 million at the currency exchange rate on December 31, 2023, as well as reimbursement of costs plus a reasonable overhead for the supply of product and royalties on net sales throughout the term of the agreement. 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 2017 Kyowa Kirin Agreement will be remitted to HealthCare Royalty Partners IV, L.P. pursuant to a Royalty and Sales Milestone Interest Acquisition Agreement.

On April 11, 2022, we entered into a second amendment to the 2017 Kyowa Kirin Agreement (2022 Amendment). Under the terms of the 2022 Amendment, we and Kyowa Kirin agreed to a reduction in the royalty rate payable to us by Kyowa Kirin upon net sales of tenapanor in Japan. The royalty rate was reduced from the 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. As discussed in *Note 8. Deferred Royalty Obligation Related to the Sale of Future Royalties*, the future royalties we may receive under the 2017 Kyowa Kirin Agreement will be remitted to HealthCare Royalty Partners IV, L.P. pursuant to a Royalty and Sales Milestone Interest Acquisition Agreement. As consideration for the reduction in the royalty rate, Kyowa Kirin agreed to pay us up to an additional $40.0 million which has been received and recognized as revenue as of September 2023 as described below.

In October 2022, we announced that Kyowa Kirin submitted an NDA to the Japanese MHLW for tenapanor for the improvement of hyperphosphatemia in adult patients with CKD on dialysis, which resulted in payment to us from Kyowa Kirin for an aggregate of $35.0 million for milestone payments and payments under the 2022 Amendment.

In September 2023, we announced that Kyowa Kirin received approval from the Japanese MHLW for the NDA for tenapanor for the improvement of hyperphosphatemia in adult patients with chronic kidney disease on dialysis, which resulted in payment to us from Kyowa Kirin for an aggregate of $30.0 million for milestone payments and payments under the 2022 Amendment.

In December 2017, we entered into an exclusive license agreement with Fosun Pharma (Fosun Agreement) for the development and commercialization of tenapanor in China for both hyperphosphatemia and IBS-C. Under the terms of the Fosun Agreement, Fosun paid us a $12.0 million upfront license fee. In July 2023, we announced that an NDA for tenapanor had been accepted for review by China's Center for Drug Evaluation of the NMPA for the control of serum phosphorus in adult patients with chronic kidney disease on hemodialysis. This acceptance triggered a $2.0 million milestone payment to us under the terms of the Fosun Agreement, which we received in the third quarter of 2023.

In October 2023, we announced that the U.S. FDA has approved 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. This triggered an additional $3.0 million milestone payment to us under the terms of the Fosun Agreement, which was received during the first quarter of 2024. Also, in October 2023, we announced that Fosun Pharma received approval from the Hong Kong Department of Health for the marketing application for tenapanor for the treatment of irritable bowel syndrome with constipation (IBS-C). We may be entitled to receive development and commercialization milestones of up to $113.0 million, of which $8.0 million has been recognized as revenue and $5.0 million has been received as of December 31, 2023 and $3.0 million was received in January 2024, as well as 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%.

FINANCIAL OPERATIONS OVERVIEW

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. We realized our first commercial product sales of IBSRELA beginning in March 2022 and our first commercial product sales of XPHOZAH in November 2023. 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, among other factors: the extent to which we are successful in our commercialization of IBSRELA and XPHOZAH; our ability to obtain and sustain an adequate level of coverage and reimbursement for IBSRELA and XPHOZAH by third-party payors; whether and the extent to which we are successful in our commercialization of XPHOZAH; whether or when XPHOZAH, along with other oral ESRD-related drugs without an injectable or intravenous equivalent, are bundled into the end stage renal disease prospective payment system (ESRD PPS), and the manner in which such introduction into the ESRD PPS may occur, including the length of any applicable Transitional Drug Add-on Payment Adjustment (TDAPA) period, the amount of the add-on payment available during the TDAPA period and whether, and the extent to which, the ESRD PPS base rate is adjusted following any applicable TDAPA period; the timing and progress of goods and services provided pursuant to our current or future collaborative partnerships; our collaborators' achievement of clinical, regulatory or commercialization milestones, to the extent achieved; the timing and amount of any payments to us relating to the aforementioned milestones; 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; attracting, hiring, and retaining qualified personnel; and the extent to which tenapanor or other licensed products are approved and successfully commercialized by a collaboration partner. If our current collaboration partners or any future collaboration partners fail to obtain regulatory approval for tenapanor or other licensed products, our ability to generate future revenue from our collaborative arrangements, and our results of operations and financial position, would be materially and adversely affected. Our past revenue performance is not necessarily indicative of results to be expected in future periods.

Cost of Goods Sold

Cost of product sales consists of the cost of commercial goods sold to our Customers. Other cost of revenue consists of the cost of materials sold to our international partners under product supply agreements, as well as payments due to AstraZeneca AB (AstraZeneca) based on sales of tenapanor. We capitalize inventory costs associated with the production of our products after regulatory approval or when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. Otherwise, such costs are expensed as research and development. A portion of the costs of IBSRELA and XPHOZAH units recognized as revenue during the years ended December 31, 2023 and 2022 were expensed in periods prior to the commencement of capitalization of inventory costs for each respective product. We believe our cost of goods sold for the years ended December 31, 2023 and 2022 would have been $4.4 million and $1.9 million higher, respectively, if we had not previously expensed certain material and production costs with respect to the units sold. As of December 31, 2023 and December 31, 2022, we had approximately $21.8 million and $28.0 million, respectively, of inventory on hand that was previously expensed as research and development expense and will not be reported as cost of goods sold in future periods when sales of IBSRELA and XPHOZAH are recognized as revenue.

Other cost of revenue includes payments due to AstraZeneca, which under the terms of a termination agreement entered into in 2015 (AstraZeneca Termination Agreement) is entitled to (i) future royalties at a 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 our collaboration partners in connection with the development and commercialization of tenapanor or other NHE3 products. We have agreed to pay AstraZeneca up to a maximum of $75.0 million in the aggregate for (i) and (ii). We recognize these expenses as other cost of revenue when we recognize the corresponding revenue that gives rise to payments due to AstraZeneca. To date, we have recognized an aggregate of $27.6 million as other cost of revenue under the AstraZeneca Termination Agreement. See details in *Note 7, Collaboration and Licensing Agreements*, under AstraZeneca, in the notes to our financial statements, included in Part II, Item 8, of this Annual Report on Form 10-K.

Research and Development

We recognize all R&D expenses as they are incurred to support the discovery, research, development and manufacturing of our product candidates. R&D expenses include, but are not limited to, the following:

- external research and development expenses incurred under agreements with consultants, third-party contract research organizations (CROs) and investigative sites where a substantial portion of our clinical studies are conducted, and with contract manufacturing organizations where our clinical supplies are produced;
- expenses associated with supplies and materials consumed in connection with our research operations;
- expenses associated with producing XPHOZAH prior to U.S. FDA approval;
- expenses associated with producing discovery and developmental assets prior to U.S. FDA approval;
- other costs associated with research, clinical development and regulatory activities;
- employee-related expenses, which include salaries, bonuses, benefits, travel and stock-based compensation; and
- facilities 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.

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.

Interest Expense

Interest expense represents the interest associated with on our 2022 Loan Agreement.

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. As further described in *Note 8. Deferred Royalty Obligation Related to the Sale of Future Royalties*, in June 2022, we and HealthCare Royalty Partners IV, L.P. (HCR) entered into a Royalty and Sales Milestone Interest Acquisition Agreement (HCR Agreement). Under the terms of the HCR Agreement, HCR agreed to pay us up to $20.0 million in exchange for the royalty payments and commercial milestone payments (collectively the Royalty Interest Payments) that we may receive under our 2017 License Agreement with Kyowa Kirin based upon Kyowa Kirin's net sales of tenapanor in Japan for hyperphosphatemia. As part of the HCR Agreement, we have received a $10.0 million upfront payment and a $5.0 million milestone payment from HCR, which we recorded as a deferred royalty obligation on our balance sheet. Non-cash interest expense will be recognized over the life of the HCR Agreement using the effective interest method based on the imputed interest rate derived from estimated amounts and timing of future royalty payments to be received from Kyowa Kirin.

Other Income, net

Other income, net consists of interest income earned on our cash, cash equivalents and available-for-sale investments, the periodic revaluation of the exit fee related to our 2022 Loan Agreement, gains on sales of property and equipment, and currency exchange gains and losses.

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 taxes reflect the tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Our deferred tax assets continue to be fully offset by a valuation allowance, including deferred tax assets related to our net operating loss carryforwards, which may be subject to annual limitations as a result of ownership changes that may have occurred or could occur in the future.

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. Critical accounting policies are those that require significant judgment and/or estimates by management at the time that financial statements are prepared such that materially different results might have been reported if other assumptions had been made. These estimates form the basis for making judgments about the carrying values of assets and liabilities. We base our estimates and judgments on experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ materially from these estimates.

We consider certain accounting policies related to revenue recognition, inventory, accrued research and development expenses to be critical policies to understanding the judgments and estimates applied in our reported financial results.

Product Sales, Net

We account for our commercial product sales, net in accordance with Topic 606 – *Revenue from Contracts with Customers*. We received approval from the FDA to market IBSRELA in the U.S. in September 2019 and to market XPHOZAH in the U.S. in October 2023. We began selling IBSRELA and XPHOZAH in the U.S. in March 2022 and November 2023, respectively. We distribute IBSRELA principally through major wholesalers, specialty pharmacies and group purchasing organizations (GPOs) (collectively, our IBSRELA Customers). XPHOZAH is principally distributed through a specialty wholesaler (XPHOZAH Customer) to select specialty pharmacies (collectively, IBSRELA Customers and XPHOZAH Customers, “Customers”). Our Customers subsequently sell IBSRELA and XPHOZAH to pharmacies and patients. Separately, we enter into arrangements with third parties that provide for government-mandated rebates, chargebacks and discounts. Revenue from product sales is recognized when our performance obligations are satisfied, which is when Customers obtain control of our product and occurs upon delivery.

Reserves for Variable Consideration

Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration which may be settled in the form of off-invoice discounts, chargebacks, or rebates. Variable consideration includes discounts to customers and government programs, wholesaler fees, group purchasing organization administrative fees, patient copay assistance, and estimated product returns. These estimates are based on the amounts earned or to be claimed for related sales and are classified as reductions of gross accounts receivable if settlement is expected to occur through a reduction in the amounts paid by our Customers or a current liability if settlement is expected to occur through a payment from us. Where appropriate, these estimates are based on factors such as industry data and forecasted customer buying and payment patterns, our experience, current contractual and statutory requirements, specific known market events and trends. These reductions to gross sales reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. Variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we adjust these estimates, which would affect product revenue and earnings in the period such variances become known. As we gain more experience, estimates will be more heavily based on the expected utilization from historical data we have accumulated since the IBSRELA and XPHOZAH product launches. Changes in estimates recorded through December 31, 2023 have not been material.

Rebates: Rebates include wholesaler fees, GPO fees, as well as mandated discounts under the Medicaid Drug Rebate Program (Medicaid) and the Medicare Coverage Gap Program (Medicare). Estimates for rebates are recorded in the same period the related gross revenue is recognized, resulting in a reduction of product revenue. We estimate our Medicaid and Medicare rebates based upon the estimated payor mix, and statutory discount rates. Our estimates for payor mix are guided by payor information received from specialty pharmacies, expected utilization for wholesaler sales to pharmacies, and available industry payor information and therefore require the most estimation and judgment of our gross to net deductions.

Chargebacks: Chargebacks are discounts that occur when certain contracted purchasers purchase directly from our wholesalers at a discounted price. The wholesaler, in turn, charges back the difference between the price initially paid to us by the wholesaler and the discounted price paid to the wholesaler by the contracted purchaser. Amounts for estimated chargebacks are established in the same period that the related gross revenue is recognized, resulting in a reduction of product revenue and accounts receivable. The accrual for wholesaler chargebacks is estimated based on known chargeback rates, known sales to wholesalers, and known sales from wholesalers to their chargeback-eligible customers.

Discounts and Fees: Our payment terms are generally 30 to 60 days. Wholesalers, GPOs and specialty pharmacies are offered various forms of consideration, including off-invoice discounts which may be paid to GPOs and specialty pharmacies. Wholesalers and GPOs may also receive prompt pay discounts for payment within a specified period. We expect discounts to be earned when offered and therefore, we deduct the full amount of these discounts from product sales when revenue is recognized, resulting in a reduction of product revenue and accounts receivable.

Other Reserves: 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 will be provided to patients associated with product which we have sold but which has not yet been dispensed to commercial patients, which requires significant estimation and judgment. Our estimates are recorded in accounts payable and accrued expenses and other current liabilities on the balance sheets. Other reserves include estimated product returns which are recorded in the same period the related gross revenue is recognized, resulting in a reduction of product revenue as well as accounts receivable. We estimate our product returns reserve based upon our experience and specific known market events and trends. As we have experienced limited product returns, establishing the appropriate level of product returns reserve require estimation and judgment.

Collaboration Revenue Recognition

We generate collaboration revenue primarily from research and collaboration and license agreements with customers. Goods and services in the agreements may include the grant of licenses for the use of our technology, the provision of services associated with the research and development of product candidates, manufacturing services, and participation in joint steering committees. The terms of these arrangements typically include payment to us of one or more of the following: non-refundable, up-front license fees; research, development, regulatory and commercial milestone payments; reimbursement of research and development services; option payments; reimbursement of certain costs; payments for manufacturing supply services; and future royalties on net sales of licensed products.

As part of the accounting for contracts with customers, we develop assumptions that require judgment to determine whether promised goods and services represent distinct performance obligations and the standalone selling price for each performance obligation identified in the contract. Determining the standalone selling price for performance obligations requires significant judgment, and when an observable price of a promised good or service is not readily available, we consider relevant assumptions to estimate the standalone selling price, including, as applicable, market conditions, development timelines, probabilities of technical and regulatory success, reimbursement rates for personnel costs, forecasted revenues, potential limitations to the selling price of the product and discount rates. We also use judgment to evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such development milestones and any related constraints, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect earnings in the period of adjustment.

Inventory

We capitalize inventory costs associated with the production of our products after regulatory approval or when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. Otherwise, such costs are expensed as research and development. Prior to the regulatory approval of drug product candidates, we incurred expenses for the manufacture of drug product that could potentially be available to support the commercial launch of our products or could be sold to our international partners under product supply agreements. 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 commercial launch of IBSRELA, which was when it was determined that the inventory had a probable future economic benefit. 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., which was when it was determined that the inventory had a probable future economic benefit.

Inventory is stated at the lower of cost or estimated net realizable value with cost determined under the specific identification method. Inventory costs include 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. We primarily use actual costs to determine the cost basis for inventory, and therefore there is limited estimation or judgment involved. The determination of whether inventory costs will be realizable requires management review of the expiration dates of IBSRELA and XPHOZAH compared to our forecasted sales. If actual market conditions are less favorable than projected by management, write-downs of inventory may be required, which would be recorded as cost of revenue in the statement of operations and comprehensive loss. As of December 31, 2023, we have not recorded any write-downs for excess and obsolete inventory.

Accrued Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process 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 in our financial statements 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.

In accruing service fees, we estimate the time period over which each component of a service will be performed, and estimate, 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 of services performed 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.

RESULTS OF OPERATIONS

Comparison of the Years Ended December 31, 2023, 2022 and 2021

Revenue

Below is a summary of our total revenue (dollars in thousands):

	Year Ended December 31,			Change 2023 vs. 2022		Change 2022 vs. 2021	
	2023	2022	2021	$	%	$	%
Product sales, net	$ 82,526	$ 15,600	$ —	$ 66,926	429 %	$ 15,600	(a)
Licensing revenue	35,809	35,031	5,013	778	2 %	30,018	599 %
Collaborative development revenue	—	—	4,177	—	(a)	(4,177)	(100)%
Product supply revenue	6,121	1,527	907	4,594	301 %	620	68 %
Total revenues	$ 124,456	$ 52,158	$ 10,097	$ 72,298	139 %	$ 42,061	417 %

(a) Percent change is not meaningful.

Below is a summary of our net product sales by product (dollars in thousands):

	Year Ended December 31,		
	2023	2022	2021
Product sales, net:			
IBSRELA	$ 80,062	$ 15,600	$ —
XPHOZAH	2,464	—	—
Total product sales, net	$ 82,526	$ 15,600	$ —

Fiscal 2023 compared to 2022:

The increase in product sales, net during the year ended December 31, 2023 as compared to the same period in 2022 is primarily attributable to increased net product sales for IBSRELA and is primarily volume based as 2023 was a full year of sales while IBSRELA sales commenced in March of 2022. IBSRELA sales volumes increased in 2023 as awareness and prescriber experience with the product continued to grow following its commercial launch in March 2022. Commercial sales of XPHOZAH commenced in November 2023.

Licensing revenue during the year ended December 31, 2023 was comparable to the same period in 2022. During the year ended December 31, 2023, we earned an aggregate of $30.0 million for milestones under the 2017 Kyowa Kirin Agreement and payments under the 2022 Kyowa Kirin Amendment upon approval from the Japanese MHLW for the NDA for tenapanor for the improvement of hyperphosphatemia in adult patients with CKD on dialysis. We also earned an aggregate of $5.0 million in milestones under the terms of the Fosun Agreement upon acceptance of the NDA for tenapanor by China's Center for Drug Evaluation of the NMPA for 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.

The increase in product supply revenue during the year ended December 31, 2023 as compared to the same periods in 2022 is attributable to increased product supply revenue to Kyowa Kirin.

Fiscal 2022 compared to 2021:

The increase in product sales, net during the year ended December 31, 2022 as compared to the same period in 2021 is attributable to net product sales for IBSRELA that commenced in March 2022.

The increase in licensing revenue during the year ended December 31, 2022 as compared to the same period in 2021 is attributable to an aggregate of $35.0 million in milestone payments and payments under the second amendment to the 2017 KKC Agreement which we earned upon Kyowa Kirin's submission of a New Drug Application to the Japanese MLHW for tenapanor for the improvement of hyperphosphatemia in adult patients with CKD on dialysis.

The decrease in collaborative development revenue during the year ended December 31, 2022 as compared to the same period in 2021 is attributable to the full recognition of collaborative development revenue for upfront payments associated with the 2019 Kyowa Kirin Agreement through the end of 2021.

The increase in product supply revenue during the year ended December 31, 2022 as compared to the same period in 2021 is attributable to increased product supply revenue in connection with the 2017 Kyowa Kirin Agreement.

Cost of Goods Sold

Below is a summary of our cost of goods sold (dollars in thousands):

	Year Ended December 31,			Change 2023 vs. 2022		Change 2022 vs. 2021	
	2023	2022	2021	$	%	$	%
Cost of product sales	2,323	566	—	1,757	310 %	566	(a)
Other cost of revenue	15,472	3,551	1,000	11,921	336 %	2,551	255 %
Total cost of goods sold	$ 17,795	$ 4,117	$ 1,000	$ 13,678	332 %	$ 3,117	312 %

(a) Percent change is not meaningful.

Fiscal 2023 compared to 2022:

The increase to cost of product sales for the year ended December 31, 2023 as compared to the same period in 2022 is primarily attributable to cost of goods sold for increased net product sales of IBSRELA.

The increase to other cost of revenue for the year ended December 31, 2023 as compared to the same period in 2022 is primarily attributable to payments due to AstraZeneca under the AstraZeneca Termination Agreement, which include a percentage of milestones earned, as well as cost of goods sold for increased product supply sold to our international partners.

