# 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, 2025**

**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 001-34620**

## IRONWOOD PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

| **Delaware** | **04-3404176** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification Number) |
| **100 Summer Street, Suite 2300 Boston, Massachusetts** | **02110** |
| (Address of Principal Executive Offices) | (Zip Code) |

**(617) 621-7722**

(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 |
|---|---|---|
| Class A Common Stock, $0.001 par value | IRWD | Nasdaq Global Select 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 ☐ Smaller reporting company ☒ Emerging growth company ☐

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

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

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

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

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

Aggregate market value of voting stock held by non-affiliates of the Registrant as of June 30, 2025: $102,692,312

As of January 31, 2026, there were 163,058,316 shares of Class A Common Stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE:**

Portions of the definitive proxy statement to be filed for our 2026 Annual Meeting of Stockholders are incorporated by reference into Part III of this report.

## NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, including the sections titled "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" contains forward-looking statements. All statements contained in this Annual Report on Form 10-K other than statements of historical fact are forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements regarding our future financial position, business strategy, budgets, projected costs, plans and objectives of management for future operations. The words "may," "continue," "estimate," "intend," "plan," "will," "believe," "project," "expect," "seek," "anticipate," "could," "should," "target," "goal," "potential" and similar expressions may identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. These forward-looking statements include, among other things, statements about:

- the demand and market potential for our products in the countries where they are approved for marketing, as well as the revenues therefrom;
- the timing, investment and associated activities involved in commercializing LINZESS® by us and AbbVie Inc. in the U.S.;
- the commercialization of CONSTELLA® in Europe and LINZESS in Japan and China, as well as our expectations regarding revenue generated from our partners;
- the timing, investment and associated activities involved in developing, obtaining regulatory approval for, launching, and commercializing our products and product candidates, such as apraglutide, by us and our partners worldwide;
- our plan to initiate a confirmatory Phase III clinical trial of apraglutide for the treatment of short bowel syndrome with intestinal failure and the timing and key design elements thereof;
- our ability and the ability of our partners to secure and maintain adequate reimbursement for our products, including the status of government regulation in the life sciences industry, particularly with respect to healthcare reform and drug pricing;
- our ability and the ability of our partners and third parties to manufacture and distribute sufficient amounts of linaclotide active pharmaceutical ingredient, finished drug product and finished goods, as applicable, on a commercial scale;
- our expectations regarding U.S. and foreign regulatory requirements for our products and our product candidates, such as apraglutide, including our post-approval development and regulatory requirements;
- the ability of apraglutide and our other product candidates to meet existing or future regulatory standards;
- the safety profile and related adverse events of our products and our product candidates;
- the therapeutic benefits and effectiveness of our products and our product candidates and the potential indications and market opportunities therefor;
- our ability and the ability of our partners to obtain and maintain intellectual property protection for our products and our product candidates and the strength thereof, as well as Abbreviated New Drug Applications filed by generic drug manufacturers and potential U.S. Food and Drug Administration approval thereof, and associated patent infringement suits that we have filed or may file, or other action that we may take against such companies, and the timing and resolution thereof;
- our ability and the ability of our partners to perform our respective obligations under our collaboration, license and other agreements, and our ability to achieve milestones and other payments under such agreements;

- our plans with respect to the development, manufacture or sale of our product candidates and the associated timing thereof, including the design and results of pre-clinical studies and clinical trials;

- our expectations as to future financial performance, revenues, expense levels, payments, cash flows, profitability, tax obligations, capital raising and liquidity sources, and real estate needs, as well as the timing and drivers thereof, and internal control over financial reporting;

- our ability to repay our outstanding indebtedness when due, or redeem or repurchase all or a portion of such debt, as well as the potential benefits of the capped call transactions described herein;

- asset impairments, and the drivers thereof, and purchase commitments;

- trends and challenges in our potential markets;

- the outcome of pending, threatened or future legal proceedings;

- our ability to attract, motivate and retain key personnel; and

- other factors discussed elsewhere in this Annual Report on Form 10-K.

Any or all of our forward-looking statements in this Annual Report on Form 10-K may turn out to be inaccurate. These forward-looking statements may be affected by inaccurate assumptions or by known or unknown risks and uncertainties, including the risks, uncertainties and assumptions identified under the heading "Risk Factors" in this Annual Report on Form 10-K. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Annual Report on Form 10-K may not occur as contemplated, and actual results could differ materially from those anticipated or implied by the forward-looking statements.

You should not unduly rely on these forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K. Unless required by law, we undertake no obligation to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise. You should, however, review the factors and risks we describe in the reports we will file from time to time with the U.S. Securities and Exchange Commission, or the SEC, after the date of this Annual Report on Form 10-K.

**Summary of Risks Associated with our Business**

Our business is subject to a number of risks, which are discussed more fully under the heading "Risk Factors" in this Annual Report on Form 10-K. These risks include the following:

- We are highly dependent on the commercial success of LINZESS® (linaclotide) in the United States, or the U.S., for the foreseeable future.

- We are subject to uncertainty relating to pricing and reimbursement policies in the U.S., including recent and future healthcare reform measures, which, if not favorable for our products, could hinder or prevent our products' commercial success.

- Healthcare reform and other governmental and private payor initiatives may have an adverse effect upon, and could prevent, our products' or product candidates' commercial success.

- We cannot give any assurance that apraglutide will receive regulatory approval, which is necessary before it can be commercialized.

- The regulatory approval processes in the U.S., in the E.U. and in other foreign jurisdictions are onerous, lengthy, time consuming, expensive and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for apraglutide or our other product candidates, our business will be harmed.

- Our failure to successfully develop and commercialize additional product candidates or approved products would impair our ability to grow and/or adversely affect our business.
- Delays in the completion of clinical testing of any of our products or product candidates could result in increased costs and could delay or limit our ability to generate revenues.
- We must work effectively and collaboratively with AbbVie Inc. (together with its affiliates) to market and sell LINZESS in the U.S., and must adapt our commercial model and market strategy to the evolving landscape for LINZESS to achieve its maximum commercial potential.
- We face competition and new products may emerge that provide different or better alternatives for treatment of the conditions that our products are approved to treat.
- Our products or product candidates may cause undesirable side effects or have other properties that could delay or prevent their development, create unpredictable clinical trial results, impact their regulatory approval or limit their commercial potential.
- Even though LINZESS is approved by the U.S. Food and Drug Administration for use in adult and certain pediatric patients, post-approval development and regulatory requirements still remain, which may present additional challenges.
- We may be unable to maintain the benefits associated with orphan drug designation, including market exclusivity, which may harm our business.
- If we are unable to successfully partner with other companies to develop and commercialize products and/or product candidates, our ability to grow would be impaired and our business would be adversely affected.
- We may need additional funding and may be unable to raise capital when needed, which could cause us to delay, reduce or eliminate our corporate or product development or commercialization efforts.
- Our indebtedness could adversely affect our financial condition or restrict our future operations.
- Our quarterly and annual operating results may fluctuate significantly.
- Limitations on our ability to obtain patent protection and/or the patent rights relating to our products and our product candidates may limit our ability to prevent third parties from competing against us.
- Pending, threatened or future legal actions may lead to costs, reputational harm, or adverse outcomes that could materially affect our business.

## NOTE REGARDING TRADEMARKS

**TABLE OF CONTENTS**

## PART I

### Item 1. *Business*

### Our Company

We are a biotechnology company developing and commercializing life-changing therapies for people living with gastrointestinal, or GI, and rare diseases. We are focused on the development and commercialization of innovative product opportunities in areas of significant unmet need, leveraging our demonstrated expertise and capabilities in GI and rare diseases.

LINZESS® (linaclotide), our commercial product, is the first product approved by the United States Food and Drug Administration, or U.S. FDA, in a class of GI medicines called guanylate cyclase type C agonists, or GC-C agonists, and is indicated for the treatment, in the U.S., of irritable bowel syndrome with constipation, or IBS-C, in adults and pediatric patients 7 years of age and older, chronic idiopathic constipation, or CIC, in adults, and functional constipation, or FC, in pediatric patients ages 6-17 years-old. LINZESS is also available for the treatment of adults with IBS-C or CIC in Mexico, adults with IBS-C or chronic constipation in Japan, and adults with IBS-C in China. Linaclotide is available under the trademarked name CONSTELLA® for the treatment of adults with IBS-C or CIC and pediatric patients ages 6-17 years old with FC in Canada, and to adults with IBS-C in certain European countries.

We have strategic partnerships with leading pharmaceutical companies to support the development and commercialization of linaclotide throughout the world, including with our partner, AbbVie Inc. (together with its affiliates), or AbbVie, in the U.S. and all countries worldwide other than China (including Hong Kong and Macau) and Japan, AstraZeneca AB (together with its affiliates), or AstraZeneca, in China (including Hong Kong and Macau) and Astellas Pharma Inc., or Astellas, in Japan.

Through our acquisition of VectivBio Holding AG, or VectivBio, in June 2023, or the VectivBio Acquisition, we are advancing apraglutide, a next-generation, synthetic long-acting peptide analog of glucagon-like peptide-2, or GLP-2, for short bowel syndrome, or SBS, patients who are dependent on parenteral support, or PS. In February 2024, we announced positive topline results from our pivotal Phase III clinical trial, STARS, which evaluated the efficacy and safety of once-weekly subcutaneous apraglutide in reducing PS dependency in adult patients with short bowel syndrome with intestinal failure, or SBS-IF. We are also conducting an open-label extension study, STARS Extend, to further assess the safety of apraglutide in adult patients with SBS-IF. In April 2025, we announced that, based on discussions with the U.S. FDA, a confirmatory Phase III clinical trial is needed to seek approval of a new drug application or NDA, for apraglutide for patients with SBS-IF who are dependent on PS. In the fourth quarter of 2025, we met with the U.S. FDA and aligned on key design elements of a confirmatory Phase III clinical trial, STARS-2, of apraglutide. Site initiations are expected to begin in the second quarter of 2026.

We were incorporated in Delaware on January 5, 1998 as Microbia, Inc. On April 7, 2008, we changed our name to Ironwood Pharmaceuticals, Inc. To date, we have dedicated a majority of our activities to the research, development and commercialization of linaclotide, as well as other research and development programs, including apraglutide.

Drug development involves a high degree of risk and investment, and the status, timing and scope of our development programs are subject to change. Important factors that could adversely affect our drug development efforts are discussed under the heading “Risk Factors” in this Annual Report on Form 10-K.

### Performance Against 2025 Core Priorities

In 2025, our GI and rare diseases-focused strategy, building on our commercial success and GI development capabilities, continued to focus on three core priorities: maximizing LINZESS, advancing apraglutide, and delivering sustained profits and cash flow.

Maximizing LINZESS

- We recognized $289.3 million in collaborative arrangements revenue related to sales of LINZESS in the U.S. during the year ended December 31, 2025, a decrease of $51.1 million compared to the year ended

December 31, 2024. The decrease was driven by net price and inventory channel fluctuations, partially offset by increased prescription demand.

Advancing Apraglutide

- In April 2025, we announced that, in preparation for the NDA submission to the U.S. FDA for apraglutide, pharmacokinetic analysis indicated that the exposure and dose delivered in the STARS Phase III clinical trial were lower than planned due to dose preparation and administration. Based on discussions with the U.S. FDA, it became clear that a confirmatory Phase III clinical trial of apraglutide is needed to seek approval of an NDA for apraglutide for patients with SBS-IF who are dependent on PS. In the fourth quarter of 2025, we met with the U.S. FDA and aligned on key design elements of a confirmatory Phase III clinical trial, STARS-2, of apraglutide. We plan to initiate the STARS-2 clincial trial in the second quarter of 2026.

Delivering sustained profits and cash flow

- We generated $127.0 million in cash from operations during the year ended December 31, 2025, ending the year with $215.5 million in cash and cash equivalents.

**Linaclotide**

IBS-C and CIC are chronic, functional GI disorders that afflict millions of sufferers worldwide. As many as 11.5 million adults suffer from IBS-C and as many as 28.5 million adults suffer from CIC in the U.S., based on Rome II criteria from the Lieberman GI Patient Landscape Survey performed in 2010, or the Lieberman Survey. Symptoms of IBS-C include abdominal pain, discomfort and/or bloating and constipation symptoms (e.g., incomplete evacuation, infrequent bowel movements, hard/lumpy stools), while CIC is primarily characterized by constipation symptoms. Greater than 65% of IBS-C patients suffer from bloating and/or discomfort at least one time per week, according to the Lieberman Survey.

**Linaclotide—U.S.** In August 2012, the U.S. FDA approved LINZESS as a once daily treatment for adults suffering from IBS-C (290 mcg dose) or CIC (145 mcg dose). We and AbbVie began commercializing LINZESS in the U.S. in December 2012. In January 2017, the U.S. FDA approved a 72 mcg dose of linaclotide for the treatment of adults with CIC in the U.S.

We and AbbVie continue to explore ways to enhance the clinical profile of LINZESS by studying linaclotide in additional indications, populations, and formulations to assess its potential to treat various conditions. In September 2020, based on the Phase IIIb data of linaclotide 290 mcg on the overall abdominal symptoms of bloating, pain and discomfort, in adult patients with IBS-C, the U.S. FDA approved our supplemental new drug application to include a more comprehensive description of the effects of LINZESS in its approved label.

In addition, we and AbbVie have established a nonclinical and clinical post-marketing plan with the U.S. FDA to understand the safety and efficacy of LINZESS in pediatric patients. In August 2021, the U.S. FDA approved a revised label for LINZESS based on clinical safety data that had been generated thus far in pediatric studies. The updated label modified the boxed warning for risk of serious dehydration and contraindication against use in children to those less than two years of age. The boxed warning and contraindication previously applied to all children less than 18 years of age and less than 6 years of age, respectively. In June 2023, the U.S. FDA approved LINZESS as a once-daily treatment for pediatric patients ages 6-17 years-old with FC, making LINZESS the first and only U.S. FDA-approved prescription therapy for FC in this patient population. On October 15, 2025, the U.S. FDA granted us a pediatric exclusivity for studies conducted on linaclotide, and in November 2025, approved LINZESS for pediatric patients 7 years of age and older with IBS-C. Additional clinical pediatric programs in FC are ongoing.

**Linaclotide—Global.** AbbVie has rights to develop and commercialize linaclotide in all countries worldwide other than China (including Hong Kong and Macau) and Japan. CONSTELLA is the first, and to date, only drug approved in the European Union, or E.U., for IBS-C. CONSTELLA first became commercially available in certain European countries beginning in 2013. AbbVie is commercializing CONSTELLA in a number of European countries, including the United Kingdom, Italy and Spain for adults with IBS-C.

AbbVie has exclusive rights to commercialize linaclotide in Canada as CONSTELLA and in Mexico as LINZESS. CONSTELLA became commercially available in Canada in 2014 for adults with IBS-C or CIC and in 2024 for pediatric patients ages 6-17 years-old with FC. LINZESS became commercially available in Mexico in 2014 for adults with IBS-C or CIC.

Astellas has rights to develop, manufacture and commercialize linaclotide in Japan. Astellas began commercializing LINZESS in Japan for adults with IBS-C in 2017, and for adults with chronic constipation in 2018.

AstraZeneca has rights to develop, manufacture and commercialize linaclotide in China (including Hong Kong and Macau). In 2019, AstraZeneca began commercializing LINZESS in China for adults with IBS-C.

**Apraglutide for SBS-IF**

Through the VectivBio Acquisition, we are advancing apraglutide, a next-generation, long-acting synthetic peptide analog of GLP-2, as a potentially differentiated therapeutic for SBS patients who are dependent on PS.

SBS is a malabsorption disorder caused by the loss of functional small intestine, with symptoms that include diarrhea, dehydration, malnutrition and weight loss. SBS typically occurs in adults as a consequence of irreparable GI damage caused by physical trauma, Crohn's disease, ulcerative colitis, ischemia or cancer requiring surgeries that result in the removal of large portions of the small intestine or colon. In infants and children, SBS is typically a consequence of congenital defects or decreases in intestinal absorptive capacity secondary to surgical procedures. The symptoms and severity of SBS can vary depending upon the length and function of the remaining portion of the intestine. Patients suffer from SBS-IF when their gut function is reduced below the minimum function necessary for the absorption of macronutrients or water and electrolytes required to survive and, in the case of infants and children, to maintain health and growth.

In February 2024, we announced positive topline results from our pivotal Phase III clinical trial, STARS, which evaluated the efficacy and safety of once-weekly subcutaneous apraglutide in reducing PS dependency in adult patients with SBS-IF. We are also conducting an open-label extension study, STARS Extend, to further assess safety of apraglutide in adult patients with SBS-IF. In preparation for an NDA submission for apraglutide, pharmacokinetic analysis indicated that the exposure and dose delivered in the STARS Phase III clinical trial of apraglutide were lower than planned due to dose preparation and administration. In April 2025, we announced that, based on discussions with the U.S. FDA, a confirmatory Phase III clinical trial is needed to seek approval of an NDA for apraglutide for patients with SBS-IF who are dependent on PS. In the fourth quarter of 2025, we met with the U.S. FDA and aligned on key design elements of a confirmatory Phase III clinical trial, STARS-2, of apraglutide. STARS-2 is expected to be a 24-week global, randomized, double-blind, placebo-controlled trial. The clinical trial will consist of a primary endpoint measuring relative change from baseline in actual weekly PS volume, as well as additional key secondary endpoints. Site initiations are expected to begin in the second quarter of 2026.

**IW-3300**

We were developing IW-3300, a GC-C agonist, for the potential treatment of visceral pain conditions, such as interstitial cystitis and bladder pain syndrome, or IC/BPS. In April 2025, based on analysis of the Phase II data, we decided to cease developing IW-3300 for IC/BPS.

**Collaborations and Partnerships**

As part of our GI and rare disease focus, we have development and commercial capabilities that we plan to leverage as we seek to bring medicines to patients. We intend to play an active role in the development and commercialization of our products in the U.S., either independently or with partners that have strong capabilities. We also intend to establish strong global brands by out-licensing development and commercialization rights to our products in other key territories to high-performing partners. We plan to seek collaborations that increase the value of our products by providing meaningful economics and incentives for us and any potential partner.

We have pursued a partnering strategy for commercializing linaclotide that has allowed us to focus our commercialization efforts in the U.S. and enabled partners with strong global capabilities to commercialize linaclotide in territories outside of the U.S.

The following chart shows our revenue for the U.S. and the rest of the world as a percentage of our total revenue for each of the years ended December 31, 2025 and 2024.

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| U.S. | 97.7 % | 97.1 % |
| Rest of world | 2.3 % | 2.9 % |
| | 100.0 % | 100.0 % |

Revenue attributable to our linaclotide partnerships comprised substantially all of our revenue for each of the years indicated. Further, we currently derive a significant portion of our revenue from our LINZESS collaboration with AbbVie for the U.S. and believe that the revenues from this collaboration will continue to constitute a significant portion of our total revenue for the foreseeable future. Our revenue from our LINZESS collaboration with AbbVie for the U.S. is highly dependent on the responsiveness of patients to fill prescriptions and other factors such as retail chain and wholesaler buying patterns, pricing and reimbursement and inventory channel levels. On November 25, 2025, the U.S. Department of Health and Human Services, or HHS, released the Maximum Fair Price, or MFP, for LINZESS, which was selected in the most recent round of government price setting as part of the Inflation Reduction Act of 2022. The MFP for a 30-day equivalent supply of LINZESS, which will become the new Medicare net price as of January 1, 2027, is set to $136. The revised MFP for LINZESS was in line with our expectations. Also, effective January 1, 2026, we and our partner, AbbVie, lowered the LINZESS list price in response to evolving health care dynamics and to support ongoing patient access. Our collaborative arrangements revenue may continue to fluctuate as a result of the timing and amount of sales of linaclotide in the markets in which it is currently approved, or any other markets where linaclotide receives approval, as well as clinical and commercial milestones received and recognized under our strategic partnerships outside of the U.S.

*Collaboration Agreement for North America with AbbVie*

In September 2007, we entered into a collaboration agreement with AbbVie to develop and commercialize linaclotide for the treatment of IBS-C, CIC and other GI conditions in North America. Under the terms of this collaboration agreement, we received an upfront licensing fee, equity investment, and development and regulatory milestones, and we share equally with AbbVie all development costs as well as net profits or losses from the development and sale of linaclotide in the U.S. In addition, we receive royalties in the mid-teens percent based on net sales in Canada and Mexico. AbbVie is solely responsible for the further development, regulatory approval and commercialization of linaclotide in those countries and funding any costs.

*License Agreement with AbbVie (All countries other than the countries and territories of North America, China (including Hong Kong and Macau), and Japan)*

In April 2009, we entered into a license agreement with Almirall, S.A., or Almirall, or the European License Agreement, to develop and commercialize linaclotide in Europe (including the Commonwealth of Independent States and Turkey) for the treatment of IBS-C, CIC, and other GI conditions. In October 2015, Almirall transferred its exclusive license to develop and commercialize linaclotide in Europe to AbbVie. In January 2017, we and AbbVie entered into an amendment to the European License Agreement. The European License Agreement, as amended, extended the license to develop and commercialize linaclotide in all countries other than China (including Hong Kong and Macau), Japan, and the countries and territories of North America. We refer to the additional licensed countries as the Expanded Territory. Under the European License agreement, AbbVie is obligated to pay us (i) certain commercial milestones totaling up to $42.5 million, (ii) royalties based on sales volume in Europe, beginning in the mid-single digits percent and escalating to the upper-teens percent, and (iii) on a country-by-country and product-by-product basis in the Expanded Territory, a royalty as a percentage of net sales of products containing linaclotide as an active ingredient in the upper-single digits for five years following the first commercial sale of a linaclotide product in a country, and in the low-double digits thereafter. The royalty rate for products in the Expanded Territory will decrease, on a country-by-country basis, to the lower-single digits, or cease entirely, following the occurrence of certain events.

*License Agreement for Japan with Astellas*

In November 2009, we entered into a license agreement with Astellas to develop and commercialize linaclotide for the treatment of IBS-C, CIC, and other GI conditions in Japan. On August 1, 2019, we and Astellas amended and restated the license agreement. Under the terms of the amended and restated license agreement, Astellas is obligated to pay royalties to us at rates beginning in the mid-single-digits percent and escalating to low-double-digits percent, based on aggregate annual net sales in Japan of products containing linaclotide active pharmaceutical ingredient, or API.

*Collaboration Agreement for China (including Hong Kong and Macau), with AstraZeneca*

In October 2012, we entered into a collaboration agreement with AstraZeneca to co-develop and co-commercialize linaclotide in China (including Hong Kong and Macau). In September 2019, we and AstraZeneca amended and restated the collaboration agreement, under which AstraZeneca obtained the exclusive right to develop, manufacture and commercialize products containing linaclotide in the territory. Under the terms of the amended and restated agreement, we transferred all manufacturing responsibilities in China (including Hong Kong and Macau) to AstraZeneca, and we were entitled to receive non-contingent payments totaling $35.0 million in three installments through 2024, with the final installment collected during the first quarter of 2024. In addition, AstraZeneca may be required to make milestone payments totaling up to $90.0 million contingent on the achievement of certain sales targets and is required to pay tiered royalties to us at rates beginning in the mid-single-digits percent and increasing up to twenty percent based on the aggregate annual net sales of products containing linaclotide in the territory.

*Development and Commercialization Agreement with AKP*

In March 2022, VectivBio entered into a development and commercialization agreement with Asahi Kasei Pharma Corporation, or AKP, in which VectivBio granted an exclusive license to AKP, with the right to sublicense in multiple tiers, to develop, commercialize and exploit products derived from apraglutide in Japan.

Pursuant to the terms of the development and commercialization agreement with AKP, VectivBio received an upfront payment of JPY 3,000 million ($24.6 million at date of agreement) and development-related payments of JPY 1,600 million in the aggregate ($13.1 million at date of agreement) and is eligible to receive development milestones of JPY 1,000 million ($8.2 million at date of agreement) and up to JPY 19,000 million ($155.8 million at date of agreement) of commercial and sales-based milestone payments. VectivBio is also eligible to receive payments in the commercial period for manufacturing supply equal to cost-plus manufacturing mark-up and tiered royalties of up to a mid-double-digit percentage on product sales continuing until the later of (i) expiration of regulatory exclusivity in Japan, or (ii) expiration of the last valid patent claim that provides exclusivity to apraglutide in Japan, or the Royalty Term. The development and commercialization agreement will terminate upon the expiration of the Royalty Term.

**Our Strategy**

Our strategy is focused on three core priorities: maximizing LINZESS, advancing apraglutide, and delivering sustained profits and cash flow.

Key elements of our strategy include:

Maximizing LINZESS

- Leveraging our U.S.-focused commercial capabilities with our partner, AbbVie, to expand the commercial potential of LINZESS.
- Exploring development opportunities to enhance the clinical profile of LINZESS by studying linaclotide in additional indications, populations, and formulations.
- Collaborating with global partners who share our vision, values, culture, and processes to develop and commercialize linaclotide outside the U.S.

Advancing Apraglutide

- Advancing apraglutide for the potential treatment of SBS-IF.

Delivering sustained profits and cash flows

- Executing our strategy by delivering sustainable profits and cash flows.

- Applying a thoughtful and disciplined capital allocation strategy to deliver value for our shareholders over the long-term.

**Competition**

Linaclotide competes globally with certain branded and generic prescription therapies and over-the-counter, or OTC, products for the treatment of IBS-C and CIC, or their associated symptoms.

OTC laxatives make up the majority of the treatments in the U.S. for IBS-C and CIC, according to our research. LINZESS is the number one prescribed branded treatment in the U.S. for adults with IBS-C and CIC, according to 2025 data from IQVIA Inc. National Prescription Audit.

Until the launch of LINZESS, the only available branded prescription therapy for IBS-C and CIC in the U.S. was AMITIZA® (lubiprostone), which is approved for the treatments of CIC, IBS-C and opioid induced constipation. Takeda Pharmaceuticals Limited, or Takeda's AMITIZA is approved for commercialization in the U.S. and in certain European countries, including the United Kingdom and Switzerland by Sucampo AG, for the treatment of adults with CIC, and for the treatment of chronic constipation in Japan by Mylan N.V. Authorized generic versions of AMITIZA have been available in the U.S. since January 2021. TRULANCE® (plecanatide) was approved in the U.S. for the treatment of adults with IBS-C and CIC and is being commercialized in the U.S. by Bausch Health Companies, or Bausch. Shire plc obtained approval of MOTEGRITY™ (prucalopride) in the U.S. for the treatment of CIC in adults, and generic versions have been available in the U.S. since January 2025. Ardelyx, Inc.'s, or Ardelyx, IBSRELA™ (tenapanor), is approved by the U.S. FDA for the treatment for IBS-C in adults, and Vibrant Gastro Inc's. Vibrant, a drug-free capsule, is approved by the U.S. FDA for the treatment of CIC in adults who have not experienced relief of their bowel symptoms by using laxative therapies at the recommended dosage for at least one month. OTC laxatives such as MiraLAX® and DULCOLAX®, and lactulose, a prescription laxative treatment, are also available for the treatment of constipation.

In addition, any product candidates that we successfully develop and commercialize will compete with existing drugs and new drugs that may become available in the future. For example, for apraglutide, we compete with companies that are commercializing or developing drugs for SBS, such as Takeda, which currently distributes the GLP-2 analog teduglutide, marketed as GATTEX® (teduglutide) in the U.S. and REVESTIVE® (teduglutide for injection) in Europe, and Zealand Pharma A/S, or Zealand, which is developing glepaglutide, a long-acting GLP-2 analog, for the potential treatment of SBS for patients who are dependent on PS and initiated an additional Phase III clinical trial in the first quarter of 2026. Hanmi Pharmaceutical is also developing a GLP-2 analog, to be administered once a month, and which is being evaluated in a Phase II clinical trial. Products with other mechanisms of action may emerge as future competition.

**Manufacturing and Supply**

Linaclotide

It is our objective that the supply of linaclotide be safe and effective, with redundancy built into critical steps of the supply chain, and that each of our collaboration partners are in a position to manage the supply and distribution of linaclotide in their respective territories through a combination of contract manufacturers and in-house manufacturing capabilities. Linaclotide production consists of three phases—manufacture of the active pharmaceutical ingredient, or API (sometimes referred to as drug substance), manufacture of finished drug product and manufacture of finished goods. We and/or our partners have commercial supply agreements with multiple third-party manufacturers for the production of linaclotide API. We believe the current commercial suppliers have the capabilities to produce linaclotide API in accordance with current good manufacturing practices, or GMP, on a sufficient scale to meet the worldwide development and commercial needs for linaclotide. The commercial suppliers of linaclotide API are subject to routine inspections by regulatory agencies worldwide and also undergo periodic audit and certification by our partners' or our own quality department.

Each of AbbVie, Astellas and AstraZeneca is responsible for linaclotide API, finished drug product and finished goods manufacturing (including bottling and packaging) and distributing the finished goods to wholesalers in its respective territories.

Prior to linaclotide, there was no precedent for long-term room temperature shelf storage formulation for an orally dosed peptide to be produced in millions of capsules per year. Our efforts to date have led to formulations that are both cost effective and able to meet the stability requirements for commercial pharmaceutical products.

Apraglutide

We do not currently own or operate manufacturing facilities for the production of clinical or, if approved, commercial quantities of apraglutide. We design and develop the manufacturing process for apraglutide together with contract development and manufacturing organizations, or CDMOs. We utilize these CDMOs to manufacture apraglutide for human use. Although we intend to rely on third-party CDMOs to produce apraglutide, we have personnel with experience managing third-party CDMOs producing apraglutide in clinical or commercial quantities.

Our clinical trials of apraglutide currently use the product in the form of a lyophilized powder in vial that is solubilized and reconstituted with a diluent prior to injection. We are also evaluating novel drug product presentations for further development, with the goal of providing increased patient convenience and increased simplicity of the dosing and self-injection.

**Sales and Marketing**

For the foreseeable future, in the U.S., we intend to develop and commercialize LINZESS with our partner, AbbVie, and apraglutide, if approved, alone. In territories outside the U.S., we expect to rely on partners to develop and commercialize our products and product candidates. In executing our strategy, our goal is to retain oversight over the worldwide development and commercialization of our products by playing an active role in their commercialization or finding partners who share our vision, values, culture and processes.

We and/or our partners have core commercial capabilities in place, including marketing, patient engagement and key sales support roles.

We are also coordinating efforts with our linaclotide partners to launch and maintain an integrated, global linaclotide brand. By leveraging the knowledge base and expertise of our experienced commercial team and the insights of each of our linaclotide commercialization partners, we continually improve our collective marketing strategies.

We continue to plan for a potential commercial launch of apraglutide, if successfully developed and approved, in the U.S. and with partners in territories outside the U.S. For example, we granted AKP an exclusive license to sublicense, develop, commercialize and exploit products derived from apraglutide in Japan. We are considering potential partnerships in other territories outside the U.S.

**Patents and Proprietary Rights**

We actively seek to protect the proprietary technology that we consider important to our business, including pursuing patents that cover our products, compositions, and formulations, their methods of use and the processes for their manufacture, as well as any other relevant inventions and improvements that are commercially important to the development of our business. We also rely on trade secrets that may be important to the development of our business.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for the technology, inventions and improvements we consider important to our business; defend our patents; preserve the confidentiality of our trade secrets; and operate without infringing the patents and proprietary rights of third parties.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the date of filing the non-provisional application. We expect to apply, and have applied, for patent term extension in countries where it is available.

*Linaclotide Patent Portfolio*

After the recent expiration of a number of patents in our linaclotide patent portfolio, our linaclotide patent portfolio is currently composed of 11 patents in the U.S., including 7 U.S. patents listed in the U.S. FDA publication,

Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book, four granted European patents, most of which have been validated in available European countries, ten granted Japanese patents, a granted Chinese patent, 46 issued patents in other foreign jurisdictions, and numerous pending U.S., foreign and Patent Cooperation Treaty, or PCT, patent applications. We and our partners own, either jointly or individually, all of the issued patents and pending applications.

The issued, unexpired U.S. patents, which will expire between 2026 and 2033, contain claims directed to the linaclotide molecule, pharmaceutical compositions thereof, methods of using linaclotide to treat GI disorders, and room temperature stable formulations of linaclotide and methods of use thereof. Linaclotide, the active ingredient in the 72 mcg, 145 mcg and 290 mcg LINZESS doses, is covered by a composition of matter patent in the U.S., which recently received pediatric exclusivity, and now expires in 2027. In addition, the commercial formulations of the 72 mcg, 145 mcg and 290 mcg LINZESS doses are covered by patents in the U.S. that expire in the early 2030s. The granted, unexpired European patents, which will expire between 2027 and 2031, some of which have received patent term extension, contain claims directed to the linaclotide molecule, pharmaceutical compositions thereof, uses of linaclotide to prepare medicaments for treating GI disorders, and room temperature stable formulations of linaclotide and their use in treating IBS-C and chronic constipation. The granted, unexpired Chinese patent, which will expire in 2029, the granted Japanese patents, which will expire between 2026 and 2036, some of which are subject to granted and potential patent term extension, and the granted patents in other foreign jurisdictions, which will expire between 2026 and 2031, some of which may be subject to potential patent term extension, contain claims directed to the linaclotide molecule, pharmaceutical compositions of linaclotide for use in treating GI disorders, and room temperature stable formulations of linaclotide.

We have pending patent applications in certain countries worldwide that, if issued, will expire between 2029 and 2045 and which include claims covering the linaclotide molecule, methods of using linaclotide to treat GI disorders, the current commercial formulations of linaclotide and uses thereof to treat GI disorders and delayed release and other potential formulations of linaclotide.