Fiscal 2022 compared to 2021:

The increase to cost of product sales for the year ended December 31, 2022 as compared to the same period in 2021 was primarily attributable to $0.5 million for the cost of goods sold for product sales of IBSRELA during year ended December 31, 2022.

The increase in other cost of revenue for the year ended December 31, 2022 as compared to the same period in 2021 was primarily attributable to payments due to AstraZeneca under the AstraZeneca Termination Agreement for IBSRELA product sales, net and for the milestone payment we received under the second amendment to the 2017 Kyowa Kirin Agreement, which we earned upon Kyowa Kirin's submission of a NDA to the Japanese MHLW for tenapanor for the improvement of hyperphosphatemia in adult patients with CKD on dialysis.

Operating Expenses

Below is a summary of our operating expenses (dollars in thousands):

	Year Ended December 31,			Change 2023 vs. 2022		Change 2022 vs. 2021	
	2023	2022	2021	$	%	$	%
Research and development	35,536	35,201	91,140	335	1 %	(55,939)	(61)%
Selling, general and administrative	134,401	76,599	72,303	57,802	75 %	4,296	6 %
Total operating expenses	$ 169,937	$ 111,800	— $ 163,443	$ 58,137	52 %	$ (51,643)	(32)%

Research and Development

Below is a summary of our research and development expenses (dollars in thousands):

	Year Ended December 31,			Change 2023 vs. 2022		Change 2022 vs. 2021	
	2023	2022	2021	$	%	$	%
External R&D expenses	$ 13,450	$ 13,378	$ 56,747	$ 72	1 %	$ (43,369)	(76)%
Employee-related expenses	17,391	15,065	27,268	2,326	15 %	(12,203)	(45)%
Facilities, equipment and depreciation expenses	2,901	3,097	5,803	(196)	(6)%	(2,706)	(47)%
Other	1,794	3,661	1,322	(1,867)	(51)%	2,339	177 %
Total research and development expenses	$ 35,536	$ 35,201	$ 91,140	$ 335	1 %	$ (55,939)	(61)%

Fiscal 2023 compared to 2022:

The change in our R&D expenses for the year ended December 31, 2023 as compared to the same period in 2022 is primarily the result of clinical trial and pharmacovigilance activities related to IBSRELA.

Fiscal 2022 compared to 2021:

The decrease in our external R&D expenses for the year ended December 31, 2022 as compared to the same period in 2021 was primarily the result of lower clinical study costs following the completion of the OPTIMIZE study, lower tenapanor manufacturing expense as we began to capitalize costs associated with the production of IBSRELA to inventory, and lower expenses for research following the elimination of our internal research organization in the fourth quarter of 2021. The decrease in our employee-related expenses for the year ended December 31, 2022 is due to lower compensation and benefits expenses for our research and development workforce following restructuring actions in 2021. Similarly, the decrease in facilities, equipment and depreciation expenses is primarily due to a smaller proportion of such expenses being attributed to R&D following the restructuring in 2021. The increase in other expenses is primarily related to disease-related education grants during the year ended December 31, 2022.

Selling, General and Administrative

Fiscal 2023 compared to 2022:

The increase in selling, general and administrative expenses for the year ended December 31, 2023 as compared to the same period in 2022 is primarily due to increased costs associated with the commercial launches of IBSRELA and XPHOZAH and increases in expenses associated with administrative support functions as our company has grown in headcount and activity level. The increases consisted of headcount and related personnel costs and external spending for disease awareness initiatives, commercial infrastructure and strategy.

Fiscal 2022 compared to 2021:

The increase in selling, general and administrative expenses for the year ended December 31, 2022 as compared to the same period in 2021 was primarily due to increased costs associated with the commercial launch of IBSRELA. The changes consisted of headcount and related personnel costs and external spending for disease awareness initiatives, commercial infrastructure and strategy. These increases were partially offset by a reduction in ongoing costs as a result of the restructuring action carried out during the third quarter of 2021.

Interest Expense

Below is a summary of our interest expense (dollars in thousands):

	Year Ended December 31,			Change 2023 vs. 2022		Change 2022 vs. 2021	
	2023	2022	2021	$	%	$	%
Interest expense	$ (4,950)	$ (3,400)	$ (4,502)	$ (1,550)	45.6 %	$ 1,102	(24.5)%

Fiscal 2023 compared to 2022:

The increase in interest expense for the year ended December 31, 2023 as compared to the same period in 2022 is due to a higher variable interest rate applied to our loan balance primarily resulting from market fluctuations, as well as a larger loan balance outstanding following the draw of an additional $22.5 million for the Term B Loan in October 2023.

Fiscal 2022 compared to 2021:

The decrease in interest expense for the year ended December 31, 2022 as compared to the same period in 2021 was due to lower principal outstanding on our loan payable in 2022 than in 2021 due to principal payments made on our 2018 Loan during the fourth quarter of 2021 through February 2022. In February 2022, we repaid the remaining outstanding principal balance of the 2018 Loan in the amount of $25.0 million and entered into the new 2022 Loan in the amount of $27.5 million.

Non-Cash Interest Expense Related to the Sale of Future Royalties

Below is a summary of our non-cash interest expense related to the sale of future royalties (dollars in thousands):

	Year Ended December 31,			Change 2023 vs. 2022		Change 2022 vs. 2021	
	2023	2022	2021	$	%	$	%
Non-cash interest expense related to the sale of future royalties	$ (3,924)	$ (1,673)	$ —	$ (2,251)	135 %	$ (1,673)	(a)

(a) Percent change is not meaningful.

Fiscal 2023 compared to 2022:

Non-cash interest expense related to the sales of future royalties for the year ended December 31, 2023 is accrued on the deferred royalty obligation that we recorded following the receipt of the $10.0 million upfront payment and the $5.0 million milestone payment received from HCR during June 2022 and October 2023, respectively. We recognized a full twelve months of expense during the year ended December 31, 2023 compared to approximately six months of expense during the year ended December 31, 2022.

Fiscal 2022 compared to 2021:

Non-cash interest expense related to the sale of future royalties reflects the recognized amortization of the deferred royalty obligation that we recorded following the receipt of the $10.0 million upfront payment from HCR in June 2022.

Other Income, net

Below is a summary of our other income, net (dollars in thousands):

	Year Ended December 31,			Change 2023 vs. 2022		Change 2022 vs. 2021	
	2023	2022	2021	$	%	$	%
Other income, net	$ 6,630	$ 1,633	$ 687	$ 4,997	306 %	$ 946	138 %

Fiscal 2023 compared to 2022:

The increase in other income, net for the year ended December 31, 2023 as compared to the same period in 2022 is primarily due to increased income on our investments resulting from both higher interest rates and larger investment balances throughout the period.

Fiscal 2022 compared to 2021:

The increase in other income, net for the year ended December 31, 2022 as compared to the same period in 2021 was primarily due to sales of certain lab equipment and supplies for a net gain of $1.5 million and increased investment income during the year ended December 31, 2022. Partially offsetting these increases were fluctuations related to revaluation of our exit fees.

LIQUIDITY AND CAPITAL RESOURCES

Below is a summary of our cash, cash equivalents and short-term investments (in thousands):

	Year Ended December 31,		Change 2023 vs. 2022	
	2023	2022	$	%
Cash and cash equivalents	$ 21,470	$ 96,140	$ (74,670)	(78)%
Short-term investments	162,829	27,769	135,060	486 %
Total liquid funds	$ 184,299	$ 123,909	$ 60,390	49 %

As of December 31, 2023, we had cash, cash equivalents and short-term investments of approximately $184.3 million.

In August 2021, we filed a prospectus supplement under a Registration Statement which was filed in July 2020 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 was authorized for issuance and sale, from time to time, under a sales agreement (2021 Open Market Sales Agreement) we entered into with Jefferies LLC (Jefferies), pursuant to which we, from time to time, sold up to $150.0 million in shares of our common stock through Jefferies. Pursuant to the 2021 Open Market Sales Agreement, Jefferies, as our sales agent, received a commission of up to 3.0% of the gross sales price for shares of common stock sold under the 2021 Open Market Sales Agreement. As of March 2023, we had received the maximum gross proceeds of $150.0 million under the 2021 Open Market Sales Agreement at a weighted average share price of approximately $1.57 per share, which included 15.5 million shares of our common stock for which we received gross proceeds of $51.9 million at a weighted average share price of approximately $3.35 during the quarter ended March 31, 2023.

In January 2023, we filed a Form S-3 Registration Statement, which became effective in January 2023 (2023 Registration Statement), 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. During the year ended December 31, 2023, we 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 per share.

In February 2022, we entered into a loan and security agreement (2022 Loan Agreement) with SLR Investment Corp (SLR). The 2022 Loan Agreement was subsequently amended on August 1, 2022 and February 9, 2023. The 2022 Loan Agreement as amended through February 9, 2023 provides for a senior secured term loan facility, with $27.5 million funded at closing (the Term A Loan) and an additional $22.5 million that we could borrow 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 (the Term B Loan).

The initial funding of $27.5 million was used to repay the 2018 Loan and is funding our ongoing operations. We had $25.0 million principal from the 2018 Loan outstanding as of the closing date, as well as the 2018 Exit Fee in the amount of $1.5 million. We paid the 2018 Exit Fee in October 2023 following approval from the U.S. FDA for XPHOZAH to reduce serum phosphorus in adults with chronic kidney disease (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. As discussed in *Note 10. Derivative Liabilities*, in connection with entering into the 2022 Loan Agreement, we entered into the 2022 Exit Fee agreement, as amended, whereby we agreed to pay an exit fee in the amount of 2% of the amounts funded for the Term A Loan and Term B Loan by SLR if certain conditions are met. Notwithstanding the prepayment or termination of the 2022 Loan, the 2022 Exit Fee will expire on February 23, 2032.

In October 2023, we entered into a Third Amendment (the Third Amendment) to the 2022 Loan Agreement by and between us and the 2022 Lenders. As discussed in *Note 9. Borrowing*, the Third Amendment, among other things, (1) provides us with the option to draw an additional $50.0 million of committed capital by March 15, 2024 (the Term C Loan); (2) provides us with the option to draw up to an additional $50.0 million of uncommitted capital, subject to approval by the Agent's investment committee (the Term D Loan); and (3) extends the interest-only period for the Four Loans to December 31, 2026, effective upon our decision to draw the Term B Loan in the amount of $22.5 million. In October 2023, we provided the Agent with notice of our decision to draw the Term B Loan to support the commercial launch of XPHOZAH and received the proceeds of the Term B Loan. We expect to provide the Agent with notice of our decision to draw the Term C Loan prior to the expiry of the option on March 15, 2024 to further support the commercial launch of XPHOZAH.

In October 2022, we announced that our collaboration partner, Kyowa Kirin, submitted an NDA to the Japanese MHLW for tenapanor for the improvement of hyperphosphatemia in adult patients with CKD on dialysis. In accordance with the terms of the 2022 Amendment, Kyowa Kirin paid an aggregate of $35.0 million to us in milestone payments and payments associated with the 2022 Amendment during the quarter ended December 31, 2022.

In September 2023, we announced that Kyowa Kirin received approval from the Japanese MHLW for the NDA for tenapanor for the improvement of hyperphosphatemia in adult patients with chronic kidney disease on dialysis, which resulted in payment to us from Kyowa Kirin for an aggregate of $30.0 million for milestone payments and payments under the 2022 Amendment and entitled us to a $5.0 million payment under the terms of the HCR Agreement. We received these payments in October 2023.

We have incurred operating losses since inception in 2007 and our accumulated deficit as of December 31, 2023 is $846.2 million. Our primary sources of cash have been from the sale and issuance of common stock (in both public offerings and private placements), private placements of convertible preferred stock, funds from our collaboration partnerships, funds from our 2018 Loan Agreement, as amended, and 2022 Loan Agreement, as amended, as well as from sales of IBSRELA and XPHOZAH. Our primary uses of cash have been to fund operating expenses, including research and development expenditures, pre-commercial and commercial expenses. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

Between December 31, 2021 and September 30, 2023, our liquidity position raised substantial doubt about our ability to continue as a going concern. We have addressed our operating cash flow requirements through cash generated from product sales of IBSRELA and XPHOZAH, proceeds from the sale of shares of our common stock under our at-the-market offering, from the receipt of milestones payments from our collaboration partners and payments from Kyowa Kirin under the 2022 Amendment to our License Agreement, which were received in October 2023, and from proceeds of the Term B Loan. We believe our available cash, cash equivalents and short-term investments as of December 31, 2023 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, including, but not limited to:

- the extent to which we are able to generate product revenue from sales of IBSRELA and XPHOZAH;
- the availability of adequate third-party reimbursement for IBSRELA and XPHOZAH;
- the manufacturing, selling and marketing costs associated with IBSRELA and XPHOZAH;
- whether or when XPHOZAH, along with other oral ESRD-related drugs without an injectable or intravenous equivalent, are bundled into the ESRD prospective payment system (ESRD PPS), the manner in which such introduction into the ESRD PPS may occur, including the length of any applicable TDAPA period and the amount of the add-on payment available during the TDAPA period and whether, and the extent to which, the ESRD PPS base rate is adjusted following any applicable TDAPA period;
- 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 cash requirements for the discovery and/or development of other potential product candidates, including RDX013 and RDX020;
- 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 the 2022 Loan Agrememt, as amended to date.

Please see the risk factors set forth in Part I, Item 1A, Risk Factors, in this Annual Report on Form 10-K for additional risks associated with our capital requirements.

CASH FLOW ACTIVITIES

The following table summarizes our cash flows for the periods indicated (in thousands):

	Year Ended December 31,			Change 2023 vs. 2022		Change 2022 vs. 2021	
	2023	2022	2021	$	%	$	%
Net cash used in operating activities	$ (89,717)	$ (70,044)	$ (152,551)	$ (19,673)	28 %	$ 82,507	(54)%
Net cash (used in) provided by investing activities	(131,248)	18,415	50,948	(149,663)	(813)%	(32,533)	(64)%
Net cash provided by financing activities	146,295	75,341	82,999	70,954	94 %	(7,658)	(9)%
Net (decrease) increase in cash and cash equivalents	$ (74,670)	$ 23,712	$ (18,604)	$ (98,382)	(415)%	$ 42,316	(227)%

Cash Flows from Operating Activities

Fiscal 2023 compared to 2022:

Net cash used in operating activities during the year ended December 31, 2023 increased by $19.7 million as compared to the same period in 2022 primarily as a result of changes in our working capital, including a $13.8 million increase in prepaid expenses primarily related to the timing of upfront payments to contract manufacturing organizations for the commercial manufacturing for the production of IBSRELA and XPHOZAH.

Fiscal 2022 compared to 2021:

Net cash used in operating activities during the year ended December 31, 2022 decreased as compared to the same period in 2021 by $82.5 million primarily as a result of decreased spending on research and development expenses during the year ended December 31, 2022 as compared to the year ended December 31, 2021, as well net product sales of IBSRELA and $35.0 million of milestone payments and payments under the 2022 Amendment, which we earned in 2022 upon Kyowa Kirin's submission of a New Drug Application to the Japanese Ministry of Health, Labour and Welfare for tenapanor for the improvement of hyperphosphatemia in adult patients with CKD on dialysis. Partially offsetting the net loss improvement were changes to our operating assets and liabilities related to expenditures for commercial manufacturing and inventory for the production of IBSRELA.

Cash Flows from Investing Activities

Fiscal 2023 compared to 2022:

Net cash provided by investing activities during the year ended December 31, 2023 decreased as compared to the same period in 2022 by $149.7 million primarily due to increased investment purchases during 2023, as we invested higher levels of cash as compared to the same period in 2022. The decrease due to investment purchases of $215.3 million was partially offset by investment maturities and redemptions of $84.3 million,

Fiscal 2022 compared to 2021:

Net cash provided by investing activities during the year ended December 31, 2022 decreased as compared to the same period in 2021 by $32.5 million due to lower investment balances and the timing of our investment maturities, which was partially offset by $1.8 million proceeds from sale of laboratory equipment and supplies during the year ended December 31, 2022.

Cash Flows from Financing Activities

Fiscal 2023 *compared to* 2022*:*

Net cash provided by financing activities during the year ended December 31, 2023 increased by $71.0 million as compared to the same period in 2022 primarily due to net proceeds from issuance of our common stock pursuant to the at the market offerings of $119.2 million during the year ended December 31, 2023 compared to $71.6 million during the year ended December 31, 2022, 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 during the year ended December 31, 2022 in conjunction with entering into the 2022 Loan and repaying the principal outstanding under the 2018 Loan. In addition we received net proceeds of $5.0 million from the sale of future royalties to HCR during the year ended December 31, 2023 as compared to $10.0 million during the year ended December 31, 2022.

Fiscal 2022 compared to 2021:

Net cash provided by financing activities during the year ended December 31, 2022 decreased as compared to the same period in 2021 by $7.7 million primarily due to $29.5 million lower proceeds from issuance of common stock under at-the-market offerings and well as increased payments in the amount of $13.6 million to repay the principal outstanding on the 2018 Loan. Partially offsetting these amounts were $27.0 million net proceeds received from the 2022 Loan and $9.6 million net proceeds from the sales of future royalties during the year ended December 31, 2022.

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, as of January 1, 2024, we are considered a large accelerated filer and we will be required to reflect the determination that we are no longer a smaller reporting company in our Quarterly Report on Form 10-Q for the fiscal quarter ending March 31, 2024. 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, 2023.

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. However, 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 and short-term investments.

As of December 31, 2023, we had cash, cash equivalents and short-term investments of $184.3 million, which consist of bank deposits and money market funds, as well as high quality fixed income instruments including commercial paper, U.S. government-sponsored agency bonds, corporate 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 Loan Agreement and our investment in money market accounts which bear a variable interest rate. Borrowings under the 2022 Loan as amended bear interest at a floating per annum interest rate with 7.95% plus the greater of (a) one percent (1.00%) per annum and (b)(i) 0.022% plus (ii) 1-month CME Term SOFR reference rate as published by the CME Term SOFR Administrator on the CME Term SOFR Administrator's Website. 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 $0.3 million for the year ended December 31, 2023. As of December 31, 2023, we had an aggregate principal amount of $50.0 million outstanding pursuant to our 2022 Loan Agreement.

Foreign Currency Exchange 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 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, 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, 2023, we had no open forward foreign currency exchange contracts.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

ARDELYX, INC.
INDEX TO FINANCIAL STATEMENTS

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, 2023 and 2022, 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, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, 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, 2023, 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 22, 2024 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.

Estimates of Reserves for Variable Consideration Impacted by Estimated Payor Mix

Description of the Matter

As described in Note 2 to the financial statements, the Company recognizes revenues from product sales at the net sales price (transaction price), which includes estimates of variable consideration relating to off-invoice discounts, chargebacks or rebates, wholesaler fees, group purchasing organization administrative fees, patient copay assistance programs, and estimated product returns. The variable consideration is based on the amounts earned or to be claimed for related sales which may not be known at the point of sale. Government-mandated rebates under the Medicaid Drug Rebate Program ("Medicaid") and the Medicare Coverage Gap Program ("Medicare") are estimated based on estimated payor mix and statutory discount rates. Patient copay assistance program amounts are estimated based on payor mix consideration, the terms of the program and redemption information provided by third-party claims processing organizations. The Company's total estimate of reserves for variable consideration was $8.6 million as of December 31, 2023. During 2023, the Company recorded $31.3 million in total reductions to gross commercial product sales as a result of reserves for variable consideration.