The patent term of a patent that covers a U.S. FDA approved drug is also eligible for patent term extension, which permits patent term extension as compensation for some of the patent term lost during the U.S. FDA regulatory review process. The Hatch Waxman Act permits a patent term extension of a single patent applicable to an approved drug for up to five years beyond the expiration of the patent, but the extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval by the U.S. FDA. The United States Patent and Trademark Office has issued a Certificate of Patent Term Extension for U.S. Patent 7,304,036, which covers linaclotide and methods of use thereof. As a result, the patent term of this patent was extended to August 30, 2026, 14 years from the date of linaclotide's approval by the U.S. FDA. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug. We have received patent term extensions in Japan for several of our linaclotide patents. We have also received patent term extensions, called supplementary protection certificates, for certain linaclotide patents from several national patent offices in Europe. In addition, in October 2025, the U.S. FDA granted us a pediatric exclusivity for studies conducted on linaclotide, which extended the patent term of U.S. Patent 7,304,036 by six months to February 28, 2027, as well as extending the patent term of the remaining Orange Book listed patent by six months.

We and AbbVie received Paragraph IV certification notice letters regarding abbreviated new drug applications, or ANDAs, submitted to the U.S. FDA by five generic drug manufacturers requesting approval to engage in commercial manufacture, use, sale and offer for sale of linaclotide capsules (72 mcg, 145 mcg and 290 mcg), proposed generic versions of LINZESS. All five manufacturers requested approval for their 145 mcg and 290 mcg generic doses of LINZESS and two requested additional approval for their 72 mcg generic doses of LINZESS. We and AbbVie have entered into settlement agreements with all five of these generic drug manufacturers providing for licenses to market their 72 mcg (if applicable), 145 mcg and 290 mcg generic versions of LINZESS, beginning as early as March 2029 (subject to U.S. FDA Approval), unless certain limited circumstances, customary for settlement agreements of this nature, occur.

*Apraglutide Patent Portfolio*

Our apraglutide patent portfolio includes a patent family which we exclusively license that is composed of one issued U.S. patent and 58 foreign patents. This patent family contains composition-of-matter claims covering apraglutide and methods of treatment using apraglutide. The patents in this patent family that we exclusively license outside of the

U.S. are issued in Europe, Japan, China, Australia, Canada, as well as other jurisdictions. The issued European patent is validated and issued in 37 countries, including Germany, the United Kingdom, France, Italy and Spain. Not accounting for any patent term adjustment, regulatory patent term extensions or terminal disclaimers, and assuming that all annuity and/or maintenance fees are paid timely, the patents in this patent family are expected to expire in 2030.

Our apraglutide portfolio also includes five wholly owned patent families. The first patent family includes two granted U.S. patent and five pending U.S. non-provisional patent applications, as well as 2 granted patents and 16 pending foreign patent applications related to apraglutide. One of the granted U.S. patents in this patent family claims a method of treating SBS at certain doses of apraglutide, and the other claims a liquid formulation of apraglutide for injection. The pending U.S. and foreign patent applications contain composition-of-matter claims to ultrapure compositions of apraglutide, methods of manufacturing apraglutide, and methods of treatment using apraglutide. Not accounting for any patent term adjustment, regulatory patent term extensions or terminal disclaimers, and assuming that all annuity and/or maintenance fees are paid timely, the U.S. patent, as well as patents granted from the pending U.S and foreign patent applications, would be expected to expire in 2041.

The second patent family which we wholly own includes one granted European patent which has been validated in Germany, the United Kingdom, France, Italy and Spain, one pending U.S. non-provisional patent applications and 13 pending foreign patent applications related to methods of treating acute Graft versus Host Disease, or aGvHD, using apraglutide. Not accounting for any patent term adjustment, regulatory patent term extension or terminal disclaimers, and assuming that all annuity and/or maintenance fees are paid timely, the granted European patent and any U.S. and foreign patents granted from the pending patent applications would be expected to expire in 2042.

We also have two additional patent families related to methods of treating SBS using apraglutide and one patent family related to methods of treating aGvHD with a combination of apraglutide and ruxolitinib. If granted, these patent applications will expire in 2045.

**Government Regulation**

Our business is subject to government regulation in the U.S., E.U., and in other countries. The U.S. FDA, the European Medicines Agency, or EMA, and other regulatory authorities have very broad enforcement authority and failure to abide by applicable regulatory requirements can result in administrative or judicial sanctions being imposed on us, including warning letters, refusals of government contracts, clinical holds, civil penalties, injunctions, restitution, disgorgement of profits, recall or seizure of products, total or partial suspension of production or distribution, withdrawal of approval, refusal to approve pending applications, and civil or criminal prosecution. Within the U.S., in addition to the U.S. FDA, numerous federal, state and local authorities have jurisdiction over, or enforce laws related to, such activities, including the U.S. Drug Enforcement Agency, Centers of Medicare & Medicaid Services, or CMS, the Department of Health and Human Services, or HHS, the U.S. Department of Justice, state Attorneys General, state departments of health and state pharmacy boards.

*U.S. FDA Approval Process*

In the U.S., pharmaceutical products are subject to extensive regulation by the U.S. FDA. The Federal Food, Drug and Cosmetic Act, or FDCA, and other federal and state statutes and regulations, as well as similar foreign regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-marketing requirements and assessments, post-approval monitoring and reporting, sampling, pricing reimbursement and import and export of pharmaceutical products.

No company may market a new drug in the U.S. until it has submitted an NDA to the U.S. FDA, and the U.S. FDA has approved it. The steps required before the U.S. FDA may approve an NDA generally include:

- conducting non-clinical laboratory tests and other studies in compliance with U.S. FDA's good laboratory practice, or GLP, requirements;

- design of a clinical protocol and submission to the U.S. FDA of an investigational new drug application, or IND, for human clinical testing, which must become effective before human clinical trial may begin;

- approval by an institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;

- development, manufacture and testing of active pharmaceutical product and dosage forms suitable for human use in compliance with current GMP;

- conducting adequate and well-controlled human clinical trials that establish the safety and efficacy of the product for its specific intended use(s), in accordance with good clinical practices, or GCP;

- preparation and submission to the U.S. FDA of an NDA;

- review of the NDA by a U.S. FDA advisory committee, where applicable;

- satisfactory completion of one or more U.S. FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with current GMP requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;

- satisfactory completion of any U.S. FDA inspections of non-clinical and clinical trial sites to assure compliance with GLP and GCP requirements;

- payment of user fees pursuant to the Prescription Drug User Fee Act, or PDUFA, and securing U.S. FDA approval of the NDA to allow marketing of the new drug product; and

- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and any post-approval studies required by the U.S. FDA.

Non-clinical tests include laboratory evaluation of the product candidate, as well as animal studies to assess the potential safety and efficacy of the product candidate. The conduct of the non-clinical tests must comply with federal regulations and requirements including GLP. With passage of the U.S. FDA's Modernization Act 2.0 in December 2022, Congress eliminated provisions in the FDCA that required animal testing in support of an NDA. In April 2025, the U.S. FDA released a roadmap to replace animal testing in preclinical safety studies with scientifically validated new approach methodologies, such as organ-on-a-chip systems, computational modeling, and advanced *in vitro* assays. We must submit the results of the non-clinical tests, together with manufacturing information, analytical data and a proposed clinical trial protocol to the U.S. FDA as part of an IND, which must become effective before we may commence human clinical trials in the U.S.

The IND will automatically become effective 30 days after its receipt by the U.S. FDA, unless the U.S. FDA raises concerns or questions before that time about the conduct of the proposed trial. In such a case, we must work with the U.S. FDA to resolve any outstanding concerns before the clinical trial can proceed. We cannot be sure that submission of an IND will result in the U.S. FDA allowing clinical trials to begin, or that, once begun, issues will not arise that will cause us or the U.S. FDA to modify, suspend or terminate such trials. The study protocol and informed consent information for patients in clinical trials must also be submitted to an IRB, for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB requirements or if the trial has been associated with unexpected serious harm to subjects. An IRB may also impose other conditions on the trial. For studies conducted outside of the U.S., similarly, we are subject to local regulations which may differ from the U.S. and local regulations must be followed appropriately. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data monitoring committee. This group may recommend continuation of the trial as planned, changes in trial conduct, or cessation of the trial at designated checkpoints based on access to certain data from the trial.

Clinical trials involve the administration of the product candidate to humans under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are typically conducted in three sequential phases, though the phases may overlap or be combined. In Phase I, the initial introduction of the drug into healthy human subjects, the drug is usually tested for safety (adverse effects), dosage tolerance and

pharmacologic action, as well as to understand how the drug is taken up by and distributed within the body. Phase II usually involves studies in a limited patient population (individuals with the disease under study) to:

- evaluate preliminarily the efficacy of the drug for specific, targeted conditions;
- determine dosage tolerance and appropriate dosage as well as other important information about how to design larger Phase III clinical trials; and
- identify possible adverse effects and safety risks.

Phase III clinical trials further evaluate clinical efficacy and test for safety within an expanded patient population. The conduct of clinical trials is subject to extensive regulation, including compliance with GCP regulations and guidance, and regulations designed to protect the rights and safety of subjects involved in investigations.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the U.S. FDA and more frequently if serious adverse events occur. In addition, IND safety reports must be submitted to the U.S. FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or *in vitro* testing that suggest a significant risk to humans exposed to the product; and any clinically important increase in the case of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The U.S. FDA will typically inspect one or more clinical sites to assure compliance with GCPs, and the integrity of the clinical data submitted. In December 2025, the U.S. FDA released final guidance outlining its processes and practices applicable to bioresearch monitoring inspections.

The U.S. FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with U.S. FDA requirements or presents an unacceptable risk to the clinical trial patients. We may also suspend clinical trials at any time on various grounds.

Sponsors of clinical trials of certain U.S. FDA-regulated products, including prescription drugs, are required to register and disclose certain clinical trial information on a public registry maintained by the National Institutes of Health. The failure to submit clinical trial information to clinicaltrials.gov is a prohibited act under the FDCA with violations subject to potential civil monetary penalties, injunctions and/or criminal prosecution or disqualification from federal grants. Although the U.S. FDA has historically not enforced these reporting requirements, the U.S. FDA has issued several notices of non-compliance to manufacturers since April 2021. While these notices of non-compliance did not result in civil monetary penalties, the failure to submit clinical trial information to clinicaltrials.gov, as required, is a prohibited act under the FDCA with violations subject to potential civil monetary penalties of up to $10,000 for each day of the violation.

The results of the non-clinical studies and clinical trials, together with other detailed information, including the manufacture and composition of the product candidate, are submitted to the U.S. FDA in the form of an NDA requesting approval to market the drug. The U.S. FDA approval of the NDA is required before marketing of the product may begin in the U.S. If the NDA contains all pertinent information and data, the U.S. FDA will "file" the application and begin review. In the event it does not, the U.S. FDA will issue a "refuse-to-file" determination and request additional information before filing the NDA. U.S. FDA reviews an NDA pursuant to certain timelines and goals established by the PDUFA. The review process, however, may be extended by U.S. FDA requests for additional information, non-clinical or clinical studies, clarification regarding information already provided in the submission, or submission of a REMS.

The U.S. FDA may refer an 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 recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. Before approving an NDA, the U.S. FDA will typically inspect the facilities at which the product candidate is manufactured and will not approve the product candidate unless current GMP compliance is satisfactory. The U.S. FDA also typically inspects facilities responsible for performing animal testing, as well as clinical investigators who participate in clinical trials.

The U.S. FDA may refuse to approve an NDA if applicable regulatory criteria are not satisfied or may require additional testing or information. If the U.S. FDA decides not to approve an NDA, it will issue a Complete Response Letter outlining the deficiencies in the application and need for additional data and information. While Complete

Response Letters were previously treated by the U.S. FDA as confidential and were only disclosed in action packages for approved products, the U.S. FDA announced in September 2025 that it will release Complete Response Letters promptly after they are issued to sponsors. Since that announcement, the U.S. FDA has posted a number of Complete Response Letters on its website. If the U.S. FDA approves an NDA, it may also limit the indications for use and/or require post marketing testing and surveillance to monitor the safety or efficacy of a product. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

The testing and approval process requires substantial time, effort and financial resources, and our product candidates may not be approved on a timely basis, if at all. The time and expense required to perform the clinical testing necessary to obtain U.S. FDA approval for regulated products can frequently exceed the time and expense of the research and development initially required to create the product. The results of non-clinical studies and initial clinical trials of our product candidates are not necessarily predictive of the results from large-scale clinical trials, and clinical trials may be subject to additional costs, delays or modifications due to a number of factors, including difficulty in obtaining enough patients, investigators or product candidate supply. Failure by us or our collaborators, licensors or licensees to obtain, or any delay in obtaining, regulatory approvals or in complying with requirements could adversely affect commercialization and our ability to receive product or royalty revenues.

*Hatch-Waxman Act*

The Hatch-Waxman Act established abbreviated approval procedures for generic drugs. Approval to market and distribute these drugs is obtained by submitting an ANDA with the U.S. FDA. The application for a generic drug is "abbreviated" because it need not include non-clinical or clinical data to demonstrate safety and effectiveness and may instead rely on the U.S. FDA's previous finding that the brand drug, or reference drug, is safe and effective. In order to obtain approval of an ANDA, an applicant must, among other things, establish that its product is bioequivalent to an existing approved drug and that it has the same active ingredient(s), strength, dosage form, and route of administration. A generic drug is considered bioequivalent to its reference drug if testing demonstrates that the rate and extent of absorption of the generic drug is not significantly different from the rate and extent of absorption of the reference drug when administered under similar experimental conditions.

The Hatch-Waxman Act also provides incentives by awarding, in certain circumstances, certain legal protections from generic competition. This protection comes in the form of a non-patent exclusivity period, during which the U.S. FDA may not accept, or approve, an application for a generic drug, whether the application for such drug is submitted through an ANDA or a through another form of application, known as a 505(b)(2) application. This type of NDA authorizes the U.S. FDA to approve a follow-on product on the basis of, among other things, the U.S. FDA's previous findings of safety and effectiveness for a reference product.

The Hatch-Waxman Act grants five years of regulatory exclusivity when a company develops and gains NDA approval of a new chemical entity that has not been previously approved by the U.S. FDA. This exclusivity provides that the U.S. FDA may not accept an ANDA or 505(b)(2) application for five years after the date of approval of previously approved drug, or four years in the case of an ANDA or 505(b)(2) application that challenges a patent claiming the reference drug (see discussion below regarding Paragraph IV Certifications). The Hatch-Waxman Act also provides three years of regulatory exclusivity for approved applications for drugs that are not new chemical entities, if the application contains the results of new clinical investigations (other than bioavailability studies) conducted or sponsored by the applicant that were essential to approval of the application. Examples of applications that may require new clinical investigations essential to approval and receive three-year exclusivity include applications for new indications, dosage forms (including new drug delivery systems), strengths, or conditions of use for an already approved product. This three-year exclusivity period only protects against U.S. FDA approval of ANDAs and 505(b)(2) applications for generic drugs for the conditions of approval (for example, indication or dosage form) that required new clinical investigations that were essential to approval; it does not prohibit the U.S. FDA from accepting or approving ANDAs or 505(b)(2) NDAs for generic drugs that do not include such conditions of approval.

*Paragraph IV Certifications.* Under the Hatch-Waxman Act, NDA applicants and NDA holders must provide information about certain patents claiming their drugs, or methods of use of the drug that is the subject of the NDA, for listing in the Orange Book. When an ANDA or 505(b)(2) application is submitted, it must contain one of several possible certifications regarding each of the patents listed in the Orange Book for the reference drug. A certification that a listed patent is invalid, unenforceable or will not be infringed by the sale of the proposed product is called a "Paragraph

IV" certification. A certification that provides the date a listed patent will expire, but does not challenge the validity, enforceability or infringement of the patent, is called a "Paragraph III" certification. The U.S. FDA can approve the ANDA or 505(b)(2) application containing the Paragraph III certification upon expiration of the patent.

Within 20 days of the acceptance by the U.S. FDA of an ANDA or 505(b)(2) application containing a Paragraph IV certification, the applicant must notify the NDA holder and patent owner that the application has been submitted and provide the factual and legal basis for the applicant's opinion that the patent is invalid, unenforceable, or not infringed. The NDA holder or patent holder may then initiate a patent infringement suit in response to the Paragraph IV notice. If this is done within 45 days of receiving notice of the Paragraph IV certification, a 30-month stay of the U.S. FDA's ability to approve the ANDA or 505(b)(2) application is triggered. The U.S. FDA may approve the proposed product before the expiration of the 30-month stay only if a court finds the patent invalid or not infringed, and the court may shorten or lengthen the 30-month stay under certain limited circumstances.

*Patent Term Extension.* Under the Hatch-Waxman Act, a portion of the patent term lost during product development and U.S. FDA review of an NDA or 505(b)(2) application is extended if approval of the application is the first permitted commercial marketing of a drug containing the active ingredient. The patent term extension period is generally one-half the time between the effective date of the IND and the date of submission of the NDA, plus the time between the date of submission of the NDA and the date of U.S. FDA approval of the product. The maximum period of patent term extension is five years, and the patent cannot be extended to more than 14 years from the date of U.S. FDA approval of the product. Only one unexpired patent claiming the drug product, a method of using the product or a method of manufacturing the product is eligible for extension and the patent holder must apply for extension within 60 days of approval. The U.S. Patent and Trademark Office, or USPTO, in consultation with the U.S. FDA, reviews and approves the application for patent term extension.

*Orphan Drug Designation and Exclusivity*

Orphan drug designation in the U.S. is designed to encourage sponsors to develop products intended for the treatment of rare diseases or conditions. In the U.S., a rare disease or condition is statutorily defined as a condition that affects fewer than 200,000 individuals in the U.S. or that affects more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making the product available for the disease or condition will be recovered from sales of the product in the U.S.

Orphan drug designation qualifies a company for certain tax credits. In addition, if a product candidate that has orphan drug designation subsequently receives the first U.S. FDA approval for that drug for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the U.S. FDA may not approve any other applications to market the same drug for the same indication for seven years following product approval unless the subsequent product candidate is demonstrated to be clinically superior on the basis of greater efficacy or safety, or by providing a major contribution to patient care. Absent a showing of clinical superiority, the U.S. FDA cannot approve the same product made by another manufacturer for the same indication during the market exclusivity period unless it has the consent of the sponsor, or the sponsor is unable to provide sufficient quantities.

*Pediatric Exclusivity*

Pediatric exclusivity is another type of regulatory exclusivity in the U.S. and, if granted, provides for the attachment of an additional six months of regulatory exclusivity to the term of any existing patent or non-patent regulatory exclusivity, including orphan exclusivity, for drug products. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the U.S. FDA for such data. If the clinical trial is deemed to fairly respond to the U.S. FDA's request, the additional exclusivity protection is granted. This is not a patent term extension, but it effectively extends the period during which the U.S. FDA cannot approve another application.

*Regulation of Drug-Device Combination Products in the U.S.*

Certain products may be comprised of components, such as drug components and device components that would normally be subject to different regulatory frameworks by the U.S. FDA and frequently regulated by different centers at the U.S. FDA. These products are known as drug-device combination products. Under the FDCA and its

implementing regulations, the U.S. FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a drug-device combination product. The determination of which center will be the lead center is based on the "primary mode of action" of the drug-device combination product. Thus, if the primary mode of action of a drug-device combination product is attributable to the drug product, the U.S. FDA center responsible for premarket review of the drug product would have primary jurisdiction for the drug-device combination product. The U.S. FDA has also established an Office of Combination Products to address issues surrounding combination products and provide more certainty to the regulatory review process. That office serves as a focal point for combination product issues for agency reviewers and industry. It is also responsible for developing guidance and regulations to clarify the regulation of combination products, and for assignment of the U.S. FDA center that has primary jurisdiction for review of drug-device combination products where the jurisdiction is unclear or in dispute.

A drug-device combination product with a primary mode of action attributable to the drug component generally would be reviewed and approved pursuant to the drug approval processes set forth in the FDCA. In reviewing the NDA for such a product, however, U.S. FDA reviewers could consult with their counterparts in the device center to ensure that the device component of the combination product met applicable requirements regarding safety, effectiveness, durability and performance. Approval may require the performance of certain clinical studies, such as clinical usability or human factors studies to demonstrate the safety and/or effectiveness of the device component of the combination product. In addition, under U.S. FDA regulations, drug-device combination products are subject to current GMP requirements applicable to both drugs and devices, including the Quality System Regulations applicable to medical devices.

*Other U.S. Regulatory Requirements*

After approval, finished drug products are subject to extensive continuing regulation by the U.S. FDA, which includes company obligations to manufacture products in accordance with current GMP, maintain and provide to the U.S. FDA updated safety and efficacy information, report adverse experiences with the product, keep certain records and submit periodic reports, obtain U.S. FDA approval of certain manufacturing or labeling changes, and comply with U.S. FDA promotion and advertising requirements and restrictions. Failure to meet these obligations can result in various adverse consequences, both voluntary and U.S. FDA-imposed, including product recalls, withdrawal of approval, restrictions on marketing, and the imposition of civil fines and criminal penalties against the NDA holder. In addition, later discovery of previously unknown safety or efficacy issues may result in restrictions on the product, manufacturer or NDA holder.

We and our partners and any third-party manufacturers we or our partners engage are required to comply with applicable U.S. FDA manufacturing requirements contained in the U.S. FDA's current GMP regulations. Current GMP regulations require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. The manufacturing facilities for our products must meet current GMP requirements to the satisfaction of the U.S. FDA pursuant to a pre-approval inspection before we can use them to manufacture our products. We and any third-party manufacturers are also subject to periodic inspections of facilities by the U.S. FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations.

With respect to post-market product advertising and promotion, the U.S. FDA imposes a number of complex regulations on entities that advertise and promote pharmaceuticals, which include, among others, standards for direct-to-consumer advertising, prohibitions on promoting drugs for uses, conditions or diseases, or in patient populations that are not consistent with the drug's approved labeling (known as "off-label use"), and principles governing industry-sponsored scientific and educational activities. Failure to comply with U.S. FDA requirements can have negative consequences, including adverse publicity, warning or untitled letters from the U.S. FDA, mandated corrective advertising or communications with doctors or patients, and civil or criminal penalties. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses. In January 2025, the U.S. FDA published final guidance outlining the agency's non-binding policies governing the distribution of scientific information on unapproved uses to healthcare providers. This final guidance calls for such communications to be truthful, non-misleading, factual, and unbiased and include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about the unapproved use.

On September 9, 2025, the President issued a Memorandum directing HHS to "ensure transparency and accuracy in direct-to-consumer prescription drug advertising, including by increasing the amount of information

regarding any risks associated with the use of any such prescription drug required to be provided in prescription drug advertisements." To that end, the U.S. FDA announced that it is initiating a rulemaking process "to eliminate the 'adequate provision' loophole that allows pharmaceutical advertisements to hide safety information by placing it in another format or location." In this context, the U.S. FDA declared that it will no longer tolerate what it characterized as "deceptive practices" in prescription drug advertising and that the agency would "aggressively deploy" its available enforcement tools, with "heightened scrutiny" of fair balance and disclosures in social media promotions. The U.S. FDA also issued a generic "notice letter" directing companies to "remove any noncompliant advertising and bring all promotional communications into compliance."

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and U.S. FDA approval of a new NDA or sNDA before the change can be implemented. An sNDA for a new indication typically requires clinical data similar in type and quality to the clinical data supporting the original application for the original indication, and the U.S. FDA uses similar procedures and actions in reviewing such sNDAs as it does in reviewing NDAs.

Adverse event reporting and submission of periodic reports are required following U.S. FDA approval of an NDA. The U.S. FDA also may require post marketing testing, known as Phase IV testing, REMS, and surveillance to monitor the effects of an approved product or to place conditions on an approval that restrict the distribution or use of the product.

Outside the U.S., our and our collaborators' abilities to market a product are contingent upon receiving marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from jurisdiction to jurisdiction. At present, foreign marketing authorizations are applied for at a national level, although within the E.U. registration procedures are available to companies wishing to market a product in more than one E.U. member state. We are subject to U.S. federal and foreign anti-corruption laws. Those laws include the U.S. Foreign Corrupt Practices Act, or FCPA, which prohibits U.S. corporations and their representatives from offering, promising, authorizing, or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA encompasses certain healthcare professionals in many countries. We are also subject to similar laws of other countries that have enacted anti-corruption laws and regulations.

*EU Marketing Approval of Medicinal Products*

In order to market any product outside of the U.S., a company also must comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Regardless of whether or not it obtains U.S. FDA approval for a product, an applicant will need to obtain the necessary marketing approvals by the comparable foreign regulatory authorities before it can initiate clinical trials or marketing of the product in those countries or jurisdictions. Specifically, there are a number of similarities between the process regarding regulatory approval of medicinal products in the European Economic Area, or EEA, and that in the U.S. Marketing approval requires satisfactory completion of pharmaceutical development, non-clinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the medicinal product for each proposed indication. It also requires the submission to relevant competent authorities for a clinical trial authorization to be granted and to the EMA, or to competent authorities in E.U. Member States for granting of a marketing authorization by these authorities before the product can be marketed and sold in the E.U.

*Clinical Trial Approval*. Similar to the U.S., the various phases of preclinical and clinical research in the E.U. are subject to significant regulatory controls. Certain preclinical (also termed "non-clinical") data is required in order to inform the scientific basis for clinical trials to be conducted and later for such data to be used in the dossier for supporting a marketing authorization application, or MAA. Preclinical data are required to guide the clinical development, from Phase I (first-in-human clinical trials) through to Phases II and III, to establish the safety and efficacy of a medicinal product. During all phases of clinical development, national competent authorities of E.U. Member States and other comparable regulatory authorities require extensive monitoring and auditing of all clinical trial related activities, to ensure safety of the trial participants, and quality and integrity of trial data.

In the E.U., clinical trials are governed by the Clinical Trials Regulation (E.U.) No. 536/2014, or CTR, which entered into application on January 31, 2022, replacing Directive 2001/20/EC, or CTD. The CTR is intended to

harmonize and streamline clinical trial authorizations, simplify adverse-event reporting procedures, improve the supervision of clinical trials and increase their transparency. Prior to commencing a clinical trial, the sponsor must obtain a clinical trial authorization from competent authorities of E.U. Member States in which the sponsor intends on carrying out clinical trials, and a positive opinion from an independent Ethics Committee. The CTR, which is directly applicable in all E.U. Member States, introduces a streamlined application procedure through a single-entry point, the "E.U. portal", the Clinical Trials Information System, or CTIS. Since January 31, 2023, the use of CTIS has become mandatory for all clinical trial sponsors submitting initial applications for the approval of their clinical trials in the E.U. The CTR also establishes a single set of documents to be prepared and submitted for the application including, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation as well as simplified reporting procedures for clinical trial sponsors.

Ongoing clinical trials authorized under CTD with at least one active site in the E.U. on January 30, 2025 needed to be transitioned to CTR. Active site in the context of transitioning means that the last visit of the last subject, or the other trial-related interventions with the subject specified in the protocol, will take place after January 30, 2025. Clinical trials with no active sites authorized under CTD do not need to be transitioned even if the global trial is still ongoing outside the E.U. after the transition deadline.

Clinical trials of medicinal products in the E.U. must be conducted in accordance with current good clinical practices requirements and the applicable regulatory requirements, including those foreseen in the Good Clinical Practice Directive 2005/28/EC, and the ethical principles that have their origin in the Declaration of Helsinki. Studies should also be conducted in accordance with all applicable EMA, European Commission and national guidelines. Medicinal products used in clinical trials must be manufactured in accordance with the guidelines on current GMP, and in a GMP compliant facility, which can be subject to GMP inspections.

*Marketing Authorization*. To obtain a marketing authorization to market a medicinal product in the EEA, an applicant must submit an MAA, either in accordance with a centralized procedure administered by the EMA or one of the procedures administered by competent authorities in E.U. Member States (decentralized procedure, national procedure or mutual recognition procedure). A marketing authorization may be granted only to an applicant established in the E.U.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid in all E.U. Member States and through the EEA Member States – Norway, Iceland and Liechtenstein. Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific medicinal products, including those (i) derived from biotechnological processes, (ii) designated as orphan medicinal products, (iii) that are classified as advanced therapy medicinal products, or ATMPs, and (iv) containing a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions and viral diseases. For medicinal products containing a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, authorization through the centralized procedure is optional for product approval.

Under the centralized procedure, the EMA's Committee for Medicinal Products for Human Use, or CHMP, conducts the scientific assessment of a medicinal product in respect of its safety, quality and efficacy for the purpose of determining its approvability.

Under the centralized procedure in the EEA, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops. Procedural clock-stops provide the applicant with the time to gather additional information in response to the outstanding questions raised by the CHMP. Accelerated assessment may be accepted by the CHMP in exceptional cases, when a medicinal product is considered to be of major interest from the point of view of public health, and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts a request for accelerated assessment, the time limit of 210 days will be reduced to 150 days. The CHMP can, however, revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

A marketing authorization granted under the E.U. regulatory system is valid for five years. The MA may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the E.U. Member State in which the original MA was granted. To support the application, the MA holder must provide the EMA or the competent authority with a consolidated version of the electronic Common Technical

Document providing up-to-date data concerning the quality, safety and efficacy of the product, including all variations introduced since the MA was granted, at least nine months before the MA ceases to be valid. The European Commission or the competent authorities of the E.U. Member States may decide on justified grounds relating to pharmacovigilance, to proceed with one further five-year renewal period for the MA. Thereafter, the MA shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the E.U. market (for a centralized MA) or on the market of the authorizing E.U. Member State within three years after authorization ceases to be valid (the so-called sunset clause).

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines, or PRIME, scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicinal products that target unmet medical needs. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the E.U. or, if there is, the new medicinal product will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted.

*Combination Products.* As in the U.S., the regulation of combination drug-device products depends in large part on which component has the primary mode of action.

Where a medical device incorporates a medicinal product as an integral part as a single use drug delivery system, it is regulated as a medicinal product in accordance with Directive 2001/83/EC. In this case, the relevant General Safety and Performance Requirements of the Medical Device Regulation will apply to the safety and performance of the drug delivery device component.

*Orphan Medicinal Product Designation and Exclusivity*. Regulation (EC) No. 141/2000, as implemented by Regulation (EC) No. 847/2000, provides that a medicinal product can be designated as an orphan medicinal product by the European Commission if its sponsor can establish that (1) the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in ten thousand persons in the E.U. when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the E.U.; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the E.U. or, if such method exists, the product will be of significant benefit to those affected by that condition.

In the E.U., an application for designation as an orphan product can be made any time prior to the filing of the MAA. Orphan medicinal product designation entitles a sponsor to incentives such as fee reductions or fee waivers, protocol assistance, and access to the centralized MA procedure. Upon grant of an MA, provided that the orphan designation is maintained following a satisfactory re-assessment by the Committee for Orphan Medicinal Products, or COMP, of the EMA of the criteria for orphan designation, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication, which means that the EMA cannot accept another MAA, or grant an MA, or accept an application to extend an MA for a similar product for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products provided that the results of all studies conducted in compliance with an agreed PIP are provided – even though the results do not lead to an approval of a pediatric indication, but the results of the studies conducted are reflected in the summary of product characteristics and, if appropriate, in the package leaflet of the medicinal product concerned. Orphan medicinal product designation does not confer any advantage in, or shorten the duration of, the regulatory review and approval process.

The period of market exclusivity may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product destination, including where it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, an MA may be granted to a similar medicinal product with the same orphan indication during the 10 year period if: (i) if the applicant consents to a second original orphan medicinal product application, (ii) if the manufacturer of the original orphan medicinal product is unable to supply sufficient

quantities; or (iii) if the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the original orphan medicinal product. A company may voluntarily remove a product from the register of orphan products.

*Post-Approval Requirements*. Where an MA is granted in relation to a medicinal product in the EEA, the holder of the MA is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products.

Similar to the U.S., both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the individual EEA countries. The holder of an MA must establish and maintain a pharmacovigilance system and appoint a qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAAs must include a risk management plan describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

In the E.U., the advertising and promotion of medicinal products are subject to both E.U. and E.U. Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. Although general requirements for advertising and promotion of medicinal products are established under E.U. law, the implementing rules in each member state may differ from one country to another. In addition, the statutory control regime could be supplemented by the voluntary control of advertising of medicinal products by self-regulatory bodies.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

*International Regulation*

In addition to regulations in the U.S. and the E.U., we could become subject to a variety of other foreign regulations regarding development, approval, commercial sales and distribution of our products if we seek to market our product candidates in other jurisdictions. Whether or not we obtain U.S. FDA or EMA approval for a product, we must obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional review periods, and the time may be longer or shorter than that required to obtain U.S. FDA or EMA approval. The requirements governing, among other things, the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. If we fail to comply with applicable foreign regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

*Pricing and Reimbursement*

Within the U.S., significant uncertainty exists regarding the coverage and reimbursement status of products approved by the U.S. FDA. Sales of our product, and any future products which obtain marketing approval, depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. The process for determining whether a third-party payor will provide coverage for a drug or biologic typically is separate from the process for setting the price of such a product or for establishing the reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to specific products on an approved list, also known as a 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 products or to restrict coverage of our products could reduce utilization of our products. Moreover, a third-party payor's

decision to provide coverage for a finished 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. Additionally, coverage and reimbursement for products can differ significantly from payor to payor. One third-party payor's decision to cover a particular product or service does not ensure that other payors will also provide coverage for the medical product or service or will provide coverage at an adequate reimbursement rate.

The containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs and biologics have been a focus in this effort. Federal and state governments have shown significant interest in implementing cost-containment programs, including restrictions on reimbursement and requirements for substitution of generic products. Adoption of new or enhanced cost-containment measures could limit our net revenue and results. Third party payors are increasingly challenging the prices charged for medical products and services and examining the medical necessity and cost effectiveness of medical products and services, in addition to their safety and efficacy. Restrictions in coverage or decreases in third-party reimbursement for our products could have a material adverse effect on our sales, results of operations and financial condition. We expect that the pharmaceutical industry will experience pricing pressures due to the increasing influence of managed care (and related implementation of managed care strategies to control utilization), additional federal and state legislative and regulatory proposals to regulate pricing of drugs, limit coverage of drugs or reduce reimbursement for drugs, and public scrutiny of drug pricing.

There have been and likely will continue to be health care reform efforts. For example, federal legislation enacted in 2021 eliminated a statutory cap on Medicaid drug rebate program rebates effective January 1, 2024. As another example, the Inflation Reduction Act, or IRA, of 2022, contains various drug pricing and payment provisions. Among other provisions, the IRA imposes a yearly cap ($2,000 in 2025) on out-of-pocket prescription drug prices in Medicare Part D. Additionally, the IRA, through a newly established Manufacturer Discount Program, eliminated, effective January 1, 2025, the size of the discount on brand-name drugs that pharmaceutical manufacturers are required to offer Medicare beneficiaries who are in the Medicare Part D coverage gap, or "donut hole," by significantly lowering the beneficiary maximum out-of-pocket cost and requiring pharmaceutical manufacturers to provide a 10% discount in the initial coverage phase of the plan and 20% discount in the catastrophic coverage phase of the plan on brand-name drugs.

In addition, the IRA requires Medicare to negotiate Medicare prices for certain high-cost drugs and biologicals, including both physician-administered products covered under Medicare Part B benefit and self-administered drugs covered under the Medicare Part D benefit. The CMS annually selects a specified number of negotiation-eligible drugs from those drugs with the highest total Medicare Part B or D expenditures over a preceding 12-month period. Eligible drugs generally include single source brand-name drugs or biological products that have been on the market without therapeutically-equivalent generic or biosimilar alternatives for a specified number of years with certain exceptions. Drugs and biologics that have been approved for a single rare disease or condition were originally categorically excluded from price negotiation. With passage of the One Big Beautiful Bill Act on July 3, 2025, Congress extended this exemption to drugs and biologics with multiple orphan drug designations. CMS will publish the negotiated price, known as the "Maximum Fair Price", or MFP, for each of the selected products. Manufacturers of selected drugs would be required to offer the drug for Medicare recipients at the MFP. Manufacturers who fail to negotiate or offer the MFP can face significant civil money penalties or excise tax liability on sales of that drug.

In 2024, the HHS published the results of the first Medicare drug price negotiations for 10 selected drugs that treat a range of conditions, including diabetes, chronic kidney disease, and rheumatoid arthritis, and the prices of the selected drugs became effective on January 1, 2026. On January 17, 2025, HHS announced the selection of 15 additional drugs, which included LINZESS, covered by Medicare Part D, for the second cycle of price negotiations, and on November 25, 2025, HHS released the MFP for LINZESS. The MFP for a 30-day equivalent supply of LINZESS, which will become the new Medicare net price as of January 1, 2027, is set to $136. The revised MFP for LINZESS was in line with our expectations.

On April 15, 2025, President Trump issued an Executive Order which directs HHS to take steps to reduce the prices of pharmaceutical products. The new Executive Order, among other things, directs the U.S. FDA to streamline and improve its existing drug importation program so as to make it easier for states to obtain approval without sacrificing the safety or quality of drug products. Other provisions of the Executive Order relate to the 340B program. With respect to the IRA's Medicare drug pricing program, the Executive Order, among other things, calls for alignment in "the treatment of small molecule prescription drugs with that of biological products, ending the distortion that undermines

relative investment in small molecule prescription drugs, coupled with other reforms to prevent any increase in overall costs to Medicare and its beneficiaries."

Further, on May 12, 2025, President Trump issued an additional Executive Order calling on pharmaceutical manufacturers to voluntarily reduce the prices of medicines in the U.S. The Executive Order directs the Secretary of HHS to communicate most-favored-nation, or MFN, price targets to pharmaceutical manufacturers to bring prices in line with comparably developed nations. The Executive Order further provides that if such actions do not lower the costs of pharmaceuticals, the Secretary of HHS would pursue other actions, including proposing a rulemaking that imposes MFN pricing in the United States. Subsequently, on May 20, 2025, HHS indicated that the proposed MFN pricing will apply only to brand products without generic or biosimilar competition and the reference foreign countries will include only those in which the branded product similarly does not have generic or biosimilar competition. Second, HHS indicated that the MFN target price will be the lowest price in a country that is a member of the Organization for Economic Co-operation and Development, or OECD, with a gross domestic product, or GDP, per capita of at least 60% of the U.S. GDP per capita. Based on previous estimates, there are likely at least 22 OECD countries that would satisfy this criterion. The implications of these actions remain unclear and are likely to result in litigation if the administration pursues an MFN regulatory pricing requirement.

Subsequently, on May 20, 2025, HHS indicated that the proposed MFN pricing will apply only to brand products without generic or biosimilar competition and the reference foreign countries will include only those in which the branded product similarly does not have generic or biosimilar competition. Second, HHS indicated that the MFN target price will be the lowest price in a country that is a member of the Organization for Economic Co-operation and Development, or OECD, with a gross domestic product, or GDP, per capita of at least 60% of the U.S. GDP per capita. Based on previous estimates, there are likely at least 22 OECD countries that would satisfy this criterion.

On July 31, 2025, the President issued letters to 17 pharmaceutical companies reiterating the requirements of the May 12, 2025 Executive Order and demanding that such companies extend MFN pricing to Medicaid patients, guarantee MFN pricing for newly-launched drug products, return increased revenues abroad to American patients and provide for direct purchasing at MFN pricing. The letters also urged these companies to stipulate that they will not offer other developed nations better prices for new drugs than the prices offered for such products in the U.S. Nearly all of these pharmaceutical companies have entered into agreements with the Trump administration to provide for lower prices on certain pharmaceuticals.

While we cannot predict what executive, legislative and regulatory proposals will be adopted or other actions will occur, such events could have a material adverse effect on our business, financial condition and profitability. For additional information relating to pricing and reimbursement and legislative and other reform initiatives that may affect coverage, pricing and reimbursement, see Item 1A, *Risk Factors*, elsewhere in this Annual Report on Form 10-K.

*Healthcare Compliance*

We are also subject to various federal and state laws pertaining to health care "fraud and abuse," including anti-kickback laws and false claims laws, for activities related to sales of any of our products or product candidates that may in the future receive marketing approval. Anti-kickback laws generally prohibit persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid or, in some cases, private third-party payors. Although the specific provisions of these laws vary, their scope is generally broad and there may not be regulations, guidance or court decisions that apply the laws to particular industry practices. False claims laws prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, information or claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent. Violations of fraud and abuse laws may be punishable by criminal or civil sanctions, including fines and civil monetary penalties, and/or exclusion from federal health care programs (including Medicare and Medicaid).

Laws and regulations have been enacted by the federal government and various states to regulate the sales and marketing practices of pharmaceutical manufacturers with marketed products. The laws and regulations generally limit financial interactions between manufacturers and health care providers, require disclosure to the government and public of such interactions and/or require reporting of pricing information or marketing expenditures. Many of these laws and regulations contain ambiguous requirements or require administrative guidance for implementation.

*Data Privacy and Security Laws*

Pharmaceutical companies may be subject to U.S. federal and state health information privacy, security and data breach notification laws, which may govern the collection, use, disclosure and protection of health-related and other personal information. State laws may be more stringent, broader in scope or offer greater individual rights with respect to protected health information, or PHI, than the federal Health Insurance Portability and Accountability Act of 1996, as amended, and its implementing regulations, which are collectively referred to as HIPAA, and state laws may differ from each other, which may complicate compliance efforts. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured PHI, a complaint about privacy practices or an audit by the HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance.

In addition to federal regulation, many states have begun to focus on efforts to regulate privacy and data security. For example, in California the California Consumer Privacy Act, or CCPA, which went into effect on January 1, 2020 and was expanded by the California Consumer Privacy Rights Act, or CPRA, which went into effect on January 1, 2023, collectively establishes a privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. There also are states that are specifically regulating health information that may affect our business. The California Confidentiality of Medical Information Act also applies to pharmaceutical companies, including requirements for written authorization to use and disclose medical information and restrictions on the circumstances under which medical information can be used for marketing purposes. In addition, Washington state passed the My Health My Data Act, a health privacy law, which regulates the collection and sharing of health information, and provides a right of action for violation of the statute. Other states have also recently enacted or are considering enacting comprehensive data privacy and security laws to which we may become subject, and all fifty states and U.S. territories have enacted data breach notification laws. Achieving and sustaining compliance with applicable international, federal and state privacy, security, and data breach notification laws may prove time-consuming and costly.

EEA Member States, the United Kingdom, Switzerland and other jurisdictions have also adopted data protection laws and regulations, which impose significant compliance obligations. In the EEA and the United Kingdom, the collection and use of personal data, including clinical trial data, is governed by the provisions of the General Data Protection Regulation, or GDPR. The GDPR, together with national legislation, regulations and guidelines of the EEA Member States, the United Kingdom and Switzerland governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. In particular, these obligations and restrictions concern the consent of the individuals to whom the personal data relates, the information provided to the individuals, the transfer of personal data out of the EEA, the United Kingdom or Switzerland, data breach notifications, security and confidentiality, responding and handling data subject rights, ensuring appropriate assessments are carried out on processing operations and documented. Under these laws, data protection authorities can impose substantial potential fines for breaches of the data protection obligations. European data protection authorities may interpret the GDPR and national laws differently and impose additional requirements, which add to the complexity of processing personal data in or from the EEA, United Kingdom or Switzerland.

**Human Capital**

As of December 31, 2025, we had 100 employees. Of these employees, 66 were on our drug development team and 34 were in selling, general and administrative functions. We consider our employee relations to be good.

In January 2025, following an analysis of our strategy and core business needs, and in an effort to streamline focus and support the continued development of our pipeline, we commenced a reduction in our workforce of approximately 50%, primarily consisting of field-based sales employees. This reduction in workforce was substantially completed during the first quarter of 2025. In August 2025, we eliminated certain positions supporting apraglutide commercialization efforts, in consideration of delays in development timelines. This reduction in workforce was comprised of 10 positions and was completed during the third quarter of 2025. Refer to Note 16, *Workforce Reductions and Restructuring*, to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K for further details.

*Culture and Development*

Fostering a welcoming and inclusive culture is essential to attracting, motivating and retaining the talent necessary to deliver on our corporate mission. To establish and maintain this culture, we have a simple vision in mind: to make Ironwood an environment rooted in valuing each employee for who they are.

Our workforce represents the diverse populations we serve and reflects our diversity principles in our employee-related trainings and policies. Women represent approximately 54% of our employee base, 23% of our leadership team (vice president and above) and 38% of our board of directors (including our board and audit committee chairs). Additionally, approximately 31% of our employees are racially or ethnically diverse and in 2025, approximately 57% of our new hires were racially or ethnically diverse (excluding Europe-based employees, for which race and ethnicity is not disclosed).

We seek to foster an environment where employees feel included and empowered. This approach includes initiatives such as learning and development opportunities, strengthened talent acquisition strategies, and the support of equality programs in our local communities.

*Compensation and Benefits*

All our employees receive equity and are encouraged to think and act as owners of Ironwood. We strive to provide pay, benefits, and services that are competitive to market and to create incentives to attract, motivate and retain our employees. We are focused on pay equity and regularly monitor our pay practices among similar roles and responsibilities throughout our organization.

*Communication and Engagement*

We strongly believe that our success depends on employees understanding how their work contributes to our ability to execute on our vision, mission and strategy. Our communication and engagement efforts seek to offset competitive talent challenges in the biopharmaceutical industry and employees' higher expectations of their employers. To this end, we utilize a variety of channels to facilitate open and direct communication, including frequent town hall meetings, Ironwood intranet, CEO blog, leadership engagement opportunities, regular communications regarding business updates, and employee engagement surveys.

**Available Information**

You may obtain free copies of our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, and amendments to those reports, as soon as reasonably practicable after they are electronically filed or furnished to the SEC, on the Investors section of our website at www.ironwoodpharma.com or by contacting our Investor Relations department at 617-374-5230. The contents of our website are not incorporated by reference into this report and you should not consider information provided on our website to be part of this report.

## PART II OTHER INFORMATION

### Item 1A. *Risk Factors*

*In addition to the other information in this Annual Report on Form 10-K, any of the factors described below could significantly and negatively affect our business, financial condition, results of operations or prospects. The trading price of our Class A Common Stock may decline due to these risks.*

**Risks Related to LINZESS, Apraglutide and Other Product Candidates**

***We are highly dependent on the commercial success of LINZESS (linaclotide) in the U.S. for the foreseeable future.***

We and our partner, AbbVie, began selling LINZESS in the U.S. in December 2012. Revenues from our LINZESS collaboration constitute a significant portion of our total revenue, and we believe they will continue to do so for the foreseeable future. The commercial success of LINZESS depends on a number of factors, including:

- the effectiveness of LINZESS as a treatment in the approved indications;

- the size of the treatable patient population;
- the effectiveness of the sales, managed markets and marketing efforts, including the ability to adapt a commercial model and market strategy to the evolving landscape;
- the coverage and reimbursement levels set by governmental authorities, private health insurers and other third-party payors;
- the status of government regulation in the life sciences industry, particularly with respect to healthcare reform and drug pricing;
- the adoption of LINZESS by physicians and other healthcare providers, which depends on whether LINZESS is viewed as a safe and effective treatment in the approved indications;
- our success in educating and activating adult and pediatric patients 7 years of age and older with IBS-C, adult patients with CIC patients, and pediatric patients ages 6-17 years-old with FC and their caregivers, to seek physician care for their symptoms;
- our ability to both secure and maintain adequate reimbursement for, and optimize patient access to, LINZESS and our ability to demonstrate that LINZESS is safer, more efficacious and/or more cost-effective than alternative therapies;
- the effectiveness of our partners' distribution networks;
- the occurrence of any side effects, adverse reactions or misuse, or any unfavorable publicity in these or other areas, associated with linaclotide; and
- the development or commercialization of products or therapies that compete with LINZESS.

Our revenues from the commercialization of LINZESS are subject to these and other factors, and therefore our revenues have been and may be unpredictable from quarter-to-quarter and year-to-year.

***We are subject to uncertainty relating to pricing and reimbursement policies in the U.S., including recent and future healthcare reform measures, which, if not favorable for our products, could hinder or prevent our products' commercial success.***

Our and our partner's ability to commercialize our products successfully depends in part on the coverage and reimbursement levels set by governmental authorities, private health insurers and other third-party payors. In determining whether to approve reimbursement for our products and at what level, we expect that third-party payors will consider factors that include the efficacy, cost effectiveness and safety of our products, as well as the availability of other treatments, including generic prescription drugs and OTC alternatives. Further, in order to obtain and maintain acceptable reimbursement levels and access for patients at copay levels that are reasonable and customary, we have offered, and expect to continue to face increasing pressure to offer, discounts or rebates from list prices or discounts to third-party payors or other unfavorable pricing modifications. As an example, effective January 1, 2026, the LINZESS list price has been lowered in response to evolving health care dynamics and to support ongoing patient access. Due to the decrease in the list price of LINZESS, the inflationary component of statutory required rebates across channels, including Medicaid, has been eliminated. Obtaining and maintaining favorable reimbursement can be a time consuming and expensive process, and there is no guarantee that we or AbbVie, with respect to LINZESS in the U.S., will be able to negotiate or continue to negotiate pricing terms with third-party payors at levels that are profitable to us, or at all. Certain third-party payors also require prior authorization for, or have refused to provide, reimbursement for our products, and others may do so in the future. Our business would be materially adversely affected if we and our partners are not able to receive approval for reimbursement of our products from third-party payors on a broad, timely or satisfactory basis; or if reimbursement is subject to overly broad or restrictive prior authorization requirements; or if reimbursement is not maintained at satisfactory levels or becomes subject to prior authorization. In addition, our business could be adversely affected if government healthcare programs, private health insurers, including managed care organizations, or other reimbursing bodies or payors limit or reduce the indications for or conditions under which our products may be

reimbursed. Moreover, as discussed further below and above in Part I, Item 1, under the heading *Pricing and Reimbursement*, changes in insurance coverage or reimbursement levels by governmental authorities, private health insurers and other third-party payors, or in the type of such coverage held by patients may materially harm our business and commercialization efforts.

We have experienced and may experience additional pricing pressures in connection with the sale of our current and future products due to the healthcare reforms discussed below and above in Part I, Item 1, under the heading *Pricing and Reimbursement*, as well as the trend toward initiatives aimed at reducing healthcare costs, the increasing influence of managed care, the scrutiny of pharmaceutical pricing, the ongoing debates on reducing government spending and additional legislative proposals. There has been significant scrutiny of pharmaceutical pricing and the resulting costs of pharmaceutical products that could cause significant operational and reimbursement changes for the pharmaceutical industry. There have been a number of federal and state efforts to address drug costs, which generally have focused on increasing transparency around drug costs or limiting drug prices, price increases or other related costs. Certain of these efforts have resulted in legislative and regulatory reforms, which could have a negative impact on our revenues.

***Healthcare reform and other governmental and private payor initiatives may have an adverse effect upon, and could prevent, our products' or product candidates' commercial success.***

The U.S. government and individual states have been aggressively pursuing healthcare reform designed to impact delivery of, and/or payment for, healthcare, which includes initiatives intended to reduce the cost of healthcare. For example, in March 2010, the U.S. Congress enacted the PPACA, as modified by the Health Care and Education Reconciliation Act, or the ACA, which, among other things, expanded healthcare coverage through Medicaid expansion and the implementation of the individual health insurance mandate; included changes to the coverage and reimbursement of drug products under government healthcare programs; imposed an annual fee on manufacturers of branded drugs; and expanded government enforcement authority.

Beyond the ACA, there have been ongoing legislative and administrative and other health care reform efforts, which have had an adverse effect on our products' or product candidates' commercial success. Some healthcare reform efforts affect pricing or payment for drug products or the healthcare industry more generally. Drug pricing and payment reform was a focus of the former Biden Administration and has continued to be a focus of the current Trump Administration.

Most significantly, in August 2022, President Biden signed the IRA into law. The IRA contains various drug pricing and payment provisions. Among other provisions, the IRA imposes a yearly cap ($2,100 in 2026) on out-of-pocket prescription drug prices in Medicare Part D. Additionally, the IRA, through the Manufacturer Discount Program, eliminated, effective January 1, 2025, the size of the discount on brand-name drugs that pharmaceutical manufacturers are required to offer Medicare beneficiaries who are in the Medicare Part D coverage gap, or "donut hole," by significantly lowering the beneficiary maximum out-of-pocket cost and requiring pharmaceutical manufacturers to provide a 10% discount in the initial coverage phase of the plan and 20% discount in the catastrophic coverage phase of the plan on brand-name drugs.

In addition, the IRA requires Medicare to negotiate prices for certain high-cost drugs and biologics, including both physician-administered products covered under Medicare Part B benefit and self-administered drugs covered under the Medicare Part D benefit. CMS annually selects a specified number of negotiation-eligible drugs from those drugs with the highest total Medicare Part B or D expenditures over a preceding 12-month period. Eligible drugs generally include single-source brand-name drugs or biological products that have been on the market without therapeutically-equivalent generic or biosimilar alternatives for a specified number of years with certain exceptions. Drugs and biologics that have been approved for a single rare disease or condition were originally categorically excluded from price negotiation. With passage of the One Big Beautiful Bill Act in July 2025, Congress extended this exemption to drugs and biologics with multiple orphan drug designations. CMS will publish the negotiated price, known as the MFP, for each of the selected products. Manufacturers of selected drugs are required to offer the drug for Medicare recipients at the MFP. Manufacturers who fail to negotiate or offer the MFP can face significant civil money penalties or excise tax liability on sales of that drug.

In 2024, HHS published the results of the first Medicare drug price negotiations for 10 selected drugs that treat a range of conditions, including diabetes, chronic kidney disease, and rheumatoid arthritis, and the prices of the selected drugs became effective on January 1, 2026. On January 17, 2025, HHS announced the selection of 15 additional drugs,

which included LINZESS, covered by Medicare Part D, for the second cycle of price negotiations, and on November 25, 2025, released the MFP for a 30-day equivalent supply of LINZESS. The MFP for a 30-day equivalent supply of LINZESS, which will become the new Medicare net price as of January 1, 2027, is set to $136.

On June 6, 2023, Merck & Co. filed a lawsuit against the HHS and CMS asserting that, among other things, the IRA's Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Subsequently, a number of other parties, including the U.S. Chamber of Commerce, also filed lawsuits in various courts with similar constitutional claims against the HHS and CMS. HHS has generally won the substantive disputes in these cases, and various federal district court judges have expressed skepticism regarding the merits of the legal arguments being pursued by the pharmaceutical industry. Most of these cases are now on appeal and the Court of Appeals for the Third Circuit heard oral argument in certain of these cases. In May 2025, the Court of Appeals for the Third Circuit rejected a challenge to the Medicare price negotiation program, finding that the program did not violate that company's due process rights under the Constitution since there is no protected property interest in selling goods to Medicare beneficiaries at a price higher than what the government is willing to pay in reimbursement. We expect that litigation involving these and other provisions of the IRA will continue, with unpredictable and uncertain results.

In addition, and as discussed further above in Part I, Item 1, under the heading Pricing and Reimbursement, President Trump has recently taken a number of actions to reduce the costs of pharmaceutical products. For example, in April 2025, President Trump issued an executive order directing HHS to take steps to reduce the prices of pharmaceutical products, including directing the U.S. FDA to improve its existing drug importation program to make it easier for states to obtain approval without sacrificing the safety or quality of drug products. Further, in May 2025, President Trump issued an executive order calling on pharmaceutical manufacturers to voluntarily reduce the prices of medicines in the United States. The executive order, among other things, directs the Secretary of HHS to communicate most-favored-nation, or MFN, price targets to manufacturers to bring prices in line with comparably developed nations. The executive order further provides that if such actions do not lower the costs of pharmaceuticals, the Secretary of HHS would pursue other actions, including proposing a rulemaking that imposes MFN pricing in the United States. Subsequently, HHS indicated that the proposed MFN pricing will apply only to brand products without generic or biosimilar competition and the referenced foreign countries will include only those in which the branded product similarly does not have generic or biosimilar competition. President Trump has issued letters to 17 pharmaceutical companies demanding that such companies extend MFN pricing to Medicaid patients, guarantee MFN pricing for newly-launched drug products, return increased revenues abroad to American patients and provide for direct purchasing at MFN pricing. Since that time, nearly all of these pharmaceutical companies have entered into agreements with the Trump administration to provide for lower prices on certain pharmaceuticals.

Healthcare reform efforts have been and may continue to be subject to scrutiny and legal challenge. For example, with respect to the ACA, tax reform legislation was enacted that eliminated the tax penalty established for individuals who do not maintain mandated health insurance coverage beginning in 2019 and, in 2021, the U.S. Supreme Court dismissed the latest judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. As another example, revisions to regulations under the federal anti-kickback statute would remove protection for traditional Medicare Part D discounts offered by pharmaceutical manufacturers to pharmacy benefit managers and health plans. The revisions were challenged in court and, pursuant to court order, the removal was delayed, and recent legislation imposed a moratorium on implementation of the rule until January 2032. Adoption of new healthcare reform legislation at the federal or state level could negatively affect demand for, or pricing of, our products or product candidates if approved for sale.

In addition to governmental efforts in the U.S., foreign jurisdictions as well as private health insurers and managed care plans are likely to continue challenging manufacturers' ability to obtain reimbursement, as well as the level of reimbursement, for pharmaceuticals and other healthcare-related products and services.

We are unable to predict what additional legislation, regulations or policies, if any, relating to the healthcare industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation, regulations or policies would have on our business. Any cost-control initiatives, legislative and administrative or other healthcare system reforms aimed at controlling and reducing healthcare costs, including through measures designed to limit reimbursement, restrict access or impose unfavorable pricing modifications on pharmaceutical products, could impact our and our partners' ability to obtain or maintain reimbursement for our products at satisfactory levels and could

significantly decrease the available coverage and the price we have or might establish for our products and product candidates, which would have an adverse effect on our business and financial results.

***We must work effectively and collaboratively with AbbVie to market and sell LINZESS in the U.S., and we must adapt our commercial model and market strategy to the evolving landscape for LINZESS to achieve its maximum commercial potential.***

We are working closely with AbbVie to execute our joint commercialization plan for LINZESS. The commercialization plan includes an agreed upon marketing campaign that targets the physicians and healthcare providers who see patients who could benefit from LINZESS treatment. LINZESS's consumer marketing campaign targets appropriate adults and pediatric patients who suffer from IBS-C, CIC or FC per approved indications.

In order to optimize the commercial potential of LINZESS, we and AbbVie must execute upon this commercialization plan effectively and efficiently. In addition, we and AbbVie must continually assess, modify and adapt our commercialization plan in a coordinated and integrated fashion, including evaluating and adjusting as necessary the level and mix of marketing and promotion efforts, in response to changing business, market or other factors in order to advance the commercial potential of LINZESS. Further, we and AbbVie must continue to focus the sales and marketing efforts for the brand on educating customers about the relevant data and information for LINZESS in treating adults and pediatric patients aged 7 years and older with IBS-C and adult patients with CIC, and taking a measured approach to educating and raising awareness on the FC and IBS-C indications for pediatric patients. We and AbbVie must ensure a highly targeted and efficient promotional mix combined to continue effectively promoting LINZESS to key healthcare professionals. If we and AbbVie fail to evolve with the changing commercial landscape successfully and perform these commercial functions in the highest quality manner and in accordance with our joint commercialization plan and related agreements, LINZESS will not achieve its maximum commercial potential and we may suffer financial harm. Our commercial efforts to further target and engage adult and pediatric patients in the approved indications may not effectively increase appropriate patient awareness or patient/physician dialogue and may not increase the revenues that we generate from LINZESS.

***We cannot give any assurance that apraglutide will receive regulatory approval, which is necessary before it can be commercialized.***

Apraglutide, a next generation, long-acting GLP-2 analog in development for SBS patients who are dependent on PS, will require extensive clinical development, management of nonclinical, clinical and manufacturing activities, regulatory approval and adequate manufacturing supply, and if approved, fully integrating apraglutide into our commercial infrastructure to support the appropriate sales, marketing, and market access efforts to generate sales in pursuit of revenue. We are not permitted to market or promote apraglutide before we receive regulatory approval from the U.S. FDA, the EMA, or comparable foreign regulatory authorities in the applicable jurisdiction, and we may never receive any such regulatory approval for apraglutide. To obtain regulatory approvals for apraglutide, we must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the U.S. FDA, EMA or comparable foreign regulatory authorities, that such product candidate is safe and effective for its intended uses. We may be required by the U.S. FDA, EMA or comparable foreign regulatory authorities to perform additional or unanticipated clinical trials to obtain regulatory approval. In April 2025, we announced that in preparation for the NDA submission to the U.S. FDA for apraglutide, pharmacokinetic analysis indicated that the exposure and dose delivered in the STARS Phase III clinical trial were lower than planned due to dose preparation and administration. Based on discussions with the U.S. FDA, it became clear that a confirmatory Phase III clinical trial is needed to seek approval of an NDA for apraglutide for patients with SBS-IF who are dependent on PS. In the fourth quarter of 2025, we met with the U.S. FDA and aligned on key design elements of a confirmatory Phase III clinical trial, STARS-2, of apraglutide. Site initiations are expected to begin in the second quarter of 2026. If we are unable to successfully initiate or complete the confirmatory Phase III clinical trial, if the results of this trial are not positive or are only modestly positive, if there are safety concerns or if we determine that the observed safety or efficacy profile would not be competitive in the marketplace, we may be delayed in obtaining regulatory approval for apraglutide or we may not obtain regulatory approval at all. It is possible that the confirmatory Phase III clinical trial may not be considered sufficient by the U.S. FDA to approve our NDA, which could further delay a regulatory approval or may require us to expend more resources than we have available. Any delay in obtaining, or an inability to obtain, any marketing approvals would prevent us from commercializing apraglutide, generating revenues and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to abandon our development efforts for apraglutide, which could significantly and materially harm our business. Even if we do receive such regulatory approval, we may be unable to successfully commercialize

apraglutide within any approved indications or develop apraglutide for the treatment of additional indications, which would materially adversely impact our business and prospects.

***The regulatory approval processes in the U.S., in the E.U. and in other foreign jurisdictions are onerous, lengthy, time consuming, expensive and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for apraglutide or our other product candidates, our business will be harmed.***

The time required to complete drug development and to obtain regulatory approval from the U.S. FDA, EMA and other comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors. In addition, regulatory approval policies, regulations, or the type and amount of clinical data necessary to gain regulatory approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the regulatory approval of or may result in the decision not to approve apraglutide or other product candidates. Regulatory approval is never guaranteed. Data obtained from nonclinical studies and clinical trials are susceptible to varying interpretations, and regulatory authorities may not interpret our data as favorably as we do, which may further delay, limit or prevent development efforts, clinical trials, or regulatory approval. Even if we believe the nonclinical or clinical data for our product candidates are sufficient to support approval, such data may not be considered sufficient to support approval by the U.S. FDA, EMA and other comparable foreign regulatory authorities. In February 2024, we announced positive topline results from our pivotal Phase III clinical trial, STARS, which evaluated the efficacy and safety of once-weekly subcutaneous apraglutide in reducing PS dependency in adult patients with SBS-IF. However, in April 2025, we announced that, based on discussions with the U.S. FDA, a confirmatory Phase III clinical trial is needed to seek approval of an NDA for apraglutide for patients with SBS-IF who are dependent on PS. In the fourth quarter of 2025, we met with the U.S. FDA and aligned on key design elements of a confirmatory Phase III clinical trial, STARS-2, of apraglutide. Of the large number of drugs in development, only a small percentage successfully complete the U.S. FDA, EMA or comparable foreign regulatory approval processes and are commercialized. Accordingly, it is possible that we will never obtain regulatory approval, or that regulatory approval may be substantially delayed, for apraglutide.

The U.S. FDA, EMA or other foreign comparable regulatory authorities may delay, limit, or deny approval of our product candidates, including apraglutide, for many reasons, including the following:

- the U.S. FDA, EMA or other comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials or with our interpretation of data from preclinical studies or clinical trials;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety or efficacy in the full population for which we seek approval;
- the data collected from our clinical trials may not be sufficient to support the submission of an NDA, MMA, or other submission or to obtain regulatory approval in the U.S., Europe or elsewhere;
- we may need to perform additional or unanticipated clinical trials;
- participants in our clinical trials or individuals using drugs similar to our product candidates may experience serious and unexpected drug-related side effects;
- we may be unable to demonstrate to the U.S. FDA, EMA or other comparable foreign regulatory authorities that a product candidate's risk-to-benefit ratio for its proposed indications is acceptable;
- the U.S. FDA, EMA or other comparable foreign regulatory authorities may disagree regarding the formulation, labeling and/or the specifications of a product candidate;
- the U.S. FDA, EMA or other comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications, or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the regulatory approval policies or regulations of the U.S. FDA, EMA, or other applicable comparable foreign regulations in the E.U. and other jurisdictions may significantly change in a manner rendering our clinical data insufficient for approval.

In addition, apraglutide may also be regulated as a drug and device combination product by the U.S. FDA, EMA and comparable foreign regulatory authorities. Developing and obtaining regulatory approval for combination products can pose unique challenges because they involve components that are regulated under different types of

regulatory requirements and potentially by different U.S. FDA centers or regulatory authorities. As a result, combination product candidates may raise regulatory, policy and review challenges. Differences in regulatory pathways for each component of a combination product can impact the regulatory processes for all aspects of product development and management, including clinical investigations, marketing applications, manufacturing and quality control, adverse event reporting, promotion and advertising, user fees and post-approval modifications. Although the U.S. FDA, EMA, and comparable foreign authorities have systems in place for the review and approval of combination products, we may experience additional delays in the development and commercialization of apraglutide due to regulatory timing constraints and uncertainties in the product development and approval process. Moreover, although we expect that the device component would be reviewed in connection with the review of the drug marketing application for apraglutide, if and when submitted, and that no separate marketing authorization or certification for the device component will be required, the U.S. FDA, EMA or comparable regulatory authorities may disagree and require that we obtain a separate marketing authorization or certification for the device component, which could further delay or prevent regulatory approval of apraglutide.

This lengthy drug development and regulatory approval process, as well as the unpredictability of the results of clinical trials, may result in our failure to obtain regulatory approval to potentially market apraglutide or our other product candidates, which would significantly harm our business, results of operations, and prospects.

***Our failure to successfully develop and commercialize additional product candidates or approved products would impair our ability to grow and/or adversely affect our business.***

We intend to explore further linaclotide development opportunities as well as to advance the development of our other pipeline programs, such as apraglutide, through internal or external opportunities.

We and AbbVie are exploring development opportunities to enhance the clinical profile of LINZESS by studying linaclotide in new or existing indications, populations and formulations to assess its potential to treat various conditions. For example, we and AbbVie have established a nonclinical and clinical post-marketing plan with the U.S. FDA to understand the safety and efficacy of LINZESS in pediatric patients. In June 2023, the U.S. FDA approved LINZESS, and in September 2024, Health Canada approved CONSTELLA, as once-daily treatments for pediatric patients ages 6-17 years-old with FC, in the U.S. and Canada, respectively. In November 2025, the U.S. FDA approved LINZESS for the treatment of IBS-C in patients aged 7 years of age and older. Additional clinical pediatric programs in FC are ongoing. These development efforts may fail or may not increase the revenues that we generate from LINZESS. Furthermore, they may result in adverse events, or perceived adverse events, in certain patient populations that are then attributed to the currently approved patient population, which may result in adverse regulatory action at the U.S. FDA or in other countries or harm linaclotide's reputation in the marketplace, each of which could materially harm our revenues from linaclotide.