Auditing the Company's estimates of reserves for variable consideration relating to Medicaid and Medicare claims and patient copay assistance was especially challenging as it involved evaluation of management's subjective judgments with respect to payor mix that is developed based on 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 amount of 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 Medicaid and Medicare claims and patient copay assistance, 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. We compared the assumptions used by management to third-party industry data and actual trends. 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 assumptions on the amount of reserves recorded for variable consideration impacted by the payor mix, where appropriate. 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 22, 2024

ARDELYX, INC.
BALANCE SHEETS
(in thousands, except share and per share amounts)

	December 31,	
	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	$ 21,470	$ 96,140
Short-term investments	162,829	27,769
Accounts receivable	22,031	7,733
Inventory	12,448	3,282
Prepaid commercial manufacturing	18,925	13,567
Prepaid expenses and other current assets	8,408	5,112
Total current assets	246,111	153,603
Property and equipment, net	1,009	1,223
Inventory, non-current	37,039	25,064
Prepaid commercial manufacturing, non-current	4,235	—
Right-of-use assets	5,589	9,295
Other assets	3,596	881
Total assets	$ 297,579	$ 190,066
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 11,138	$ 10,859
Accrued compensation and benefits	12,597	7,548
Current portion of operating lease liability	4,435	3,894
Current portion of long-term debt	—	26,711
Deferred revenue	7,182	4,211
Accrued expenses and other current liabilities	15,041	12,380
Total current liabilities	50,393	65,603
Operating lease liability, net of current portion	1,725	5,855
Long-term debt, net of current portion	49,822	—
Deferred revenue, non-current	8,644	9,025
Deferred royalty obligation related to the sale of future royalties	20,179	11,254
Total liabilities	130,763	91,737
Commitments and contingencies (Note 20)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.0001 par value; 500,000,000 and 300,000,000 shares authorized; 232,453,190 and 198,575,016 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively.	23	20
Additional paid-in capital	1,012,773	878,500
Accumulated deficit	(846,204)	(780,137)
Accumulated other comprehensive income (loss)	224	(54)
Total stockholders' equity	166,816	98,329
Total liabilities and stockholders' equity	$ 297,579	$ 190,066

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,		
	2023	2022	2021
Revenues:			
Product sales, net	$ 82,526	$ 15,600	$ —
Licensing revenue	35,809	35,031	5,013
Product supply revenue	6,121	1,527	907
Collaborative development revenue	—	—	4,177
Total revenues	124,456	52,158	10,097
Cost of goods sold:			
Cost of product sales	2,323	566	—
Other cost of revenue	15,472	3,551	1,000
Total cost of goods sold	17,795	4,117	1,000
Operating expenses:			
Research and development	35,536	35,201	91,140
Selling, general and administrative	134,401	76,599	72,303
Total operating expenses	169,937	111,800	163,443
Loss from operations	(63,276)	(63,759)	(154,346)
Interest expense	(4,950)	(3,400)	(4,502)
Non-cash interest expense related to the sale of future royalties	(3,924)	(1,673)	—
Other income, net	6,630	1,633	687
Loss before provision for income taxes	(65,520)	(67,199)	(158,161)
Provision for income taxes	547	8	4
Net loss	$ (66,067)	$ (67,207)	$ (158,165)
Net loss per share of common stock - basic and diluted	$ (0.30)	$ (0.42)	$ (1.52)
Shares used in computing net loss per share - basic and diluted	219,331,253	158,690,083	104,205,645
Comprehensive loss:			
Net loss	$ (66,067)	$ (67,207)	$ (158,165)
Unrealized gains (losses) on available-for-sale securities	278	(48)	(2)
Comprehensive loss	$ (65,789)	$ (67,255)	$ (158,167)

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 Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2020	93,599,975	$ 9	$ 680,872	$ (554,765)	$ (4)	$ 126,112
Issuance of common stock under employee stock purchase plan	386,664	—	819	—	—	819
Issuance of common stock for services	25,989	—	190	—	—	190
Issuance of common stock upon exercise of options	331,310	—	584	—	—	584
Issuance of common stock upon vesting of restricted stock units	167,158	—	—	—	—	—
Taxes paid for net share settlement of equity awards	—	—	(106)	—	—	(106)
Issuance of common stock in at the market offering	35,671,439	4	101,142	—	—	101,146
Stock-based compensation	—	—	12,039	—	—	12,039
Unrealized losses on available-for-sale securities	—	—	—	—	(2)	(2)
Net loss	—	—	—	(158,165)	—	(158,165)
Balance as of December 31, 2021	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)
Balance as of December 31, 2022	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)
Balance as of December 31, 2023	232,453,190	$ 23	$ 1,012,773	$ (846,204)	$ 224	$ 166,816

The accompanying notes are an integral part of these financial statements.

ARDELYX, INC.
STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2023	**2022**	**2021**
Operating activities			
Net loss	$ (66,067)	$ (67,207)	$ (158,165)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense	1,292	1,144	2,807
Non-cash lease expense	3,624	3,457	3,085
Stock-based compensation	13,530	10,750	12,039
Non-cash interest expense	4,220	1,962	283
Gain on sale of equipment	—	(1,260)	—
Other, net	(2,930)	685	(678)
Changes in operating assets and liabilities:			
Accounts receivable	(14,298)	(7,231)	(502)
Inventory	(21,141)	(28,346)	—
Prepaid commercial manufacturing	(9,593)	(4,161)	(9,406)
Prepaid expenses and other assets	(6,035)	2,299	502
Accounts payable	279	6,582	(1,349)
Accrued compensation and benefits	5,049	2,126	(250)
Operating lease liabilities	(3,928)	(3,491)	(2,853)
Accrued and other liabilities	3,691	4,138	1,386
Deferred revenue	2,590	8,509	550
Net cash used in operating activities	(89,717)	(70,044)	(152,551)
Investing activities			
Proceeds from maturities and redemptions of investments	84,321	67,000	125,550
Purchases of investments	(215,225)	(50,328)	(72,735)
Proceeds from sale of property and equipment	—	1,798	—
Purchases of property and equipment	(344)	(55)	(1,867)
Net cash (used in) provided by investing activities	(131,248)	18,415	50,948
Financing activities			
Proceeds from issuance of common stock in at the market offering, net of issuance costs	119,236	71,625	101,146
Proceeds from 2022 Loan, net of issuance costs	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	1,173	202	1,403
Payment of the 2018 Exit Fee	(1,500)	—	—
Payments for the 2018 Loan, net of costs	—	(33,038)	(19,444)
Payments for taxes related to net share settlement of equity awards	—	—	(106)
Net cash provided by financing activities	146,295	75,341	82,999
Net (decrease) increase in cash and cash equivalents	(74,670)	23,712	(18,604)
Cash and cash equivalents at beginning of period	96,140	72,428	91,032
Cash and cash equivalents at end of period	$ 21,470	$ 96,140	$ 72,428
Supplementary disclosure of cash flow information:			
Cash paid for interest	$ 4,240	$ 2,901	$ 3,469
Cash paid for income taxes	$ 51	$ 6	$ 4
Supplementary disclosure of non-cash activities:			
Right-of-use assets obtained in exchange for lease obligations	$ 339	$ —	$ 1,604
Issuance of common stock for services	$ 337	$ 390	$ 190
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

1. ORGANIZATION AND BASIS OF PRESENTATION

Ardelyx, Inc. (Company, we, us or our) is 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®, is approved in the U.S. for the treatment of adults with irritable bowel syndrome with constipation (IBS-C). Tenapanor, branded as XPHOZAH®, was approved by the U.S. Food and Drug Administration (U.S. FDA) on October 17, 2023, to reduce serum phosphorus in adults with chronic kidney disease (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 also have a development stage asset, RDX013 for adult patients with CKD and/or heart failure with hyperkalemia, or elevated serum potassium, and a discovery phase asset, RDX020 for adult patients with metabolic acidosis, a serious electrolyte disorder, in patients with CKD.

We operate in one business segment, which is the development and commercialization of biopharmaceutical products.

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”).

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and judgments that affect the amounts reported in the financial statements and accompanying notes thereto. On an ongoing basis, management evaluates its estimates, including those related to recognition of revenue, clinical trial accruals, contract manufacturing accruals, expected demand for inventory, fair value of assets and liabilities, income taxes and stock-based compensation. 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.

Liquidity

As of December 31, 2023, we had cash, cash equivalents and short-term investments of approximately $184.3 million. We have incurred operating losses since inception in 2007 and our accumulated deficit as of December 31, 2023 is $846.2 million. Since December 31, 2021 and prior to September 30, 2023, our liquidity position raised substantial doubt about our ability to continue as a going concern. We have addressed our operating cash flow requirements through cash generated from product sales of IBSRELA and XPHOZAH, proceeds from the sale of shares of our common stock under our at-the-market offering, from the receipt of milestones payments from our collaboration partners and payments from our Japanese collaboration partner under the second amendment to our License Agreement, and through funds from our loan agreements with SLR Investment Corp. (SLR), as amended. We believe our available cash, cash equivalents and short-term investments as of December 31, 2023 will be sufficient to fund our planned operations for at least a period of one year from the issuance of these financial statements.

Cash and Cash Equivalents

We consider all highly liquid investments purchased with an original maturity date of 90 days or less on the date of purchase to be cash equivalents.

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. Unrealized gains and losses on available-for-sale securities are included in accumulated other comprehensive income (loss) on our balance sheets. The cost of available-for-sale securities sold is based on the specific-identification method.

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 sheet. Cash, cash equivalents and short-term investments are invested through banks and other financial institutions in the U.S.

Foreign Currency

We manage our foreign currency exposures with the use of foreign currency purchases. We primarily conduct business 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. We have been in a loss position and therefore our primary objective is to conserve and manage cash. There are generally two methods by which we may manage the cash flow risk of foreign exchange fluctuations when a contract is signed (i) we can purchase the foreign funds, in full or in part, upon the execution of the contract, or (ii) we can obtain the right to purchase such funds, in full or in part, at the execution of the contract, i.e., obtain a forward contract from an appropriate bank, that can be exercised to obtain the currency of interest at a particular point in time. The derivative instruments that we may use to hedge the exposure shall generally not be designated as cash flow hedges, and as a result, changes in their fair value would be recorded in other income (expense), net, in our statements of operations and comprehensive loss. The fair values of forward foreign currency exchange contracts would be estimated using current exchange rates and interest rates and the current creditworthiness of the counterparties is taken into consideration.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets, with ranges generally from three to five years. 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

We use the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases 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 some 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 the 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, 2023 our accounts receivable balance was comprised of $4.9 million from our collaboration agreements and $17.1 million from commercial customers. As of December 31, 2022 our accounts receivable balance was comprised of $0.7 million from our collaboration agreements and $7.0 million from commercial customers.

Inventory

We capitalize inventory costs associated with the production of our products after regulatory approval or when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. Otherwise, such costs are expensed as research and development. Prior to the regulatory approval of drug product candidates, we incurred expenses for the manufacture of drug product that could potentially be available to support the commercial launch of our products or could be sold to our international partners under product supply agreements. 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 commercial launch of IBSRELA, which was when it was determined that the inventory had a probable future economic benefit. 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., which was when it was determined that the inventory had a probable future economic benefit.

Inventory is stated at the lower of cost or estimated net realizable value with cost determined under the specific identification method. Inventory costs include 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. We primarily use actual costs to determine the cost basis for inventory. The determination of whether inventory costs will be realizable requires management review of the expiration dates of IBSRELA and XPHOZAH compared to our forecasted sales. If actual market conditions are less favorable than projected by management, write-downs of inventory may be required, which would be recorded as cost of revenue in the statement of operations and comprehensive loss. As of December 31, 2023, we have not recorded any write-offs for excess and obsolete inventory. 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 on our balance sheets.

Product Sales, Net

We account for our commercial product sales, net in accordance with Topic 606 – *Revenue from Contracts with Customers*. We received approval from the FDA to market IBSRELA in the U.S. in September 2019 and to market XPHOZAH in the U.S. in October 2023. We began selling IBSRELA and XPHOZAH in the U.S. in March 2022 and November 2023, respectively. We distribute IBSRELA principally through major wholesalers, specialty pharmacies and group purchasing organizations (GPOs) (collectively, our IBSRELA Customers). XPHOZAH is principally distributed through a specialty wholesaler (XPHOZAH Customer) to select specialty pharmacies (collectively, IBSRELA Customers and XPHOZAH Customers, "Customers"). Our Customers subsequently sell IBSRELA and XPHOZAH to pharmacies and patients. Separately, we enter into arrangements with third parties that provide for government-mandated rebates, chargebacks and discounts. Revenue from product sales is recognized when our performance obligations are satisfied, which is when Customers obtain control of our product and occurs upon delivery.

Reserves for Variable Consideration

Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration which may be settled in the form of off-invoice discounts, chargebacks, or rebates. Variable consideration includes discounts to customers and government programs, wholesaler fees, group purchasing organization administrative fees, patient copay assistance, and estimated product returns. These estimates are based on the amounts earned or to be claimed for related sales and are classified as reductions of gross accounts receivable if settlement is expected to occur through a reduction in the amounts paid by our Customers or a current liability if settlement is expected to occur through a payment from us. Where appropriate, these estimates are based on factors such as industry data and forecasted customer buying and payment patterns, our experience, current contractual and statutory requirements, specific known market events and trends. These reductions to gross sales reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. Variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we adjust these estimates, which would affect product revenue and earnings in the period such variances become known. As we gain more experience, estimates will be more heavily based on the expected utilization from historical data we have accumulated since the IBSRELA and XPHOZAH product launches. Changes in estimates recorded through December 31, 2023 have not been material.

Rebates: Rebates include wholesaler fees, GPO fees, as well as mandated discounts under the Medicaid Drug Rebate Program (Medicaid) and the Medicare Coverage Gap Program (Medicare). Estimates for rebates are recorded in the same period the related gross revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses on the balance sheets. We estimate our Medicaid and Medicare rebates based upon the estimated payor mix, and statutory discount rates. Our estimates for payor mix are guided by payor information received from specialty pharmacies, expected utilization for wholesaler sales to pharmacies, and available industry payor information and, therefore, require the most estimation and judgment of our gross to net deductions.

Chargebacks: Chargebacks are discounts that occur when certain contracted purchasers purchase directly from our wholesalers at a discounted price. The wholesaler, in turn, charges back the difference between the price initially paid to us by the wholesaler and the discounted price paid to the wholesaler by the contracted purchaser. Amounts for estimated chargebacks are established in the same period that the related gross revenue is recognized, resulting in a reduction of product revenue and accounts receivable. The accrual for wholesaler chargebacks is estimated based on known chargeback rates, known sales to wholesalers, and known sales from wholesalers to their chargeback-eligible customers.

Discounts and Fees: Our payment terms are generally 30 to 60 days. Wholesalers, GPOs and specialty pharmacies are offered various forms of consideration, including off-invoice discounts which may be paid to GPOs and specialty pharmacies. Wholesalers and GPOs may also receive prompt pay discounts for payment within a specified period. We expect discounts to be earned when offered and, therefore, we deduct the full amount of these discounts from product sales when revenue is recognized, resulting in a reduction of product revenue and accounts receivable.

Other Reserves: 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 will be provided to patients associated with product which we have sold but which has not yet been dispensed to commercial patients, which requires significant estimation and judgment. Our estimates are recorded in accounts payable and accrued expenses and other current liabilities on the balance sheets. Other reserves include estimated product returns which are recorded in the same period the related gross revenue is recognized, resulting in a reduction of product revenue as well as accounts receivable. We estimate our product returns reserve based upon our experience and specific known market events and trends. As we have experienced limited product returns, establishing the appropriate level of returns reserve require estimation and judgment.

Collaboration Revenue Recognition

We generate collaboration revenue primarily from research and collaboration and license agreements with customers. Goods and services in the agreements may include the grant of licenses for the use of our technology, the provision of services associated with the research and development of product candidates, manufacturing services, and participation in joint steering committees. The terms of these arrangements typically include payment to us of one or more of the following: non-refundable, up-front license fees; research, development, regulatory and commercial milestone payments; reimbursement of research and development services; option payments; reimbursement of certain costs; payments for manufacturing supply services; and future royalties on net sales of licensed products.

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. Contracts are combined and accounted for as a single arrangement if one or more of the following criteria are met: (i) the contracts are negotiated as a package with a single commercial objective; (ii) the amount of consideration to be paid in one contract depends on the price or performance of the other contract; or (iii) the goods or services promised in the contracts (or some goods or services promised in each of the contracts) are a single performance obligation.

In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under each of our agreements, management performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including any constraints on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) we satisfy each performance obligation. As part of the accounting for contracts with customers, we develop assumptions that require judgment to determine whether promised goods and services represent distinct performance obligations and the standalone selling price for each performance obligation identified in the contract. This evaluation is subjective and requires us to make judgments about the promised goods and services and whether those goods and services are separable from other aspects of the contract. Further, determining the standalone selling price for performance obligations requires significant judgment, and when an observable price of a promised good or service is not readily available, we consider relevant assumptions to estimate the standalone selling price, including, as applicable, market conditions, development timelines, probabilities of technical and regulatory success, reimbursement rates for personnel costs, forecasted revenues, potential limitations to the selling price of the product and discount rates.

We apply judgment in determining whether a combined performance obligation is satisfied at a point in time or over time, and, if over time, concluding upon the appropriate method of measuring progress to be applied for purposes of recognizing revenue. We evaluate the measure of progress each reporting period and, as estimates related to the measure of progress change, related revenue recognition is adjusted accordingly. Changes in our estimated measure of progress are accounted for prospectively as a change in accounting estimate. We recognize collaboration revenue by measuring the progress toward complete satisfaction of the performance obligation using an input measure. In order to recognize revenue over the research and development period, we measure actual costs incurred to date compared to the overall total expected costs to satisfy the performance obligation. Revenues are recognized as the program costs are incurred. We will re-evaluate the estimate of expected costs to satisfy the performance obligation each reporting period and make adjustments for any significant changes. Amounts received prior to satisfying the revenue recognition criteria are recorded as contract liabilities in our balance sheets. If the related performance obligation is expected to be satisfied within the next twelve months, this will be classified in current liabilities. Amounts recognized as revenue prior to receipt are recorded as contract assets in our balance sheets. If we expect to have an unconditional right to receive the consideration in the next twelve months, this will be classified in current assets. A net contract asset or liability is presented for each contract with a customer.

Milestone Payments: At the inception of each arrangement that includes research and development milestone payments, we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur and when the uncertainty associated with the variable consideration is subsequently resolved. Milestone payments that are not within the control of us or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative standalone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such development milestones and any related constraints, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect earnings in the period of adjustment.

Manufacturing supply services: Arrangements that include a promise for the future supply of drug substance or drug product for either clinical development or commercial supply at the customer's discretion are generally considered as options. We assess if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations. If we are entitled to additional payments when the customer exercises these options, any payments are recorded in product supply revenue when the customer obtains control of the goods, which is upon delivery.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and where the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, royalty revenue resulting from licensing arrangements has not been material.

Licenses of intellectual property: If a license granted to a customer to use our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenue from consideration allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, we apply judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, to conclude upon the appropriate method of measuring progress for purposes of recognizing revenue related to consideration allocated to the performance obligation.