We may spend several years and make significant investments in developing any current or future product candidate, and failure may occur at any point. Our product candidates must satisfy rigorous standards of safety and efficacy before they can be approved for sale by the U.S. FDA, EMA or comparable foreign authorities. To satisfy these standards, we must allocate resources among development programs and we must engage in costly and lengthy research and development efforts, which are subject to unanticipated delays and other significant uncertainties. Despite our efforts, our product candidates may not offer therapeutic or other improvement over existing competitive drugs, be proven safe and effective in clinical trials, or meet applicable regulatory standards. It is possible that none of the product candidates we develop will be approved for commercial sale, which would impair our ability to grow.

We have ongoing or planned nonclinical studies and clinical trials for linaclotide and apraglutide. Many companies in the pharmaceutical industry have suffered significant setbacks in clinical trials even after achieving promising results in earlier nonclinical studies or clinical trials. Findings from ongoing or completed nonclinical studies may not be replicated in later clinical trials or further data analyses, and findings from early-stage clinical trials may not be predictive of the results we may obtain in later-stage clinical trials or of the likelihood of regulatory approval. A failure of one or more clinical trials can occur at any stage of testing, which may result from a multitude of factors, including, among other things, flaws in study design or implementation, dose selection issues, placebo effects, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits. For example, in April 2025, we announced that in preparation for the NDA submission to the U.S. FDA for apraglutide, pharmacokinetic analysis indicated that the exposure and dose delivered in the STARS Phase III clinical trial were lower than planned due to dose

preparation and administration. Based on discussions with the U.S. FDA, it became clear that a confirmatory Phase III clinical trial is needed to seek approval of an NDA for apraglutide for patients with SBS-IF who are dependent on PS.

Results from clinical trials and findings from nonclinical studies could lead to abrupt changes in development activities, including the possible limitation or cessation of development activities associated with a particular product candidate or program. We cannot be certain that linaclotide or apraglutide will be successful in ongoing, planned or future clinical trials. Furthermore, our analysis of data obtained from nonclinical and clinical activities is subject to confirmation and interpretation by the U.S. FDA, EMA and other applicable regulatory authorities, which could delay, limit or prevent regulatory approval. The U.S. FDA, EMA or other regulatory authorities may also require additional clinical trials, which may be costly or delay, limit, prevent or otherwise impact regulatory submission or approval. Satisfaction of U.S. FDA, EMA or other applicable regulatory requirements is costly, time-consuming, uncertain and subject to unanticipated delays. We cannot give any assurance that apraglutide or our other product candidates will receive regulatory approval. Even if we do receive such regulatory approval, we may be unable to successfully commercialize apraglutide or any other product candidate in any approved indications or develop such product candidates for the treatment of additional indications, which would materially adversely impact our business and prospects.

***Delays in the completion of clinical testing of any of our products or product candidates could result in increased costs and could delay or limit our ability to generate revenues.***

Delays in the completion of clinical testing could significantly affect our product development costs and timing of data readouts and regulatory submissions and potential approvals. We do not know whether planned clinical trials, including the confirmatory Phase III clinical trial for apraglutide, will be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- obtaining regulatory authorization to commence a clinical trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- manufacturing sufficient quantities of a product candidate for use in clinical trials;
- obtaining institutional review board or ethics committee approval to conduct a clinical trial at a prospective site;
- recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including competition from other clinical trial programs for the treatment of similar conditions; and
- maintaining patients who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up.

Additionally, changes in regulatory requirements and guidance may occur, and we may need or otherwise determine to amend clinical trial protocols to reflect these changes. Each protocol amendment would require institutional review board or ethics committee review and approval, which may adversely impact the costs, timing or successful completion of the associated clinical trials. If we or our partners terminate or experience delays in the completion of any clinical trials, the commercial prospects for our products or product candidates may be harmed, and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval.

***The pricing of apraglutide and our other product candidates, if and when approved for marketing, will depend in part on pricing and reimbursement strategies adopted by our competitors.***

The pricing of apraglutide and our other product candidates, if and when approved for marketing, will depend, in part, on the pricing and reimbursement strategies adopted by our competitors. For example, with respect to apraglutide, a marketed GLP-2 product already exists in the U.S., E.U. and other international markets, which may or may not be genericized within the coming years. Additionally, it is possible that other investigational GLP-2 products may be approved and launched in advance of the potential approval of apraglutide in the U.S., EMA and Japan. Order of market entry and reimbursement decisions could place apraglutide at a competitive disadvantage, possibly deny market exclusivity rights, and/or elevate the need for significant clinical differentiation to support certain pricing decisions. If

these or other factors impact the price we can charge for apraglutide, we may reduce our revenue and results of operations could be affected. Similar competitive factors could apply to pricing and reimbursement decisions for our other product candidates, if approved, in the future.

***We face competition and new products may emerge that provide different or better alternatives for treatment of the conditions that our products are approved to treat.***

The pharmaceutical industry and the markets in which we operate are intensely competitive. We compete in the marketing and sale of our products, the development of new products or product candidates and the acquisition of rights to new products with commercial potential. Certain of our competitors have substantially greater financial, technical and human resources than us. Mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated in our competitors and enable them to compete more effectively. Competition may also increase further as a result of advances made in the commercial applicability of technologies and greater availability of capital for investment in these fields. Additionally, new developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical and medical technology industries at a rapid pace. These developments may render our products obsolete or non-competitive.

Linaclotide competes with certain prescription therapies and OTC products, some of which have attained significant levels of market acceptance. The availability of prescription competitors and OTC products could limit the demand, and the price we are able to charge, for LINZESS unless we are able to maintain market acceptance among the medical community and patients and differentiate LINZESS on the basis of actual or perceived clinical benefits supported by broad payer access. For example, Takeda's AMITIZA (lubiprostone) is approved by the U.S. FDA for sale in the U.S. for the treatment of IBS-C, CIC and opioid-induced constipation; Bausch's TRULANCE (plecanatide) is approved by the U.S. FDA for sale in the U.S. for the treatment of adults with IBS-C and CIC; Takeda's MOTEGRITY (prucalopride) is approved by the U.S. FDA for the treatment of CIC in adults and generic versions have been available in the U.S. since January 2025; Ardelyx's IBSRELA™ (tenapanor) is approved by the U.S. FDA for the treatment for IBS-C in adults; and Vibrant Gastro Inc.'s Vibrant, a drug-free capsule, is approved by the U.S. FDA for the treatment of CIC in adults who have not experienced relief of their bowel symptoms by using laxative therapies at the recommended dosage for at least one month. OTC laxatives such as MiraLAX® and DULCOLAX®, and lactulose, a prescription laxative treatment, are also available for the treatment of constipation. Additionally, we believe other companies are developing products that could compete with linaclotide, should they be approved by the U.S. FDA or comparable foreign regulatory authorities and become commercially available. In addition, there are other compounds in late-stage development and other potential competitors that are in earlier stages of development that, if approved, may compete with linaclotide. If our current or potential competitors are successful in completing drug development for their drug candidates and obtain approval from the U.S. FDA or comparable foreign regulatory authorities, they could limit the demand for linaclotide. In addition to competition from such prescription and OTC products, we may also face competition from multiple low-cost generic versions of such products when available in the U.S. For example, an authorized generic version of AMITIZA was first launched in the U.S. in January of 2021 and multiple versions are now available. It is possible that additional generic versions may become available in the future.

In addition, any product candidates that we successfully develop and commercialize will compete with existing drugs and new drugs that may become available in the future. Apraglutide, if successfully developed and approved, will compete with companies that are commercializing or developing drugs for SBS, such as Takeda, which currently distributes the GLP-2 analog teduglutide, marketed as GATTEX® (teduglutide) in the U.S. and REVESTIVE® (teduglutide for injection) in Europe, and Zealand, which is developing glepaglutide, a long-acting GLP-2 analog, for the treatment of SBS for patients who are dependent on PS and initiated an additional Phase III clinical trial in the first quarter of 2026. Hanmi Pharmaceutical is also developing a GLP-2 analog, to be administered once a month, and which is in a Phase II clinical trial. Products with other mechanisms of action may emerge as future competition.

***Our products or product candidates may cause undesirable side effects or have other properties that could delay or prevent their development, create unpredictable clinical trial results, impact their regulatory approval or limit their commercial potential.***

Undesirable side effects caused by our products or product candidates, including adverse events associated with our product candidates, could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the U.S. FDA, EMA or other comparable foreign regulatory authorities. Additionally, with respect to our approved products, as patient experience increases and

expands, or if one or more of our product candidates receives marketing approval, we, our partners, or others may later identify previously unknown side effects, known side effects may be found to be more frequent and/or severe than in the past, or detect unexpected safety signals for our products or any products perceived to be similar to our products. The foregoing, or the perception of the foregoing, may have the following effects, among others:

- sales of our products may be impaired;
- regulatory approvals for our products may be delayed, denied, restricted or withdrawn;
- we or our partners may decide to, or be required to, change the products' labeling or send product warning letters or field alerts to physicians, pharmacists or hospitals;
- reformulation of the products, additional nonclinical studies or clinical trials, changes in labeling or changes to or re-approvals of manufacturing facilities may be required;
- we or our partners may be precluded from pursuing approval of our products in new territories or from studying additional development opportunities to enhance our products' clinical profiles, including within new or existing indications, populations or formulations, as well as in potential combination products;
- we may be required to create a Risk Evaluation and Mitigation Strategy, or REMS, plan, or similar actions in other jurisdictions which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers or other elements to assure safe use;
- our or our products' reputation in the marketplace may suffer; and
- government investigations or lawsuits, including class action suits, may be brought against us or our partners.

Any of the above occurrences could prevent us from achieving or maintaining market acceptance of our product candidates, if they are approved, and could significantly harm our business, results of operations, and prospects, prevent sales of our products, increase expenses and impair our and our partners' ability to successfully commercialize our products.

Linaclotide has been prescribed to millions of patients since its launch in the U.S. and other territories beginning in December 2012. The number and type of patients treated with linaclotide could continue to grow if physicians prescribe linaclotide to more patients and as we and our partners conduct clinical trials, including in new indications, populations or formulations, as well as explore potential combination products, in existing and new territories. As the patient experience with linaclotide increases and expands, we and others may identify previously unknown side effects, known side effects may be found to be more frequent or severe than in the past, and others may detect unexpected safety signals for linaclotide or any products perceived to be similar to linaclotide. The most commonly reported adverse reaction since linaclotide became commercially available, as well as in the clinical trials for linaclotide in IBS-C and CIC, has been diarrhea. In the linaclotide Phase III IBS-C and CIC clinical trials in adults, severe diarrhea was reported in 2% or less of the linaclotide-treated patients and its incidence was similar between the IBS-C and CIC populations. In the linaclotide clinical trials in pediatric patients ages 6-17 years-old with FC and pediatric patients ages 7-17 years-old with IBS-C, severe diarrhea was reported in one linaclotide-treated patient in each respective trial.

In addition, the U.S. FDA-approved labeling for LINZESS contains a boxed warning describing the risk of serious dehydration in pediatric patients less than two years of age and a contraindication against its use in these patients. These and other restrictions could limit the commercial potential of LINZESS. We and AbbVie have established a nonclinical and clinical post-marketing plan with the U.S. FDA to understand the safety and efficacy of LINZESS in pediatric patients. In June 2023, the U.S. FDA approved LINZESS as a once-daily oral treatment for pediatric patients ages 6-17 years-old with FC, making LINZESS the first and only U.S. FDA-approved prescription therapy for FC in this patient population. In November 2025, the U.S. FDA approved LINZESS for the treatment of IBS-C in patients aged 7 years of age and older. This new indication establishes LINZESS as the first and only prescription drug approved for the

treatment of IBS-C in patients 7-17 years old. Additional clinical pediatric programs in FC are ongoing. There can be no assurances, however, whether there may be any significant unknown side effects that could limit the commercial potential of LINZESS in these pediatric populations.

Patients treated with apraglutide may experience well-known class-specific adverse events. The most frequent adverse events in our pivotal Phase III clinical trial, STARS, were nausea, vascular device infection, headache, abdominal pain, fatigue, and nasopharyngitis. There may be additional mechanistic side effects that are only observed in future clinical trials and/or through real-world experience with patients using our products.

***Even though LINZESS is approved by the U.S. FDA for use in adult and certain pediatric patients, post-approval development and regulatory requirements still remain, which may present additional challenges, and we may not be successful in obtaining approval for additional indications for LINZESS that we are seeking or may seek in the future.***

In August 2012, the U.S. FDA approved LINZESS as a once-daily treatment for adults suffering from IBS-C or CIC. Although we and AbbVie completed additional nonclinical studies and clinical trials in adults and pediatric patients that were required by the U.S. FDA in connection with the approval of LINZESS, LINZESS remains subject to ongoing U.S. FDA requirements, including those governing the testing, manufacturing, labeling, packaging, storage, advertising, promotion, sale, distribution, recordkeeping and submission of safety and other post-market information. For example, the U.S. FDA has the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information, and compliance with REMS approved by the U.S. FDA.

The U.S. FDA-approved labeling for LINZESS contains a boxed warning describing the risk of serious dehydration in pediatric patients less than two years of age and a contraindication against its use in these patients. We and AbbVie have established a nonclinical and clinical post-marketing plan with the U.S. FDA to understand the safety and efficacy of LINZESS in pediatric patients. In June 2023, the U.S. FDA approved LINZESS as a once-daily treatment for pediatric patients ages 6-17 years-old with FC, making LINZESS the first and only U.S. FDA-approved prescription therapy for FC in this patient population. In October 2025, the U.S. FDA granted us a pediatric exclusivity for studies conducted on linaclotide, and in November 2025, approved LINZESS for the treatment of IBS-C in patients aged 7 years of age and older. This new indication establishes LINZESS as the first and only prescription drug approved for the treatment of IBS-C in patients 7 years of age and older.

Post-approval requirements impose resource and cost burdens on us. Failure to monitor and report adverse events and meet our other post-approval commitments would lead to negative regulatory action at the U.S. FDA, which could include restrictions on the sale of our products or withdrawal of regulatory approval of our products for their currently approved indications and patient populations.

***We and our linaclotide partners are subject to uncertainty relating to pricing and reimbursement policies outside the U.S., as well as risks relating to the improper importation of linaclotide and sale of counterfeit versions of linaclotide. If such policies are not favorable, or if linaclotide is improperly imported or is counterfeited, our business and financial results could be adversely affected.***

In some foreign countries, particularly Canada, the countries of Europe, Japan and China, the pricing and payment of prescription pharmaceuticals are subject to governmental control. In these countries, pricing negotiations with governmental authorities can take 6 to 12 months or longer after the receipt of regulatory approval and product launch. Reimbursement sources are different in each country, and each country may include a combination of distinct potential payors, including private insurance and governmental payors. Some countries may restrict the range of medicinal products for which their national health insurance systems provide reimbursement and control the prices of medicinal products for human use. To obtain favorable reimbursement for the indications sought or pricing approval in some countries, we and our partners may be required to conduct a clinical trial that compares the cost and clinical effectiveness of linaclotide to other available therapies. Further, several countries have implemented government measures to either freeze or reduce pricing of pharmaceutical products. Many third-party payors and governmental authorities also consider the price for which the same product is being sold in other countries to determine their own pricing and reimbursement strategy, so if linaclotide is priced low or gets limited reimbursement in a particular country, this could result in similarly low pricing and reimbursement in other countries. If reimbursement for linaclotide is unavailable in any country in which reimbursement is sought, limited in scope or amount, or if pricing is set at or reduced to unsatisfactory levels, our and our partners' ability to successfully commercialize linaclotide in such country

would be impacted negatively. Furthermore, if these measures prevent us or any of our partners from selling linaclotide on a profitable basis in a particular country, they could prevent the commercial launch or continued sale of linaclotide in that country.

CONSTELLA was first launched in certain European countries for the symptomatic treatment of moderate to severe IBS-C in adults in the second quarter of 2013 and our partner, AbbVie, is currently commercializing CONSTELLA in a number of European countries and in Canada. LINZESS was first launched in Japan for the treatment of IBS-C in adults in the first quarter of 2017, and for the treatment of chronic constipation in adults in the third quarter of 2018, and our partner Astellas is currently commercializing LINZESS in Japan. In addition, LINZESS was first launched in China for the treatment of IBS-C in adults in November 2019, and our partner AstraZeneca, is currently commercializing LINZESS in China (including Hong Kong and Macau). The pricing and reimbursement strategy is a key component of our partners' commercialization plans for CONSTELLA in Europe and Canada and LINZESS in Japan and China. Our revenues may suffer if our partners are unable to successfully and timely conclude reimbursement, price approval or funding processes and market CONSTELLA in key member states of the E.U. and Canada or LINZESS in Japan or China, or if coverage and reimbursement for either CONSTELLA or LINZESS is limited or reduced. If our partners are not able to obtain or maintain coverage, pricing or reimbursement on acceptable terms or at all, or if such terms change in any countries in its territory, our partners may not be able to, or may decide not to, sell either CONSTELLA or LINZESS in such countries.

We and our partners also face the risk that linaclotide is imported or reimported into markets with relatively higher prices from markets with relatively lower prices, which would result in a decrease of sales and any payments we receive from the affected market. Additionally, third parties may illegally produce, distribute and/or sell counterfeit or otherwise unfit or adulterated versions of linaclotide. In either case, we and our partners may not be able to detect or, if detected, prevent or prohibit the sale of such products, which could result in dangerous health consequences for patients, loss of confidence in us, our partners and our products, and adverse regulatory or legal consequences. Any of the foregoing or other consequences could adversely impact our reputation, financial results and business.

***Even though linaclotide is approved for marketing in the U.S. and in a number of other countries, we or our partners may never receive approval to commercialize linaclotide in additional parts of the world.***

In order to market any products outside of the countries where linaclotide is currently approved, we or our partners must comply with numerous and varying regulatory requirements of other jurisdictions regarding, among other things, safety and efficacy. Approval procedures vary among jurisdictions and can involve product testing and administrative review periods different from, and greater than, those in the U.S. and the other countries where linaclotide is approved. Potential risks include that the regulatory authorities:

- may not deem linaclotide safe and effective;
- may not find the data from nonclinical studies and clinical trials sufficient to support approval;
- may not approve of manufacturing processes and facilities;
- may not approve linaclotide for any or all indications or patient populations for which approval is sought;
- may require significant warnings or restrictions on use to the product labeling for linaclotide; or
- may change their approval policies or adopt new regulations.

If any of the foregoing were to occur, our or our partners' receipt of regulatory approval in the applicable jurisdiction could be delayed or we or our partners may never receive approval at all. Further, regulatory approval in one jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory processes in others. If linaclotide is not approved for all indications or patient populations or with the labeling requested, this would limit the uses of linaclotide and have an adverse effect on its commercial potential or require costly post-marketing studies.

***If we are unable to successfully partner with other companies to develop and commercialize products and/or product candidates, our ability to grow would be impaired and our business would be adversely affected.***

As part of our business strategy, we may partner with pharmaceutical, biotechnology or other companies to develop and commercialize products or product candidates. Although we have entered into such arrangements with respect to the development and commercialization of linaclotide worldwide and of apraglutide in Japan, there can be no assurance that we will be able to do so in the future with respect to other products or product candidates that we either develop internally or in- license or that we will be able to gain the interest of potential partners; establish and maintain development, manufacturing, marketing, sales or distribution relationships on acceptable terms; that such relationships, if established, will be successful or on favorable terms; or that we will gain market acceptance for such products or product candidates. The process of proposing, negotiating and implementing a partnership arrangement is lengthy and complex. If we enter into any partnering arrangements with third parties, any revenues we receive will depend upon the efforts of such third parties. If we are unable to establish successful partnering arrangements when advantageous, we may not gain access to the financial resources and industry experience necessary to develop, commercialize or successfully market our products or product candidates, may be forced to curtail, delay or stop a development program or one or more of our other development programs, delay commercialization, reduce the scope of our planned sales or marketing activities or undertake development or commercialization activities at our own expense, and therefore may be unable to generate revenue from products or product candidates or do so to their full potential.

**Risks Related to the VectivBio Acquisition**

***We may not realize the expected benefits and anticipated synergies of the VectivBio Acquisition.***

The success of the VectivBio Acquisition will depend, in part, on our ability to realize all or some of the expected benefits from the acquisition. Risks we may face in connection with the VectivBio Acquisition include, among others:

- failure to successfully develop apraglutide for SBS patients who are dependent on PS;
- failure of the VectivBio Acquisition to further our business strategy as we expected, including the commercialization of apraglutide, if approved, for SBS patients who are dependent on PS;
- unexpected losses of key employees, customers or suppliers;
- unanticipated issues in conforming VectivBio's standards, processes, procedures and controls with our operations;
- coordinating product candidate and process development;
- increasing the scope, geographic diversity and complexity of our operations;
- unanticipated changes in applicable laws and regulations;
- unanticipated expenses and liabilities associated with the VectivBio Acquisition; and
- other difficulties in the assimilation of VectivBio operations, technologies, product candidates and systems.

We may have unanticipated or larger than anticipated liabilities for patent and trademark infringement claims, violations of laws, commercial disputes, taxes and other known and unknown types of liabilities. There may be liabilities that we underestimated or did not discover in the course of performing our due diligence investigation.

If any of the above risks occur, our business, financial condition, results of operations and cash flows may be materially and adversely impacted, we may fail to meet the expectations of investors or analysts, and our stock price may decline as a result.

**Risks Related to Our Dependence on Third Parties**

***Because we work with partners to develop, manufacture and commercialize linaclotide, we and our partners are dependent upon third parties, and our and our partners' relationships with those third parties, in our and our partners' efforts to obtain regulatory approval for, and to commercialize, linaclotide, as well as to comply with regulatory and other obligations with respect to linaclotide.***

AbbVie played a significant role in the conduct of the clinical trials for linaclotide and in the subsequent collection and analysis of data, and AbbVie holds the NDA for LINZESS. AbbVie also continues to play a significant role in the conduct of our pediatric program for linaclotide. In addition, we are commercializing LINZESS in the U.S. with AbbVie. AbbVie is also responsible for the development, regulatory approval and commercialization of linaclotide in countries worldwide other than Japan and China (including Hong Kong and Macau). AbbVie is commercializing LINZESS in Mexico and CONSTELLA in Canada as well as in certain countries including in Europe. Astellas and AstraZeneca are responsible for development and commercialization of LINZESS in Japan and China (including Hong Kong and Macau), respectively. Each of our partners for linaclotide also is responsible for active pharmaceutical ingredient, or API, finished drug product and finished goods manufacturing (including bottling and packaging) for its respective territories and distributing the finished goods to wholesalers. We and/or our partners have commercial supply agreements with independent third parties to manufacture the linaclotide API.

The integration of our efforts with our partners' efforts is subject to the uncertainty of the markets for pharmaceutical products in each partner's respective territories, and accordingly, these relationships must evolve to meet any new challenges that arise in those regions. These integrated functions may not be carried out effectively and efficiently if we fail to communicate and coordinate with our linaclotide partners, and vice versa. Our linaclotide partnering strategy imposes obligations, risks and operational requirements on us as the central node in our global network of partners. If we do not effectively communicate with each partner and ensure that the entire network is making integrated and cohesive decisions focused on the global brand for linaclotide, linaclotide will not achieve its maximum commercial potential. Further, we have limited ability to control the amount or timing of resources that our partners devote to linaclotide. If any of our partners fails to devote sufficient time and resources to linaclotide, or if its performance is substandard or otherwise hindered, it will delay the potential submission or approval of regulatory applications for linaclotide, as well as the manufacturing and commercialization of linaclotide in the particular territory. A material breach by any of our partners of our collaboration or license agreement with such partner, or a significant disagreement between us and a partner, could also delay the regulatory approval and commercialization of linaclotide, potentially lead to costly litigation, and could have a material adverse impact on our financial condition. Moreover, although we have non-compete restrictions in place with each of our linaclotide partners, they may have competitive products or relationships with other commercial entities, some of which may compete with us. If any of our partners competes with us or assists our competitors, it could harm our competitive position.

In addition, adverse event reporting requires significant coordination with our partners and third parties. We are the holder of the global safety database for linaclotide responsible for coordinating the safety surveillance and adverse event reporting efforts worldwide with respect to linaclotide; each of Astellas, AstraZeneca and AbbVie is responsible for reporting adverse event information from its territory to us. If we fail to perform such activities and maintain the global safety database for linaclotide or if our partners do not report adverse events related to linaclotide, or fail to do so in a timely manner, we may not receive the information that we or our partners are required to report to the U.S. FDA or a comparable foreign regulatory authority regarding such products. Furthermore, we or our partners may fail to adequately monitor, identify or investigate adverse events, or to report adverse events to the U.S. FDA or a comparable foreign regulatory authority accurately and within the prescribed timeframe. If we or our partners are unsuccessful in any of the foregoing due to poor process, execution, systems, oversight, communication, adjudication or otherwise, then we may suffer any number of consequences, including the imposition of additional restrictions on the use of linaclotide, removal of linaclotide from the market, criminal prosecution, the imposition of civil monetary penalties, seizure of such products, or delay in approval of future products.

***We rely entirely on contract manufacturers, our partners and other third parties to manufacture linaclotide, apraglutide, and our other product candidates and to distribute linaclotide. 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 and distribute sufficient quantities to meet demand, our development and commercialization efforts may be materially harmed.***

We have no internal manufacturing or distribution capabilities. Instead, we rely on a combination of contract manufacturers and our partners to manufacture API, finished drug product and finished goods for linaclotide, apraglutide, and our other product candidates. For linaclotide, each of our partners is responsible for API, finished drug product and finished goods manufacturing (including bottling and packaging) for its respective territories and distributing the finished goods to wholesalers. We and/or our partners have commercial supply agreements with independent third parties to manufacture linaclotide API. For apraglutide, we design and develop the manufacturing process together with CDMOs, and we rely on these CDMOs and other third-party suppliers for the manufacture and supply, including filling and packaging of all the components of the finished product for human use. Should we, or any of our partners or any third-party manufacturers we or our partners engage, experience setbacks or challenges in our manufacturing efforts, our development and commercialization efforts may be materially harmed.

Each of our partners and the third-party manufacturers we or our partners engage, must comply with GMP and other stringent regulatory requirements enforced by the U.S. FDA, EMA and other comparable foreign regulatory authorities in other jurisdictions. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation, which occur in addition to our and our partners' own quality assurance releases.

If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with a facility where the product is manufactured, a regulatory agency may impose restrictions on that product or the manufacturer, including withdrawal of the product from the market or suspension of manufacturing. If we, our partners or the manufacturing facilities for our products fail to comply with applicable regulatory requirements, a regulatory agency may take the following actions, among others:

- issue warning letters or untitled letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications submitted by us or our partners;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require us to initiate a product recall.

Manufacturers of our products may be unable to comply with these GMP requirements and with other regulatory requirements. We have little control over compliance with these regulations and standards by our partners and the third-party manufacturers we or our partners engage.

In addition, we expect that apraglutide may be regulated by the U.S. FDA as a drug-device combination product. Our third-party manufacturers may not be able to comply with GMP regulations applicable to drug-device combination products, including applicable provisions of the U.S. FDA's drug GMP regulations and device GMP requirements embodied in the Quality System Regulation, or similar regulatory requirements outside the U.S.

Our partners and the third-party manufacturers we or our partners engage may experience problems with their respective manufacturing and distribution operations and processes, including, for example, quality issues, such as product specification and stability failures, procedural deviations, improper equipment installation or operation, utility failures, contamination, natural disasters and public health epidemics. In addition, the raw materials necessary to make API for our products and product candidates are acquired from a limited number of sources. Any delay or disruption in

the availability of raw materials or a change in raw material suppliers could result in production disruptions, delays or higher costs with consequent adverse effects on us.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in commercial production. These problems 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 partners or the third-party manufacturers we or our partners engage 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.

If our partners or the third-party manufacturers we or our partners engage 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 will suffer significant consequences, including 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. If we experience any of these results, or if maximum or available manufacturing capacities are insufficient to meet demand, our and our partners' development or commercialization efforts may be materially harmed.

***If any of our linaclotide partners undergoes a change of control or in management, this may adversely affect our collaborative relationship or the success of the commercialization of linaclotide in the U.S. or in the other countries where it is approved, or the ability to achieve regulatory approval, launch and commercialize linaclotide in other territories.***

We work jointly and collaboratively with partners on many aspects of the development, manufacturing and/or commercialization of linaclotide. In doing so, we have established relationships with several key members of the management teams of our linaclotide partners in functional areas such as development, quality, regulatory, drug safety and pharmacovigilance, operations, marketing, sales, field operations and medical science. Further, the success of our collaborations is highly dependent on the resources, efforts and skills of our partners and their key employees. As we and our partners develop and commercialize linaclotide in the U.S. and the other countries where it is approved, and develop, launch and commercialize linaclotide in other parts of the world, the drug's success becomes more dependent on us maintaining highly collaborative and well aligned partnerships. If any of our linaclotide partners undergoes a change of control or in management, we would similarly need to reestablish many relationships and confirm alignment, including on our development and commercialization strategy for linaclotide. Further, in connection with any change of control or change in management, there is inherent uncertainty and disruption in operations, which could result in distraction, inefficiencies, and misalignment of priorities. As a result, in the event of a change of control or in management at one of our linaclotide partners, we cannot be sure that we will be able to successfully execute on our development and commercialization strategy for linaclotide in an effective and efficient manner and without disruption or reduced performance. Finally, any change of control or in management may result in a reprioritization of linaclotide within a partner's portfolio, or such partner may fail to maintain the financial or other resources necessary to continue supporting its portion of the development, manufacturing or commercialization of linaclotide.

If any of our linaclotide partners undergoes a change of control and the acquirer either (i) is unable to perform such partner's obligations under its collaboration or license agreement with us or (ii) does not comply with the divestiture or certain other provisions of the applicable agreement, we have the right to terminate the collaboration or license agreement and re-acquire that partner's rights with respect to linaclotide. If we elect to exercise these rights in such circumstances, we will need to either establish the capability to develop, manufacture and commercialize linaclotide in that partnered territory on our own or we will need to establish a relationship with a new partner. We have assembled a team that represents the functional areas necessary to support the commercialization of LINZESS in the U.S. If AbbVie was subject to a change of control that allowed us to further commercialize LINZESS in the U.S. on our own, and we chose to do so, we would need to enhance each of these functional aspects, as well as develop others, to replace the capabilities that AbbVie was previously providing to the collaboration. Any such transition might result in a

period of reduced efficiency or performance by our operations and commercialization teams, which could adversely affect our ability to commercialize LINZESS.

We do not have certain operational capabilities outside of the U.S. If AbbVie, Astellas or AstraZeneca was subject to a change of control that allowed us to continue linaclotide's development or commercialization anywhere outside of the U.S. on our own, and we chose to do so rather than establishing a relationship with a new partner, we would need to build operational capabilities in the relevant territory. In any of these situations, the development and commercialization of linaclotide could be negatively impacted.

***We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to continue the development of our product candidates, obtain regulatory approval for or commercialize our product candidates and our business could be harmed.***

We have relied upon and plan to continue to rely upon third-party CROs to execute our ongoing clinical trial programs, including an anticipated confirmatory Phase III clinical trial for apraglutide. We control only certain aspects of the CROs' activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We, our CROs and other vendors are required to comply with GMP, good clinical practices, and good laboratory practices, which are regulations and guidelines enforced by the U.S. FDA, the competent authorities of the individual EEA countries and comparable foreign regulatory authorities for our current product candidate in clinical development. Regulatory authorities enforce these regulations through periodic inspections of study sponsors, principal investigators, study sites and other contractors. If we or any of our CROs or vendors fail to comply with applicable regulations, the data generated in our clinical trials may be deemed unreliable and the U.S. FDA, EMA, or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. There are no guarantees that, upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with the relevant regulations.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether they devote sufficient time and resources to our clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements, or for other reasons, our clinical trials may be extended or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. CROs may also generate higher costs than anticipated.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result of switching CROs, delays may occur, which could impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges in their implementation of our clinical studies or that these challenges will not have an adverse impact on our business, results of operations and prospects.

**Risks Related to Regulatory, Legal and Compliance Matters**

***We face potential product liability exposure, and, if claims brought against us are successful, we could incur substantial liabilities.***

The use of our product candidates in clinical trials and the sale of our approved products, including the sale of linaclotide, expose us to product liability claims. If we do not successfully defend ourselves against product liability claims, we could incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for approved products;
- impairment of our business reputation;

- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- litigation costs;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- loss of revenues; and
- the inability to commercialize our product candidates.

We currently have product liability insurance coverage for the commercial sale of our products and for the clinical trials of our product candidates which is subject to industry-standard terms, conditions and exclusions. Our insurance coverage may not be sufficient to reimburse us for expenses or losses associated with claims. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. On occasion, large judgments have been awarded in lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

***We will incur significant liability if it is determined that we are promoting any "off-label" uses of our products.***

Physicians are permitted to prescribe drug products and medical devices for uses that are not described in the product's labeling and that differ from those approved by the U.S. FDA or other applicable regulatory agencies. Such "off-label" uses are common across medical specialties. Although the U.S. FDA and other regulatory agencies do not regulate a physician's choice of treatments, the U.S. FDA and other regulatory agencies do restrict manufacturer communications on off-label use. Companies are not permitted to promote drugs or medical devices for off-label uses or to promote unapproved drugs or medical devices. Accordingly, we do not permit promotion of any product that we develop, license, commercialize, promote, co-promote or otherwise partner prior to approval or for any indication, population or use not described in or consistent with such product's labeling. The U.S. FDA and other regulatory and enforcement authorities actively enforce laws and regulations prohibiting promotion of off-label uses and the promotion of products for which marketing approval has not been obtained. A company that is found to have promoted off-label uses or have engaged in improper pre-approval promotion will be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. Even if it is later determined that we were not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our actions and have to divert significant management resources from other matters.