Options: Customer options, such as options granted to allow a licensee to choose to research, develop and commercialize licensed compounds are evaluated at contract inception in order to determine whether those options provide a material right (i. e., an optional good or service offered for free or at a discount) to the customer. If the customer options represent a material right, the material right is treated as a separate performance obligation at the outset of the arrangement. We allocate the transaction price to material rights based on the standalone selling price, and revenue is recognized when or as the future goods or services are transferred or when the option expires. Customer options that are not material rights do not give rise to a separate performance obligation, and as such, the additional consideration that would result from a customer exercising an option in the future is not included in the transaction price for the current contract. Instead, the option is deemed a marketing offer, and additional option fee payments are recognized or being recognized as revenue when the licensee exercises the option. The exercise of an option that does not represent a material right is treated as a separate contract for accounting purposes.

Contract modifications: Contract modifications, defined as changes in the scope or price (or both) of a contract that are approved by the parties to the contract, such as a contract amendment, exist when the parties to a contract approve a modification that either creates new or changes existing enforceable rights and obligations of the parties to the contract. Depending on facts and circumstances, we account for a contract modification as one of the following: (i) a separate contract; (ii) a termination of the existing contract and a creation of a new contract; or (iii) a combination of the preceding treatments. A contract modification is accounted for as a separate contract if the scope of the contract increases because of the addition of promised goods or services that are distinct and the price of the contract increases by an amount of consideration that reflects our standalone selling prices of the additional promised goods or services. When a contract modification is not considered a separate contract and the remaining goods or services are distinct from the goods or services transferred on or before the date of the contract modification, we account for the contract modification as a termination of the existing contract and a creation of a new contract. When a contract modification is not considered a separate contract and the remaining goods or services are not distinct, we account for the contract modification as an add-on to the existing contract and as an adjustment to revenue on a cumulative catch-up basis.

We receive payments from our licensees as established in each contract. Upfront payments and fees are recorded as deferred revenue upon receipt or when due and may require deferral of revenue recognition to a future period until we perform our obligations under these arrangements. Where applicable, amounts are recorded as unbilled revenue when our right to consideration is unconditional. We do not assess whether a contract with a customer has a significant financing component if the expectation at contract inception is such that the period between payment by the licensees and the transfer of the promised goods or services to the licensees will be one year or less.

Cost of Goods Sold

Cost of product sales consists of the cost of commercial goods sold to our Customers. Other cost of revenue consists of the cost of materials sold to our international partners under product supply agreements, as well as payments due to AstraZeneca AB (AstraZeneca) based on sales of tenapanor. We capitalize inventory costs associated with the production of our products after regulatory approval or when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. Otherwise, such costs are expensed as research and development. A portion of the costs of IBSRELA and XPHOZAH units recognized as revenue during the years ended December 31, 2023 and 2022 were expensed in periods prior to the commencement of capitalization of inventory costs for each respective product. As of December 31, 2023 and December 31, 2022, we had approximately $21.8 million and $28.0 million, respectively, of inventory on hand that was previously expensed as research and development expense and will not be reported as cost of goods sold in future periods when sales of IBSRELA and XPHOZAH are recognized as revenue.

Other cost of revenue includes payments due to AstraZeneca, which under the terms of a termination agreement entered into in 2015 (AstraZeneca Termination Agreement) is entitled to (i) future royalties at a 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 our collaboration partners in connection with the development and commercialization of tenapanor or other NHE3 products. We have agreed to pay AstraZeneca up to a maximum of $75.0 million in the aggregate for (i) and (ii). We recognize these expenses as other cost of revenue when we recognize the corresponding revenue that gives rise to payments due to AstraZeneca. To date, we have recognized an aggregate of $27.6 million as other cost of revenue under the AstraZeneca Termination Agreement. See details in *Note 7, Collaboration and Licensing Agreements*, under AstraZeneca, in the notes to our financial statement of this Annual Report on Form 10-K.

Research and Development Costs

Research and development costs are charged to expense as incurred and consisted of costs incurred to further our research and development activities and include salaries and related employee benefits, costs associated with clinical trials, costs related to pre-commercialization manufacturing activities such as manufacturing process validation activities and the manufacturing of clinical drug supply, nonclinical research and development activities, regulatory activities, research-related overhead expenses and fees paid to external service providers and contract research and manufacturing organizations that conduct certain research and development activities on our behalf.

Accrued Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process 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 in our financial statements 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.

In accruing service fees, we estimate the time period over which each component of a service will be performed, and estimate, 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 of services performed 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.

Stock-Based Compensation

We recognize compensation expense for all stock-based payment awards made to employees, non-employees and directors based on estimated fair values. For employee and non-employee stock options, we determine the grant date fair value of the awards using the Black-Scholes option-pricing model and generally recognize the fair value as stock-based compensation expense on a straight-line basis over the vesting period of the respective awards. For restricted stock and performance-based restricted stock, to the extent they are probable, the compensation cost for these awards is based on the closing price of our common stock on the date of grant and recognized as compensation expense on a straight-line basis over the requisite service period. Stock-based compensation expense is based on the value of the portion of stock-based payment awards that is ultimately expected to vest. As such, our stock-based compensation is reduced for the estimated forfeitures at the date of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Derivatives and Hedging Activities

We account for our derivative instruments as either assets or liabilities on the balance sheet and measure them at fair value. Derivatives are adjusted to fair value through other income (expense), net in the statements of operations and comprehensive loss.

Non-cash Interest Expense on Deferred Royalty Obligation

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. As further described in *Note 8. Deferred Royalty Obligation Related to the Sale of Future Royalties*, in June 2022, we and HealthCare Royalty Partners IV, L.P. (HCR) entered into a Royalty and Sales Milestone Interest Acquisition Agreement (HCR Agreement). Under the terms of the HCR Agreement, HCR agreed to pay us up to $20.0 million in exchange for the royalty payments and commercial milestone payments (collectively the Royalty Interest Payments) that we may receive under our 2017 License Agreement with Kyowa Kirin, as amended, based upon Kyowa Kirin's net sales of tenapanor in Japan for hyperphosphatemia. As part of the HCR Agreement, we received a $10.0 million upfront payment from HCR in June 2022 and recorded it as a deferred royalty obligation on our balance sheet. In September 2023, we announced that Kyowa Kirin received approval from the Japanese MHLW for the New Drug Application for tenapanor for the improvement of hyperphosphatemia in adult patients with chronic kidney disease on dialysis, which entitled us to a $5.0 million payment under the terms of the HCR Agreement, which we received in October 2023. Non-cash interest expense will be recognized over the life of the HCR Agreement using the effective interest method based on the imputed interest rate derived from estimated amounts and timing of future royalty payments to be received from Kyowa Kirin.

Leases

We determine if an arrangement is a lease at the inception of the arrangement. Operating leases are included in right-of-use assets, current portion of operating lease liability, and operating lease liability, net of current portion in 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 the information available at the lease commencement date. The 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 the lease when it is reasonably certain that we will exercise any such options. 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 it accounts 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, since the effects of potentially dilutive securities are antidilutive due to the net loss for all periods presented.

Recent Accounting Pronouncements

New Accounting Pronouncements - Recently Adopted

In July 2023, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2023-03, Presentation of Financial Statements (Topic 205), Income Statement - Reporting Comprehensive Income (Topic 220), Distinguishing Liabilities from Equity (Topic 480), Equity (Topic 505), and Compensation - Stock Compensation (Topic 718) Presentation of Financial Statements (ASU 2023-03). ASU 2023-03 amends the FASB Accounting Standards Codification to include Amendments to SEC Paragraphs pursuant to SEC Staff Accounting Bulletin No. 120, SEC Staff Announcement at the March 24, 2022 EITF Meeting, and SEC Staff Accounting Bulletin Topic 6.B, Accounting Series Release 280 - General Revision of Regulation S-X: Income or Loss Applicable to Common Stock. As the ASU does not provide any new guidance, there is no transition or effective date associated with its adoption. Accordingly, we adopted ASU 2023-03 immediately upon its issuance. The adoption of ASU 2023-03 did not have any impact on our financial statement presentation or related disclosures.

Recent Accounting Pronouncements Not Yet Adopted

In October 2023, the FASB issued ASU No. 2023-06, *Disclosure Improvements - Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative*. The amendments in this Update modify the disclosure or presentation requirements of a variety of Topics in the Codification. The amendments are in response to the U.S. Securities and Exchange Commission's (SEC) Release No. 33-10532, *Disclosure Update and Simplification*, in which the SEC referred certain of its disclosure requirements that overlap with, but require incremental information to, generally accepted accounting principles to the FASB for potential incorporation into the Codification. For entities subject to the SEC's existing disclosure requirements and for entities required to file or furnish financial statements with or to the SEC in preparation for the sale of or for purposes of issuing securities that are not subject to contractual restrictions on transfer, the effective date for each amendment will be the date on which the SEC's removal of that related disclosure from Regulation S-X or Regulation S-K becomes effective, with early adoption prohibited. For all other entities, the amendments will be effective two years later. For all entities, if by June 30, 2027, the SEC has not removed the applicable requirement from Regulation S-X or Regulation S-K, the pending content of the related amendment will be removed from the Codification and will not become effective for any entity. Management is currently assessing the impact of this standard on the Company's financial statements.

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280) - Improvements to Reportable Segment Disclosures*. The amendments in this Update improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. The amendments in this update improve financial reporting by requiring disclosure of incremental segment information on an annual and interim basis for all public entities to enable investors to develop more decision-useful financial analyses. The amendments in this update are effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. Management is currently assessing the impact of this standard on the Company's financial statements.

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 the Company's financial statements.

There were various other accounting standards and interpretations issued recently, none of which are expected to have a material impact on our financial position, operations or cash flows.

3. CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS

Securities classified as cash, cash equivalents and short-term investments as of December 31, 2023 and 2022 are summarized below (in thousands):

	December 31, 2023			
		Gross Unrealized		
	Amortized Cost	Gains	Losses	Fair Value
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

	December 31, 2022			
		Gross Unrealized		
	Amortized Cost	Gains	Losses	Fair Value
Cash and cash equivalents:				
Cash	$ 11,827	$ —	$ —	$ 11,827
Money market funds	84,313	—	—	84,313
Total cash and cash equivalents	96,140	—	—	96,140
Short-term investments				
Commercial paper	$ 25,336	$ 6	$ (51)	$ 25,291
Corporate bonds	1,000	—	(1)	999
U.S. government-sponsored agency bonds	1,487	—	(8)	1,479
Total short-term investments	27,823	6	(60)	27,769
Total cash, cash equivalents and investments	$ 123,963	$ 6	$ (60)	$ 123,909

Cash equivalents consist of money market funds with original maturities of three months or less at the time of purchase, and the carrying amount is a reasonable approximation of fair value. We invest our cash in high quality securities of financial and commercial institutions. These securities are carried at fair value, which is based on readily available market information, with unrealized gains and losses included in accumulated other comprehensive income (loss) within stockholders' equity on our balance sheets. We use the specific identification method to determine the amount of realized gains or losses on sales of marketable securities. Realized gains or losses have been insignificant and are included in other income, net, in the statement of operations and comprehensive loss.

All of the short-term available-for sale securities held as of December 31, 2023 and 2022 had contractual maturities of less than one year. Our available-for-sale securities are subject to a periodic impairment review. We consider a debt security to be impaired when its fair value is less than its carrying cost, in which case we would further review the investment to determine whether it is other-than-temporarily impaired. When we evaluate an investment for other-than-temporary impairment, we review factors such as the length of time and extent to which fair value has been below cost basis, the financial condition of the issuer and any changes thereto, intent to sell, and whether it is more likely than not we will be required to sell the investment before the recovery of its cost basis. If an investment is other-than-temporarily impaired or subject to credit losses, we write it down through the statement of operations and comprehensive loss to its fair value and establish that value as a new cost basis for the investment. Our unrealized losses as of December 31, 2023 and 2022 were not material. We determined that none of our available-for-sale securities were other-than-temporarily impaired as of December 31, 2023 and 2022, and no investment was in a continuous unrealized loss position for more than one year. As such, 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 for these securities as of December 31, 2023 and 2022.

4. FAIR VALUE MEASUREMENTS

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

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 to 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, 2023			
	Total Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 18,641	$ 18,641	$ —	$ —
U.S. government-sponsored agency bonds	102,093	—	102,093	—
Commercial paper	49,654	—	49,654	—
Asset-backed securities	8,625	—	8,625	—
U.S. treasury securities	2,457	—	2,457	—
Total	$ 181,470	$ 18,641	$ 162,829	$ —
Liabilities:				
Derivative liabilities for exit fee	$ 675	$ —	$ —	$ 675
Total	$ 675	$ —	$ —	$ 675

	December 31, 2022			
	Total Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 84,313	$ 84,313	$ —	$ —
Commercial paper	25,291	—	25,291	—
U.S. government-sponsored agency bonds	1,479	—	1,479	—
Corporate bonds	999	—	999	—
Total	$ 112,082	$ 84,313	$ 27,769	$ —
Liabilities:				
Derivative liability for exit fees	$ 1,656	$ —	$ —	$ 1,656
Total	$ 1,656	$ —	$ —	$ 1,656

Where quoted prices are available in an active market, securities are classified as Level 1. We classify money market funds as Level 1. When quoted market prices are not available for the specific security, we estimate fair value by using benchmark yields, reported trades, broker/dealer quotes and issuer spreads. We classify U.S. government-sponsored agency bonds, U.S. treasury securities, corporate bonds, commercial paper, and asset-backed securities as Level 2. In certain cases, where there is limited activity or less transparency around inputs to valuation, securities or derivative liabilities, such as the 2018 Exit Fee and 2022 Exit Fee, as defined and discussed in *Note 10. Derivative Liabilities*, are classified as Level 3.

The carrying amounts reflected in the balance sheets for cash equivalents, short-term investments, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values at both December 31, 2023 and 2022, due to their short-term nature.

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 for these securities as of December 31, 2023 and 2022.

Fair Value of Debt

The principal amount outstanding under our term loan facilities is subject to a variable interest rate. Therefore, we believe the carrying amount of the term loan facility approximates fair value as of December 31, 2023 and 2022. See *Note 9. Borrowings* 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, 2023 and is based on our current estimates of future royalties and commercialization milestones expected to be paid to us by Kyowa Kirin Co., Ltd. (KKC) 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.

5. INVENTORY

Inventory as of December 31, 2023 and 2022 consisted of the following (in thousands):

	December 31, 2023	December 31, 2022
Raw materials	$ 22,920	$ 22,299
Work in process	24,582	5,324
Finished goods	1,985	723
Total	$ 49,487	$ 28,346
Reported as:		
Inventory	$ 12,448	$ 3,282
Inventory, non-current	37,039	25,064
Total	$ 49,487	$ 28,346

In addition to inventory, we had prepaid commercial manufacturing of $23.2 million and $13.6 million as of December 31, 2023 and 2022, respectively, which consisted of prepayments to third party contract manufacturing organizations, including prepayments of $4.2 million and zero as of December 31, 2023 and 2022, respectively, that are expected to be converted into inventory after 12 months.

6. REVENUE

Total revenues during the years ended December 31, 2023, 2022, and 2021 were as follows (in thousands):

	Year Ended December 31,		
	2023	**2022**	**2021**
Product sales, net:			
IBSRELA	$ 80,062	$ 15,600	$ —
XPHOZAH	2,464	—	—
Total product sales, net	82,526	15,600	—
Licensing revenue	35,809	35,031	5,013
Product supply revenue	6,121	1,527	907
Collaborative development revenue	—	—	4,177
Total revenues	$ 124,456	$ 52,158	$ 10,097

Revenue from the following Customers who contributed greater than 10% of our gross product revenue during the years ended December 31, 2023 and 2022 as a percentage of total gross product revenue was as follows:

	Year Ended December 31,	
	2023	**2022**
BioRidge Pharma, LLC	26.3 %	— %
Cardinal Health	21.6 %	23.1 %
AmerisourceBergen Drug Corporation	20.9 %	26.8 %
McKesson Corporation	17.2 %	21.6 %

The activities and ending reserve balances for each significant category of discounts and allowances, which constitute variable consideration, were as follows (in thousands):

	Discounts and Chargebacks	**Rebates, Wholesaler and GPO Fees**	**Copay and Returns**	**Total**
Balance as of December 31, 2021	$ —	$ —	$ —	$ —
Provisions	825	2,721	2,502	6,048
Credits/payments	(683)	(1,277)	(1,244)	(3,204)
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

Adjustments to prior period provisions recorded in the current period were not material.

7. COLLABORATION AND LICENSING AGREEMENTS

Kyowa Kirin Co., Ltd. (Kyowa Kirin)

In November 2017, we entered into an exclusive license agreement with Kyowa Kirin (2017 Kyowa Kirin Agreement), under which we granted Kyowa Kirin an exclusive license to develop and commercialize certain NHE3 inhibitors including tenapanor in Japan for the treatment of cardiorenal diseases and conditions, excluding cancer. We retained the rights to tenapanor outside of Japan, and also retained the rights to tenapanor in Japan for indications other than those stated above. Pursuant to the 2017 Kyowa Kirin Agreement, Kyowa Kirin is responsible for all costs and expenses incurred in the development and commercialization of tenapanor for all licensed indications in Japan. We are responsible for supplying the tenapanor drug substance for Kyowa Kirin's use in development and commercialization throughout the term of the 2017 Kyowa Kirin Agreement, provided that Kyowa Kirin may exercise an option to manufacture the tenapanor drug substance under certain conditions. In October 2022, we entered into a Commercial Supply Agreement with Kyowa Kirin to further define the obligations of the parties with respect to the commercial supply of tenapanor drug substance (2022 Kyowa Kirin Supply Agreement). As detailed below under the heading *Deferred Revenue* we have received advanced payments from Kyowa Kirin for the manufacturing of tenapanor drug substance that will be used to satisfy Kyowa Kirin needs.

We assessed these arrangements in accordance with Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers* (Topic 606) and related amendments (ASC 606) and concluded that the contract counterparty, Kyowa Kirin, is a customer. Under the terms of the 2017 Kyowa Kirin Agreement, we received $30.0 million in upfront license fees, which was recognized as revenue when the agreement was executed. Based on our assessment, management determined that the license and the manufacturing supply services were its material performance obligations at the inception of the 2017 Kyowa Kirin Agreement, and as such, each of the performance obligations is distinct.

We may be entitled to receive up to $55.0 million in total development and regulatory milestones, of which $35.0 million has been received and recognized as revenue as of December 31, 2023. We may also be eligible to receive approximately ¥8.5 billion for commercialization milestones, or approximately $60.3 million at the currency exchange rate on December 31, 2023, as well as reimbursement of costs plus a reasonable overhead for the supply of product and royalties on net sales throughout the term of the agreement. 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 2017 Kyowa Kirin Agreement will be remitted to HealthCare Royalty Partners IV, L.P. pursuant to a Royalty and Sales Milestone Interest Acquisition Agreement. The variable consideration related to the remaining milestone payments was fully constrained at December 31, 2023.

In April 2022, we entered into a second amendment to the 2017 Kyowa Kirin Agreement (2022 Amendment). Under the terms of the 2022 Amendment, we and Kyowa Kirin agreed to a reduction in the royalty rate payable to us by Kyowa Kirin upon net sales of tenapanor for hyperphosphatemia in Japan. The royalty rate will be reduced from the 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. As discussed in *Note 8. Deferred Royalty Obligation Related to the Sale of Future Royalties*, the future commercial milestones and royalties we may receive under the 2017 Kyowa Kirin Agreement will be remitted to HealthCare Royalty Partners IV, L.P. pursuant to a Royalty and Sales Milestone Interest Acquisition Agreement. As consideration for the 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 Ministry of Health, Labour and Welfare (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.

In October 2022, we announced that Kyowa Kirin submitted a New Drug Application (NDA) to the Japanese MHLW for tenapanor for the improvement of hyperphosphatemia in adult patients with CKD on dialysis, which resulted in payment to us from Kyowa Kirin for an aggregate of $35.0 million for milestone payments and payments under the 2022 Amendment. We received these payments during the fourth quarter of 2022 and recorded them as licensing revenue on our statement of operations and comprehensive income (loss).

In September 2023, we announced that Kyowa Kirin received approval from the Japanese MHLW for the NDA for tenapanor for the improvement of hyperphosphatemia in adult patients with CKD on dialysis, which resulted in payment to us from Kyowa Kirin for an aggregate of $30.0 million for milestone payments and payments under the 2022 Amendment. We received these payments in October 2023 and recorded them as licensing revenue on our statement of operations and comprehensive income (loss) when earned during the three months ended September 30, 2023.

During the years ended December 31, 2023, 2022, and 2021, we recognized $30.0 million, $35.0 million, and $5.0 million of licensing revenue pursuant to the 2017 Kyowa Kirin Agreement, as amended.

During the years ended December 31, 2023, 2022, and 2021, we recognized $6.1 million, $1.5 million, and $0.9 million respectively, of product supply revenue pursuant to the 2017 Kyowa Kirin Agreement.

Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd. (Fosun Pharma)

In December 2017, we entered into 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. We assessed these arrangements in accordance with ASC 606 and concluded that the contract counterparty, Fosun Pharma, is a customer. Under the terms of the Fosun Agreement, we received $12.0 million in upfront license fees which was recognized as revenue when the agreement was executed. Based on our assessment, we determined that the license and the manufacturing supply services represented the material performance obligations at the inception of the agreement and, as such, each of the performance obligations are distinct.

We may be entitled to receive development and commercialization milestones of up to $113.0 million, of which $8.0 million has been recognized as revenue and $5.0 million has been received as of December 31, 2023 and $3.0 million was received in January 2024, as well as 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%. The variable consideration related to the remaining development milestone payments was fully constrained at December 31, 2023.

In July 2023, we announced that an NDA for tenapanor had been accepted for review by China's Center for Drug Evaluation of the National Medical Products Administration (NMPA) for the control of serum phosphorus in adult patients with CKD on hemodialysis. This acceptance triggered a $2.0 million milestone payment to us under the terms of the Fosun Agreement. We received this payment during the third quarter of 2023 and recorded it as licensing revenue on our statement of operations and comprehensive loss when earned during the three months ended September 30, 2023. In October 2023, we announced that the U.S. FDA has approved 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. This triggered an additional $3.0 million milestone payment to us under the terms of the Fosun Agreement, which was received during the first quarter of 2024. Also, in October 2023, we announced that Fosun Pharma received approval from the Hong Kong Department of Health for the marketing application for tenapanor for the treatment of irritable bowel syndrome with constipation (IBS-C).

During the year ended December 31, 2023, we recognized $5.0 million of licensing revenue pursuant to the Fosun Agreement. During the years ended December 31, 2022, and 2021, we did not recognize a material amount of revenue pursuant to the Fosun Agreement.

Knight Therapeutics, Inc. (Knight)

In March 2018, we entered into an exclusive license agreement with Knight Therapeutics, Inc., (Knight Agreement) for the development, commercialization and distribution of tenapanor in Canada for hyperphosphatemia and IBS-C. We assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, Knight, is a customer. Based on our assessment, we determined that the license and the manufacturing supply services were the material performance obligations at the inception of the agreement and, as such, each of the performance obligations are distinct.

Under the terms of the Knight Agreement, we received a $2.3 million non-refundable, one-time upfront payment in March 2018 and may be eligible to receive additional development and commercialization milestone payments worth up to CAD 22.2 million, or approximately $16.7 million at the currency exchange rate on December 31, 2023, of which $0.7 million has been received and recognized as revenue as of December 31, 2023. We are also 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 services. The variable consideration related to the remaining development milestone payments was fully constrained at December 31, 2023.

During the years ended December 31, 2023, 2022, and 2021, we did not recognize a material amount of revenue pursuant to the Knight Agreement.

METiS Therapeutics Inc. (METiS)

In April 2023, we entered into an exclusive, worldwide license agreement with METiS Therapeutics Inc., (METiS Agreement) for the development and commercialization of a portfolio of TGR5 agonist compounds that were discovered and developed by Ardelyx for all therapeutic areas. We assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, METiS, is a customer. Based on our assessment, we determined that the license was the material performance obligation at the inception of the agreement.

Under the terms of the METiS Agreement, we received a $0.8 million non-refundable, one-time upfront payment in April 2023 and may be eligible to receive additional 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. The variable consideration related to the remaining development and commercialization milestone payments was fully constrained at December 31, 2023.

During the year ended December 31, 2023, we recognized $0.8 million of licensing revenue pursuant to the METiS Agreement upon delivery of the license.

AstraZeneca AB (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). As of December 31, 2023, to date in aggregate, we have recognized $27.6 million of the $75.0 million, which has been recorded as other cost of revenue on our statements of operations and comprehensive income (loss). During the years ended December 31, 2023, 2022, and 2021, we recognized $12.4 million and $3.6 million, and $1.0 million, respectively, as other cost of revenue related to the AstraZeneca Termination Agreement.

Deferred Revenue

The following tables present changes in our current and non-current deferred revenue balances during the reporting period, which are all attributable to the 2017 Kyowa Kirin Agreement (in thousands):

	2023		2022	
	Current	Non-Current	Current	Non-Current
Balance at January 1,	$ 4,211	$ 9,025	$ —	$ 4,727
Amounts invoiced as prepayments for product supply	1,547	5,629	250	8,259
Decrease for revenue recognized for product supply	(4,586)	—	—	—
Reclassify amounts to be recognized in the next twelve months	6,010	(6,010)	3,961	(3,961)
Balance at December 31,	$ 7,182	$ 8,644	$ 4,211	$ 9,025

8. DEFERRED ROYALTY OBLIGATION RELATED TO THE SALE OF FUTURE ROYALTIES

In June 2022, we and HealthCare Royalty Partners IV, L.P. (HCR) entered into a Royalty and Sales Milestone Interest Acquisition Agreement (HCR Agreement). Under the terms of the HCR Agreement, HCR has agreed to pay us up to $20.0 million in exchange for the royalty payments and commercial milestone payments (collectively the Royalty Interest Payments) that we may receive under our 2017 License Agreement with Kyowa Kirin, as amended, based upon Kyowa Kirin's net sales of tenapanor in Japan for hyperphosphatemia. As consideration for the sale of the Royalty Interest Payments, HCR paid to us a $10.0 million upfront payment, and we were eligible to receive a $5.0 million payment as a result of Kyowa Kirin's receipt of regulatory approval to market tenapanor for hyperphosphatemia in Japan, and another $5.0 million payment in the event net sales by Kyowa Kirin in Japan exceed a certain annual target level by the end of 2025.

In September 2023, we announced that Kyowa Kirin received approval from the Japanese MHLW for the New Drug Application for tenapanor for the improvement of hyperphosphatemia in adult patients with chronic kidney disease on dialysis, which entitled us to a $5.0 million payment under the terms of the HCR Agreement. We received the payment in October 2023.

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, including, among others, requirements as to prosecution, maintenance, defense and enforcement of certain patent rights in Japan, restrictions regarding our ability to forgive, release or reduce any Royalty Interest Payments due to us under the 2017 Kyowa Kirin Agreement, to create or incur any liens with respect to the Royalty Interest Payments, the 2017 Kyowa Kirin Agreement or certain patents, or to sell, license or transfer certain patents in the field and territory described in the 2017 Kyowa Kirin Agreement.

In addition, the HCR Agreement contains customary events of default with respect to which we may incur indemnification obligations to HCR for any losses incurred by HCR and related parties as a result of the event of default, subject to a specified limitation of liability cap. Under the HCR Agreement, an event of default will occur if, among other things, any of the representations and warranties included in the HCR Agreement proves not to have been true and correct in all material respects, at the time it was made, we breach any of our covenants under the HCR Agreement, subject to specified cure periods with respect to certain breaches, we are in breach or default under the 2017 Kyowa Kirin Agreement in any manner which is likely to cause a material adverse effect on the Royalty Interest Payments, the occurrence of a termination of the 2017 Kyowa Kirin Agreement under certain circumstances or we or our assets become subject to certain legal proceedings, such as bankruptcy proceedings, or we are unable to pay our debts as they become due.

The $10.0 million upfront payment from HCR received in June 2022 and the $5.0 million payment received in October 2023 have been recorded as a deferred royalty obligation related to the sale of future royalties (deferred royalty obligation) on our balance sheets. Due to our ongoing manufacturing obligations under the 2017 Kyowa Kirin Agreement, we account for the proceeds as imputed debt and therefore will recognize royalties earned under the arrangement as non-cash royalty revenue. Non-cash interest expense will be recognized over the life of the HCR Agreement using the effective interest method based on the imputed interest rate derived from estimated amounts and timing of future royalty payments to be received from Kyowa Kirin. As part of the sale, we incurred approximately $0.4 million in transaction costs, which, along with the deferred royalty obligation, are being amortized to non-cash interest expense over the estimated life of the HCR Agreement using the effective interest method. As future royalties are remitted to us by Kyowa Kirin, and subsequently from us to HCR, the balance of the deferred royalty obligation will be effectively repaid over the life of the HCR Agreement. There are a number of factors that could materially affect the fair value of the deferred royalty obligation. Such factors include, but are not limited to, the amount and timing of potential future royalty payments to be received from Kyowa Kirin under the 2017 Kyowa Kirin agreement, changing standards of care, the introduction of competing products, manufacturing or other delays, intellectual property matters, adverse events that result in governmental health authority imposed restrictions on the use of the drug products, significant changes in foreign exchange rates as the royalties remitted to HCR are made in U.S. dollars while the underlying sales of the products by Kyowa Kirin are made in Japanese yen, and other events or circumstances that could result in reduced royalty payments from Kyowa Kirin, which are not within our control, and all of which would result in a reduction of non-cash royalty revenues and the non-cash interest expense over the life of the deferred royalty obligation. 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. As of December 31, 2023, our effective interest rate used to amortize the liability is 34.7%. During the years ended December 31, 2023 and 2022, we recognized approximately $3.9 million and $1.7 million, respectively, of non-cash interest expense related to the deferred royalty obligation. As of December 31, 2023, we have received no royalty payments from Kyowa Kirin and, therefore, the deferred royalty obligation has not begun to be reduced.

9. BORROWING

Solar Capital and Western Alliance Bank Loan Agreement

In May 2018, we entered into a loan and security agreement (as amended on October 9, 2020, March 1, 2021, May 5, 2021, and July 29, 2021) (2018 Loan Agreement) with Solar Capital Ltd. and Western Alliance Bank (collectively, the 2018 Lenders). The 2018 Loan Agreement provided for a loan facility for up to $50.0 million with a maturity date of November 1, 2022 (2018 Loan). As of the Closing Date for the 2022 Loan, as discussed below, we owed $25.0 million in principal payments from the 2018 Loan, which we repaid in full at that time.

As discussed in *Note 10. Derivative Liabilities*, in connection with entering into the 2018 Loan Agreement, we entered into an agreement pursuant to which we agreed to pay $1.5 million in cash upon the occurrence of certain conditions (2018 Exit Fee). Our obligations for the 2018 Exit Fee remained outstanding following the full repayment of the 2018 Loan in February 2022 until October 2023 when 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. This triggered our obligation to pay the 2018 Exit Fee to the 2018 Lenders and we subsequently paid the 2018 Exit Fee in October 2023.

SLR Investment Corp. Loan Agreement

On February 23, 2022 (Closing Date), we entered into a loan and security agreement (2022 Loan Agreement) with SLR Investment Corp. as collateral agent (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) and February 2023 (the Second Amendment). We concluded that the First Amendment and the Second Amendment were modifications to the 2022 Loan Agreement. The 2022 Loan Agreement, as amended by the First Amendment and the Second Amendment, provided for a senior secured loan facility, with $27.5 million (Term A Loan) funded on the Closing Date and an additional $22.5 million which we may borrow on or prior to December 20, 2023; provided that (i) we have received approval by the U.S. FDA for our NDA for XPHOZAH by November 30, 2023, and (ii) we have achieved certain product revenue milestone targets described in the 2022 Loan Agreement (Term B Loan, and together with the Term A Loan, the 2022 Original Loans). The 2022 Term A Loan funds were used to repay the 2018 Loan with the 2018 Lenders.

On October 17, 2023, we entered into a Third Amendment (the Third Amendment) to the 2022 Loan Agreement by and between us and the 2022 Lenders. The Third Amendment, among other things, (1) provides us with the option to draw an additional $50.0 million of committed capital by March 15, 2024 (the Term C Loan) provided we have drawn the Term B Loan; and (2) provides us with the option to draw up to an additional $50.0 million of uncommitted capital by December 31, 2026, subject to approval by the Agent's investment committee (the Term D Loan and together with the Term A, B, and C Loans, the Four 2022 Loans). We concluded that the Third Amendment was a modification to the 2022 Loan Agreement and is accounted for accordingly. We expect to provide the Agent with notice of our decision to draw the Term C Loan prior to the expiry of the option on March 15, 2024 to further support the commercial launch of XPHOZAH.

Under the Third Amendment, the maturity date for the Four 2022 Loans is March 1, 2027. The interest rate for each of the Term A Loan and the Term B Loan is 7.95% 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 one percent. The interest rate for each of the Term C Loan and the Term D Loan is 4.25% 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%.

In addition, the period under which we are permitted to make interest-only payments on the Four 2022 Loans was extended to December 31, 2026, effective upon our decision to draw the Term B Loan in the amount of $22.5 million. In October 2023, we provided the Agent with notice of our decision to draw the Term B Loan to support the commercial launch of XPHOZAH and received the proceeds of the Term B Loan.

We were obligated to pay $0.2 million, upon the closing of the Term A Loan, and we were obligated to pay $0.1 million on the funding date of the Term B Loan. We are obligated to pay $0.3 million on the earliest of (1) the funding date of the Term C Loan, (2) March 15, 2024, and (3) the prepayment, refinancing, substitution or replacement of the Term B Loans on or prior to March 15, 2024. In addition, we will be obligated to pay 0.5% of the aggregate original principal amount of the Term D Loan commitment, if requested by us and approved by the Agent's investment committee, which shall be due on the earliest of (1) the funding of the Term D Loan, (2) if we request and the 2022 Lenders provide the Term D Loan commitment, the day immediately preceding the amortization date, and (3) if we request and the 2022 Lenders provide the Term D Loan commitment, the prepayment, refinancing, substitution or replacement of the Term C Loan on or prior to the date immediately preceding the amortization date.

We are obligated to pay a final fee equal to 4.95% of the aggregate original principal amount of the Four 2022 Loans, to the extent such loans are funded, upon the earliest to occur of the maturity date, the acceleration of the Four 2022 Loans, and the prepayment, refinancing, substitution, or replacement of the Four 2022 Loans.

We may voluntarily prepay all amounts outstanding under the Four 2022 Loans, subject to a prepayment premium of (i) 3% of the outstanding principal amount of the Four 2022 Loans if prepaid prior to or on October 17, 2024, (ii) 2% of the outstanding principal amount of the Four 2022 Loans if prepaid after October 17, 2024 through and including October 17, 2025, or (iii) 1% of the outstanding principal amount of the Four 2022 Loans if prepaid after October 17, 2025 and prior to the maturity date. The Four 2022 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 2022 Original Loans, we entered into an agreement whereby we agreed to pay an exit fee in the amount of 2% of the 2022 Original Loans funded (2022 Exit Fee). Notwithstanding the prepayment or termination of the 2022 Loan, the 2022 Exit Fee will expire 10 years from the Closing Date.

The 2022 Loan Agreement, as amended, contains customary representations and warranties and customary affirmative and negative covenants, including, among others, 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 or to redeem capital stock. We have agreed to not allow our cash and cash equivalents to be less than the eighty percent (80%) of the outstanding Four 2022 Term Loan balance 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 Four 2022 Loan balance.

In addition, the 2022 Loan Agreement, as amended, contains customary events of default that entitle the Agent to cause our indebtedness under the 2022 Loan Agreement to become immediately due and payable, and to exercise remedies against us and the collateral securing the Four 2022 Term Loans, including our cash. 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, certain Lenders determine 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 holder of indebtedness to accelerate the maturity of such indebtedness or that could have a material adverse change on us. Upon the occurrence and for the duration of an event of default, an additional default interest rate equal to 4% per annum will apply to all obligations owed under the 2022 Loan Agreement. We have classified the 2022 Original Loan balance as a non-current liability as of December 31, 2023 due to principal repayments beginning in January 2027. We have concluded that the provisions that could cause acceleration of the principal repayments are remote.

As of December 31, 2023, our future payment obligations related to the 2022 Loan, excluding interest payments and the 2022 final fee, were as follows (in thousands):

2024	$ —
2025	—
2026	—
2027	52,475
Thereafter	—
Total repayment obligations	52,475
Less: Unamortized discount and debt issuance costs	(912)
Less: Unaccreted value of final fee	(1,741)
Long-term debt	49,822
Less: Current portion of long-term debt	—
Long-term debt, net of current portion	$ 49,822

10. DERIVATIVE LIABILITIES

2018 Exit Fee

In May 2018, in connection with entering into the 2018 Loan Agreement, we entered into an agreement pursuant to which we agreed to pay $1.5 million in cash (2018 Exit Fee) upon any change of control transaction in respect of the Company or if we obtain both (i) U.S. FDA approval of XPHOZAH and (ii) U.S. FDA approval of IBSRELA, which was obtained on September 12, 2019 (2018 Exit Fee Agreement). Notwithstanding the February 2022 prepayment of the 2018 Loan, our obligation to pay the 2018 Exit Fee would have expired on May 16, 2028. We concluded that the 2018 Exit Fee was a freestanding derivative which should be accounted for at fair value on a recurring basis.

In October 2023, we received approval from the U.S. FDA for XPHOZAH to reduce serum phosphorus in adults with chronic kidney disease (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. This triggered our obligation to pay the 2018 Exit Fee to the 2018 Lenders, which we subsequently paid in October 2023. The estimated fair value of the 2018 Exit Fee was recorded as a derivative liability and included in accrued expense and other current liabilities on the accompanying balance sheets. As of December 31, 2023 and December 31, 2022, the estimated fair value of the 2018 Exit Fee was zero and $1.2 million, respectively.

The fair value of the derivative liability at December 31, 2022 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. Specifically, the key assumptions included in the calculation of the estimated fair value of the derivative instrument included: (i) our estimates of both the probability and timing of a potential $1.5 million payment to the 2018 Lenders as a result of the U.S. FDA approvals, and (ii) a discount rate which was derived from our estimated cost of debt, adjusted with current LIBOR.