Notwithstanding the regulatory restrictions on off-label promotion, the U.S. FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional disease awareness and scientific exchange concerning their products, investigational assets and therapeutic areas of interest. We intend to engage in disease awareness and medical and scientific exchange and education activities and communicate with healthcare providers in compliance with all applicable laws, regulatory guidance and industry best practices. Although we believe we have put in place a robust compliance program, which is designed to ensure that all such activities are performed in a legal and compliant manner, we cannot be certain that our program will address all areas of potential exposure and the risks in this area cannot be entirely eliminated.

***If we fail to comply with healthcare and other regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.***

The marketing of pharmaceutical and biopharmaceutical products and related arrangements with healthcare providers, third-party payors, patients and other third parties in the healthcare industry are subject to a wide range of healthcare laws and regulations within the U.S. and in foreign jurisdictions in which we operate. These laws and

regulations may constrain our business and/or financial arrangements. Within the U.S., federal laws and regulations include:

- federal healthcare program anti-kickback laws, which prohibit, among other things, persons from offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual for, or the purchasing or ordering of, a good or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, information or claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to manufacturers for reasons including providing coding and billing advice to customers or engaging in prohibited off-label promotional activities;

- federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information on certain types of entities, which include many healthcare providers with whom we interact and health plans with which we may interact;

- the Federal Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug product and medical device marketing, prohibits manufacturers from marketing such products prior to approval or for off-label use and regulates the distribution of samples;

- the 21st Century Cures Act, which amends Section 114 of the Food and Drug Administration Modernization Act of 1997 to define healthcare economic information and the circumstances under which healthcare economic information may be disseminated;

- federal laws, including the Medicaid Drug Rebate Program, that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs; and

- the so-called "federal sunshine" law, which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with physicians, certain non-physician practitioners and teaching hospitals to the federal government for re-disclosure to the public.

There are also state law equivalents of certain of the above federal laws, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts, which laws include anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers, state transparency laws, state laws limiting interactions between pharmaceutical manufacturers and members of the healthcare industry, and state laws governing the privacy and security of health information in certain circumstances.

Other laws and regulations have also been enacted by various states to regulate the sales and marketing practices of pharmaceutical or biopharmaceutical manufacturers. The laws and regulations generally limit financial interactions between manufacturers and health care providers; require manufacturers to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government; and/or require disclosure to the government and/or public of financial interactions (so-called "sunshine laws"). State laws may also require disclosure of pharmaceutical pricing information and marketing expenditures. Certain state and local laws require the registration of pharmaceutical sales representatives. Additionally, some individual states have begun establishing Prescription Drug Affordability Boards (or similar entities) to review high-cost drugs and, in some cases, set upper payment limits. Many of these laws and regulations contain ambiguous requirements or require administrative guidance for implementation.

Additionally, in its 2024 decision in *Loper Bright Enterprises v. Raimondo*, the U.S. Supreme Court overruled the "Chevron doctrine," which gives deference to regulatory agencies' statutory interpretations in litigation against

federal government agencies, such as the U.S. FDA, CMS and other federal agencies where the law is ambiguous. This Supreme Court decision may lead to challenges of long standing decisions and policies of these agencies, which could lead to uncertainties in the industry and disrupt the federal agency's operations.

Outside the U.S., our activities may be subject to healthcare laws. For example, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order, or use of medicinal products is prohibited in the E.U. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of E.U. Member States, and by Bribery Act 2010 in the United Kingdom. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain E.U. Member States must be publicly disclosed, and in the United Kingdom a public consultation on the introduction of equivalent transparency requirements is currently underway. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization, and/or the regulatory authorities of the individual E.U. Member States and the United Kingdom. These requirements are provided in the national laws, self-regulatory industry codes, or professional codes of conduct applicable in the E.U. Member States and the United Kingdom. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines, or imprisonment.

We also are subject to the FCPA which prohibits corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity, related to any ex-U.S. activities, as well as other similar anti-bribery laws in any other country in which we may do business.

It is possible that governmental authorities will conclude that our business practices, or the business practices of third parties with whom we collaborate, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, or those of third party partners, are found to be in violation of any of these laws or any other governmental regulations, we may be subject to lawsuits, significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations.

***We are subject to stringent and changing U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; disruptions of our operating results and business; and other adverse business consequences.***

We may be subject to privacy and security laws in the various jurisdictions, both inside and outside the U.S., in which we operate and/or obtain or store personally identifiable information, such as the E.U. GDPR, the United Kingdom's GDPR and the Swiss Federal Act on Data Protection, or FADP. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. For example, the GDPR, which took effect in May 2018, applies to the processing of personal data in the EEA. The GDPR increases obligations with respect to clinical trials and non-clinical studies conducted in the EEA, by certain companies that process data in relation to (i) offering goods or services to, or (ii) monitoring the behavior of, individuals located in the EEA. As such, we are subject to the GDPR for data processing associated, for example, with conducting clinical trials in the EEA or entering into research collaborations in the EEA. The GDPR imposes stringent obligations for processing of personal data, such as setting high standards for consent, requiring the provision of detailed processing notices, facilitating the exercise of data subject rights and requiring reporting certain data breaches to regulators and affected individuals, as well as establishing standards for how we document our relationships with third parties that process GDPR-covered personal data on our behalf. The FADP also applies to the collection and processing of personal data by companies located in Switzerland, or in certain circumstances, by companies located outside of Switzerland. The FADP has been revised and adopted by the Swiss Parliament and took effect on September 1, 2023. The revisions to the FADP may result in increased costs of compliance, risks of noncompliance and penalties for noncompliance.

The GDPR, United Kingdom's GDPR and FADP also increase the scrutiny applied to transfers of personal data from the EEA, UK, and Switzerland, respectively (including from clinical trial sites in the EEA) to countries that are considered by the European Commission, United Kingdom or Switzerland, respectively, to lack an adequate level of data protection, such as the U.S. In July 2023, the European Commission adopted an adequacy decision for the EU-U.S. Data Privacy Framework, which permits U.S. companies who self-certify under the framework to rely on it as a valid data transfer mechanism for data transfers from the E.U. to the U.S. There is currently one pending litigation against the EU-U.S. Data Privacy Framework before the Court of Justice of the E.U. and we expect there to be additional legal challenges in the future. If these challenges are successful, they may not only impact the EU-U.S. Data Privacy Framework, but also further limit the viability of the so-called standard contractual clauses and other data transfer mechanisms. The uncertainty around this issue has the potential to impact our business. As supervisory authorities issue further guidance on personal data export mechanisms or where the standard contractual clauses cannot be used, we could incur additional compliance costs, complaints, and/or regulatory investigations and, if we are unable to otherwise transfer personal data among jurisdictions in which we operate, our services and geographical location or segregation of our relevant systems and operations could be affected.

In addition, in the U.S., we are subject to the CCPA, as amended by the CPRA, which became effective on January 1, 2023 (the CPRA, together with CCPA, the California Privacy Law). The California Privacy Law gives California consumers (defined to include all California residents) certain rights regarding personal information collected about them; the California Privacy Law also imposes certain obligations and limitations on companies regarding the collection, use, selling or sharing (as defined in the California Privacy Law) of personal information collected from or about California consumers. Other states have passed or may pass comprehensive privacy laws or laws specifically regulating health information that may affect our business. For example, Washington state passed the My Health My Data Act to which we are subject, which regulates the collection and sharing of health information, and provides a right of action for violation of the statute.

The compliance obligations imposed by the GDPR, United Kingdom's GDPR, FADP, the California Privacy Law, Washington's My Health My Data Act, and other applicable privacy laws, have required us to revise our operations. Breaches of applicable data protection requirements may result in substantial fines and other regulatory penalties, as well as confer a private right of action on data subjects or consumers and their representatives for breaches of certain data protection requirements. We expect to be subject to additional privacy laws at both the U.S. state level and abroad as many jurisdictions either recently have data privacy legislation or are considering enacting such legislation to which we may become subject. Achieving and sustaining compliance with applicable international, federal and state privacy, security, fraud and reporting laws may prove time-consuming and costly.

If our operations, or the operations of third parties upon which we rely, are found to be in violation of any of the laws described above or any other laws, rules or regulations that apply to us, we will be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. For example, under the GDPR and the United Kingdom's GDPR, penalties for noncompliance could be up to 20 million Euros or 4% of our total worldwide annual revenue of the preceding financial year, whichever is greater. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, rules or regulations, we cannot be certain that our program will address all areas of potential exposure and the risks in this area cannot be entirely eliminated, particularly because the requirements and government interpretations of the requirements in this space are constantly evolving. Any action against us for violation of these laws, rules or regulations, 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, as well as damage our business or reputation.

***The VectivBio Acquisition increases our exposure to doing business in foreign jurisdictions.***

Following the VectivBio Acquisition, we retained VectivBio's legacy headquarters in Basel, Switzerland and, as a result, we now have employees and operations in foreign jurisdictions. Operating in foreign jurisdictions exposes us to additional risks such as fluctuations in currency exchange rates; compliance with different legal and regulatory environments; foreign regulatory regimes applicable to clinical trials and obtaining approvals for product candidates; compliance with applicable data privacy laws and regimes such as the E.U. GDPR, the United Kingdom's GDPR and the Swiss FADP; risk relating to the political and economic status of foreign governments; differences in the manner in which different cultures do business; difficulties in staffing and managing foreign operations; differences in financial reporting; and operating difficulties; among other factors. The realization of any of these risks, if severe enough, could have an adverse effect on our consolidated financial position, results of operations and cash flows.

**Risks Related to Intellectual Property**

***Limitations on our ability to obtain patent protection and/or the patent rights relating to our products and our product candidates may limit our ability to prevent third parties from competing against us.***

Our success depends on our ability to obtain and maintain sufficient patent protection for our products and product candidates, preserve our trade secrets, prevent third parties from infringing upon our proprietary rights and operate without infringing upon the proprietary rights of others.

The strength of patents in the pharmaceutical industry involves complex legal and scientific questions and can be uncertain. Patent applications in the U.S. and most other countries are confidential for a period of time until they are published, and publication of discoveries in scientific or patent literature typically lags actual discoveries by several months or more. As a result, we cannot be certain that we were the first to conceive inventions covered by our patents and pending patent applications or that we were the first to file patent applications for such inventions. In addition, we cannot be certain that our patent applications will be granted, that any issued patents will adequately protect our intellectual property, or that such patents will not be challenged, narrowed, invalidated or circumvented.

We have several issued patents in the U.S. related to LINZESS, including a LINZESS composition of matter and methods of use patent (U.S. Patent 7,304,036), which in October 2025 received pediatric exclusivity, and consequently will now expire in 2027. Additional U.S. patents related to LINZESS include multiple patents relating to our commercial, room temperature stable formulations of the 72 mcg, 145 mcg and 290 mcg doses of linaclotide and methods of using these formulations, the latest of which expires in the early 2030s, as well as other patents and patent applications covering formulations of linaclotide, and molecules related to linaclotide.

In addition, we have exclusive rights to apraglutide including issued composition of matter and method of use patents in the U.S. in lead indications. We aim to maintain a strong and broad estate of patents in the U.S. and other geographic areas. To this end, we have exclusively licensed 59 patents and 3 pending patent applications in the U.S., E.U., Japan, China and other jurisdictions protecting apraglutide. We also own two U.S. granted patents, one granted European patent and two granted Japanese patents as well as approximately 40 pending patent applications worldwide that cover apraglutide, including ultrapure compositions, methods of manufacture and methods of use in various diseases.

Although none of these issued patents currently is subject to a patent reexamination or review, we cannot guarantee that they will not be subject to reexamination or review by the USPTO in the future. We believe in the strength of our LINZESS and apraglutide patent portfolio and that we have sufficient freedom to operate; however, if any of our present or future patents is challenged, narrowed, invalidated or circumvented, or our pending patent applications are not granted, our ability to prevent third parties from competing with LINZESS or apraglutide could be limited and our business and financial results may be materially harmed.

Furthermore, the America Invents Act, which was signed into law in 2011, has made several major changes in the U.S. patent statutes. These changes permit third parties to challenge our patents more easily and create uncertainty with respect to the interpretation and practice of U.S. patent law. Moreover, the U.S. Supreme Court has ruled on several patent cases that narrow the scope of patent protection available and weakening the rights of patent owners in certain circumstances. Depending on the impact of these decisions and other actions by the U.S. Congress, the federal courts, the USPTO, and their foreign counterparts, the laws and regulations governing patents may change, or their interpretation or implementation may change, in unpredictable ways that could impact, potentially adversely, our ability to obtain new patents or to enforce and defend patents that we have already obtained or that we might obtain in the future. For example, such changes may increase the costs and complexity associated with obtaining, enforcing or defending our patents, including in ANDA litigation.

We also rely upon unpatented trade secrets, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees and our partners and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us. It is possible, however, that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees and consultants that are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies, and we could lose our trade secrets through such breaches or violations. Additionally, our trade secrets could otherwise become known or be independently discovered by our competitors.

In addition, the laws of certain foreign countries do not protect proprietary rights to the same extent or in the same manner as the U.S., and, therefore, we or our partners may encounter problems in protecting and defending our intellectual property in certain foreign jurisdictions.

***If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in such litigation could have a material adverse effect on our business.***

Our commercial success depends on our ability, and the ability of our partners, to develop, manufacture, market and sell our products and use our proprietary technologies without infringing the proprietary rights of third parties.

Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our partners are developing products. As the biotechnology and pharmaceutical industry expands and more patents are issued, the risk increases that our potential products may give rise to claims of infringement of the patent rights of others. There may be issued patents of third parties of which we are currently unaware that may be infringed by LINZESS, apraglutide, or our product candidates. Because patent applications can take many years to issue, there may be currently pending applications which may later result in issued patents that LINZESS, apraglutide, or our product candidates may infringe.

We may be exposed to, or threatened with, litigation by third parties alleging that LINZESS, apraglutide, or our product candidates infringe their intellectual property rights. If LINZESS, apraglutide, or one of our product candidates is found to infringe the intellectual property rights of a third party, we or our partners could be enjoined by a court and required to pay damages and could be unable to develop or commercialize LINZESS, apraglutide, or the applicable product candidate unless we obtain a license to the intellectual property rights. A license may not be available to us on acceptable terms, if at all. In addition, during litigation, the counterparty could obtain a preliminary injunction or other equitable relief which could prohibit us from making, using or selling our products, pending a trial on the merits, which may not occur for several years.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally. If a third party claims that we or our partners infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from selling our product unless the third party licenses its rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties, fees or grant cross-licenses to our intellectual property rights; and
- redesigning our products so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

***If we fail to comply with our obligations or have disagreements over contract interpretation in agreements under which we license intellectual property and other rights from third parties or otherwise experience disruptions to our business***

***relationship with our licensor, the scope of our intellectual property or technology rights could be narrowed and we could lose license rights that are important to our business.***

Licensing intellectual property is of critical importance to our business and involves complex legal, business, and scientific issues. Disputes may arise regarding intellectual property subject to a licensing agreement, including but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors, our collaborators and us;
- the priority of invention of patented technology; and
- the fulfilment of our obligations under the license.

In addition, certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could harm our business, financial condition, results of operations and prospects. If our licenses or material relationships or any in-licenses upon which our licenses are based are terminated or breached, we may:

- lose our rights to develop and market product candidates;
- lose patent protection for product candidates;
- experience significant delays in the development or commercialization of product candidates;
- not be able to obtain any other licenses on acceptable terms, if at all; or
- incur liability for damages.

We are currently a party to and may in the future be party to license agreements. Apraglutide is among the assets that are subject to licensing agreements with third parties. For example, we are a party to an amended and restated exclusive license agreement, dated as of December 6, 2016, as amended, by and between GlyPharma Therapeutic Inc. (as predecessor to VectivBio AG) and Ferring, or the Ferring Agreement, pursuant to which we have exclusive rights to apraglutide including an issued composition of matter and method of use patent in the U.S. in lead indications. The Ferring Agreement imposes, and other current or future license agreements may impose, various diligence, milestone payment, royalty, and other obligations on us. These milestone, royalty, and other payments associated with the license, will make it less profitable for us to develop apraglutide or other product candidates that are the subject of current or future licenses. If we fail to comply with our obligations under the Ferring Agreement, or we are subject to a bankruptcy, we may be required to make certain payments to Ferring, we may lose the exclusivity of our license, or Ferring may have the right to terminate the license. If the Ferring Agreement is terminated, we could lose intellectual property rights that are important to our business, be liable for damages to the licensor or be prevented from developing and commercializing our apraglutide. Termination of the agreement or reduction or elimination of our rights under the agreement may also result in us being required to negotiate a new or reinstated agreement with less favorable terms, and it is possible that we may be unable to obtain any such additional license at a reasonable cost or on reasonable terms and

will be unable to develop and commercialize apraglutide. These or similar risks may apply to other license agreements, including future license agreements. If disputes over intellectual property and other rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize apraglutide.

On October 2, 2025, Ferring filed a complaint against our wholly-owned subsidiary, VectivBio AG, for trade secret misappropriation and correction of patent inventorship and ownership in the U.S. District Court in the Eastern District of Texas, alleging that VectivBio AG misappropriated Ferring's technology for its own benefit and improperly filed patent applications claiming that technology without reference to Ferring's inventorship and ownership interests. On December 18, 2025, we, VectivBio AG and Ferring entered into a third amendment to the Ferring Agreement and a settlement agreement and release pursuant to which VectivBio AG and Ferring have settled all claims between the parties arising out of Ferring's complaint. A dismissal of Ferring's complaint with prejudice was entered in the U.S. District Court in the Eastern District of Texas on December 19, 2025.

In some cases, patent prosecution of our licensed technology is controlled solely by the licensor. If our licensor fails to obtain or maintain a patent or other protection for the proprietary intellectual property we license from them, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. In certain cases, we control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners.

***We may be unable to maintain the benefits associated with orphan drug designation, including market exclusivity, which may harm our business.***

In the U.S., orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product receives the first U.S. FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the U.S. FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. In the E.U., orphan drug designation entitles a company to financial incentives such as reduction of fees or fee waivers and ten years of data and market exclusivity for the approved therapeutic indication following marketing authorization of a medicinal product, including biological medicinal products. This period may be reduced to six years if, at the end of the fifth year, the medicinal product no longer fulfills the orphan designation criteria, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Because the extent and scope of patent protection for our products may in some cases be limited, orphan drug designation is especially important for our product candidates for which orphan drug designation may be available. For eligible drugs, we plan to rely on the exclusivity period under the Orphan Drug Act to maintain a competitive position. If we do not obtain orphan drug exclusivity for our drug product candidates that does not have a broad patent protection, our competitors may then sell the same drug to treat the same condition sooner than if we had obtained orphan drug exclusivity and our revenue will be reduced.

Even though we have orphan drug designation for apraglutide in the U.S. and in the E.U., we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Based on available preclinical and clinical data, both the U.S. FDA and the EMA have granted apraglutide orphan drug designation for the treatment of SBS. Orphan drug applicability will be reassessed by health authorities upon completion of clinical studies and submission of our marketing application. In the E.U., the orphan designation for apraglutide may not be maintained at the time of grant of the marketing authorization if the EMA and COMP do not consider that there is sufficient confirmatory evidence to support that the orphan designation criteria continue to be met.

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan drug is approved, the U.S. FDA or EMA can subsequently approve the same drug with the same active moiety for the same condition if the U.S. FDA or EMA concludes that the later drug is safer, more effective, or makes a

major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

***We have received notices of Paragraph IV certifications related to LINZESS in conjunction with ANDAs filed by generic drug manufacturers, and we may receive additional notices from others in the future. We have, and may continue to, become involved in legal proceedings to protect or enforce intellectual property rights relating to our products and our product candidates, which could be expensive and time consuming, and unfavorable outcomes in such proceedings could have a material adverse effect on our business.***

Competitors may infringe the patents relating to our products and our product candidates or may assert that such patents are invalid. To counter ongoing or potential infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Litigation with generic manufacturers has become increasingly common in the biotechnology and pharmaceutical industries. In addition, in an infringement or invalidity proceeding, a court or patent administrative body may determine that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question.

Generic drug manufacturers were first able to file ANDAs for generic versions of LINZESS in August 2016. When filing an ANDA for one of our products, a generic drug manufacturer may choose to challenge one or more of the patents that cover such product and seek to commercialize generic versions of one or more LINZESS doses. As such, we have brought, and may bring in the future, legal proceedings against generic drug manufacturers.

We and AbbVie have received Paragraph IV certification notice letters regarding ANDAs submitted to the U.S. FDA by generic drug manufacturers requesting approval to engage in commercial manufacture, use, sale and offer for sale of linaclotide capsules (72 mcg, 145 mcg and 290 mcg), proposed generic versions of our U.S. FDA-approved drug LINZESS. We filed patent infringement lawsuits against five companies making such ANDA filings and subsequently entered into settlement agreements with each of these filers. Frequently, innovators receive multiple ANDA filings. Consequently, we may receive additional notice letters regarding ANDAs submitted to the U.S. FDA (and we may receive amendments to those notice letters), but we may not become aware of these filings for several months after any such submission due to procedures specified under applicable U.S. FDA regulations.

After evaluation, we have in the past filed, and may, in the future, file patent infringement lawsuits or take other action against companies making ANDA filings. If a patent infringement suit has been filed within 45 days of receipt of a notice letter, the U.S. FDA is not permitted to approve any ANDA that is the subject of such lawsuit for 30 months from the date of the NDA holder's and patent owner's receipt of the ANDA filer's notice letter, or until a court decides that the relevant patents are invalid, unenforceable and/or not infringed. Additionally, the validity of the patents relating to our products and our product candidates may be challenged by third parties pursuant to administrative procedures introduced by the America Invents Act, specifically *inter partes* review, or IPR, and/or post grant review, or PGR, before the USPTO. Generic drug manufacturers may challenge our patents through IPRs or PGRs instead of or in addition to ANDA legal proceedings.

Patent litigation (including any lawsuits that we file against generic drug manufacturers in connection with the receipt of a notice letter), IPRs and PGRs involve complex legal and factual questions and we may need to devote significant resources to such legal proceedings. We can provide no assurance concerning the duration or the outcome of any such patent-related lawsuits or administrative proceedings, including any settlements or other resolutions thereof which could, in addition to other risks, result in a shortening of exclusivity periods. An adverse result in any litigation or defense proceedings could put one or more of the patents relating to our products and our product candidates at risk of being invalidated or interpreted narrowly, or could otherwise result in a loss of patent protection for the product or product candidate at issue, and could put our patent applications at risk of not issuing, which would materially harm our business. Upon any loss of patent protection for one of our products, or upon an "at-risk" launch (despite pending patent infringement litigation, before any court decision or while an appeal of a lower court decision is pending) by a manufacturer of a generic version of one of our patented products, our revenues for that product could be significantly reduced in a short period of time, which would materially and adversely affect our business.

Interference or derivation proceedings brought by the USPTO may be necessary to determine the priority of inventions with respect to the patents relating to our products and our product candidates and patent applications or those of our partners. An unfavorable outcome could require us to cease using the technology or to attempt to license rights to

it from the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. In addition, we may not be able to prevent, alone or with our partners, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the U.S.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, as well as the potential for public announcements of the results of hearings, motions or other interim proceeding or developments, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

**Risks Related to Our Finances and Capital Requirements**

***We incurred significant losses from our inception in 1998 through the year ended December 31, 2018, and we may incur losses in future periods.***

In recent years, we have focused primarily on developing, manufacturing and commercializing linaclotide, as well as developing our other product candidates. For example, in June 2023, we acquired VectivBio and added apraglutide to our pipeline. We have financed our business to date primarily through the issuance of equity, our collaboration and license arrangements, and debt issuances, including our $200.0 million aggregate principal amount of Convertible Senior Notes, bearing an interest of 1.50% and due in June 2026, or the Convertible Senior Notes, and our $550.0 million secured revolving credit facility, or the Revolving Credit Facility. We currently derive a significant portion of our revenue from our LINZESS collaboration with AbbVie for the U.S. We believe that the revenues from the LINZESS collaboration will continue to constitute a significant portion of our total revenue for the foreseeable future. Such revenue is highly dependent on LINZESS demand and other factors such as fluctuations in retail chains' and wholesalers' buying patterns and inventory levels, pricing and reimbursement. Our collaborative arrangements revenue outside of the U.S. has and may continue to fluctuate as a result of the timing and amount of sales of linaclotide in the markets in which it is currently approved, or any other markets where linaclotide receives approval, as well as clinical and commercial milestones received and recognized under our current and future strategic partnerships outside of the U.S.

For the year ended December 31, 2023, we incurred a net loss in connection with the VectivBio Acquisition. Prior to the year ended December 31, 2019, we incurred net losses in each year since our inception in 1998. As of December 31, 2025, we had an accumulated deficit of approximately $1.7 billion. We cannot be certain that sales of our products, and the revenue from our other commercial activities, will not fall short of our projections or be delayed. Further, we expect to continue to incur substantial expenses in connection with our efforts to commercialize linaclotide and research, develop, and commercialize our product candidates, including apraglutide, and access externally developed products or product candidates. Because of the numerous risks and uncertainties associated with developing and commercializing pharmaceutical products, as well as those related to our expectations for our products and our other activities, we are unable to predict the extent of any future losses. Failure to achieve sustainable net income and maintain positive cash flows would have an adverse effect on stockholders' equity and working capital.

***We may need additional funding and may be unable to raise capital when needed, which could cause us to delay, reduce or eliminate our corporate or product development or commercialization efforts.***

We have previously raised funds to finance our operations through capital raising activities, including the sale of shares of our Class A Common Stock in public offerings and convertible and other debt issuances. However, marketing and selling gastrointestinal drugs, purchasing commercial quantities of pharmaceutical products, developing product candidates, conducting clinical trials and accessing externally developed products or product candidates are expensive and uncertain. Circumstances, our strategic imperatives, or opportunities to create or acquire new programs, as well as maturities, redemptions or repurchases of our outstanding debt securities, could require us to, or we may choose to, seek to raise additional funds. The amount and timing of our future funding requirements will depend on many factors, including, but not limited to:

- the level of underlying demand and price we are able to charge for our products in the countries in which they are approved;

- the costs associated with commercializing our products in the U.S.;
- the costs of establishing, maintaining and/or expanding sales, marketing, distribution, and market access capabilities for our products;
- the regulatory approval of linaclotide within new indications, populations and formulations, as well as the associated development and commercial milestones and royalties;
- the rate of progress, the cost of our clinical trials and the other costs associated with our development programs, including our planned confirmatory Phase III clinical trial of apraglutide in adult patients with SBS-IF, post-approval nonclinical and clinical studies of linaclotide in pediatrics and our investment to enhance the clinical profile of LINZESS, as well as to study linaclotide in additional indications, populations and formulations to assess its potential to treat various conditions;
- the regulatory approval of apraglutide;
- the costs and timing of in-licensing additional products or product candidates or acquiring other complementary companies or assets;
- the status, terms and timing of any collaboration, licensing, co-commercialization or other arrangements;
- whether the holders of our Convertible Senior Notes hold the notes to maturity without conversion into our Class A Common Stock or cash and whether we are required to repurchase any of our Convertible Senior Notes prior to maturity upon a fundamental change, as defined in each of the indentures governing the Convertible Senior Notes; and
- whether we seek to redeem, repurchase or retire all or part of our outstanding debt through cash purchases and/or exchanges, in open market purchases, privately negotiated transactions, by tender offer or otherwise.

Additional funding may not be available on acceptable terms or at all. If adequate funds are not available, we may be required to delay or reduce the scope of our commercialization efforts, delay, reduce or eliminate one or more of our development programs or delay or abandon potential strategic opportunities.

***Our ability to pay principal of and interest on our outstanding debt will depend in part on the receipt of payments from AbbVie under our collaboration agreement for North America.***

Semi-annual payments on our Convertible Senior Notes began in December 2019. In addition, in 2023, we entered into the Revolving Credit Facility. As of December 31, 2025, the outstanding principal balance on the Revolving Credit Facility was $385.0 million. We expect that for the next few years, at a minimum, the net quarterly payments from AbbVie will be a significant source of cash flows from operations. If the cash flows derived from the net quarterly payments that we receive from AbbVie under the collaboration agreement for North America are insufficient on any particular payment date to fund the interest payment on our outstanding indebtedness, at a minimum, we will be obligated to pay the amounts of such shortfall out of our general funds. The determination of whether AbbVie will be obligated to make a net quarterly payment to us in respect of a particular quarterly period is a function of the revenue generated by LINZESS in the U.S. as well as the development, manufacturing and commercialization expenses incurred by each of us and AbbVie under the collaboration agreement for North America. Accordingly, since we cannot guarantee that our company will maintain net income or positive cash flows, we cannot provide assurances for any particular quarterly period that (i) we will have the available funds to fund the interest payment on our outstanding indebtedness, at a minimum, in the event that there is a deficiency in the net quarterly payment received from AbbVie, (ii) there will be a net quarterly payment from AbbVie at all or (iii) we will not also be required to make a true-up payment to AbbVie under the collaboration agreement for North America.

***Our indebtedness could adversely affect our financial condition or restrict our future operations.***

As of December 31, 2025, we had total indebtedness of $585.0 million and available cash and cash equivalents of $215.5 million.

We incurred significant new indebtedness in connection with the VectivBio Acquisition. In May 2023, we entered into the Revolving Credit Facility, which includes a $10.0 million letter of credit subfacility. In June 2023, we borrowed $400.0 million to fund a portion of the consideration paid to purchase VectivBio's outstanding ordinary shares in connection with the VectivBio Acquisition. As of December 31, 2025, the outstanding principal balance on the Revolving Credit Facility was $385.0 million.

The agreement governing the Revolving Credit Facility, or the Revolving Credit Agreement, as amended in September 2024, contains certain covenants applicable to us and certain of our subsidiaries that may, under certain circumstances, impose significant operating and financial restrictions on us, including, without limitation, limitations on additional indebtedness, liens, various fundamental changes, dividends and distributions, investments (including acquisitions), transactions with affiliates, asset sales, prepayment of junior financing, changes in business and other limitations customary in senior secured credit facilities. The Revolving Credit Agreement also includes cross-default features providing that defaults under certain other indebtedness would result in a default under the Revolving Credit Agreement. In addition, the Revolving Credit Agreement requires us to maintain a maximum consolidated secured net leverage ratio of 3.50 to 1.00 until the end of the final quarter of 2025, or the Initial Period, (ii) 3.25 to 1.00 until the end of the first quarter of 2026, or the Interim Period, and (iii) 3.00 to 1.00 thereafter, and a minimum interest coverage ratio of 3.00 to 1.00, in each case at the end of each fiscal quarter. The Revolving Credit Agreement allows us to elect to increase the permitted maximum consolidated secured net leverage ratio to (i) 4.00 to 1.00 during the Initial Period, (ii) 3.75 to 1.00 during the Interim Period, and (iii) 3.50 to 1.00 thereafter, in each case for up to for four fiscal quarters in the event it consummates an acquisition for consideration in excess of $50.0 million, subject to certain limitations on how often this election can be made. Additionally, the lenders under the Revolving Credit Agreement will be permitted to accelerate all outstanding borrowings and other obligations, terminate outstanding commitments and exercise other specified remedies upon the occurrence of customary events of default.

In addition, while the indenture governing our Convertible Senior Notes does not include covenants restricting the operation of our business except in certain limited circumstances, in the event of a default under the Convertible Senior Notes, the noteholders or the trustee under the indenture governing the Convertible Senior Notes may accelerate our payment obligations under the Convertible Senior Notes, which could have a material adverse effect on our business, financial condition and results of operations. We are also required to offer to repurchase the Convertible Senior Notes upon the occurrence of a fundamental change, which could include, among other things, any acquisition of our company (other than an acquisition in which at least 90% of the consideration is Class A Common Stock listed on The Nasdaq Global Select Market or The New York Stock Exchange), subject to the terms of the indenture governing the Convertible Senior Notes. The repurchase price must be paid in cash, and this obligation may have the effect of discouraging, delaying or preventing an acquisition of our company that would otherwise be beneficial to our security holders.

The indenture governing our Convertible Senior Notes also includes cross-default features providing that certain failures to pay for outstanding indebtedness would result in a default under the indenture governing our Convertible Senior Notes. In the event of such default, the trustee or noteholders could elect to declare all amounts outstanding to be immediately due and payable under the indenture, which could have a material adverse effect on our business, financial condition and results of operations.

To the extent we become subject to such covenants, our ability to comply with such covenants in future periods will depend on our ongoing financial and operating performance, which in turn will be subject to economic conditions and to financial, market and competitive factors, many of which are beyond our control.

Our significant indebtedness, combined with our other financial obligations and contractual commitments, could have important consequences on our business, including:

- limiting our ability to obtain additional financing to fund future working capital, capital expenditures or other general corporate purposes, including product development, commercialization efforts, research and development activities, strategic arrangements, acquisitions and refinancing of our outstanding debt;

- requiring a substantial portion of our cash flows to be dedicated to debt service payments instead of other purposes, thereby reducing the amount of cash flows available for working capital, capital expenditures, corporate transactions and other general corporate purposes;

- increasing our vulnerability to adverse changes in general economic, industry and competitive conditions;

- limiting our flexibility in planning for and reacting to changes in the industry in which we compete;

- placing us at a disadvantage compared to other, less leveraged competitors or competitors with comparable debt at more favorable interest rates; and

- increasing our cost of borrowing.

If we do not generate sufficient cash flows from operations or if future borrowings are not available to us in an amount sufficient to service our indebtedness, including payments of principal when due on our outstanding indebtedness or, in the case of our Convertible Senior Notes, in connection with a transaction involving us that constitutes a fundamental change under the indentures governing the Convertible Senior Notes, or under our Revolving Credit Facility, or to fund our liquidity needs, we may be forced to refinance all or a portion of our indebtedness on or before the maturity dates thereof, sell assets, reduce or delay currently planned activities or curtail operations, seek to raise additional capital or take other actions. We may not be able to execute any of these actions on commercially reasonable terms or at all. This, together with any of the factors described above, could materially and adversely affect our business, financial condition and results of operations.

***The capped call transactions entered into in connection with our Convertible Senior Notes may affect the value of our Class A Common Stock.***

In connection with the issuance of our Convertible Senior Notes, we entered into capped call transactions, or the Capped Calls, with certain financial institutions. These transactions are expected generally to reduce the potential dilution upon any conversion of our Convertible Senior Notes, as applicable, or offset any cash payments we are required to make in excess of the principal amount of converted Convertible Senior Notes, as the case may be.

In connection with these transactions, the financial institutions likely purchased our Class A Common Stock in secondary market transactions and entered into various OTC derivative transactions with respect to our Class A Common Stock. These entities or their affiliates are likely to modify their hedge positions from time to time prior to conversion or maturity of the Convertible Senior Notes by purchasing and selling shares of our Class A Common Stock or other instruments they may wish to use in connection with such hedging. Any of these activities could adversely affect the value of our Class A Common Stock and, as a result, the number of shares and the value of the Class A Common Stock noteholders will receive upon conversion of the Convertible Senior Notes. In addition, under certain circumstances the counterparties have the right to terminate the Capped Calls on terms set forth in the applicable confirmations, which may result in us not receiving all or any portion of the anticipated benefit of the Capped Calls. If the price of our Class A Common Stock increases such that the hedge transactions settle in our favor, we could also be exposed to credit risk related to the counterparties to the Capped Calls, which would limit or eliminate the benefit of such transactions to us.

***Our quarterly and annual operating results may fluctuate significantly.***

Our operating results have been, and we expect they will continue to be, subject to frequent fluctuations. Our net income (loss) and other operating results will be affected by numerous factors, including:

- the level of underlying demand and price for our products in the countries in which they are approved;

- retail chains' and wholesalers' buying patterns, pricing and reimbursement and inventory levels with respect to our products;

- the costs associated with commercializing our products in the U.S.;

- the achievement and timing of milestone payments and royalties due or payable under our collaboration and license agreements;
- our execution of any collaboration, partnership, licensing or other strategic arrangements, and the timing of payments we may make or receive under these arrangements;
- any impairments of assets or goodwill, and associated write-downs;
- any variations in the level of expenses related to our development programs;
- addition or termination of clinical trials;
- results of or developments in nonclinical studies and clinical trials of our product candidates or those of our competitors or potential collaborators;
- any impact on taxes or changes in tax rules;
- regulatory developments affecting our products and product candidates;
- the success of competitive products or technologies;
- any material lawsuit in which we may become involved;
- general economic, industry, and market conditions; and
- the impact of public health emergencies, geopolitical events or natural disasters.

If our operating results fall below the expectations of investors or securities analysts for any of the foregoing reasons or otherwise, the price of our Class A Common Stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

***Our ability to use net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments is limited by provisions of the Internal Revenue Code, and it is possible that our net operating loss and tax credit carryforwards may expire before we generate sufficient taxable income to use such carryforwards, or that certain transactions or a combination of certain transactions may result in material additional limitations on our ability to use our net operating loss and tax credit carryforwards.***

For the year ended December 31, 2023, we incurred a net loss in connection with the VectivBio Acquisition. Prior to the year ended December 31, 2019, we incurred significant net losses since our inception. To the extent that we do not generate federal and state taxable income in the future, unused net operating loss and tax credit carryforwards will carry forward to offset future taxable income, if any, until the date, if any, on which such unused carryforwards expire. Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, contain rules that limit the ability of a company that undergoes an ownership change, which is generally any change in ownership of more than 50% of its stock over a three-year period, to utilize its net operating loss and tax credit carryforwards and certain built-in losses recognized in years after the ownership change. These rules generally operate by focusing on ownership changes involving stockholders owning directly or indirectly 5% or more of the stock of a company and any change in ownership arising from a new issuance of stock by the company. Generally, if an ownership change occurs, the yearly taxable income limitation on the use of net operating loss and tax credit carryforwards and certain built-in losses is equal to the product of the applicable long-term tax exempt rate and the value of the company's stock immediately before the ownership change. Certain future equity offerings or strategic transactions, if any, could potentially result in a 50% or greater ownership change.

If we do not generate sufficient taxable income prior to the expiration, if any, of the applicable carryforwards or if the carryforwards are subject to the limitations described above, we may be unable to offset our taxable income with losses, or our tax liability with credits, before such losses and credits expire and therefore would incur larger federal or

state income tax liability. We have completed several financings since our inception which may have resulted in an "ownership change," as defined by Section 382, or could result in an ownership change in the future.

***Our ability to use foreign tax loss carryforwards acquired in the VectivBio Acquisition may be limited.***

Prior to our acquisition of VectivBio, VectivBio incurred significant net losses since its inception. In Switzerland, tax loss carryforwards may, with certain limitations, be used to offset future taxable income. However, if not utilized, the tax loss carryforwards, under Swiss laws, expire seven years after the tax year in which they were incurred. Due to our current limited income in Switzerland, there is a high risk that the tax loss carryforwards will expire in part or in their entirety and will not be used to offset future taxable income. Any limitations in our ability to use tax loss carryforwards to offset taxable income could adversely affect our financial condition.

***If the distribution of the shares of Cyclerion Therapeutics, Inc., or Cyclerion, common stock in connection with the Separation is not generally tax- free for U.S. federal income tax purposes, we and our stockholders could be subject to significant tax liabilities.***

The distribution of the shares of Cyclerion common stock in connection with the separation of our soluble guanylate cycle business, and certain other assets and liabilities, into Cyclerion, or the Separation, on April 1, 2019, together with certain related transactions, is intended to qualify for tax-free treatment to us and our stockholders for U.S. federal income tax purposes. We received a favorable private letter ruling from the Internal Revenue Service, or IRS, under the pilot program established in Revenue Procedure 2017-52 relating to the U.S. federal income tax treatment of the distribution. Consistent with the guidelines set forth in Revenue Procedure 2017-52, the IRS private letter ruling does not cover all of the issues that are relevant to determining whether the distribution is generally tax free for U.S. federal income tax purposes. Accordingly, completion of the distribution was conditioned upon, among other things, our receipt of an opinion from an outside tax advisor that the distribution will qualify as a transaction that is generally tax-free to both us and our stockholders for U.S. federal income tax purposes under Sections 355 and 368(a)(1)(D) of the Internal Revenue Code. The private letter ruling and opinion were based on and relied on, among other things, certain facts and assumptions, as well as certain representations, statements and undertakings from us and Cyclerion (including those relating to the past and future conduct of us and Cyclerion). If any of these facts, assumptions, representations, statements or undertakings is, or becomes, inaccurate or incomplete, or if we or Cyclerion breach any of our respective covenants relating to the distribution, the IRS private letter ruling and any tax opinion may be invalid. Moreover, the opinion is not binding on the IRS or any courts. Accordingly, notwithstanding receipt of the IRS private letter ruling and the opinion, the IRS could determine that the distribution and certain related transactions should be treated as taxable transactions for U.S. federal income tax purposes.

If the distribution, together with certain related transactions, fails to qualify as a transaction that is generally tax-free under Sections 355 and 368(a)(1)(D) of the Internal Revenue Code, in general, for U.S. federal income tax purposes, we would recognize taxable gain with respect to Cyclerion's distributed common stock and our stockholders who received shares of Cyclerion common stock in the distribution would be subject to tax as if they had received a taxable distribution equal to the fair market value of such shares.

**General Risk Factors**

***We may not be able to manage our business effectively if we lose any of our current management team or if we are unable to attract, motivate and retain key personnel.***

We may not be able to attract, motivate or retain qualified management and scientific, clinical, operations and commercial personnel due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the greater-Boston area. If we are not able to attract, motivate and retain necessary personnel to accomplish our business objectives, we will experience constraints that will significantly impede the achievement of our objectives.

We are highly dependent on the drug research, development, regulatory, commercial, financial and other expertise of our senior management team. Transitions in our senior management team or other key employees, or the unavailability of any such persons for any reason, can be inherently difficult to manage and may disrupt our operations or business or otherwise harm our business, for example, due to the diversion of our board and management's time and attention and a decline in employee morale. In addition to the competition for personnel, the Boston area in particular is

characterized by a high cost of living. As such, we could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment efforts, which may or may not be successful.

We also have scientific and clinical advisors who assist us in formulating our product development, clinical strategies and our global supply chain plans, as well as sales and marketing advisors who have assisted us in our commercialization strategy and brand plan for our products. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us, or may have arrangements with other companies to assist in the development and commercialization of products that may compete with ours.

***Security breaches and other disruptions to our information technology structure could compromise our information, disrupt our business and expose us to liability, which would cause our business and reputation to suffer.***

In the ordinary course of our business, we collect, process and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers and business partners, as well as personally identifiable information of our patients, clinical trial participants and employees. We also rely to a large extent on information technology systems to operate our business, including to deliver our products. We have outsourced elements of our confidential information processing and information technology structure, and as a result, we are managing independent vendor relationships with third parties who may or could have access to our confidential information. Similarly, our business partners and other third-party providers possess certain of our sensitive data. The secure maintenance of this information is critical to our operations and business strategy. Despite our security measures, our large and complex information technology and infrastructure (and those of our partners, vendors and third-party providers) are vulnerable to attacks by hackers and may be breached due to employee, partner, vendor or third-party error, malfeasance or other disruptions. We, our partners, vendors and other third-party providers could be susceptible to third party attacks on our, and their, information security systems, which attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives and expertise, including organized criminal groups, hacktivists, nation states and others. While we have invested in information technology and security and the protection of confidential information, there can be no assurance that our efforts will prevent service interruptions or security breaches. Further, while some or all of our workforce, and those of our partners, vendors and other third-party providers, work remotely, we may have greater vulnerability to cyberattacks or other losses of confidential information, as well as interruptions in information technology systems. Any such interruptions, losses or breaches would substantially impair our ability to operate our business and would compromise our, or our partners, vendors and other third-party providers, networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations, negatively impact our financial condition and damage our reputation, any of which could adversely affect our business. While we maintain cyber liability insurance, this insurance may not be sufficient to cover the financial or other losses that may result from an interruption or breach of our (or our partners', vendors' and third-party providers') systems.

***Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could negatively impact the market price of our Class A Common Stock.***

Provisions in our certificate of incorporation and bylaws may have the effect of delaying or preventing a change of control. These provisions include the following:

- Our board of directors has the right to elect directors 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.

- Our board of directors may issue, without stockholder approval, shares of preferred stock. The ability to authorize preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us.

- Stockholders must provide advance notice to nominate individuals for election to the board of directors or to propose matters that can be acted upon at a stockholders' meeting. These provisions may discourage or

deter a potential acquirer from conducting a solicitation of proxies to elect such acquirer's own slate of directors or otherwise attempting to obtain control of our company.

- Our stockholders may not act by written consent. As a result, a holder, or holders, controlling a majority of our capital stock are not able to take certain actions outside of a stockholders' meeting.

- Special meetings of stockholders may be called only by the chairman of our board of directors, our chief executive officer or a majority of our board of directors. As a result, a holder, or holders, controlling a majority of our capital stock are not able to call a special meeting.

- A super-majority (80%) of the outstanding shares of Class A Common Stock are required to amend our bylaws, which make it more difficult to change the provisions described above.

In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our certificate of incorporation and our bylaws and in the Delaware General Corporation Law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors.

***If we identify a material weakness in our internal control over financial reporting, it could have an adverse effect on our business and financial results, and our ability to meet our reporting obligations could be negatively affected, each of which could negatively affect the trading price of our Class A Common Stock.***

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Accordingly, a material weakness increases the risk that the financial information we report contains material errors.

We regularly review and update our internal controls, disclosure controls and procedures, and corporate governance policies. In addition, we are required under the Sarbanes-Oxley Act of 2002 to report annually on our internal control over financial reporting. Our system of internal controls, however well-designed and operated, is based in part on certain assumptions and includes elements that rely on information from third parties, including our partners. Our system can provide only reasonable, not absolute, assurances that the objectives of the system are met.

Further, we are dependent on our partners for information related to our results of operations. Our net profit or net loss generated from the sales of LINZESS in the U.S. is partially determined based on amounts provided by AbbVie and involves the use of estimates and judgments, which could be modified in the future. For example, during 2024, we recorded adjustments to our collaborative arrangement revenues to reflect changes in estimates of certain LINZESS gross-to-net reserves, as reported by AbbVie. We are highly dependent on our linaclotide partners for timely and accurate information regarding any revenues realized from sales of linaclotide in their respective territories, and in the case of AbbVie for the U.S., the costs incurred in developing and commercializing it in order to accurately report our results of operations. Our results of operations are also dependent on the timeliness and accuracy of information from any other licensing, collaboration or other partners we may have, as well as our and our partners' use of estimates and judgments. If we do not receive timely and accurate information or if estimated activity levels associated with the relevant collaboration or partnership at a given point in time are incorrect, whether the result of a material weakness or not, we could be required to record adjustments in future periods. Such adjustments could have an adverse effect on our financial results, which could lead to a decline in our Class A Common Stock price.

If we cannot conclude that we have effective internal control over our financial reporting, or if our independent registered public accounting firm is unable to provide an unqualified opinion regarding the effectiveness of our internal control over financial reporting, investors could lose confidence in the reliability of our financial statements, which could lead to a decline in our stock price. Failure to comply with reporting requirements could also subject us to sanctions and/or investigations by the SEC, The Nasdaq Stock Market or other regulatory authorities.

In connection with the audit of our consolidated financial statements for the year ended December 31, 2024, we and our independent registered public accounting firm identified material weaknesses in our internal control over financial reporting and we determined that our internal control over financial reporting was not effective as of December

31, 2024. We remediated the material weaknesses during the year ended December 31, 2025 and concluded that our internal control over financial reporting was effective as of December 31, 2025. For further discussion of those material weaknesses and our remediation efforts, see Part II, Item 9A, under the heading "Controls and Procedures" in this Annual Report on Form 10-K.

***We expect that the price of our Class A Common Stock will fluctuate substantially.***

The market price of our Class A Common Stock may be highly volatile due to many factors, including:

- the commercial performance of our products in the countries in which they are approved, as well as the costs associated with such activities;
- any third-party coverage and reimbursement policies for our products;
- market conditions in the pharmaceutical and biotechnology sectors;
- developments, litigation or public concern about the safety of our products or our potential products;
- announcements of the introduction of new products by us or our competitors;
- announcements concerning product development, including clinical trial results or timelines or regulatory interactions, or intellectual property rights of us or others;
- actual and anticipated fluctuations in our quarterly and annual operating results;
- deviations in our operating results from any guidance we may provide or the estimates of securities analysts;
- sales of additional shares of our Class A Common Stock or sales of securities convertible into Class A Common Stock or the perception that these sales might occur;
- any conversions of our Convertible Senior Notes into Class A Common Stock or activities undertaken by the counterparties to the Capped Calls;
- additions or departures of key personnel;
- developments concerning current or future collaboration, partnership, licensing or other strategic arrangements;
- discussion of us or our stock price in the financial or scientific press or in online investor communities;
- general economic, industry, and market conditions; and
- the impact of public health epidemics, geopolitical events or natural disasters.

***Our business could be negatively affected as a result of a proxy contest or certain other stockholder actions.***

Responding to certain stockholder actions can be costly, disruptive and time-consuming, and could also impact our ability to attract, retain and motivate our employees. For example, a proxy contest for our annual meeting of stockholders relating to stockholder proposals or director nominees would require significant time and could divert the attention of our management, other employees and our board of directors. In addition, a proxy contest would require us to incur significant costs, including legal fees and proxy solicitation expenses.

The realization of any of the risks described in these "Risk Factors" could have a dramatic and material adverse impact on the market price of our Class A Common Stock. In addition, class action litigation has often been instituted against companies whose securities have experienced periods of volatility. Any such litigation brought against us could

result in substantial costs and a diversion of management attention, which could hurt our business, operating results and financial condition.

**Item 1B.** ***Unresolved Staff Comments***

None.

**Item 1C.** ***Cybersecurity***

We have a multilayered framework for assessing, identifying, detecting and responding to reasonably foreseeable cybersecurity risks and threats. To protect our information technology, or IT, systems from cybersecurity threats, we use various security tools that help prevent, identify, escalate, investigate, resolve and recover from identified vulnerabilities and security incidents in a timely manner. In the event of a material change to our systems or operations, we would conduct an assessment of the internal and external threats to the security, confidentiality, integrity, and availability of our data and systems, along with other material risks to our operations. We leverage third-party security services for audit, benchmarking, and improvement and use various tools and methodologies to manage cybersecurity risks that are tested regularly, including a cybersecurity assessment guided by the National Institute of Standards and Technology cybersecurity framework and ongoing security awareness training. We oversee third-party service providers by conducting vendor diligence upon onboarding and ongoing monitoring. Vendors are assessed for risk based on the nature of their digital footprint, company profile, domain name services health, internet protocol reputation, external access threats and social engineering landscapes. Based on that assessment, we conduct diligence that may include completing security questionnaires, onsite evaluation, and scans or other technical evaluations. We also monitor and evaluate our cybersecurity posture and performance on an ongoing basis through regular vulnerability scans, simulated phishing tests, penetration tests, and threat intelligence feeds. The results of these assessments are reported to the Audit Committee of the Board of Directors.

We have developed an incident response plan designed to coordinate the activities that we and our third-party service providers take to prepare to respond and recover from cybersecurity incidents, which include processes to triage, assess severity, investigate, escalate, contain, and remediate an incident, as well as to comply with potentially applicable legal obligations and mitigate any reputational damage.

Our business strategy, results of operations and financial condition have not been materially affected as a result of previously identified cybersecurity incidents, but we cannot provide assurance that they will not be materially affected in the future by such cybersecurity risks or any future material incidents. For more information on our cybersecurity-related risks, see Item 1A, *Risk Factors*, elsewhere in this Annual Report on Form 10-K.

The Company's Senior Vice President, Corporate Controller & Chief Accounting Officer is responsible for managerial oversight of our cybersecurity program and reporting on cybersecurity matters to the Audit Committee of the Board of Directors and management. Our Senior Vice President, Corporate Controller & Chief Accounting Officer oversees the cybersecurity team, which include members of our internal IT department and is also supported by third-party service providers.

Our Board of Directors is responsible for overseeing our enterprise risk management activities in general, and each of our Board committees assists the Board in the role of risk oversight. The Audit Committee of the Board of Directors oversees our cybersecurity risk and receives regular reports, with a minimum frequency of once per year, from our Senior Vice President, Corporate Controller & Chief Accounting Officer on various cybersecurity matters, including risk assessments, mitigation strategies, areas of emerging risks, incidents and industry trends, and other areas of importance. Promptly after becoming aware of a material cybersecurity incident affecting our IT systems or data, the Audit Committee would work with management to formulate a mitigation plan and review compliance with such plan, as well as to ensure compliance with any external regulatory or disclosure requirements, including any disclosures of material cybersecurity breaches.

**Item 2.** ***Properties***

Our corporate headquarters are located in Boston, Massachusetts, where, as of December 31, 2025, we occupied approximately 39,000 square feet of office space under our lease expiring in June 2030. We also have operations in Basel, Switzerland. We believe that our facilities are suitable and adequate for our needs for the foreseeable future.

**Item 3.** ***Legal Proceedings***

**Apraglutide**

As previously disclosed in our Quarterly Report on Form 10-Q for the period ended September 30, 2025, filed on November 10, 2025, on October 2, 2025, Ferring International Center S.A., or Ferring, filed a complaint against our wholly-owned subsidiary, VectivBio AG, for trade secret misappropriation and correction of patent inventorship and ownership in the U.S. District Court in the Eastern District of Texas (Case No. 2:25-cv-01001-RWS-RSP), alleging that VectivBio AG misappropriated Ferring's technology for its own benefit and improperly filed patent applications claiming that technology without reference to Ferring's inventorship and ownership interests. Ferring sought monetary damages, a declaratory order regarding ownership of certain intellectual property Ferring purported to own, an injunction ordering the transfer or control of such intellectual property, a constructive trust, and certain exemplary damages and costs. As previously disclosed in the Current Report on Form 8-K, filed on December 23, 2025, on December 18, 2025, we, VectivBio AG, and Ferring entered into a settlement agreement and release pursuant to which VectivBio AG and Ferring have settled all claims between the parties arising out of Ferring's complaint referenced above. In addition, on December 18, 2025, the parties also entered into that certain third amendment, or the Ferring License Amendment, to the amended and restated exclusive license agreement, dated as of December 6, 2016, as amended, by and between GlyPharma Therapeutic Inc. (as predecessor to VectivBio AG) and Ferring. For details regarding the Ferring legal matter, refer to Note 4, *Collaboration, License and Other Agreements*, to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K for further details. The Ferring License Amendment is qualified in its entirety by reference to the complete text of such agreement, a copy of which is filed as Exhibit 10.19.1 hereto. A dismissal of Ferring's complaint with prejudice was entered in the U.S. District Court in the Eastern District of Texas on December 19, 2025.

**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***

Shares of our Class A Common Stock are traded on the Nasdaq Global Select Market under the symbol "IRWD." Our shares have been publicly traded since February 3, 2010. As of January 31, 2026, there were 29 stockholders of record of our Class A Common Stock. The number of record holders is based upon the actual number of holders registered on the books of the company at such date and does not include holders of shares in "street names" or persons, partnerships, associations, corporations or other entities identified in security position listings maintained by depositories.

Subject to preferences that may apply to any shares of preferred stock outstanding at the time, the holders of Class A Common Stock are entitled to share equally in any dividends that our board of directors may determine to issue from time to time. In the event a dividend is paid in the form of shares of common stock or rights to acquire shares of common stock, the holders of Class A Common Stock will receive Class A Common Stock, or rights to acquire Class A Common Stock, as the case may be.

We have never declared or paid any cash dividends on our capital stock, and we do not currently anticipate declaring or paying cash dividends on our capital stock in the foreseeable future. We currently intend to retain all of our future earnings, if any, to finance operations and any acquisitions of businesses, products and technologies or other strategic transactions. Any future determination relating to our dividend policy will be made at the discretion of our board of directors and will depend on a number of factors, including future earnings, capital requirements, financial conditions, future prospects, contractual restrictions and covenants and other factors that our board of directors may deem relevant.

The information required to be disclosed by Item 201(d) of Regulation S-K, "Securities Authorized for Issuance Under Equity Compensation Plans," is referenced under Item 12 of Part III of this Annual Report on Form 10-K.

***Performance Graph***

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide a performance graph.

**Item 6.** ***[Reserved]***

## Item 7. *Management's Discussion and Analysis of Financial Condition and Results of Operations*

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the notes to those financial statements appearing elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, such as those set forth under "Risk Factors" in Item 1A of this Annual Report on Form 10-K, our actual results may differ materially from those anticipated in these forward-looking statements.

### Overview

We are a biotechnology company developing and commercializing life-changing therapies for people living with gastrointestinal, or GI, and rare diseases. We are focused on the development and commercialization of innovative product opportunities in areas of significant unmet need, leveraging our demonstrated expertise and capabilities in GI and rare diseases.

LINZESS® (linaclotide), our commercial product, is the first product approved by the U.S. FDA, in a class of GI medicines called GC-C agonists and is indicated for the treatment of irritable bowel syndrome with constipation, or IBS-C, in adults and pediatric patients 7 years of age and older, chronic idiopathic constipation, or CIC, in adults, and functional constipation, or FC, in pediatric patients ages 6-17 years-old. LINZESS is also available for the treatment of adults with IBS-C or CIC in Mexico, adults with IBS-C or chronic constipation in Japan, and adults with IBS-C in China. Linaclotide is available under the trademarked name CONSTELLA® for the treatment of adults with IBS-C or CIC and pediatric patients ages 6-17 years old with FC in Canada, and to adults with IBS-C in certain European countries.

We have strategic partnerships with leading pharmaceutical companies to support the development and commercialization of linaclotide throughout the world, including with AbbVie in the U.S. and all countries worldwide other than China (including Hong Kong and Macau) and Japan, AstraZeneca in China (including Hong Kong and Macau), and Astellas in Japan.

Through the VectivBio Acquisition, we are advancing apraglutide, a next-generation, synthetic long-acting peptide analog of GLP-2 for SBS patients who are dependent on PS. In February 2024, we announced positive topline results from our pivotal Phase III clinical trial, STARS, which evaluated the efficacy and safety of once-weekly subcutaneous apraglutide in reducing parenteral support dependency in adult patients with SBS-IF. We are also conducting an open-label extension study, STARS Extend, to further assess the safety of apraglutide in adult patients with SBS-IF. In April 2025, we announced that, based on discussions with the U.S. FDA, a confirmatory Phase III clinical trial is needed to seek approval of a new drug application or NDA, for apraglutide for patients with SBS-IF who are dependent on PS. In the fourth quarter of 2025, we met with the U.S. FDA and aligned on key design elements of a confirmatory Phase III clinical trial, STARS-2, of apraglutide. Site initiations are expected to begin in the second quarter of 2026.

To date, we have dedicated a majority of our activities to the research, development and commercialization of linaclotide, as well as other research and development programs, including apraglutide. Prior to the year ended December 31, 2019, we incurred net losses in each year since inception. As of December 31, 2025, we had an accumulated deficit of approximately $1.7 billion. We are unable to predict the extent of any future losses or guarantee that our company will be able to generate and maintain positive cash flows.

We were incorporated in Delaware on January 5, 1998 as Microbia, Inc. On April 7, 2008, we changed our name to Ironwood Pharmaceuticals, Inc. We operate in one reportable business segment – human therapeutics.

### Key 2025 Financial Highlights

- We recognized $296.2 million in total revenues during the year ended December 31, 2025, compared to $351.4 million during the year ended December 31, 2024. The decrease was primarily related to a $51.1 million decrease in our share of net profits from the sale of LINZESS in the U.S., which was driven by decreased net price and inventory channel fluctuations, partially offset by increased prescription demand. In addition, results for the year ended December 31, 2024 included a $43.0 million reduction to collaboration revenue as a result of changes in estimates of sales reserves and allowances associated with

governmental and contractual rebates.

- We generated income from operations of $98.5 million during the year ended December 31, 2025, compared to income from operations of $93.1 million during the year ended December 31, 2024. The increase was primarily driven by a $60.6 million decrease in operating expenses resulting from restructuring activities in 2025 in an effort to streamline focus and support the continued development of our pipeline, which offset the decrease in collaborative arrangements revenue.

- We generated $127.0 million in cash from operations during the year ended December 31, 2025, ending the year with $215.5 million in cash and cash equivalents.

**Financial Operations Overview**

*Revenues.* Our revenues are generated primarily through our collaborative arrangements and license agreements related to research and development and commercialization of linaclotide.

The majority of our revenues are generated from the sales of LINZESS in the U.S. We record our share of the net profits and losses from the sales of LINZESS in the U.S. less commercial expenses on a net basis and present the settlement payments to and from AbbVie as collaboration expense or collaborative arrangements revenue, as applicable. Net profits or losses consist of net sales to third-party customers and sublicense income in the U.S. less the cost of goods sold as well as selling, general and administrative expenses. Although we expect net sales to increase over time, the settlement payments between AbbVie and us, resulting in collaborative arrangements revenue or collaboration expense, are subject to fluctuation based on the ratio of selling, general and administrative expenses incurred by each party. In addition, our collaborative arrangements revenue may fluctuate as a result of the timing and amount of license fees and clinical and commercial milestones received and recognized under our current and future strategic partnerships as well as timing and amount of royalties from the sales of linaclotide in the European, Canadian, Mexican, Japanese, or Chinese markets or any other markets where linaclotide receives approval and is commercialized.

*Research and Development Expenses.* The core of our research and development strategy is to leverage our demonstrated expertise and capabilities in GI and rare diseases to bring medicines to patients. Research and development expenses consist of expenses incurred in connection with the research into and development of products and product candidates. These expenses consist primarily of compensation, benefits and other employee-related expenses, research and development related facility costs, third-party contract costs relating to nonclinical study and clinical trial activities, development of manufacturing processes, regulatory registration of third-party manufacturing facilities, and licensing fees for our product candidates.

Research and development expenses include amounts owed to AbbVie on an ongoing basis under cost-sharing provisions in our collaboration agreement for linaclotide. Reimbursements received for research and development activities under this agreement are netted against research and development expenses.

Linaclotide. Our commercial product, LINZESS, is commercially available in the U.S. for the treatment of IBS-C in adults and pediatric patients 7 years of age and older, CIC in adults and FC in pediatric patients ages 6-17 years-old. Linaclotide is also available to adults suffering from IBS-C or CIC in certain countries of the world, including China, Japan, and in a number of European countries.

We and AbbVie continue to explore ways to enhance the clinical profile of LINZESS by studying linaclotide in additional indications, populations and formulations to assess its potential to treat various conditions. In September 2020, based on the Phase IIIb data of linaclotide 290 mcg on the overall abdominal symptoms of bloating, pain and discomfort in adult patients with IBS-C, the U.S. FDA approved our sNDA to include a more comprehensive description of the effects of LINZESS in its approved label.

In addition, we and AbbVie have established a nonclinical and clinical post-marketing plan with the U.S. FDA to understand the safety and efficacy of LINZESS in pediatric patients. In August 2021, the U.S. FDA approved a revised label for LINZESS based on clinical safety data that had been generated thus far in pediatric studies. The updated label modified the boxed warning for risk of serious dehydration and contraindication against use in children to those less than two years of age. The boxed warning and contraindication previously applied to all children less than 18 years of age and less than 6 years of age, respectively. In June 2023, the U.S. FDA approved LINZESS as a once-daily

treatment for pediatric patients ages 6-17 years-old with FC, making LINZESS the first and only U.S. FDA-approved prescription therapy for FC in this patient population. On October 15, 2025, the U.S. FDA granted us a pediatric exclusivity for studies conducted on linaclotide, and in November 2025, approved LINZESS for pediatric patients 7 years of age and older with IBS-C. Additional clinical pediatric programs in FC are ongoing.

Apraglutide for SBS-IF. In February 2024, we announced positive topline results from our pivotal Phase III clinical trial, STARS, which evaluated the efficacy and safety of once-weekly subcutaneous apraglutide in reducing PS dependency in adult patients with SBS-IF. SBS-IF, a rare and severe organ failure condition in which patients are dependent on PS, affects an estimated 18,000 adult patients in the U.S., Europe, and Japan. We are also conducting an open-label extension study, STARS Extend, to further assess the safety of apraglutide in adult patients with SBS-IF. In April 2025, we announced that, based on discussions with the U.S. FDA, a confirmatory Phase III clinical trial is needed to seek approval of an NDA for apraglutide for patients with SBS-IF who are dependent on PS. In the fourth quarter of 2025, we met with the U.S. FDA and aligned on key design elements of a confirmatory Phase III clinical trial, STARS-2, of apraglutide. Site initiations are expected to begin in the second quarter of 2026.

IW-3300. We were developing IW-3300, a GC-C agonist, for the potential treatment of visceral pain conditions, such as IC/BPS. In April 2025, based on analysis of the Phase II data, we decided to cease developing IW-3300 for IC/BPS.

CNP-104. Through a collaboration and license option agreement, or the COUR Collaboration Agreement, we and COUR Pharmaceutical Development Company, Inc., or COUR, were developing CNP-104 for the treatment of PBC, a rare autoimmune disease targeting the liver. In the third quarter of 2024, we received from COUR the topline data from COUR's Phase II Clinical study for the treatment of PBC. In September 2024, we notified COUR of our decision not to exercise the option to acquire an exclusive license to CNP-104. As a result, the COUR Collaboration Agreement has terminated, and we retain no rights and have no obligations related to CNP-104.

Early research and development. Our early research and development efforts have been focused on supporting our development stage GI and rare diseases programs, including exploring strategic options for further development of certain of our internal programs, as well as evaluating external development-stage programs.

The following table sets forth our research and development expenses related to our product pipeline for the years ended December 31, 2025 and 2024, respectively. These expenses relate primarily to compensation, benefits and other employee-related expenses and external costs associated with nonclinical studies and clinical trial costs for our product candidates. We allocate costs related to facilities, depreciation, share-based compensation, research and development support services and certain other costs directly to programs.

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Linaclotide[1] | $ 15,103 | $ 17,858 |
| Apraglutide | 71,172 | 73,008 |
| IW-3300 | 4,574 | 13,179 |
| CNP-104 | 75 | 4,253 |
| Early research and development[2] | 4,212 | 3,123 |
| Total research and development expenses | $ 95,136 | $ 111,421 |

(1) Includes linaclotide in all indications, populations and formulations.
(2) Includes $4.8 million reduction to research and development expense recognized in the first quarter of 2024 in connection with the settlement of a license-related contract liability.