2022 Exit Fee

In February 2022, in connection with entering into the 2022 Original Loans, we entered into an agreement, whereby we agreed to pay an exit fee in the amount of 2% of the 2022 Original Loan 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 Term C and Term D Loans do not result in payment of an additional exit fee. Notwithstanding the prepayment or termination of the 2022 Original Loans, the 2022 Exit Fee will expire on February 23, 2032. We concluded that the 2022 Exit Fee is a freestanding derivative which should be accounted for at fair value on a recurring basis. The estimated fair value of the 2022 Exit Fee is recorded as a derivative liability and included in accrued expenses and other current liabilities on the accompanying balance sheets. As of December 31, 2023 and December 31, 2022, the estimated fair value of the 2022 Exit Fee was $0.7 million and $0.4 million, respectively.

The fair value of the derivative liability was determined using a discounted cash flow analysis and is classified as a Level 3 measurement within the fair value hierarchy since our valuation utilized significant unobservable inputs. Specifically, the key assumptions included in the calculation of the estimated fair value of the 2022 Exit Fee derivative liability include: (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 two of the noted valuation estimates had been removed, as the Term B Loan had been funded and 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. Generally, increases or decreases in the probability of occurrence would result in a directionally similar impact in the fair value measurement of the derivative liability and it is estimated that a 10% increase (decrease) in the probability of occurrence would not result in a material fair value fluctuation.

Changes in the fair value of recurring measurements included in Level 3 of the fair value hierarchy are presented as other income, net in our statements of operations and comprehensive income (loss) and were as follows for the years ended December 31, 2023, 2022, and 2021 (in thousands):

	2023	2022
Balance at January 1,	$ 1,656	$ 698
2022 Exit Fee addition at fair value	—	375
Changes in estimated fair value:		
2018 Exit Fee	292	510
2022 Exit Fee	227	73
2018 Exit Fee payment	$ (1,500)	$ —
Fair value of exit fee derivative liabilities at December 31,	$ 675	$ 1,656

11. LEASES

We have recorded right-of-use operating lease assets under three lease agreements. We have evaluated our facility leases and determined that, effective upon the adoption of Topic 842, the leases evaluated are all operating leases. We have performed an evaluation of our other contracts with suppliers and collaborators in accordance with Topic 842 and have determined that, except for the facility leases described below, none of our contracts contain a lease.

We recorded right-of-use operating lease assets for our facility in Waltham, Massachusetts under a lease agreement entered into during December 2020 with lease commencement dates during April and May 2021. In August 2023, we entered into an amendment to the lease agreement to expand the leased premises to include an additional 4,247 square feet of office space. As of December 31, 2023, the Waltham office space consists of 17,111 square feet with the lease terminating in June 2026. We have an option to extend the lease term for one additional five year period. This option to extend the lease term has not been included in the calculation of the right-of-use asset and lease liability since the exercise of the option is uncertain and therefore deemed not probable. We recorded a $1.6 million right-of-use asset and lease liability for the Waltham lease upon commencement of the lease and an additional $0.3 million right-of-use asset and lease liability upon commencement of the lease amendment.

We have also recorded a right-of-use operating lease asset for our facility located in Fremont, California under a lease agreement entered into in September 2008 that was amended multiple times to add space and to extend the lease term through March 2025. The office space consists of 72,500 square feet. We do not have an option to renew the lease at our current Fremont location beyond March 2025. In March 2023, we entered into a sub-lease Agreement (Sub-lease) with Chronus Health, Inc. (Chronus). We have sub-leased to Chronus approximately 21,644 square feet of the 72,500 square foot building's interior space, plus corresponding exterior support space and parking. The term of the Sub-lease expires on February 1, 2025. In accordance with the Sub-lease, we recognized an impairment of long-lived assets totaling $0.4 million during the three months ended March 31, 2023, which consisted primarily of impairment to the Fremont facility right-of-use asset, as determined by measuring the undiscounted future cash flows from the sub-leased space. The Sub-lease commenced in April 2023 and we recognized $0.8 million of income from the Sub-lease during the year ended December 31, 2023.

We have recorded a right-of-use operating lease asset for our facility located in Milwaukee, Wisconsin under a lease agreement entered into in October 2020 with a lease commencement date in November 2020. The office space consists of 4,768 square feet with the lease terminating in February 2026. We have an option to extend the lease term by one additional five-year period. This option to extend the lease term has not been included in the calculation of the right-of-use asset and lease liability since the exercise of the option is uncertain and therefore deemed not probable. We recorded a $0.4 million right-of use asset and lease liability for the Milwaukee lease upon commencement of the lease.

All of our leases are operating leases and each contain customary rent escalation clauses. Certain of the leases have both lease and non-lease components. We have elected to account for each separate lease component and the non-lease components associated with that lease component as a single lease component for all classes of underlying assets.

The following table provides additional details of our facility leases presented in our balance sheets (dollars in thousands):

	December 31,	
Facilities	**2023**	**2022**
Right-of-use assets	$ 5,589	$ 9,295
Current portion of lease liabilities	4,435	3,894
Operating lease liability, net of current portion	1,725	5,855
Total lease liabilities	$ 6,160	$ 9,749
Weighted-average remaining life (years)	1.6	2.4
Weighted-average discount rate	6.8 %	6.8 %

The lease costs, which are included in operating expenses in our statements of operations, were as follows (in thousands):

	Year Ended December 31,		
	2023	**2022**	**2021**
Operating lease expense	$ 3,857	$ 4,257	$ 3,671
Cash paid for operating lease	$ 4,481	$ 4,292	$ 3,438

The following table summarizes our undiscounted cash payment obligations for our operating lease liabilities as of December 31, 2023 (in thousands):

Ending December 31,		
2024	$	4,715
2025		1,450
2026		329
Thereafter		—
Total undiscounted operating lease payments		6,494
Imputed interest expenses		(334)
Total operating lease liabilities		6,160
Less: Current portion of operating lease liability		(4,435)
Operating lease liability, net of current portion	$	1,725

12. STOCKHOLDERS' EQUITY

In July 2020, we filed a Form S-3 registration statement, which became effective in August 2020 (2020 Registration Statement), 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 $100.0 million of our common stock that may be issued and sold, from time to time, under a sales agreement with Jefferies LLC (Jefferies), deemed to be "at-the-market offerings" (2020 Open Market Sales Agreement). Pursuant to the 2020 Open Market Sales Agreement, Jefferies, as sales agent, received a commission of up to 3.0% of the gross sales price for shares of common stock sold under the 2020 Open Market Sales Agreement. As of December 31, 2021, we had sold 23.3 million shares and received the maximum gross proceeds of $100.0 million pursuant to the 2020 Open Market Sales Agreement at a weighted average share prices of $4.30 per share.

In August 2021, we filed an additional prospectus supplement under the 2020 Registration Statement 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 an additional sales agreement we entered into with Jefferies (2021 Open Market Sales Agreement), pursuant to which we may, from time to time, sell up to $150.0 million in shares of our common stock through Jefferies. We are required to sell shares under the 2021 Open Market Sales Agreement. Pursuant to the 2021 Open Market Sales Agreement, Jefferies, as our sales agent, receives a commission of up to 3.0% of the gross sales price for shares of common stock sold under the 2021 Open Market Sales Agreement. As of March 2023, we had received the maximum gross proceeds of $150.0 million under the 2021 Open Market Sales Agreement at a weighted average share price of approximately $1.57 per share, which included 15.5 million shares of our common stock for which we received gross proceeds of $51.9 million at a weighted average share price of approximately $3.35 during the quarter ended March 31, 2023.

In January 2023, we filed a Form S-3 registration statement, which became effective in January 2023 (2023 Registration Statement), 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. During the year ended December 31, 2023, we sold 16.8 million shares of our common stock and received gross proceeds of $70.0 million at a weighted average sales price of approximately $4.17 per share under the 2023 Open Market Sales Agreement.

13. EQUITY INCENTIVE PLANS

2008 Plan

We granted options under our 2008 Stock Incentive Plan (2008 Plan) until June 2014 when it was terminated as to future awards, although it continues to govern the terms of options that remain outstanding under the 2008 Plan. The 2008 Plan provided for the granting of incentive and non-qualified stock options, and stock purchase rights to employees, directors and consultants at the discretion of the board of directors. Stock options granted generally vested over a period of four years from the date of grant. In connection with the board of directors and stockholders' approval of the 2014 Plan, all remaining shares available for future award under the 2008 Plan were transferred to 2014 Plan, as discussed below, and the 2008 Plan was terminated.

2014 Plan

The 2014 Equity Incentive Award Plan (2014 Plan) became effective on June 18, 2014. Under the 2014 Plan, 1.4 million shares of common stock were initially reserved for issuance pursuant to a variety of stock-based compensation awards, including stock options, stock appreciation rights (SARs), restricted stock awards, service-based restricted stock unit (RSU) awards, performance-based restricted stock unit (PRSU) awards, deferred stock awards, deferred stock unit awards, dividend equivalent awards, stock payment awards and performance awards. In addition, 35 thousand shares that had been available for future awards under the 2008 Plan as of June 18, 2014, were added to the initial reserve available under the 2014 Plan, bringing the total reserve upon the effective date of the 2014 Plan to 1.5 million shares. The number of shares initially reserved for issuance or transfer pursuant to awards under the 2014 Plan will be increased by (i) the number of shares represented by awards outstanding under 2008 Plan on June 18, 2014, that are either forfeited or lapse unexercised or that are repurchased for the original purchase price thereof, up to a maximum of 1.2 million shares, and (ii) if approved by the administrator of the 2014 Plan, an annual increase on the first day of each fiscal year ending in 2024 equal to the lesser of (A) four percent (4.0%) of the shares of stock outstanding (on an as converted basis) on the last day of the immediately preceding fiscal year and (B) such smaller number of shares of stock as determined by our board of directors; provided, however, that no more than 10.7 million shares of stock may be issued upon the exercise of incentive stock options. As of December 31, 2023, approximately 2.5 million shares of our common stock were available for future issuance under the 2014 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, 2023, 6.0 million shares of our common stock were subject to inducement grants that were issued pursuant to the Inducement Plan. As of December 31, 2023, approximately 0.9 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, 2023 is as follows (in thousands, except per share dollar amounts and years):

	Options Issued and Outstanding			
	Number of Shares	Weighted-Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value
Balance at December 31, 2022	13,963	$ 4.83		
Options granted	8,914	$ 3.14		
Options exercised	(226)	$ 1.61		
Options canceled	(483)	$ 3.83		
Balance at December 31, 2023	22,168	$ 4.20	7.3	$ 58,606
Vested and expected to vest at December 31, 2023	22,168	$ 4.20	7.3	$ 58,606
Exercisable at December 31, 2023	12,199	$ 5.30	6.1	$ 25,116

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, 2023, based on our common stock closing price of $6.20 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, 2023, 2022 and 2021, was $1.1 million, $30 thousand, and $1.7 million, respectively.

The weighted-average grant-date estimated fair value of options granted during the years ended December 31, 2023, 2022 and 2021 was $2.36, $0.63 and $3.92 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,		
	2023	2022	2021
Expected term (years)	5.1	4.9	5.0
Expected volatility	97.6 %	92.1 %	77.0 %
Risk-free interest rate	3.8 %	2.2 %	4.7 %
Dividend yield	— %	— %	— %

Expected Term—We have limited historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock-option grants. As such, the expected term was initially estimated using the simplified method whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option. Beginning in 2021, we estimate the expected term of our options based upon historical exercises and post-vesting termination behavior, which has not resulted in a material difference as compared to using the simplified method.

Expected Volatility—Since January 1, 2017, 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, 2023 is as follows (in thousands, except per share dollar amounts):

	Number of RSUs	Weighted-Average Grant Date Fair Value Per Share
Non-vested restricted stock units at December 31, 2022	1,406	$ 2.17
Granted	3,269	$ 3.39
Vested	(942)	$ 2.76
Forfeited	(87)	$ 3.05
Non-vested restricted stock units at December 31, 2023	3,646	$ 3.09

The total estimated fair value of RSUs vested during the years ended December 31, 2023, 2022 and 2021 was $3.5 million, $2.6 million and $0.8 million, respectively.

Issuance of Common Stock for Services

During the years ended December 31, 2023, 2022 and 2021, we issued approximately 0.1 million, 0.7 million and 26 thousand 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, 2023, 2022 and 2021 were valued at $0.3 million, $0.4 million and $0.2 million for each year, respectively, based on the fair value of the common stock on the date of grant.

Employee Stock Purchase Plan

We adopted the 2014 Employee Stock Purchase Plan (ESPP) and initially reserved approximately 0.2 million shares of common stock as of its effective date of June 18, 2014. If approved by the administrator of the ESPP, on the first day of each calendar year, ending in 2024, the number of shares in the reserve will increase 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; provided, however, no more than 2.2 million shares of our common stock may be issued under the ESPP.

During the years ended December 31, 2023, 2022 and 2021, we issued approximately 436 thousand, 308 thousand and 387 thousand shares, respectively, at an average share price of $1.85, $0.63 and $2.12, respectively, pursuant to the ESPP. As of December 31, 2023, approximately 1.1 million shares of our common stock were available for future issuance under the 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,		
	2023	2022	2021
Expected term (years)	0.5	0.5	0.5
Expected volatility	86.0 %	97.2 %	123.0 %
Risk-free interest rate	5.3 %	1.9 %	0.7 %
Dividend yield	— %	— %	— %

Stock-based Compensation Expense

Stock-based compensation expense recognized for stock options, RSUs, and our ESPP are recorded as operating expenses in our statements of operations and comprehensive loss, as follows (in thousands):

	Year Ended December 31,		
	2023	2022	2021
Selling, general and administrative	$ 9,952	$ 7,525	$ 7,923
Research and development	3,578	3,225	4,116
Total	$ 13,530	$ 10,750	$ 12,039

A summary of our total unrecognized stock-based compensation expense, net of estimated forfeitures, as of December 31, 2023 is as follows (dollars in thousands):

	December 31, 2023	
	Unrecognized Compensation Expense	Average Remaining Vesting Period (Years)
Stock option grants	$ 19,960	2.75
RSU grants	$ 10,579	3.03
ESPP	$ 154	0.2

14. RESTRUCTURING

During 2021, we implemented restructuring plans in August and October following the receipt of a Complete Response Letter (CRL) from the U.S. FDA relating to our NDA for XPHOZAH and following the conclusion of an End of Review Type A meeting with the U.S. FDA, respectively. Both restructuring plans were substantially completed in December 2021 and most of the cash payments related to the reduction in workforce were disbursed prior to December 31, 2021.

In connection with restructuring, we incurred restructuring charges of $6.2 million, which were recorded during the year ended December 31, 2021, related to one-time termination notice and severance payments and other employee-related costs.

We did not incur any significant contract termination costs pursuant to restructuring. Of the charges, $2.7 million was recorded in research and development expenses, and $3.5 million was recorded in selling, general and administrative expense in the accompanying statements of operations and comprehensive loss.

15. PROPERTY AND EQUIPMENT, NET

Property and equipment consist of the following (in thousands):

	December 31,	
	2023	2022
Laboratory equipment	$ 46	$ 46
Office equipment and furniture	2,433	2,089
Leasehold improvements	8,731	8,745
Property and equipment, gross	11,210	10,880
Less: accumulated depreciation	(10,201)	(9,657)
Total property and equipment, net	$ 1,009	$ 1,223

We recognized depreciation expense in the amount of $0.6 million, $0.7 million, and $1.4 million for the years ended December 31, 2023, 2022 and 2021, respectively.

During the year ended December 31, 2022, following the elimination of our internal research organization in the fourth quarter of 2021, we sold laboratory equipment with total net carrying value of $0.5 million and received cash proceeds of $1.8 million, resulting in a gain of $1.3 million which has been reported within other income, net on our statement of operations and comprehensive loss.

16. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consist of the following (in thousands):

	December 31,	
	2023	2022
Accrued payments due to AstraZeneca	$ 3,680	$ 3,385
Accrued gross to net revenue liabilities	3,258	1,991
Accrued contract manufacturing expenses	1,946	1,657
Accrued sales and marketing expenses	3,223	587
Accrued professional and consulting services	486	808
Derivative liability for exit fees	675	1,656
Accrued clinical expenses	377	223
Accrued non-clinical research and development expenses	30	1,188
Other	1,366	885
Total accrued expenses and other current liabilities	$ 15,041	$ 12,380

17. INCOME TAXES

The components of our provision for income taxes for the years ended December 31, 2023, 2022 and 2021, are as follows (in thousands):

	Year Ended December 31,		
	2023	2022	2021
Current:			
State	$ 47	$ 8	$ 4
Foreign	500	—	—
Total current	547	8	4
Deferred:			
Federal	—	—	—
Total deferred	—	—	—
Provision for income taxes	$ 547	$ 8	$ 4

A reconciliation of the statutory federal income tax rate to our effective tax rate is as follows:

	Year Ended December 31,		
	2023	2022	2021
Income tax at the federal statutory rate	21.0 %	21.0 %	21.0 %
State taxes, net of federal benefit	3.4	1.9	0.4
Tax credits	1.7	1.5	1.0
Stock based compensation	0.1	(2.3)	(1.3)
Foreign withholding tax	(0.8)	—	—
Executive compensation disallowed under IRC Sec 162(m)	(1.9)	(1.6)	(1.1)
Other	—	(0.8)	—
Change in valuation allowance	(24.3)	(19.7)	(20.0)
Income tax provision	(0.8)%	— %	— %

Deferred income taxes reflect the tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of our deferred tax assets are as follows as of December 31, 2023 and 2022 (in thousands):

	December 31,	
	2023	2022
Deferred tax assets:		
Amortization and depreciation	$ 64,919	$ 64,111
Net operating loss carryforwards	98,702	86,547
Tax credits	15,375	14,411
Stock-based compensation	6,946	5,244
Deferred royalty obligation	4,907	2,577
Other	6,707	4,909
Gross deferred tax assets	197,556	177,799
Valuation allowance	(196,197)	(175,670)
Deferred tax assets net of valuation allowance	1,359	2,129
Deferred tax liabilities:		
Right-of-use asset	(1,359)	(2,129)
Other	—	—
Net deferred tax assets	$ —	$ —

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, 2023. 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, 2023, 2022 and 2021, a full valuation allowance has been recorded against our net deferred tax asset. The valuation allowance increased by $20.5 million in 2023 primarily due to increases in net operating losses. The amount of the deferred tax asset considered realizable, however, could be adjusted if estimates of future taxable income during the carryforward period are reduced or increased or if objective negative evidence in the form of cumulative losses is no longer present and additional weight is given to subjective evidence such as our projections for growth.

As of December 31, 2023, we had net operating loss carryforwards for federal income tax purposes of approximately $479.0 million, of which approximately $328.8 million can be carried forward indefinitely and the remaining net operating losses expire beginning in 2030, if not utilized. Federal research and development tax credit carryforwards of approximately $17.8 million that expire beginning in 2027, if not utilized, and foreign tax credit carryforwards of approximately $1.7 million that begin to expire in 2027, if not utilized.

In addition, we had net operating loss carryforwards for California income tax purposes of approximately $92.9 million that expire beginning of 2030, if not utilized, and state research and development tax credit carryforwards of approximately $8.9 million which can be carried forward indefinitely. We had approximately $0.1 million of minimum tax credit carryovers for California income tax purposes. The minimum tax credits have no expiration date. We had other state net operating losses of approximately $50.5 million that begin to expire in 2031.

The future utilization of net operating loss and tax credit carryforwards and credits 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.