We and AbbVie are exploring development opportunities to enhance the clinical profile of LINZESS by studying linaclotide in additional indications, populations and formulations to assess its potential to treat various conditions. We cannot currently estimate with any degree of certainty the amount of time or money that we will be required to expend in the future on linaclotide for additional indications, populations or formulations.

The lengthy process of securing regulatory approvals for product candidates, including apraglutide, requires the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals would materially adversely affect our product development efforts and our business overall. Given the inherent uncertainties

that come with the development of pharmaceutical products, we cannot estimate with any degree of certainty how our programs will evolve, and therefore the amount of time or money that would be required to obtain regulatory approval to market them.

As a result of these uncertainties surrounding the timing and outcome of any approvals, we are currently unable to estimate precisely when, if ever, linaclotide's utility will be expanded within its currently approved indications; if or when linaclotide will be developed outside of its current markets, indications, populations or formulations; or when, if ever, apraglutide or any of our other product candidates will generate revenues and cash flows.

We invest carefully in our pipeline, and the commitment of funding for each subsequent stage of our development programs is dependent upon the receipt of clear, supportive data. In addition, we intend to access externally discovered drug candidates that fit within our core strategy. In evaluating these potential assets, we apply the same investment criteria as those used for investments in internally discovered assets.

The successful development of our product candidates is highly uncertain and subject to a number of risks including, but not limited to:

- The duration of clinical trials may vary substantially according to the type, complexity and novelty of the product candidate;
- The U.S. FDA and comparable foreign agencies impose substantial and varying requirements on the introduction of therapeutic pharmaceutical products, typically requiring lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures;
- Data obtained from nonclinical and clinical activities at any step in the testing process may be adverse and lead to discontinuation or redirection of development activity. Data obtained from these activities also are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval;
- The U.S. FDA and comparable foreign agencies may require additional clinical trials and other studies, which may be costly or delay, limit, prevent or otherwise impact regulatory submission or approval;
- The duration and cost of early research and development, including nonclinical studies and clinical trials, may vary significantly over the life of a product candidate and are difficult to predict;
- The costs, timing and outcome of regulatory review of a product candidate may not be favorable, and, even if approved, a product may face post-approval development and regulatory requirements;
- There may be substantial costs, delays and difficulties in successfully integrating externally developed product candidates into our business operations; and
- The emergence of competing technologies and products and other adverse market developments may negatively impact us.

As a result of the factors discussed above, including the factors discussed under "Risk Factors" in Item 1A of this Annual Report on Form 10-K, we are unable to determine the duration and costs to complete current or future nonclinical and clinical stages of our product candidates or when, or to what extent, we will generate revenues from the commercialization and sale of our product candidates. Development timelines, probability of success and development costs vary widely. We anticipate that we will make determinations as to which additional programs to pursue and how much funding to direct to each program on an ongoing basis in response to the data of each product candidate, the competitive landscape and ongoing assessments of such product candidate's commercial potential.

We expect to invest in our development programs and incur substantial research and development expenses for the foreseeable future. We will continue to invest in linaclotide, including the investigation of ways to enhance the clinical profile within its currently approved indications, and the exploration of its potential utility in other indications, populations and formulations, and in apraglutide, as we advance it through clinical trials, in addition to funding research and development activities under our external collaboration and license agreements with respect to our products and product candidates.

*Selling, General and Administrative Expense.* Selling, general and administrative expense consists primarily of compensation, benefits and other employee-related expenses for personnel in our administrative, finance, legal, information technology, business development, commercial, sales, marketing, communications and human resource functions. Other costs include legal costs of pursuing patent protection of our intellectual property, general and administrative related facility costs, insurance costs and professional fees for accounting, tax, consulting, legal and other services. As we continue to invest in the development and commercialization of LINZESS, apraglutide and other product candidates, we expect our selling, general and administrative expenses will be substantial for the foreseeable future.

We include AbbVie's selling, general and administrative cost-sharing payments in the calculation of the net profits and net losses from the sale of LINZESS in the U.S. and present the net payment to or from AbbVie as collaboration expense or collaborative arrangements revenue, respectively.

*Restructuring Expenses.* Restructuring expenses pertain to a workforce reduction initiative in connection with the VectivBio Acquisition, as well as workforce reductions in January 2025 consisting primarily of field-based sales employees and August 2025 consisting of certain positions supporting apraglutide commercialization efforts. The workforce reduction and restructuring initiatives are more fully described in Note 15, *Workforce Reductions and Restructuring*, to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

*Interest Expense and Other Financing Costs.* Interest expense consists primarily of cash and non-cash interest costs related to our convertible senior notes and our $550.0 million secured revolving credit facility, or the Revolving Credit Facility. Non-cash interest expense consists of amortization of debt issuance costs.

*Interest and Investment Income.* Interest and investment income consists of interest earned on our cash and cash equivalents, as well as significant financing components of payments due from collaboration partners.

*Income Taxes.* We prepare our income tax provision based on our interpretation of the income tax accounting rules and each jurisdiction's enacted tax laws and regulations. For additional information refer to Note 13, *Income Taxes,* to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

**Critical Accounting Policies and Estimates**

Our discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make certain estimates and assumptions that may affect the reported amounts of assets and liabilities, the disclosure of assets and liabilities at the date of the consolidated financial statements, and the amounts of revenues and expenses during the reported periods. We base our estimates on our historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ materially from our estimates under different assumptions or conditions. Changes in estimates are reflected in reported results in the period in which they become known.

We believe that our application of the following accounting policies, each of which require significant judgments and estimates on the part of management, are the most critical to aid in fully understanding and evaluating our reported financial results. Our significant accounting policies are more fully described in Note 2, *Summary of Significant Accounting Policies*, to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

***Revenue Recognition***

Upon executing a revenue generating arrangement, we assess whether it is probable we will collect consideration in exchange for the good or service it transfers to the customer and perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy the performance obligations. We must develop assumptions that require significant judgment to determine the standalone selling price for each performance obligation identified in the contract. The assumptions that are used to determine the standalone selling price may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success.

Our revenues are generated primarily through collaborative arrangements and license agreements related to the development and commercialization of linaclotide. The terms of the collaborative arrangements and other agreements contain multiple performance obligations which may include (i) licenses, (ii) research and development activities, including participation on joint steering committees, (iii) the manufacture of finished drug product, API, or development materials for a partner, which are reimbursed at a contractually determined rate, and (iv) education or co-promotion activities by our clinical sales specialists. Non-refundable payments to us under these agreements may include (i) up-front license fees, (ii) payments for research and development activities, (iii) payments for the manufacture of finished drug product, API, or development materials, (iv) payments based upon the achievement of certain milestones, (v) payments for sales detailing, promotional support services and medical education initiatives, and (vi) royalties on product sales. Additionally, we receive our share of the net profits or bear our share of the net losses from the sale of linaclotide in the U.S. We have adopted a policy to recognize revenue net of tax withholdings, as applicable.

Collaboration, License, and Other Agreements

Upon licensing intellectual property, we determine if the license is distinct from the other performance obligations identified in the arrangement. We recognize revenues from the transaction price, including non-refundable, up-front fees allocated to the license when the license is transferred to the customer if the license has distinct benefit to the customer. For licenses that are combined with other promises, we 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. For performance obligations that are satisfied over time, we evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Our license and collaboration agreements include milestone payments, such as development and other milestones. 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 at the inception of the agreement. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control, 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. We re-evaluate the probability of achievement of such milestones and any related constraint at each reporting period, and any adjustments are recorded on a cumulative catch-up basis.

Agreements that include the supply of API 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 our partner, 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 additional payments are recorded as revenue when the customer obtains control of the goods, which is typically upon shipment for sales of API and finished drug product.

For agreements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue when the related sales occur in accordance with the sales-based royalty exception.

Net Profit or Net Loss Sharing

In accordance with Accounting Standards Codification, or ASC, Topic 808, *Collaborative Arrangements*, or ASC 808, we considered the nature and contractual terms of the arrangement and the nature of our business operations to determine the classification of payments under our collaboration agreements. While ASC 808 provides guidance on classification, the standard is silent on matters of separation, initial measurement, and recognition. Therefore, we apply the separation, initial measurement, and recognition principles of ASC Topic 606, *Revenue from Contracts with Customers*, to our collaboration agreements.

Our collaborative arrangements revenue generated from sales of LINZESS in the U.S. are considered akin to sales-based royalties. We recognize our share of the pre-tax commercial net profit or net loss generated from the sales of LINZESS in the U.S. in the period the product sales are earned, as reported by AbbVie, and related cost of goods sold and selling, general and administrative expenses as incurred by us and our collaboration partner. These amounts are partially determined based on amounts provided by AbbVie and involve the use of estimates and judgments, such as product sales allowances and accruals related to prompt payment discounts, chargebacks, governmental and contractual rebates, wholesaler fees, product returns, and co-payment assistance costs, which could be adjusted based on actual results in the future. We are highly dependent on AbbVie for timely and accurate information regarding any net revenues

realized from sales of LINZESS in the U.S. in accordance with ASC 808, and the related costs, in order to accurately report its results of operations. If we do not receive timely and accurate information or incorrectly estimate activity levels associated with the collaboration at a given point in time, we could be required to record adjustments in future periods.

We record revenue transactions as net product revenue in our consolidated statements of income if we are deemed the principal in the transaction, which includes being the primary obligor, retaining inventory risk, and control over pricing. Given that we are not the primary obligor and do not have the inventory risks in the collaboration agreement with AbbVie for North America, we record our share of the net profits or net losses from the sales of LINZESS in the U.S. on a net basis and present the settlement payments to and from AbbVie as collaboration expense or collaborative arrangements revenue, as applicable. We and AbbVie settle the cost sharing quarterly, such that our consolidated statements of income reflect 50% of the pre-tax net profit or loss generated from sales of LINZESS in the U.S.

Deferred Revenue

Our deferred revenue balance consists of advance billings and payments received from customers in excess of revenue recognized.

***Research and Development Expense***

We have committed significant resources into the research and development of our product candidates and intend to continue to do so for the foreseeable future. Research and development expenses are generally expensed as incurred. We capitalize nonrefundable advance payments we make for research and development activities and defer expense recognition until the related goods are received or the related services are performed.

Research and development expenses are comprised of costs incurred in performing research and development activities, including salary, benefits, share-based compensation, and other employee-related expenses; laboratory supplies and other direct expenses; facilities expenses; overhead expenses; third-party contractual costs relating to nonclinical studies and clinical trial activities and related contract manufacturing expenses, development of manufacturing processes and regulatory registration of third-party manufacturing facilities; licensing fees for our product candidates; and other outside expenses.

Clinical trial expenses include expenses associated with CROs. The invoicing from CROs for services rendered can lag several months. We accrue the cost of services rendered in connection with CRO activities based on our estimate of site management, monitoring costs, project management costs, and investigator fees. We maintain regular communication with our CRO vendors to gauge the reasonableness of our estimates. Differences between actual clinical trial expenses and estimated clinical trial expenses recorded have not been material and are adjusted for in the period in which they become known. However, if we incorrectly estimate activity levels associated with the CRO services at a given point in time, we could be required to record material adjustments in future periods. Under our collaboration agreement with AbbVie for North America, we are reimbursed for certain research and development expenses and we net these reimbursements against our research and development expenses as incurred.

Research and development expenses also include up-front payment, non-contingent payment, and milestone payment obligations under certain collaboration arrangements. Recognition of expense for such payments requires judgment with respect to when the obligation is probable.

***Share-Based Compensation Expense***

We grant awards under our share-based compensation programs, including stock awards, restricted stock awards, or RSAs, restricted stock units, or RSUs (including performance-based RSUs, or PSUs), stock options, and shares issued under our employee stock purchase plan, or ESPP. Share-based compensation is recognized as expense in the consolidated statements of income based on the grant date fair value over the requisite service period, net of estimated forfeitures. We estimate forfeitures over the requisite service period using historical forfeiture activity and record share-based compensation expense only for those awards that are expected to vest.

We estimate the fair value of stock options on the date of grant using the Black-Scholes option-pricing model, which requires the use of subjective assumptions including volatility and expected term, among others. The fair value of

stock awards, RSAs, and RSUs is based on the market value of our Class A Common Stock on the date of grant, with the exception of PSUs with market conditions, which are measured using the Monte Carlo simulation method. Discounted stock purchases under our ESPP are valued on the first date of the offering period using the Black-Scholes option-pricing model to compute the fair value of the lookback provision plus the purchase discount.

For awards that vest based on service conditions and market conditions, we use the straight-line method to recognize compensation expense over the respective service period. For awards that contain performance conditions, we determine the appropriate amount to expense based on the anticipated achievement of performance targets, which requires judgment, including forecasting the achievement of future specified targets. At the date performance conditions are determined to be probable of achievement, we record a cumulative expense catch-up, with remaining expense amortized over the remaining service period. Throughout the performance period, we re-assess the estimated performance and update the number of performance-based awards that we believe will ultimately vest. Discounted stock purchases under our ESPP are recognized over the offering period.

Compensation expense related to modified awards is measured based on the fair value for the awards as of the modification date. Any incremental compensation expense arising from the excess of the fair value of the awards on the modification date compared to the fair value of the awards immediately before the modification date is recognized at the modification date or ratably over the remaining service period, as appropriate.

While the assumptions used to calculate and account for share-based compensation awards represent management's best estimates, these estimates involve inherent uncertainties and the application of management's judgment. As a result, if revisions are made to our underlying assumptions and estimates, our share-based compensation expense could vary significantly from period to period.

***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 difference between the financial statement carrying amounts and tax basis of assets and liabilities using enacted tax rates in effect for years in which the temporary differences are expected to reverse.

At each quarterly reporting date, we reassess the valuation allowance on our deferred tax assets, weighing positive and negative evidence to assess the recoverability of the deferred tax assets. We provide a valuation allowance when it is more likely than not that deferred tax assets will not be realized. Our valuation allowance is comprised primarily of certain tax credits that are expected to expire prior to utilization.

Significant judgment is required in making these assessments to maintain or reverse our valuation allowances and, to the extent our future expectations change we would have to assess the recoverability of these deferred tax assets at that time. If we determine that our net deferred tax assets are not realizable in a future period, we would record material changes to income tax expense or benefit in that period.

We record uncertain tax positions on the basis of a two-step process. First, we determine whether it is more likely than not that the tax positions will be sustained based on the technical merits of the position. Second, for those tax positions that meet the more-likely-than-not recognition threshold, we recognize the largest amount of tax benefit that is greater than 50 percent likely to be realized upon ultimate settlement with the relevant tax authority. Significant judgment is required in evaluating whether our tax positions meet this two-step process. The nature of the uncertain tax positions is often complex and subject to change, and the amounts at issue can be substantial. We re-evaluate these uncertain tax positions on a quarterly basis based on a number of factors including, but not limited to, changes in facts or circumstances, changes in tax law, and effectively settled issues under audit and new audit activity. Any change in these factors could result in the recognition of a tax benefit or an additional charge to the tax provision.

***Defined Benefit Pension Plan***

Determining pension expense and obligations for our defined benefit pension plan uses actuarial estimates of participants' age at retirement, life span, the long-term rate of return on assets and other factors. In addition, pension expense is sensitive to the discount rate used to value the pension obligation. As a sensitivity measure, an increase or decrease in our discount rate assumption of 1.00% would decrease and increase our pension benefit obligation by $2.0

million and $2.6 million, respectively. These assumptions are subject to the risk of change, including macroeconomic conditions, as they require significant judgment and have inherent uncertainties that management or its actuaries may not control or anticipate. A detailed discussion of our defined benefit pension plan is contained in Note 14, *Retirement Plans,* to our consolidated financial statements, which appears in this Annual Report on Form 10-K.

**Results of Operations**

The following discussion summarizes the key factors our management believes are necessary for an understanding of our consolidated financial statements.

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| | (in thousands) | |
| Revenues: | | |
| Collaborative arrangements revenue | $ 296,151 | $ 351,410 |
| Total revenues | 296,151 | 351,410 |
| Costs and expenses: | | |
| Research and development | 95,136 | 111,421 |
| Selling, general and administrative | 82,256 | 144,272 |
| Restructuring, net | 20,257 | 2,593 |
| Total costs and expenses | 197,649 | 258,286 |
| Income from operations | 98,502 | 93,124 |
| Other income (expense): | | |
| Interest expense and other financing costs | (32,746) | (33,034) |
| Interest and investment income | 4,076 | 4,468 |
| Other | 193 | 640 |
| Other income (expense), net | (28,477) | (27,926) |
| Income before income taxes | 70,025 | 65,198 |
| Income tax expense | (46,008) | (64,318) |
| Net income | $ 24,017 | $ 880 |

***Year Ended December 31, 2025 Compared to Year Ended December 31, 2024***

*Revenues*

| | Year Ended December 31, | | Change |
|---|---|---|---|
| | 2025 | 2024 | $ |
| | (in thousands) | | |
| Revenues: | | | |
| Collaborative arrangements revenue | $ 296,151 | $ 351,410 | $ (55,259) |
| Total revenues | $ 296,151 | $ 351,410 | $ (55,259) |

*Collaborative arrangements revenue.* The decrease in collaborative arrangements revenue of $55.3 million for the year ended December 31, 2025 compared to the year ended December 31, 2024 was primarily related to a $51.1 million decrease in our share of net profits from the sale of LINZESS in the U.S., which was driven by decreased net price and inventory channel fluctuations, partially offset by increased prescription demand.

*Costs and Expenses*

| | Year Ended December 31, | | Change |
|---|---|---|---|
| | 2025 | 2024 | $ |
| | | (in thousands) | |
| Costs and expenses: | | | |
| Research and development | $ 95,136 | $ 111,421 | $ (16,285) |
| Selling, general and administrative | 82,256 | 144,272 | (62,016) |
| Restructuring, net | 20,257 | 2,593 | 17,664 |
| Total costs and expenses | $ 197,649 | $ 258,286 | $ (60,637) |

*Research and development.* The decrease in research and development expenses of $16.3 million for the year ended December 31, 2025 compared to the year ended December 31, 2024 was primarily related to $9.6 million decrease in external apraglutide costs, a $5.9 million decrease in costs associated with the IW-3300 development program, a $2.8 million decrease in costs associated with the COUR Collaboration Agreement, and a $1.8 million decrease in external linaclotide costs, partially offset by a $4.8 million reduction to research and development expense recognized during the first quarter of 2024 in connection with the settlement of a license-related contract liability.

*Selling, general and administrative.* Selling, general and administrative expenses decreased by $62.0 million for the year ended December 31, 2025 compared to the year ended December 31, 2024, primarily due to a $47.8 million decrease in compensation, benefits, and other employee-related expenses, and a $13.5 million decrease in sales and marketing expenses, both resulting from the restructuring initiatives during 2025, as well as a decrease of $5.9 million in professional services expenses. The decrease was partially offset by a $12.5 million legal settlement incurred in 2025 which is more fully described in Note 4, *Collaboration, License, and Other Agreements*.

*Restructuring expenses*. The increase in restructuring expense of $17.7 million for the year ended December 31, 2025 compared to the year ended December 31, 2024, is primarily related to the workforce reduction in January 2025. Workforce reduction and restructuring initiatives are more fully described in Note 15, *Workforce Reduction and Restructuring*.

*Other Income (Expense), Net*

| | Year Ended December 31, | | Change |
|---|---|---|---|
| | 2025 | 2024 | $ |
| | | (in thousands) | |
| Other income (expense): | | | |
| Interest expense and other financing costs | $ (32,746) | $ (33,034) | $ 288 |
| Interest and investment income | 4,076 | 4,468 | (392) |
| Other | 193 | 640 | (447) |
| Total other income (expense), net | $ (28,477) | $ (27,926) | $ (551) |

*Interest expense and other financing costs.* Interest expense decreased by $0.3 million for the year ended December 31, 2025 compared to the year ended December 31, 2024, primarily due to a decrease of $1.1 million in interest expense associated with the 2024 Convertible Notes, which were fully repaid upon maturity in June 2024, partially offset by a $0.7 million increase in other financing costs.

*Interest and investment income.* Interest and investment income decreased by $0.4 million for the year ended December 31, 2025 compared to the year ended December 31, 2024, primarily due to a decrease in interest rates.

*Other.* During the years ended December 31, 2025 and 2024, we recorded a gain of $0.2 million and $0.6 million, respectively, for pension-related activities.

*Income taxes.* During the year ended December 31, 2025, we recorded income tax expense of $46.0 million, comprised of non-cash tax expense of $40.9 million and cash tax expense of $5.1 million for state income taxes in certain states in which state taxable income exceeded available net operating losses. During the year ended December 31, 2024, we recorded income tax expense of $64.3 million, comprised of non-cash tax expense of $57.8 million and cash tax expense of $6.5 million for state income taxes in certain states in which state taxable income exceeded available net operating losses.

**Liquidity and Capital Resources**

As of December 31, 2025, we had $215.5 million of cash and cash equivalents. Our cash equivalents include amounts held in money market funds, U.S. Treasury securities and commercial paper. We invest cash in excess of immediate requirements in accordance with our investment policy, which limits the amounts we may invest in certain types of investments and requires all investments held by us to be at least A- rated, with a remaining final maturity when purchased of less than twenty-four months, so as to primarily achieve liquidity and capital preservation objectives.

We anticipate our cash and cash equivalents balance, our expected net cash inflows from operations, our borrowing capacity on our Revolving Credit Facility, and/or additional capital sources to allow us to meet our short-term and long-term cash obligations, which are reflected in our consolidated balance sheets. Our most significant fixed obligations are debt obligations, supply purchase commitments, and lease commitments, for which annual payments are disclosed in Note 9, *Debt*, Note 10, *Commitments and Contingencies*, and Note 6, *Leases*, respectively, to our financial statements included elsewhere in this Annual Report on Form 10-K.

We may from time to time seek to retire, redeem or repurchase all or part of our outstanding debt through cash purchases and/or exchanges, in open market purchases, privately negotiated transactions, by tender offer or otherwise. Such repurchases, redemptions or exchanges, if any, of our debt will depend on prevailing market conditions, liquidity requirements, contractual restrictions and other factors, and the amounts involved may be material.

***Sources of Liquidity***

We have financed our operations to date primarily through both the private sale of our preferred stock and the public sale of our common stock, debt financings, and cash generated from our operations. As of December 31, 2025, our debt is comprised of $200.0 million aggregate principal amount of convertible notes, due in June 2026, and $385.0 million aggregate principal amount outstanding under our Revolving Credit Facility, which we entered into in May 2023 to partially finance the VectivBio Acquisition. The Revolving Credit Facility provides for $550.0 million of borrowing capacity and includes a $10.0 million letter of credit subfacility. Refer to Note 9, *Debt*, to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K, for information related to our debt obligations.

***Summary of Cash Flows***

The following table summarizes cash flows from operating, investing, and financing activities for the years ended December 31, 2025 and 2024:

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| | (in thousands) | |
| Net cash provided by (used in): | | |
| Operating activities | $ 127,044 | $ 103,549 |
| Investing activities | (34) | (142) |
| Financing activities | 216 | (106,970) |
| Effect of exchange rate changes on cash and cash equivalents | (329) | (32) |
| Net increase (decrease) in cash and cash equivalents | $ 126,897 | $ (3,595) |

***Cash Flows from Operating Activities***

Net cash provided by operating activities is derived by adjusting net income (loss) for non-cash items and changes in operating assets and liabilities, which reflect timing differences between the receipt and payment of cash associated with transactions and when they are recognized in the results of operations.

Net cash inflows during the year ended December 31, 2025 and 2024 totaled $127.0 million and $103.5 million, respectively, and were derived primarily from collaboration arrangements revenue related to sales of LINZESS in the U.S., partially offset by research and development expenditures for apraglutide.

***Cash Flows from Investing Activities***

Cash used in investing activities for the year ended December 31, 2025 and 2024 were insignificant and pertained to the purchase of property and equipment.

***Cash Flows from Financing Activities***

Cash provided by financing activities for the year ended December 31, 2025 was $0.2 million and was generated from employee stock purchases.

Cash used in financing activities for the year ended December 31, 2024 totaled $107.0 million was comprised primarily of the repayment of $200.0 million aggregate principal on the 2024 Convertible Notes upon their maturity in June 2024, partially offset by $85.0 million of net borrowings under the Revolving Credit Facility and $11.0 million from stock option exercises and employee stock purchases.

***Funding Requirements***

We began commercializing LINZESS in the U.S. with our collaboration partner, AbbVie, in the fourth quarter of 2012, and we currently derive a significant portion of our revenue from this collaboration. Our goal is to generate and maintain positive cash flows, driven by increased revenue generated through sales of LINZESS and other commercial activities and financial discipline, while continuing to invest in the development and commercialization of linaclotide, apraglutide, and other product candidates.

Under our collaboration with AbbVie for North America, total net sales of LINZESS in the U.S., as recorded by AbbVie, are reduced by commercial costs incurred by each party, and the resulting amount is shared equally between us and AbbVie. Additionally, we receive royalties from AbbVie based on sales of linaclotide in its licensed territories outside of the U.S. We believe revenues from our LINZESS partnership for the U.S. with AbbVie will continue to constitute a significant portion of our total revenue for the foreseeable future and we cannot be certain that such revenues, as well as the revenues from our other commercial activities, will continue to enable us to generate positive cash flows, or to do so in the timeframes we expect.

We also anticipate that we will continue to incur substantial expenses for the next several years as we further develop and commercialize linaclotide in the U.S., develop and commercialize other product candidates, including apraglutide, and invest in building our pipeline through internal or external opportunities. We believe that our cash and cash equivalents on hand as of December 31, 2025, our expected cash inflows from operations, and our borrowing capacity on our Revolving Credit Facility will be sufficient to meet our projected operating needs at least through the next twelve months from the issuance of these financial statements. We have short-term and long-term debt obligations, including convertible notes that mature on June 15, 2026, which are disclosed in Note 9, *Debt*, to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. There is no assurance we will have sufficient liquidity to meet our debt obligations when they become due.

Our forecast of the period of time through which our financial resources will be adequate to support our operations, including the underlying revenue expectations and estimates regarding the costs to continue to develop, obtain regulatory approval for, and commercialize linaclotide in the U.S., develop and commercialize other product candidates, including apraglutide, and our goal to generate and maintain positive cash flows, are forward-looking statements that involve risks and uncertainties. Our actual results could vary materially and negatively from these and other forward-looking statements as a result of a number of factors, including the factors discussed in the "Risk Factors" section of this Annual Report on Form 10-K. We have based our estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

Due to the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate precisely the amounts of capital outlays and operating expenditures necessary to develop, obtain regulatory approval for, and commercialize linaclotide, apraglutide and our other product candidates, in each case, for all of the markets, indications, populations and formulations for which we believe each is suited. Our funding requirements will depend on many factors, including, but not limited to, the following:

- the revenue generated by sales of LINZESS and CONSTELLA and from any other sources;

- the rate of progress and cost of our commercialization activities, including the expense we incur in marketing and selling LINZESS in the U.S. and from any other sources;
- the success of our third-party manufacturing activities;
- the time and costs involved in developing, and obtaining regulatory approvals for, our product candidates, including apraglutide, as well as the timing and cost of any post-approval development and regulatory requirements;
- the time and costs associated with commercial manufacturing, sales, marketing and distribution of apraglutide, if approved;
- the success of our research and development efforts;
- the emergence of competing or complementary products;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the terms and timing of any collaborative, licensing or other arrangements that we may establish, including milestones, royalties or other payments due or payable under such agreements;
- the settlement method used for our outstanding convertible notes; and
- the acquisition of businesses, products and technologies and the impact of other strategic transactions, as well as the cost and timing of evaluating, acquiring, and, if completed, integrating into our business operations any such assets.

***Financing Strategy***

We may, from time to time, consider additional funding through a combination of new collaborative arrangements, strategic alliances, and additional equity and debt financings or from other sources. We will continue to manage our capital structure and to consider all financing opportunities, whenever they may occur, that could strengthen our long-term liquidity profile. Any such capital transactions may or may not be similar to transactions in which we have engaged in the past. There can be no assurance that any such financing opportunities will also be available on acceptable terms, if at all.

***Off-Balance Sheet Arrangements***

We do not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, that would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As such, we are not exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in those types of relationships. We enter into guarantees in the ordinary course of business related to the guarantee of our own performance and the performance of our subsidiaries.

**New Accounting Pronouncements**

For a discussion of recent accounting pronouncements, refer to Note 2, *Summary of Significant Accounting Policies*, to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K. We did not otherwise adopt any new accounting pronouncements during the fiscal year ended December 31, 2025 that had a material effect on our consolidated financial statements included in this report.

## Item 7A. *Quantitative and Qualitative Disclosures about Market Risk*

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide the information otherwise required under this item.

## Item 8. *Financial Statements and Supplementary Data*

Our consolidated financial statements, together with the report of independent registered public accounting firms appear at pages F-1 through F-44, of this Annual Report on Form 10-K for the years ended December 31, 2025 and 2024.

## Item 9. *Changes in and Disagreements With Accountants on Accounting and Financial Disclosure*

None.

## Item 9A. *Controls and Procedures*

### Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

### Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) of the Securities Exchange Act of 1934, or Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation as of the end of the period covered by this Annual Report on Form 10-K of the effectiveness of the design and operation of our disclosure controls and procedures. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2025, at the reasonable assurance level in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

### Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of our financial statements for external purposes in accordance with generally accepted accounting principles, and 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 assets;

(2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with the authorizations of management and directors; and

(3) provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on our financial statements.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework provided in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2025.

The effectiveness of our internal control over financial reporting as of December 31, 2025 has been audited by KPMG LLP, an independent registered public accounting firm, as stated in their report, which appears in this Annual Report on Form 10-K.

**Remediation of Previously Identified Material Weaknesses**

As previously described in described in "Part II, Item 9A – Controls and Procedures" of our Annual Report on Form 10-K for the year ended December 31, 2024, management identified material weaknesses in our internal control over financial reporting related to the design, implementation and/or operating effectiveness of entity-level controls, information technology, or IT, general controls, controls over the financial statements close process, IT application controls, and IT dependent manual controls.

During the year ended December 31, 2025, management took several steps to remediate the previously disclosed material weaknesses including the following:

1) Engaging third-party specialists to assess and strengthen our design and operating effectiveness of our IT general controls and IT application controls, including change management controls;
2) Implementing system approval and monitoring controls to mitigate segregation of duties risks within certain financial processes;
3) Hiring and engaging incremental personnel with appropriate expertise in accounting, financial reporting and internal controls commensurate with the type, volume and complexity of our operations; and
4) Conducting and delivering employee trainings around completeness and accuracy procedures of key data and reports used in control activities.

As a result of these remediation activities, management has concluded that the controls were designed, implemented and operating effectively, such that the material weaknesses previously identified as of December 31, 2024 have been remediated as of December 31, 2025.

**Changes in Internal Control Over Financial Reporting**

As required by Rule 13a-15(d) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation of the internal control over financial reporting to determine whether any changes occurred during the quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

Based on management's evaluation, and except with respect to changes in connection with our implementation of the remediation efforts as described above, our principal executive officer and principal financial officer concluded that no other changes during the quarter ended December 31, 2025 materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B.** ***Other Information***

*(b) Director and Officer Trading Arrangements*

During the quarter ended December 31, 2025, no director or officer (as defined in Rule 16a-1(f) under the Exchange Act) of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

**Item 9C.** ***Disclosure Regarding Foreign Jurisdictions that Prevent Inspections***

Not applicable.

## PART III

**Item 10.** ***Directors, Executive Officers and Corporate Governance***

We have adopted a code of business conduct and ethics applicable to our directors, officers, employees, consultants and all their immediate family or other household members. A copy of that code is available on our corporate website at http://www.ironwoodpharma.com. Any amendments to the code of business conduct and ethics, and any waivers thereto that are required to be disclosed pursuant to SEC rules, will be also available on our corporate website. A printed copy of these documents will be made available upon request. The content on our website is not incorporated by reference into this Annual Report on Form 10-K.

We have adopted an insider trading prevention policy governing the purchase, sale and other dispositions of our securities that applies to each of our directors, officers, employees, consultants and their immediate family members. We believe the insider trading prevention policy is reasonably designed to promote compliance with insider trading laws, rules and regulations, and Nasdaq listing standards. A copy of our insider trading prevention policy is filed as Exhibit 19.1 hereto. It is also our policy that we do not engage in transactions in Company securities while in possession of material nonpublic information concerning the Company or our securities.

The other information required by this item is incorporated by reference from our proxy statement for our 2026 Annual Meeting of Stockholders.

**Item 11.** ***Executive Compensation***

The information required by this item is incorporated by reference from our proxy statement for our 2026 Annual Meeting of Stockholders.

**Item 12.** ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

The information relating to security ownership of certain beneficial owners of our common stock and information relating to the security ownership of our management required by this item is incorporated by reference from our proxy statement for our 2026 Annual Meeting of Stockholders.

The table below sets forth information with regard to securities authorized for issuance under our equity compensation plans as of December 31, 2025. As of December 31, 2025, we had four active equity compensation plans, each of which was approved by our stockholders:

- Amended and Restated 2010 Employee, Director and Consultant Equity Incentive Plan;
- 2019 Equity Incentive Plan;
- Amended and Restated 2019 Equity Incentive Plan; and
- Amended and Restated 2010 Employee Stock Purchase Plan.

| Plan Category | Number of securities to be issued upon exercise of outstanding options, warrants and rights (1) | Weighted-average exercise price of outstanding options, warrants, and rights (2) | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (3) |
|---|---|---|---|
| | (a) | (b) | (c) |
| Equity compensation plans approved by security holders | 10,473,433 | $12.00 | 9,920,123 |
| Equity compensation plans not approved by security holders | — | — | — |
| Total | 10,473,433 | $12.00 | 9,920,123 |

(1) Amount includes the number of shares subject to issuance upon exercise of 3,399,109 outstanding stock options and vesting of 7,074,324 RSUs.