Under the Tax Cuts and Jobs Act of 2017, research and development costs are no longer fully deductible and are required to be capitalized and amortized for U.S. tax purposes effective January 1, 2022. 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 capitalized 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,		
	2023	2022	2021
Balance at beginning of year	$ 24,075	$ 24,426	$ 23,624
Additions based on tax positions related to current year	262	460	1,613
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	$ 23,625	$ 24,075	$ 24,426

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, 2023, 2022 and 2021, 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.

18. 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 revenue by geographic areas for the years ended December 31, 2023, 2022 and 2021, is as follows (in thousands):

	Year Ended December 31,		
	2023	2022	2021
United States (1)	$ 83,276	$ 15,600	$ —
International:			
Asia Pacific (2)	41,121	36,527	10,084
North America (3)	59	31	13
Total revenue	$ 124,456	$ 52,158	$ 10,097

(1) 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.
(2) Revenues from Asia Pacific are primarily comprised of amounts earned in accordance with the 2017 Kyowa Kirin Agreement, the 2019 Kyowa Kirin Agreement and the Fosun Agreement.
(3) Revenues from North America are comprised of amounts earned from Canada in accordance with the Knight Agreement.

Revenues from Customers and collaboration partnerships accounting for more than 10% of total revenues during the years ended December 31, 2023, 2022 and 2021 were as follows:

	Year Ended December 31,		
	2023	2022	2021
Kyowa Kirin	29.0 %	70.0 %	100.0 %
Bioridge Phama	24.0 %	3.2 %	— %
Cardinal	19.8 %	9.6 %	— %
AmerisourceBergen Drug Corporation	19.1 %	11.1 %	— %
McKesson	15.7 %	8.9 %	— %

19. 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, 2023, 2022 and 2021, all potential common shares were determined to be anti-dilutive.

The following table sets forth the computation of net loss per common share (in thousands, except per share dollar amounts):

	Year Ended December 31,		
	2023	2022	2021
Numerator:			
Net loss	$ (66,067)	$ (67,207)	$ (158,165)
Denominator:			
Weighted average common shares outstanding - basic and diluted	219,331	158,690	104,206
Net loss per share - basic and diluted	$ (0.30)	$ (0.42)	$ (1.52)

For the years ended December 31, 2023, 2022 and 2021, 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,		
	2023	2022	2021
Options to purchase common stock	20,877	13,522	11,871
Restricted stock units	3,086	2,694	1,602
ESPP shares issuable	249	166	207
Total	24,212	16,382	13,680

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, 2023, 2022 and 2021, was approximately 6.3 million, 0.6 million and 1.1 million, respectively.

20. 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, 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 an amended complaint on September 29, 2022. Defendants filed a motion to dismiss the amended complaint on December 2, 2022. In January and February 2023, in lieu of filing a response to defendant's motion to dismiss, plaintiffs filed a motion seeking leave to further amend their complaint and defendants filed an opposition to the motion for leave to further amend the complaint. On April 6, 2023, the court granted plaintiff's motion for leave to further amend the complaint. With the second amended complaint, 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 August 22, 2023, the court cancelled the hearing scheduled for September 14, 2023 on the motion to dismiss the amended complaint and indicated its decisions to instead rule on the filed briefs. We believe the plaintiff's claims are without merit and we have not recorded any accrual for a contingent liability associated with these legal proceedings.

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. We believe the plaintiff's claims are without merit and we have not recorded any accrual for a contingent liability associated with these legal proceedings.

From time to time, we may be involved in legal proceedings arising in the ordinary course of business. As of December 31, 2023, there is no litigation pending that would reasonably be expected to have a material adverse effect on our results of operations and financial condition, and no contingent liabilities were accrued as of December 31, 2023.

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, 2023, management, with the participation of our Chief Executive Officer (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, 2023, 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, 2023, 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, 2023, 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, 2023 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, 2023. 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, 2023, 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, 2023, 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, 2023 and 2022, 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, 2023, and the related notes, and our report dated February 22, 2024 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 22, 2024

ITEM 9B. OTHER INFORMATION

Trading Plans

During the three months ended December 31, 2023, 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**		
Michael Raab, President and Chief Executive Officer	Adoption	December 13, 2023	X		331,300	January 6, 2025
Elizabeth Grammer, Chief Legal Officer	Adoption	December 20, 2023	X		131,000	July 16, 2024
Robert Blanks, Chief Regulatory Officer	Adoption	December 21, 2023	X		48,000	June 21, 2024
Laura Williams, Chief Medical Officer	Adoption	December 27, 2023	X		79,949	March 27, 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

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information required by this item will be contained in our definitive proxy statement to be filed with the Securities and Exchange Commission on Schedule 14A in connection with our 2024 Annual Meeting of Stockholders (Proxy Statement), which will be filed not later than 120 days after the end of our fiscal year ended December 31, 2023, under the headings "Executive Officers," "Election of Directors," "Corporate Governance," and " Section 16(a) Beneficial Ownership Reporting Compliance," and is incorporated herein by reference.

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. 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. 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.

ITEM 11. EXECUTIVE COMPENSATION

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.

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

The information required by this item regarding security ownership of certain beneficial owners and management will be incorporated by reference to the information set forth in the section titled "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" in our Proxy Statement.

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

The information required by this item regarding certain relationships and related transactions and director independence will be incorporated by reference to the information set forth in the sections titled "Certain Relationships and Related Party Transactions" and "Election of Directors", respectively, in our Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item regarding principal accountant fees and services will be incorporated by reference to the information set forth in the section titled "Principal Accountant Fees and Services" in our Proxy Statement.

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 [IN PROCESS]

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	10.31	
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	

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.3	Lease Agreement, dated December 30, 2020, by and between Ardelyx, Inc. and Prospect Fifth Ave, LLC.	10-K	3/8/2021	10.31	
10.4(a)#	Ardelyx, Inc. 2008 Stock Incentive Plan, as amended	S-1	5/19/2014	10.5(a)	
10.4(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)	
10.4(c)#	Form of Restricted Stock Purchase Grant Notice and Restricted Stock Purchase Agreement under the 2008 Stock Incentive Plan, as amended	S-1	5/19/2014	10.5(c)	
10.5(a)#	Ardelyx, Inc. 2014 Equity Incentive Award Plan	S-8	7/14/2014	99.3	
10.5(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)	
10.5(c)#	Form of Restricted Stock Award Agreement and Restricted Stock Unit Award Grant Notice under the 2014 Equity Incentive Award Plan	S-1/A	6/9/2014	10.6(c)	
10.6#	Ardelyx, Inc. 2014 Employee Stock Purchase Plan	S-8	7/14/2014	99.6	
10.7(a)#	Ardelyx, Inc. 2016 Employment Commencement Incentive Plan				X
10.7(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	
10.7(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	
10.7(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	
10.8	Registration Rights Agreement by and among Ardelyx, Inc. and the investors signatory thereto, dated June 2, 2015	S-3	7/13/2015	99.1	
10.9	Registration Rights Agreement by and among Ardelyx, Inc. and the investors signatory thereto, dated July 14, 2016	10-Q	8/8/2016	10.2	
10.10#	Form of Indemnification Agreement for directors and officers	S-1/A	6/9/2014	10.7	
10.11#	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	
10.12#	Offer Letter, dated December 28, 2009, by and between Ardelyx, Inc. and David Rosenbaum, Ph.D.	S-1/A	6/9/2014	10.13	
10.13(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	
10.13(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 David Rosenbaum	10-K	2/28/2022	10.20	
10.14#	Offer Letter, dated November 21, 2012, by and between Ardelyx, Inc. and Elizabeth Grammer, Esq.	S-1/A	6/9/2014	10.14	
10.15#	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	
10.16#	Offer Letter, dated April 27, 2020, by and between Ardelyx, Inc. and Susan Rodriguez	10-Q	8/6/2020	10.1	
10.17#	Change in Control Severance Agreement dated June 2, 2020, by and between Ardelyx, Inc. and Susan Rodriguez	10-Q	8/6/2020	10.2	
10.18#	Offer Letter, dated June 2, 2020, by and between Ardelyx, Inc. and Justin Renz	10-Q	8/6/2020	10.3	
10.19#	Change in Control Severance Agreement, dated June 8, 2020, by and between Ardelyx, Inc. and Justin Renz	10-Q	8/6/2020	10.4	
10.20(a)#	Second Amended and Restated Non-Employee Director Compensation Program	10-Q	8/4/2022	10.3	

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.20(b)#	Third Amended and Restated Non-Employee Director Compensation Program				X
10.21(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	
10.21(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(c)	
10.21(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	10.1	
10.22††	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	
10.23††	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	
10.24(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	
10.24(b)	First Amendment to the Loan and Security Agreement dated August 1, 2022, by and between Ardelyx, Inc. and SLR Investment Corp.	10-Q	8/4/2022	10.2	
10.24(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)	
10.24(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	
10.25	Exit Fee Agreement dated February 23, 2022, by and between Ardelyx, Inc. and SLR Investment Corp.	10-Q	5/5/2022	10.2	
10.26	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	
10.27(a)††	Manufacturing Services Agreement, dated May 18, 2020, between Ardelyx, Inc. and Patheon Pharmaceuticals Inc.	10-Q	8/6/2020	10.5	
10.27(b)††	First Amendment to the Manufacturing Services Agreement dated February 27, 2023, between Ardelyx, Inc. and Patheon Pharmaceuticals Inc.	10-K	3/2/2023	10.3	
10.28	Open Market Sales Agreement, dated August 31, 2021 between Ardelyx, Inc. and Jefferies LLC.	8-K	8/13/2021	10.1	
10.29	Open Market Sales Agreement, dated January 18, 2023 between Ardelyx, Inc. and Jefferies LLC.	S-3	1/19/2023	1.2	
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				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document			—	X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document			—	X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document			—	X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document			—	X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document			—	X

† 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 22, 2024

By: /s/ Robert Felsch

Robert Felsch
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 Robert Felsch, 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.

Signature	Title	Date
/s/ Michael Raab Michael Raab	President, Chief Executive Officer and Director *(Principal Executive Officer)*	February 22, 2024
/s/ Justin Renz Justin Renz	Chief Financial and Operations Officer *(Principal Financial Officer)*	February 22, 2024
/s/ Robert Felsch Robert Felsch	Chief Accounting Officer *(Principal Accounting Officer)*	February 22, 2024
/s/ David Mott David Mott	Chairman of the Board of Directors	February 22, 2024
/s/ Robert Bazemore Robert Bazemore	Director	February 22, 2024
/s/ William Bertrand, Jr. William Bertrand, Jr., J.D.	Director	February 22, 2024
/s/ Muna Bhanji Muna Bhanji, R.Ph	Director	February 22, 2024
/s/ Onaiza Cadoret-Manier Onaiza Cadoret-Manier	Director	February 22, 2024
/s/ Jan M. Lundberg Jan M. Lundberg, Ph.D.	Director	February 22, 2024
/s/ Richard Rodgers Richard Rodgers	Director	February 22, 2024

ARDELYX, INC.
2016 EMPLOYMENT COMMENCEMENT INCENTIVE PLAN

ARTICLE 1.

PURPOSE

The purpose of the Ardelyx, Inc. 2016 Employment Commencement Incentive 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 Eligible Individuals 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 Employees upon whose judgment, interest, and special effort the successful conduct of the Company's operation is largely dependent. Only Eligible Individuals may receive awards under the Plan.

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. For the avoidance of doubt, only the Committee or the Board may grant Awards under the Plan.

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.

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 "Deferred Stock" shall mean a right to receive Shares awarded under Section 9.4 hereof.

2.14 "Deferred Stock Unit" shall mean a right to receive Shares awarded under Section 9.5 hereof.

2.15 "Director" shall mean a member of the Board, as constituted from time to time.

2.16 "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.

2.17 "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.

2.18 "Effective Date" shall mean the date on which the Board has adopted the Plan.

2.19 "Eligible Individual" shall mean any Employee who has not previously been an Employee or Director of the Company or a Subsidiary, or is commencing employment with the Company or a Subsidiary following a bona fide period of non-employment by the Company or a Subsidiary, if he or she is granted an Award in connection with his or her commencement of employment with the Company or a Subsidiary and such grant is an inducement material to his or her entering into employment with the Company or a Subsidiary. The Board may in its discretion adopt procedures from time to time to ensure that an Employee is eligible to participate in the Plan prior to the granting of any Awards to such Employee under the Plan (including, without limitation, a requirement, that each such Employee certify to the Company prior to the receipt of an Award under the Plan that he or she has not been previously employed by the Company or a Subsidiary, or if previously employed, has had a bona fide period of non-employment, and that the grant of Awards under the Plan is an inducement material to his or her agreement to enter into employment with the Company or a Subsidiary).

2.20 "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.

2.21 "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.

2.22 "Exchange Act" shall mean the Securities Exchange Act of 1934, as amended from time to time.

2.23 "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 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.

2.24 "Holder" shall mean an Eligible Individual who has been granted an Award.

2.25 "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. Incentive Stock Options may not be granted under the Plan.

2.26 "Non-Employee Director" shall mean a Director of the Company who is not an Employee of the Company and who qualifies as "independent" within the meaning of Nasdaq Stock Market Rule 5605(a)(2), or any successor rule, if the Company's securities are traded on the Nasdaq Stock Market, or if the requirements of any other established stock exchange on which the Company's securities are traded, as such rules or requirements may be amended from time to time.

2.27 "Non-Qualified Stock Option" shall mean an Option that is not an Incentive Stock Option.

2.28 "Option" shall mean a right to purchase Shares at a specified exercise price, granted under Article 5 hereof. Any Option granted under this Plan shall be a Non-Qualified Stock Option.

2.29 "Option Term" shall have the meaning set forth in Section 5.4 hereof.

2.30 "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.

2.31 "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.

2.32 "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.

2.33 "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.

2.34 "Plan" shall have the meaning set forth in Article 1 hereof.

2.35 "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.

2.36 "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.

2.37 "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.

2.38 "Securities Act" shall mean the Securities Act of 1933, as amended.

2.39 "Shares" shall mean shares of Common Stock.

2.40 "Share Limit" shall have the meaning set forth in Section 3.1(a) hereof.

2.41 "Stock Appreciation Right" shall mean a stock appreciation right granted under Article 10 hereof.

2.42 "Stock Appreciation Right Term" shall have the meaning set forth in Section 10.4 hereof.

2.43 "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.

2.44 "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.

2.45 "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.

2.46 "Termination of Service" shall mean 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. 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 shall be 12,207,767 Shares (the "Share Limit"). 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. In addition, the following Shares shall be available for future grants of Awards under the Plan and shall be added back to the Share Limit: (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; and (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. Any Shares repurchased by the Company under 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 will again be available for Awards. 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.

(c) Substitute Awards shall not reduce the Shares authorized for grant under the Plan. 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; 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.

ARTICLE 4.

GRANTING OF AWARDS

4.1 Participation. The Committee and the Board 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. 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.

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 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, 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, 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 Section 3.1 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 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. Each of the Committee and the Board 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 Option Exercise Price. Except as provided in Article 13 hereof, the exercise price per Share subject to each Option shall be set by the Committee or the Board, 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.

5.3 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. 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 of the Code or the first sentence of this Section 5.3, 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.

5.4 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.

5.5 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.

5.6 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.

ARTICLE 7.

AWARD OF RESTRICTED STOCK

7.1 Award of Restricted Stock.

(a) Each of the Committee and the Board 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 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.

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. Each of the Committee and the Board 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 (15th) day of the third (3rd) month following the end of calendar year in which the Restricted Stock Unit vests; or (b) the fifteenth (15th) day of the third (3rd) 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; 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) Each of the Board and the Committee 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 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, each of the Board and the Committee may grant Performance Awards to any Eligible Individual in the form of a cash bonus payable upon the attainment of objective performance criteria, 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 each of the Board and the Committee 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.

(b) Notwithstanding the foregoing, no Dividend Equivalents shall be payable with respect to Options or Stock Appreciation Rights.

9.3 Stock Payments. Each of the Board and the Committee 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 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. Each of the Board and the Committee 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 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. Each of the Board and the Committee 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 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. 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) Each of the Board and the Committee 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 or employment tax 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 may in its sole discretion and in satisfaction of the foregoing requirement allow a Holder to satisfy such obligations by any payment means described in Section 11.1 hereof, including without limitation, by allowing such 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. 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 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 in the case of any (a) leave of absence approved by the Company or (b) transfer between locations of the Company or between the Company and any of its Affiliates or any successor thereof.

ARTICLE 12.

ADMINISTRATION

12.1 Administrator. The Committee and the Board shall administer the Plan (except as otherwise permitted herein). Any action taken by the Board in connection with the administration of the Plan shall not be deemed approved by the Board unless such actions are approved by a majority of the Non-Employee Directors. Except as may otherwise be provided in any charter of the Committee or the Board, appointment of Committee and Board members shall be effective upon acceptance of appointment. Committee and Board members may resign at any time by delivering

written or electronic notice to the Board. Vacancies in the Committee and the Board may only be filled by the Board.

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. 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 as described in Section 12.1 above and 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) Adopt procedures from time to time in the Administrator's discretion to ensure that an Employee is eligible to participate in the Plan prior to the granting of any Awards to such Employee under the Plan (including, without limitation, a requirement, if any, that each such Employee certify to the Company prior to the receipt of an Award under the Plan that he or she has not been previously employed by the Company or a Subsidiary, or if previously employed, has had a bona fide period of non-employment, and that the grant of Awards under the Plan is an inducement material to his or her agreement to enter into employment with the Company or a Subsidiary);

(b) Designate Eligible Individuals to receive Awards;

(c) Determine the type or types of Awards to be granted to each Eligible Individual;

(d) Determine the number of Awards to be granted and the number of Shares to which an Award will relate;

(e) 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;

(f) 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;

(g) Prescribe the form of each Award Agreement, which need not be identical for each Holder;

(h) Decide all other matters that must be determined in connection with an Award;

(i) Establish, adopt, or revise any rules and regulations as it may deem necessary or advisable to administer the Plan;

(j) Interpret the terms of, and any matter arising pursuant to, the Plan, any Program or any Award Agreement;

(k) 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

(l) 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 Sections 3.4 and 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 Non-Employee Directors or officers of the Company the authority to amend Awards or to take other administrative actions pursuant to Article 12. Notwithstanding the foregoing, only the Committee and the Board, acting in accordance with this Article 12, may grant Awards 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 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. 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) reduce the price per share of any outstanding Option or Stock Appreciation Right granted under the Plan, or (b) 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.

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 terms and conditions of any outstanding Awards (including, without limitation, any applicable performance targets or criteria with respect thereto); and (iv) 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) 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.

(g) 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 Stockholder Approval of the Plan not Required. It is expressly intended that approval of the Company's stockholders not be required as a condition of the effectiveness of the Plan, and the Plan's provisions shall be interpreted in a manner consistent with such intent for all purposes. Specifically, Nasdaq Stock Market Rule 5635(c) generally requires stockholder approval for stock option plans or other equity compensation arrangements adopted by companies whose securities are listed on the Nasdaq Stock Market pursuant to which stock awards or stock may be acquired by officers, directors, employees, or consultants of such companies. Nasdaq Stock Market Rule 5635(c)(4) provides an exception to this requirement for issuances of securities to a person not previously an employee or director of the issuer, or following a bona fide period of non-employment, as an inducement material to the individual's entering into employment with the issuer; provided, such issuances are approved by either the issuer's compensation committee comprised of a majority of independent directors or a majority of the issuer's independent directors. Notwithstanding anything to the contrary herein, Awards under the Plan may only be made to Employees who have not previously been an Employee or Director of the Company or a Subsidiary, or following a bona fide period of non-employment by the Company or a Subsidiary, as an inducement material to the Employee's entering into employment with the Company or a Subsidiary. Awards under the Plan will be approved by (i) the Company's Compensation Committee comprised of a majority of the Company's Non-Employee Directors or (ii) a majority of the Company's Non-Employee Directors. Accordingly, pursuant to Nasdaq Stock Market Rule 5635(c)(4), the issuance of Awards and the Shares issuable upon exercise or vesting of such Awards pursuant to the Plan are not subject to the approval of the Company's stockholders.

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 or other service providers 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.

ARDELYX, INC.
THIRD AMENDED AND RESTATED
NON-EMPLOYEE DIRECTOR COMPENSATION PROGRAM

Non-employee members of the board of directors (the "***Board***") of Ardelyx, Inc. (the "***Company***") shall be eligible to receive cash and equity compensation as set forth in this Non-Employee Director Compensation Program (this "***Program***"), which was adopted pursuant to the Board's resolutions on May 23, 2014, and amended pursuant to the Board's resolutions on March 3, 2017, March 14, 2019, March 11, 2021, June 15, 2022, and December 5, 2023. The cash and equity compensation described in this Program shall be paid or be made, as applicable, automatically and without further action of the Board, to each member of the Board who is not an employee of the Company or any parent or subsidiary of the Company (each, a "***Non-Employee Director***") who may be eligible to receive such cash or equity compensation, unless such Non-Employee Director declines the receipt of such cash or equity compensation by written notice to the Company. This Program shall remain in effect until it is revised or rescinded by further action of the Board. This Program may be amended, modified or terminated by the Board at any time in its sole discretion. The terms and conditions of this Program shall supersede any prior cash and/or equity compensation arrangements for service as a member of the Board between the Company and any of its Non-Employee Directors. This Program shall become effective on the date of the closing of the initial public offering of Company common stock (the "***Effective Date***").

1. Cash Compensation.

(a) Annual Retainers. Each Non-Employee Director shall be eligible to receive an annual retainer of $50,000 for service on the Board.

(b) Additional Annual Retainers. In addition, a Non-Employee Director shall receive the following annual retainers:

(i) Chairman of the Board. A Non-Employee Director serving as Chairman of the Board shall receive an additional annual retainer of $35,000 for such service.

(ii) Audit Committee. A Non-Employee Director serving as Chairperson of the Audit Committee shall receive an additional annual retainer of $20,000 for such service. A Non-Employee Director serving as a member of the Audit Committee (other than the Chairperson) shall receive an additional annual retainer of $10,000 for such service.

(iii) Compensation Committee. A Non-Employee Director serving as Chairperson of the Compensation Committee shall receive an additional annual retainer of $15,000 for such service. A Non-Employee Director serving as a member of the Compensation Committee (other than the Chairperson) shall receive an additional annual retainer of $7,500 for such service.

(vi) Nominating and Corporate Governance Committee. A Non-Employee Director serving as Chairperson of the Nominating and Corporate Governance Committee shall receive an additional annual retainer of $10,000 for such service. A Non-Employee Director serving as a member of the Nominating and Corporate Governance Committee (other than the Chairperson) shall receive an additional annual retainer of $5,000 for such service.

(c) Payment of Retainers. The annual retainers described in Sections 1(a) and 1(b) (the "***Annual Retainers***") shall be paid by the Company in a single cash lump sum immediately following the Effective Date and on the date of each annual meeting of the Company's stockholders after the Effective Date. In the event a Non-Employee Director is initially elected or appointed to the Board or a committee thereunder on a date other than the date of an annual meeting of the Company's stockholders, the Annual Retainers paid to such Non-Employee Director shall be paid on the date of election or appointment, prorated to reflect the number of months (rounded up to the next whole month) remaining until the next annual meeting of the Company's stockholders.

(d) Election to Receive Stock in Lieu of Cash. After the first payment of Annual Retainers following the Effective Date, Non-Employee Directors shall have the ability to elect to receive the Annual Retainers in an award of stock in lieu of cash pursuant to an election form provided by the Company for such purpose. Non-Employee Directors must complete and deliver the election form to the Company no later than 15 days prior to the next annual meeting of the Company's stockholders. In the event that a Non-Employee Director makes an election to receive the Annual Retainers in an award of stock in lieu of cash, on the annual meeting of the Company's stockholders, he or she will automatically be granted that number of shares of fully vested Company common stock calculated by dividing the aggregate amount of the Annual Retainers by the Fair Market Value (as defined in the Equity Plan (as defined below)) of a share of Company common stock on the date of grant, rounded down to the nearest whole share. The stock awards shall be granted under and shall be subject to the terms and provisions of the Company's 2014 Equity Incentive Award Plan or any other applicable Company equity incentive plan then-maintained by the Company (the "***Equity Plan***"). In the event of any inconsistency between the Equity Plan and this Program, the terms of this Program shall control.

2. Equity Compensation. Non-Employee Directors shall be granted the equity awards described below. The awards described below shall be granted under and shall be subject to the terms and provisions of the Equity Plan and shall be granted subject to the execution and delivery of award agreements, including attached exhibits, in substantially the forms previously approved by the Board. All applicable terms of the Equity Plan apply to this Program as if fully set forth herein, and all grants of stock options hereby are subject in all respects to the terms of the Equity Plan. In the event of any inconsistency between the Equity Plan and this Program, the terms of this Program shall control.

(a) Initial Awards. Each Non-Employee Director who is initially elected or appointed to the Board after the Effective Date shall be eligible to receive, on the date of such initial election or appointment, an option to purchase shares of the Company's common stock with a grant date fair value of $300,000, but with a maximum number of shares of 200,000 shares of the Company's common stock. The awards described in this Section 2(a) shall be referred to as "***Initial Awards***." No Non-Employee Director shall be granted more than one Initial Award.

(b) Subsequent Awards. A Non-Employee Director who (i) has been serving on the Board for at least six months as of the date of any annual meeting of the Company's stockholders after the Effective Date and (ii) will continue to serve as a Non-Employee Director immediately following such meeting, shall be automatically granted, on the date of such annual meeting, an option to purchase shares of the Company's common stock with a grant date fair value of $200,000, but with a maximum number of shares of 100,000 shares of the Company's common stock. The awards described in this Section 2(b) shall be referred to as "***Subsequent Awards***." For the avoidance of doubt, a Non-Employee Director elected for the first time to the Board at an annual meeting of the Company's stockholders shall only receive an Initial Award in connection with such election, and shall not receive any Subsequent Award on the date of such meeting as well.

(c) Termination of Service of Employee Directors. Members of the Board who are employees of the Company or any parent or subsidiary of the Company who subsequently terminate their service with the Company and any parent or subsidiary of the Company and remain on the Board will not receive an Initial Award pursuant to Section 2(a) above, but to the extent that they are otherwise eligible, will be eligible to receive, after termination from service with the Company and any parent or subsidiary of the Company, Subsequent Awards as described in Section 2(b) above.

(d) Terms of Awards Granted to Non-Employee Directors

(i) Purchase Price. The per share exercise price of each option granted to a Non-Employee Director shall equal the Fair Market Value (as defined in the Equity Plan) of a share of common stock on the date the option is granted.

(ii) Vesting. Each Initial Award shall vest and become exercisable with respect to 1/36th of the shares subject to the Initial Award on each monthly anniversary of the date of grant, subject to the Non-Employee Director continuing in service on the Board through each such vesting

date. Each Subsequent Award shall vest and become exercisable with respect to 1/12th of the shares subject to the Subsequent Award on each monthly anniversary of the date of grant, which vesting will accelerate in full immediately prior to the next annual meeting of the Company's stockholders after the date of grant to the extent unvested as of such date, subject to the Non-Employee Director continuing in service on the Board through each such vesting date. Unless as otherwise specified herein, no portion of an Initial Award or Subsequent Award which is unvested or unexercisable at the time of a Non-Employee Director's termination of service on the Board shall become vested and exercisable thereafter. All of a Non-Employee Director's Initial Awards and Subsequent Awards, and any other stock options or other equity-based awards outstanding and held by the Non-Employee Director, shall vest in full immediately prior to the occurrence of a Change in Control (as defined in the Equity Plan), to the extent outstanding at such time.

(iii) Term. The term of each stock option granted to a Non-Employee Director shall be ten (10) years from the date the option is granted.

3. Reimbursements. The Company shall reimburse each Non-Employee Director for all reasonable, documented, out-of-pocket travel and other business expenses incurred by such Non-Employee Director in the performance of his or her duties to the Company in accordance with the Company's applicable expense reimbursement policies and procedures as in effect from time to time.

* * * * *

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

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

1. Registration Statement on Form S-8 (No. 333-197408) pertaining to the 2008 Stock Incentive Plan, as amended, the 2014 Equity Incentive Award Plan and the 2014 Employee Stock Purchase Plan of Ardelyx, Inc.,

2. Registration Statements on Form S-8 (Nos. 333-202663 and 333-230156) pertaining to the 2014 Equity Incentive Award Plan and the 2014 Employee Stock Purchase Plan of Ardelyx, Inc.,

3. Registration Statements on Form S-3 (Nos. 333-205630, 333-213085, 333-239764 and 333-269297) of Ardelyx, Inc.,

4. Registration Statements on Form S-8 (Nos. 333-210079, 333-216154, 333-223694 and 333-237057) pertaining to the 2014 Equity Incentive Award Plan of Ardelyx, Inc.,

5. Registration Statement on Form S-8 (No. 333-214538) pertaining to the 2016 Employment Commencement Incentive Plan of Ardelyx, Inc.,

6. Registration Statement on Form S-8 (Nos. 333-254187 and 333-270314) pertaining to the 2014 Equity Incentive Award Plan, the 2014 Employee Stock Purchase Plan and the 2016 Employment Commencement Incentive Plan of Ardelyx, Inc., and

7. Registration Statement on Form S-8 (333-263145) pertaining to the 2014 Equity Incentive Award Plan and the 2016 Employment Commencement Incentive Plan of Ardelyx, Inc.;

of our reports dated February 22, 2024, with respect to the financial statements of Ardelyx, Inc. and the effectiveness of internal control over financial reporting of Ardelyx, Inc. included in this Annual Report (Form 10-K) of Ardelyx, Inc. for the year ended December 31, 2023.

/s/ Ernst & Young LLP
Boston, Massachusetts

February 22, 2024

Exhibit 31.1

CERTIFICATION

I, Michael Raab, certify that:

1. I have reviewed this Annual Report on Form 10-K of Ardelyx, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 22, 2024

By: /s/ Michael Raab

Michael Raab
President, Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Justin Renz, certify that:

1. I have reviewed this Annual Report on Form 10-K of Ardelyx, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 22, 2024

By: /s/ Justin Renz

Justin Renz
Chief Financial & Operations Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Ardelyx, Inc. (the "Company") on Form 10-K for the period ending December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Michael Raab, President and Chief Executive Officer of the Company, and Justin Renz, Chief Financial & Operations Officer of the Company, respectively, do each hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: February 22, 2024 By: /s/ Michael Raab

Michael Raab
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: February 22, 2024 By: /s/ Justin Renz

Justin Renz
Chief Financial & Operations Officer
(Principal Financial Officer)

ARDELYX, INC.

POLICY FOR RECOVERY OF ERRONEOUSLY AWARDED COMPENSATION

Ardelyx, Inc. (the "***Company***") has adopted this Policy for Recovery of Erroneously Awarded Compensation (the "***Policy***"), effective as of October 2, 2023 or such later date when Listing Rule 5608 of the Nasdaq Stock Market ("***Nasdaq***") becomes effective (the "***Effective Date***"). Capitalized terms used in this Policy but not otherwise defined herein are defined in Section 11.

1. Persons Subject to Policy

This Policy shall apply to current and former Officers of the Company.

2. Compensation Subject to Policy

This Policy shall apply to Incentive-Based Compensation received on or after the Effective Date. For purposes of this Policy, the date on which Incentive-Based Compensation is "received" shall be determined under the Applicable Rules, which generally provide that Incentive-Based Compensation is "received" in the Company's fiscal period during which the relevant Financial Reporting Measure is attained or satisfied, without regard to whether the grant, vesting or payment of the Incentive-Based Compensation occurs after the end of that period.

3. Recovery of Compensation

In the event that the Company is required to prepare a Restatement, the Company shall recover, reasonably promptly, the portion of any Incentive-Based Compensation that is Erroneously Awarded Compensation, unless the Committee has determined that recovery would be Impracticable. Recovery shall be required in accordance with the preceding sentence regardless of whether the applicable Officer engaged in misconduct or otherwise caused or contributed to the requirement for the Restatement and regardless of whether or when restated financial statements are filed by the Company. For clarity, the recovery of Erroneously Awarded Compensation under this Policy will not give rise to any person's right to voluntarily terminate employment for "good reason," or due to a "constructive termination" (or any similar term of like effect) under any plan, program or policy of or agreement with the Company or any of its affiliates.

4. Manner of Recovery; Limitation on Duplicative Recovery

The Committee shall, in its sole discretion, determine the manner of recovery of any Erroneously Awarded Compensation, which may include, without limitation, reduction or cancellation by the Company or an affiliate of the Company of Incentive-Based Compensation or Erroneously Awarded Compensation, reimbursement or repayment by any person subject to this Policy of the Erroneously Awarded Compensation, and, to the extent permitted by law, an offset of the Erroneously Awarded Compensation against other compensation payable by the Company or an affiliate of the Company to such person. Notwithstanding the foregoing, unless otherwise prohibited by the Applicable Rules, to the extent this Policy provides for recovery of Erroneously Awarded Compensation already recovered by the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 or Other Recovery Arrangements, the amount of Erroneously Awarded Compensation already recovered by the Company from the recipient of such

Erroneously Awarded Compensation may be credited to the amount of Erroneously Awarded Compensation required to be recovered pursuant to this Policy from such person.

5. Administration

This Policy shall be administered, interpreted and construed by the Committee, which is authorized to make all determinations necessary, appropriate or advisable for such purpose. The Board of Directors of the Company (the "***Board***") may re-vest in itself the authority to administer, interpret and construe this Policy in accordance with applicable law, and in such event references herein to the "Committee" shall be deemed to be references to the Board. Subject to any permitted review by the applicable national securities exchange or association pursuant to the Applicable Rules, all determinations and decisions made by the Committee pursuant to the provisions of this Policy shall be final, conclusive and binding on all persons, including the Company and its affiliates, equityholders and employees. The Committee may delegate administrative duties with respect to this Policy to one or more directors or employees of the Company, as permitted under applicable law, including any Applicable Rules.

6. Interpretation

This Policy will be interpreted and applied in a manner that is consistent with the requirements of the Applicable Rules, and to the extent this Policy is inconsistent with such Applicable Rules, it shall be deemed amended to the minimum extent necessary to ensure compliance therewith.

7. No Indemnification; No Liability

The Company shall not indemnify or insure any person against the loss of any Erroneously Awarded Compensation pursuant to this Policy, nor shall the Company directly or indirectly pay or reimburse any person for any premiums for third-party insurance policies that such person may elect to purchase to fund such person's potential obligations under this Policy. None of the Company, an affiliate of the Company or any member of the Committee or the Board shall have any liability to any person as a result of actions taken under this Policy.

8. Application; Enforceability

Except as otherwise determined by the Committee or the Board, the adoption of this Policy does not limit, and is intended to apply in addition to, any other clawback, recoupment, forfeiture or similar policies or provisions of the Company or its affiliates, including any such policies or provisions of such effect contained in any employment agreement, bonus plan, incentive plan, equity-based plan or award agreement thereunder or similar plan, program or agreement of the Company or an affiliate or required under applicable law (the "***Other Recovery Arrangements***"). The remedy specified in this Policy shall not be exclusive and shall be in addition to every other right or remedy at law or in equity that may be available to the Company or an affiliate of the Company.

9. Severability

The provisions in this Policy are intended to be applied to the fullest extent of the law; provided, however, to the extent that any provision of this Policy is found to be unenforceable or invalid under any applicable law, such provision will be applied to the maximum extent

permitted, and shall automatically be deemed amended in a manner consistent with its objectives to the extent necessary to conform to any limitations required under applicable law.

10. Amendment and Termination

The Board or the Committee may amend, modify or terminate this Policy in whole or in part at any time and from time to time in its sole discretion. This Policy will terminate automatically when the Company does not have a class of securities listed on a national securities exchange or association.

11. Definitions

"***Applicable Rules***" means Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder, the listing rules of Nasdaq, and any applicable rules, standards or other guidance adopted by the Securities and Exchange Commission or Nasdaq (or any other national securities exchange or association that the Company has a class of its securities listed).

"***Committee***" means the committee of the Board responsible for executive compensation decisions comprised solely of independent directors (as determined under the Applicable Rules), or in the absence of such a committee, a majority of the independent directors serving on the Board.

"***Erroneously Awarded Compensation***" means the amount of Incentive-Based Compensation received by a current or former Officer that exceeds the amount of Incentive-Based Compensation that would have been received by such current or former Officer based on a restated Financial Reporting Measure, as determined on a pre-tax basis in accordance with the Applicable Rules.

"***Exchange Act***" means the Securities Exchange Act of 1934, as amended.

"***Financial Reporting Measure***" means any measure determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, including GAAP, IFRS and non-GAAP/IFRS financial measures, as well as stock or share price and total equityholder return.

"***GAAP***" means United States generally accepted accounting principles.

"***IFRS***" means international financial reporting standards as adopted by the International Accounting Standards Board.

"***Impracticable***" means (a) the direct costs paid to third parties to assist in enforcing recovery would exceed the Erroneously Awarded Compensation; provided that the Company (i) has made reasonable attempts to recover the Erroneously Awarded Compensation, (ii) documented such attempt(s), and (iii) provided such documentation to the relevant listing exchange or association, (b) to the extent permitted by the Applicable Rules, the recovery would violate the Company's home country laws pursuant to an opinion of home country counsel; provided that the Company has (i) obtained an opinion of home country counsel, acceptable to the relevant listing exchange or association, that recovery would result in such violation, and (ii) provided such opinion to the relevant listing exchange or association, or (c) recovery would

likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and the regulations thereunder.

"***Incentive-Based Compensation***" means, with respect to a Restatement, any compensation that is granted, earned, or vested based wholly or in part upon the attainment of one or more Financial Reporting Measures and received by a person: (a) after beginning service as an Officer; (b) who served as an Officer at any time during the performance period for that compensation; (c) while the Company has a class of its securities listed on a national securities exchange or association; and (d) during the applicable Three-Year Period.

"***Officer***" means each person who serves as an executive officer of the Company, as defined in Rule 10D-1(d) under the Exchange Act.

"***Restatement***" means an accounting restatement to correct the Company's material noncompliance with any financial reporting requirement under securities laws, including restatements that correct an error in previously issued financial statements (a) that is material to the previously issued financial statements or (b) that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***Three-Year Period***" means, with respect to a Restatement, the three completed fiscal years immediately preceding the date that the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare such Restatement, or, if earlier, the date on which a court, regulator or other legally authorized body directs the Company to prepare such Restatement. The "Three-Year Period" also includes any transition period (that results from a change in the Company's fiscal year) within or immediately following the three completed fiscal years identified in the preceding sentence. However, a transition period between the last day of the Company's previous fiscal year end and the first day of its new fiscal year that comprises a period of nine to 12 months shall be deemed a completed fiscal year.