(2) Amount includes all outstanding stock options but does not include RSUs, which do not have an exercise price.

(3) Consists of 6,185,663 shares available for future issuance under the Amended and Restated 2019 Equity Incentive Plan and 3,734,460 shares available for future issuance under the Amended and Restated 2010 Employee Stock Purchase Plan.

**Item 13.** ***Certain Relationships and Related Transactions, and Director Independence***

The information required by this item is incorporated by reference from our proxy statement for our 2026 Annual Meeting of Stockholders.

**Item 14.** ***Principal Accountant Fees and Services***

The information required by this item is incorporated by reference from our proxy statement for our 2026 Annual Meeting of Stockholders.

## PART IV

**Item 15.** ***Exhibits and Financial Statement Schedules***

1. List of documents filed as part of this report

    1. Consolidated Financial Statements listed under Part II, Item 8 and included herein by reference.

    2. Consolidated Financial Statement Schedules

        No schedules are submitted because they are not applicable, not required or because the information is included in the Consolidated Financial Statements or Notes to Consolidated Financial Statements.

    3. Exhibits

| | | Incorporated by reference herein | |
|---|---|---|---|
| **Number** | **Description** | **Form** | **Date** |
| 2.1 | Separation Agreement, dated as of March 30, 2019, by and between Ironwood Pharmaceuticals, Inc. and Cyclerion Therapeutics, Inc. | Current Report on Form 8-K (File No. 001-34620) | April 4, 2019 |
| 2.2 | Transaction Agreement, dated May 21, 2023, by and between Ironwood Pharmaceuticals, Inc. and VectivBio Holding AG | Current Report on Form 8-K (File No. 001-34620) | May 22, 2023 |
| 3.1 | Eleventh Amended and Restated Certificate of Incorporation | Annual Report on Form 10-K (File No. 001-34620) | March 30, 2010 |
| 3.2 | Certificate of Retirement | Registration Statement on Form 8-A/A (File No. 001-34620) | January 3, 2019 |
| 3.3 | Certificate of Amendment | Current Report on Form 8-K (File No. 001-34620) | May 31, 2019 |
| 3.4 | Fifth Amended and Restated Bylaws | Annual Report on Form 10-K (File No. 001-34620) | March 30, 2010 |
| 4.1 | Specimen Class A Common Stock certificate | Registration Statement on Form S-1, as amended (File No. 333-163275) | January 20, 2010 |
| 4.2 | Indenture, dated as of August 12, 2019, by and between Ironwood Pharmaceuticals, Inc. and U.S. Bank National Association (including the form of the 1.50% Convertible Senior Note due 2026) | Current Report on Form 8-K (File No. 001-34620) | August 13, 2019 |
| 4.2.1 | Form of 1.50% Convertible Senior Note due 2026 | Current Report on Form 8-K (File No. 001-34620) | August 13, 2019 |
| 4.3 | Description of Securities of Ironwood Pharmaceuticals, Inc. | Annual Report on Form 10-K (File No. 001-34620) | February 17, 2021 |

| | | | |
|---|---|---|---|
| 10.1# | Amended and Restated 2010 Employee, Director and Consultant Equity Incentive Plan | Registration Statement on Form S-8, as amended (File No. 333-184396) | October 12, 2012 |
| 10.1.1# | Form of Stock Option Agreement under the Amended and Restated 2010 Employee, Director and Consultant Equity Incentive Plan | Quarterly Report on Form 10-Q (File No. 001-34620) | November 6, 2018 |
| 10.1.2# | Form of Restricted Stock Unit Agreement under the Amended and Restated 2010 Employee, Director and Consultant Equity Incentive Plan | Quarterly Report on Form 10-Q (File No. 001-34620) | November 6, 2018 |
| 10.2# | 2019 Equity Incentive Plan | Quarterly Report on Form 10-Q (File No. 001-34620) | July 30, 2019 |
| 10.2.1# | Form of Non-statutory Stock Option Agreement under the 2019 Equity Incentive Plan | Quarterly Report on Form 10-Q (File No. 001-34620) | July 30, 2019 |
| 10.2.2# | Form of Restricted Stock Unit Agreement under the 2019 Equity Incentive Plan | Quarterly Report on Form 10-Q (File No. 001-34620) | July 30, 2019 |
| 10.2.3# | Form of Restricted Stock Agreement under the 2019 Equity Incentive Plan | Quarterly Report on Form 10-Q (File No. 001-34620) | July 30, 2019 |
| 10.2.4# | Form of Performance-Based Restricted Stock Unit Award Agreement under the 2019 Equity Incentive Plan | Quarterly Report on Form 10-Q (File No. 001-34620) | May 6, 2020 |
| 10.3# | Amended and Restated 2019 Equity Incentive Plan | Current Report on Form 8-K (File No. 001-34620) | June 22, 2023 |
| 10.3.1# | Form of Restricted Stock Unit Agreement under the Amended and Restated 2019 Equity Incentive Plan | Quarterly Report on Form 10-Q (File No. 001-34620) | November 9, 2023 |
| 10.4# | Amended and Restated 2010 Employee Stock Purchase Plan | Annual Report on Form 10-K (File No. 001-34620) | February 13, 2020 |
| 10.5# | Change of Control Severance Benefit Plan, as amended and restated | Quarterly Report on Form 10-Q (File No. 001-34620) | April 29, 2014 |
| 10.6# | Form of Executive Severance Agreement | Annual Report on Form 10-K (File No. 001-34620) | February 25, 2019 |
| 10.7# | Form of Executive Severance Agreement | Current Report on Form 8-K (File No. 001-34620) | December 1, 2021 |
| 10.8# | Second Amended and Restated Executive Severance Agreement, dated as of June 22, 2021, between Ironwood Pharmaceuticals, Inc. and Thomas McCourt | Current Report on Form 8-K/A (File No. 001-34620) | June 24, 2021 |

| | | | |
|---|---|---|---|
| 10.9# | Second Amended and Restated Non-employee Director Compensation Policy, effective January 1, 2024 | Annual Report on Form 10-K (File No. 001-34620) | February 16, 2024 |
| 10.10# | Form of Indemnification Agreement with Directors and Officers | Registration Statement on Form S-1, as amended (File No. 333-163275) | December 23, 2009 |
| 10.11+ | Collaboration Agreement, dated as of September 12, 2007, as amended on November 3, 2009, by and between Forest Laboratories, Inc. and Ironwood Pharmaceuticals, Inc. | Registration Statement on Form S-1, as amended (File No. 333-163275) | February 2, 2010 |
| 10.11.1 | Amendment No. 2 to the Collaboration Agreement, dated as of January 8, 2013, by and between Forest Laboratories, Inc. and Ironwood Pharmaceuticals, Inc. | Annual Report on Form 10-K (File No. 001-34620) | February 21, 2013 |
| 10.12+ | Commercial Agreement, dated as of January 31, 2017, by and among Allergan USA, Inc., Forest Laboratories, LLC and Ironwood Pharmaceuticals, Inc. | Quarterly Report on Form 10-Q (File No. 001-34620) | May 8, 2017 |
| 10.13+ | License Agreement, dated as of April 30, 2009, by and between Allergan Pharmaceuticals International Ltd. (formerly with Almirall, S.A.) and Ironwood Pharmaceuticals, Inc. | Registration Statement on Form S-1, as amended (File No. 333-163275) | February 2, 2010 |
| 10.13.1+ | Amendment No. 1 to License Agreement, dated as of June 11, 2013, by and between Allergan Pharmaceuticals International Ltd. (formerly with Almirall, S.A.) and Ironwood Pharmaceuticals, Inc. | Quarterly Report on Form 10-Q (File No. 001-34620) | August 8, 2013 |
| 10.13.2+ | Amendment to the License Agreement, dated as of October 26, 2015, by and between Allergan Pharmaceuticals International Ltd. and Ironwood Pharmaceuticals, Inc. | Annual Report on Form 10-K (File No. 001-34620) | February 19, 2016 |
| 10.13.3+ | Amendment to the License Agreement dated as of January 31, 2017, by and between Allergan Pharmaceuticals International Ltd., and Ironwood Pharmaceuticals, Inc. | Quarterly Report on Form 10-Q (File No. 001-34620) | May 8, 2017 |
| 10.14+ | Novation Agreement, dated as of October 26, 2015, by and among Almirall, S.A., Allergan Pharmaceuticals International Ltd. and Ironwood Pharmaceuticals, Inc. | Annual Report on Form 10-K (File No. 001-34620) | February 19, 2016 |

| | | | |
|---|---|---|---|
| 10.15++ | Amended and Restated License Agreement, dated as of August 1, 2019, by and between Ironwood Pharmaceuticals, Inc. and Astellas Pharma Inc. | Current Report on Form 8-K (File No. 001-34620 | August 1, 2019 |
| 10.15.1 | Amendment to the Amended and Restated License Agreement, dated as of January 8, 2021, by and between Ironwood Pharmaceuticals, Inc. and Astellas Pharma Inc. | Annual Report on Form 10-K (File No. 001-34620) | February 17, 2021 |
| 10.16++ | Amended and Restated License and Collaboration Agreement, dated as of September 16, 2019, by and between AstraZeneca AB and Ironwood Pharmaceuticals, Inc. | Current Report on Form 8-K (File No. 001-34620) | September 18, 2019 |
| 10.17+ | Commercial Supply Agreement, dated as of June 23, 2010, by and among PolyPeptide Laboratories, Inc. and Polypeptide Laboratories (SWEDEN) AB, Forest Laboratories, Inc. and Ironwood Pharmaceuticals, Inc. | Quarterly Report on Form 10-Q (File No. 001-34620) | August 10, 2010 |
| 10.18+ | Commercial Supply Agreement, dated as of March 28, 2011, by and among Corden Pharma Colorado, Inc. (f/k/a Roche Colorado Corporation), Ironwood Pharmaceuticals, Inc. and Forest Laboratories, Inc. | Quarterly Report on Form 10-Q (File No. 001-34620) | May 13, 2011 |
| 10.18.1+ | Amendment No. 3 to Commercial Supply Agreement, dated as of November 26, 2013, by and between Corden Pharma Colorado, Inc. (f/k/a Roche Colorado Corporation), Ironwood Pharmaceuticals, Inc. and Forest Laboratories, Inc. | Annual Report on Form 10-K (File No. 001-34620) | February 7, 2014 |
| 10.19++ | Amended and Restated Exclusive License Agreement by and between Ferring International Center S.A. and GlyPharma Therapeutic Inc. dated as of December 6, 2016, as amended | Registration Statement on Form F-1 (File No. 333-254523) | March 19, 2021 |
| 10.19.1++ | Third Amendment to the Amended and Restated Exclusive License Agreement dated as of December 18, 2025, by and among VectivBio AG and Ferring International Center S.A., and, solely for purposes of a limited payment guarantee, Ironwood Pharmaceuticals, Inc. | Current Report on Form 8-K (File No. 001-34620) | December 23, 2025 |

| | | | |
|---|---|---|---|
| 10.20++ | Development and Commercialization Agreement by and between VectivBio AG and Asahi Kasei Pharma Corporation, dated as of March 30, 2022 | Annual Report on Form 20-F (File No. 001-40316) | April 19, 2023 |
| 10.21 | Credit Agreement, dated May 21, 2023, by and among Ironwood Pharmaceuticals, Inc., as borrower, Wells Fargo Bank, National Association, as administrative agent, collateral agent, a letter of credit issuer and a lender, and the other agents, lenders and letter of credit issuers parties thereto | Current Report on Form 8-K (File No. 001-34620) | May 22, 2023 |
| 10.21.1 | Amendment No. 1 to Credit Agreement, dated September 27, 2024, by and among Ironwood Pharmaceuticals, Inc., as borrower, Wells Fargo Bank, National Association, as administrative agent, collateral agent, a letter of credit issuer and a lender, and the other agents, lenders and letter of credit issuers parties thereto | Current Report on Form 8-K (File No. 001-34620) | September 30, 2024 |
| 10.22 | Lease Agreement for facilities at 100 Summer Street, Boston, Massachusetts, dated as of June 11, 2019, by and between Ironwood Pharmaceuticals, Inc. and MA-100 Summer Street Owner, L.L.C. | Current Report on Form 8-K (File No. 001-34620) | June 13, 2019 |
| 10.23 | Tax Matters Agreement, dated as of March 30, 2019, by and between Ironwood Pharmaceuticals, Inc. and Cyclerion Therapeutics, Inc. | Current Report on Form 8-K (File No. 001-34620) | April 4, 2019 |
| 10.24 | Employee Matters Agreement, dated as of March 30, 2019, by and between Ironwood Pharmaceuticals, Inc. and Cyclerion Therapeutics, Inc. | Current Report on Form 8-K (File No. 001-34620) | April 4, 2019 |
| 10.25 | Base Call Option Transaction Confirmation for the 2026 Notes, dated as of August 7, 2019, between Ironwood Pharmaceuticals, Inc. and JPMorgan Chase Bank, National Association | Current Report on Form 8-K (File No. 001-34620) | August 13, 2019 |
| 10.26 | Base Call Option Transaction Confirmation, for the 2026 Notes, dated as of August 7, 2019, between Ironwood Pharmaceuticals, Inc. and Credit Suisse Capital LLC | Current Report on Form 8-K (File No. 001-34620) | August 13, 2019 |
| 10.27 | Additional Call Option Transaction Confirmation for the 2026 Notes, dated as of August 12, 2019, between Ironwood Pharmaceuticals, Inc. and JPMorgan Chase Bank, National Association | Current Report on Form 8-K (File No. 001-34620) | August 13, 2019 |

| | | | |
|---|---|---|---|
| 10.28 | Additional Call Option Transaction Confirmation for the 2026 Notes, dated as of August 12, 2019, between Ironwood Pharmaceuticals, Inc. and Credit Suisse Capital LLC | Current Report on Form 8-K (File No. 001-34620) | August 13, 2019 |
| 19.1 | Insider Trading Prevention Policy | Annual Report on Form 10-K (File No. 001-34620) | March 31, 2025 |
| 21.1* | Subsidiaries of Ironwood Pharmaceuticals, Inc. | | |
| 23.1* | Consent of KPMG LLP, Independent Registered Public Accounting Firm | | |
| 23.2* | Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm | | |
| 31.1* | Certification of Chief Executive Officer pursuant to Rules 13a-14 or 15d-14 of the Exchange Act | | |
| 31.2* | Certification of Chief Financial Officer pursuant to Rules 13a-14 or 15d-14 of the Exchange Act | | |
| 32.1‡ | Certification of Chief Executive Officer pursuant to Rules 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350 | | |
| 32.2‡ | Certification of Chief Financial Officer pursuant to Rules 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350 | | |
| 97.1 | Policy for Recoupment of Incentive Compensation | Annual Report on Form 10-K (File No. 001-34620) | February 16, 2024 |
| 101.INS* | XBRL Instance Document – The Instance Document does not appear in the Interactive Data Files because its XBRL tags are embedded within the Inline XBRL document | | |
| 101.SCH* | XBRL Taxonomy Extension Schema Document | | |
| 101.CAL* | XBRL Taxonomy Extension Calculation Linkbase Document | | |
| 101.LAB* | XBRL Taxonomy Extension Label Linkbase Database | | |

| | |
|---|---|
| 101.PRE* | XBRL Taxonomy Extension Presentation Linkbase Document |
| 101.DEF* | XBRL Taxonomy Extension Definition Linkbase Document |
| 104* | The cover page from this Annual Report on Form 10-K, formatted in Inline XBRL |

---

* Filed herewith.
‡ Furnished herewith.
+ Confidential treatment has been granted as to certain portions of the exhibit, which portions have been omitted and have been separately filed with the SEC pursuant to the confidential treatment request.
++ Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.
# Management contract or compensatory plan, contract, or arrangement.

**Item 16.** ***Form 10-K Summary***

None.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Boston, Commonwealth of Massachusetts, on the 26th day of February 2026.

**Ironwood Pharmaceuticals, Inc.**
By: /s/ THOMAS MCCOURT
Thomas McCourt
*Chief Executive Officer*

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the date indicated.

| Signature | Title | Date |
|---|---|---|
| /s/ THOMAS MCCOURT<br>Thomas McCourt | Chief Executive Officer and Director (Principal Executive Officer) | February 26, 2026 |
| /s/ GREGORY MARTINI<br>Gregory Martini | Senior Vice President, Chief Financial Officer (Principal Financial Officer) | February 26, 2026 |
| /s/ RONALD SILVER<br>Ronald Silver | Senior Vice President, Corporate Controller & Chief Accounting Officer (Principal Accounting Officer) | February 26, 2026 |
| /s/ JULIE H. MCHUGH<br>Julie H. McHugh | Chair of the Board | February 26, 2026 |
| /s/ MARK CURRIE<br>Mark Currie | Director | February 26, 2026 |
| /s/ ALEXANDER DENNER<br>Alexander Denner | Director | February 26, 2026 |
| /s/ JON DUANE<br>Jon Duane | Director | February 26, 2026 |
| /s/ MARLA KESSLER<br>Marla Kessler | Director | February 26, 2026 |
| /s/ CATHERINE MOUKHEIBIR<br>Catherine Moukheibir | Director | February 26, 2026 |
| /s/ JAY P. SHEPARD<br>Jay P. Shepard | Director | February 26, 2026 |

**Index to Consolidated Financial Statements of**
**Ironwood Pharmaceuticals, Inc.**

## Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors
Ironwood Pharmaceuticals, Inc.:

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

We have audited the accompanying consolidated balance sheet of Ironwood Pharmaceuticals, Inc. and subsidiaries (the Company) as of December 31, 2025, the related consolidated statements of income, comprehensive income, stockholders' deficit, and cash flows for the year then ended, and the related notes (collectively, the consolidated financial statements). We also have audited the Company's internal control over financial reporting as of December 31, 2025, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2025, and the results of its operations and its cash flows for the year then ended, in conformity with U.S. generally accepted accounting principles. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2025 based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

*Basis for Opinions*

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's consolidated financial statements and an opinion on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audit of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

*Definition and Limitations of Internal Control Over Financial Reporting*

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of

management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

*Critical Audit Matter*

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

*Measurement of the pension benefit obligation*

As discussed in Notes 2 and 14 to the consolidated financial statements, the Company maintains a defined benefit plan for employees in Switzerland. As of December 31, 2025, the Company's projected benefit obligation was $15.5 million. The measurement of the projected benefit obligation is based on actuarial assumptions that require judgment, which include the discount rate used in determining the projected benefit obligation.

We identified the evaluation of the projected benefit obligation as a critical audit matter. Subjective auditor judgment was required to evaluate the discount rate used in determining the projected benefit obligation because of the need to involve professionals with specialized skills and knowledge.

The following are the primary procedures we performed to address the critical audit matter. We evaluated the design and tested the operating effectiveness of certain controls over the Company's projected benefit obligation measurement process, including a control related to the determination of the discount rate. We involved an actuarial professional with specialized skills and knowledge, who assisted in 1) understanding and assessing the actuarial method and assumptions used to measure the projected benefit obligation, and 2) evaluating changes in the discount rate from prior year against changes in published indices.

/s/ KPMG LLP

We have served as the Company's auditor since 2025.

Boston, Massachusetts
February 26, 2026

## Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Ironwood Pharmaceuticals, Inc.

### Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Ironwood Pharmaceuticals, Inc. (the Company) as of December 31, 2024, the related consolidated statement of income, comprehensive income, stockholders' deficit, and cash flows for the year ended December 31, 2024, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2024, and the results of its operations and its cash flows for the year ended December 31, 2024, in conformity with U.S. generally accepted accounting principles.

### 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.

/s/ Ernst & Young LLP

We have served as the Company's auditor from 1998 to 2025.

Boston, Massachusetts
March 31, 2025

**Ironwood Pharmaceuticals, Inc.**
**Consolidated Balance Sheets**
**(In thousands, except share and per share amounts)**

| | December 31, 2025 | December 31, 2024 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 215,456 | $ 88,559 |
| Accounts receivable, net | 46,745 | 81,886 |
| Prepaid expenses and other current assets | 11,977 | 11,923 |
| Total current assets | 274,178 | 182,368 |
| Property and equipment, net | 3,408 | 4,495 |
| Operating lease right-of-use assets | 9,340 | 11,028 |
| Intangible assets, net | 2,040 | 2,860 |
| Deferred tax assets | 103,433 | 144,234 |
| Other assets | 4,502 | 5,923 |
| Total assets | $ 396,901 | $ 350,908 |
| **LIABILITIES AND STOCKHOLDERS' DEFICIT** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,898 | $ 2,127 |
| Accrued research and development costs | 3,149 | 6,681 |
| Accrued expenses and other current liabilities | 33,239 | 26,849 |
| Current portion of operating lease liabilities | 3,252 | 3,189 |
| Current portion of convertible senior notes | 199,680 | — |
| Total current liabilities | 242,218 | 38,846 |
| Operating lease obligations, net of current portion | 9,870 | 12,304 |
| Convertible senior notes, net of current portion | — | 198,988 |
| Revolving credit facility | 385,000 | 385,000 |
| Other liabilities | 21,648 | 17,105 |
| Commitments and contingencies (Note 10) | | |
| Stockholders' deficit: | | |
| Preferred stock, $0.001 par value, 75,000,000 shares authorized, no shares issued and outstanding | — | — |
| Class A Common Stock, $0.001 par value, 500,000,000 shares authorized and 163,058,316 shares issued and outstanding as of December 31, 2025 and 500,000,000 shares authorized and 160,205,899 shares issued and outstanding as of December 31, 2024 | 163 | 160 |
| Additional paid-in capital | 1,412,780 | 1,395,317 |
| Accumulated deficit | (1,673,718) | (1,697,735) |
| Accumulated other comprehensive income (loss) | (1,060) | 923 |
| Total stockholders' deficit | (261,835) | (301,335) |
| Total liabilities and stockholders' deficit | $ 396,901 | $ 350,908 |

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

**Ironwood Pharmaceuticals, Inc.**
**Consolidated Statements of Income**
**(In thousands, except per share amounts)**

| | Years Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Revenues: | | |
| Collaborative arrangements revenue | $ 296,151 | $ 351,410 |
| Total revenues | 296,151 | 351,410 |
| Costs and expenses: | | |
| Research and development | 95,136 | 111,421 |
| Selling, general and administrative | 82,256 | 144,272 |
| Restructuring, net | 20,257 | 2,593 |
| Total costs and expenses | 197,649 | 258,286 |
| Income from operations | 98,502 | 93,124 |
| Other income (expense): | | |
| Interest expense and other financing costs | (32,746) | (33,034) |
| Interest and investment income | 4,076 | 4,468 |
| Other | 193 | 640 |
| Other income (expense), net | (28,477) | (27,926) |
| Income before income taxes | 70,025 | 65,198 |
| Income tax expense | (46,008) | (64,318) |
| Net income | $ 24,017 | $ 880 |
| | | |
| Net income per share — basic and diluted | $ 0.15 | $ 0.01 |
| Weighted average shares used in computing net income per share — basic: | 161,842 | 159,083 |
| Weighted average shares used in computing net income per share — diluted: | 162,983 | 160,084 |

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

**Ironwood Pharmaceuticals, Inc.**
**Consolidated Statements of Comprehensive Income**
**(In thousands, except per share amounts)**

| | Years Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Net income | $ 24,017 | $ 880 |
| Other comprehensive income (loss), net of tax: | | |
| Currency translation adjustment | (2,754) | 2,901 |
| Defined benefit pension plan | 771 | 1,053 |
| Total other comprehensive income (loss), net of tax | (1,983) | 3,954 |
| Comprehensive income | $ 22,034 | $ 4,834 |

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

**Ironwood Pharmaceuticals, Inc.**
**Consolidated Statements of Stockholders' Deficit**
**(In thousands, except share amounts)**

| | Class A Common Stock | | Additional paid-in capital | Accumulated deficit | Accumulated other comprehensive income (loss) | Total stockholders' deficit |
|---|---|---|---|---|---|---|
| | Shares | Amount | | | | |
| Balance as of December 31, 2023 | 156,354,238 | $ 156 | $ 1,355,195 | $ (1,698,615) | $ (3,031) | $ (346,295) |
| Issuance of common stock related to share-based awards and employee stock purchase plan | 3,851,661 | 4 | 11,009 | — | — | 11,013 |
| Share-based compensation expense related to share-based awards and employee stock purchase plan | — | — | 29,850 | — | — | 29,850 |
| Taxes paid related to net share settlement of share-based awards | — | — | (737) | — | — | (737) |
| Net income | — | — | — | 880 | — | 880 |
| Other comprehensive income, net of tax | — | — | — | — | 3,954 | 3,954 |
| Balance as of December 31, 2024 | 160,205,899 | $ 160 | $ 1,395,317 | $ (1,697,735) | $ 923 | $ (301,335) |
| Issuance of common stock related to share-based awards and employee stock purchase plan | 2,852,417 | 3 | 213 | — | — | 216 |
| Share-based compensation expense related to share-based awards and employee stock purchase plan | — | — | 17,250 | — | — | 17,250 |
| Net income | — | — | — | 24,017 | — | 24,017 |
| Other comprehensive loss, net of tax | — | — | — | — | (1,983) | (1,983) |
| Balance as of December 31, 2025 | 163,058,316 | $ 163 | $ 1,412,780 | $ (1,673,718) | $ (1,060) | $ (261,835) |

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

**Ironwood Pharmaceuticals, Inc.**
**Consolidated Statements of Cash Flows**
**(In thousands)**

| | Year Ended December 31, | |
|---|---|---|
| | **2025** | **2024** |
| **Cash flows from operating activities:** | | |
| Net income | $ 24,017 | $ 880 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | |
| Depreciation and amortization | 1,881 | 2,011 |
| Loss on disposal of property and equipment | 89 | 75 |
| Share-based compensation expense | 17,250 | 29,850 |
| Non-cash interest expense | 1,668 | 1,904 |
| Non-cash lease expense | 1,688 | 1,558 |
| Deferred income taxes | 40,801 | 68,090 |
| Changes in assets and liabilities: | | |
| Accounts receivable, net | 35,148 | 47,236 |
| Prepaid expenses and other current assets | 367 | 89 |
| Other assets | 447 | (854) |
| Accounts payable and accrued expenses | 6,201 | (20,208) |
| Accrued research and development costs | (4,106) | (14,650) |
| Operating lease liabilities | (2,371) | (2,176) |
| Other liabilities | 3,964 | (10,256) |
| Net cash provided by operating activities | 127,044 | 103,549 |
| **Cash flows from investing activities:** | | |
| Purchases of property and equipment | (34) | (142) |
| Net cash used in investing activities | (34) | (142) |
| **Cash flows from financing activities:** | | |
| Proceeds from exercise of stock options and employee stock purchase plan | 216 | 11,013 |
| Taxes paid related to net share settlement of share-based awards | — | (737) |
| Repayment of 2024 Convertible Notes | — | (200,000) |
| Proceeds from revolving credit facility | — | 150,000 |
| Costs associated with revolving credit facility | — | (2,246) |
| Repayments of revolving credit facility | — | (65,000) |
| Net cash provided by (used in) financing activities | 216 | (106,970) |
| Effect of exchange rate changes on cash and cash equivalents | (329) | (32) |
| Net increase (decrease) in cash and cash equivalents | 126,897 | (3,595) |
| Cash and cash equivalents, beginning of period | 88,559 | 92,154 |
| Cash and cash equivalents, end of period | $ 215,456 | $ 88,559 |
| | | |
| **Supplemental cash flow disclosure:** | | |
| Cash paid for interest | $ 30,333 | $ 32,563 |
| Cash paid for income taxes | $ 3,543 | $ 8,408 |

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

**Ironwood Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements**

## 1. Nature of Business

Ironwood Pharmaceuticals, Inc. ("Ironwood" or the "Company") is a biotechnology company developing and commercializing life-changing therapies for people living with gastrointestinal ("GI") and rare diseases. The Company is focused on the development and commercialization of innovative product opportunities in areas of significant unmet need, leveraging its demonstrated expertise and capabilities in GI and rare diseases.

LINZESS® (linaclotide), the Company's commercial product, is the first product approved by the United States Food and Drug Administration (the "U.S. FDA") in a class of GI medicines called guanylate cyclase type C agonists ("GC-C agonists") and is indicated, in the U.S., for the treatment of irritable bowel syndrome with constipation ("IBS-C") in adults and pediatric patients 7 years of age and older, chronic idiopathic constipation ("CIC") in adults, and functional constipation ("FC") in pediatric patients ages 6-17 years-old. LINZESS is also available for the treatment of adults with IBS-C or CIC in Mexico, adults with IBS-C or chronic constipation in Japan, and adults with IBS-C in China. Linaclotide is available under the trademarked name CONSTELLA® for the treatment of adults with IBS-C or CIC and pediatric patients ages 6-17 years old with FC in Canada, and to adults with IBS-C in certain European countries.

The Company has strategic partnerships with leading pharmaceutical companies to support the development and commercialization of linaclotide throughout the world. The Company and its partner, AbbVie Inc. (together with its affiliates, "AbbVie"), began commercializing LINZESS in the U.S. in December 2012. Under the Company's collaboration for North America with AbbVie, total net sales of LINZESS in the U.S., as recorded by AbbVie, are reduced by commercial costs incurred by each party, and the resulting amount is shared equally between the Company and AbbVie. Additionally, development costs are shared equally between the Company and AbbVie.

Outside of the U.S., the Company earns royalties as a percentage of net sales of products containing linaclotide as an active ingredient by the Company's collaboration partners. AbbVie has an exclusive license from the Company to develop and commercialize linaclotide in all countries other than China (including Hong Kong and Macau), Japan and the countries and territories of North America (the "AbbVie License Territory"). In addition, AbbVie has exclusive rights to commercialize linaclotide in Canada as CONSTELLA and in Mexico as LINZESS. Astellas Pharma Inc. ("Astellas"), the Company's partner in Japan, has an exclusive license to develop, manufacture, and commercialize linaclotide in Japan. AstraZeneca AB (together with its affiliates) ("AstraZeneca"), the Company's partner in China, has the exclusive right to develop, manufacture, and commercialize products containing linaclotide in China (including Hong Kong and Macau) (the "AstraZeneca License Territory").

Through the acquisition of VectivBio Holding AG ("VectivBio") in June 2023 (the "VectivBio Acquisition"), the Company is advancing apraglutide, a next-generation, synthetic peptide long-acting analog of glucagon-like peptide-2, developed for short bowel syndrome ("SBS") patients who are dependent on parenteral support ("PS").

The Company was incorporated in Delaware on January 5, 1998 as Microbia, Inc. On April 7, 2008, the Company changed its name to Ironwood Pharmaceuticals, Inc. To date, the Company has dedicated a majority of its activities to the research, development and commercialization of linaclotide, as well as to other research and development programs, including apraglutide.

## 2. Summary of Significant Accounting Policies

### *Principles of Consolidation*

The accompanying consolidated financial statements as of December 31, 2025 include the accounts of Ironwood, its wholly-owned subsidiaries, Ironwood Pharmaceuticals Securities Corporation, Ironwood Pharmaceuticals GmbH, VectivBio AG, and GlyPharma Therapeutic Inc. ("GlyPharma"). All intercompany transactions and balances are eliminated in consolidation.

***Segment Information***

Operating segments are components of an enterprise for which separate financial information is available and is evaluated regularly by the Company's chief operating decision-maker in deciding how to allocate resources and in assessing performance. The Company currently operates in one reportable business segment – human therapeutics. The Company's reportable business segment is more fully described in Note 16, *Segment Reporting*, to these consolidated financial statements.

***Use of Estimates***

The preparation of consolidated financial statements in accordance with U.S. generally accepted accounting principles requires the Company's management to make estimates and judgments that may affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the amounts of revenues and expenses during the reported periods. On an ongoing basis, the Company's management evaluates its estimates, judgments and methodologies. Estimates and assumptions in the consolidated financial statements include those related to revenue recognition; accounts receivable; useful lives of long-lived assets; impairment of long-lived assets, including goodwill; valuation procedures for right-of-use assets and operating lease liabilities; income taxes, including uncertain tax positions and the valuation allowance for deferred tax assets; research and development expenses; contingencies; defined benefit pension liabilities and certain investment fund assets; and share-based compensation. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ materially from these estimates under different assumptions or conditions. Changes in estimates are reflected in reported results in the period in which they become known.

***Cash and Cash Equivalents***

The Company considers all highly liquid investment instruments with a remaining maturity when purchased of three months or less to be cash equivalents. Investments qualifying as cash equivalents primarily consist of money market funds, U.S. Treasury securities, and commercial paper. The carrying amount of cash equivalents approximates fair value. The amount of cash equivalents included in cash and cash equivalents was $184.3 million and $55.0 million as of December 31, 2025 and 2024, respectively.

***Concentrations of Suppliers***

The Company relies on its collaboration partners and their suppliers to manufacture linaclotide API, linaclotide finished drug product, and finished goods.

If any of the Company's collaboration partners and their suppliers were to limit or terminate production or otherwise fail to meet the quality or delivery requirements needed to satisfy the supply commitments, the process of locating and qualifying alternate sources could require up to several months, during which time production could be delayed. Such delays could have a material adverse effect on the Company's business, financial position and results of operations.

***Accounts Receivable***

The Company makes judgments as to its ability to collect outstanding receivables and provides an allowance for credit losses when collection becomes doubtful. Provisions are made based upon a specific review of all significant outstanding invoices and the overall quality and age of those invoices not specifically reviewed. The Company's receivables relate primarily to amounts reimbursed under its collaboration, license, and other agreements. The Company believes that credit risks associated with these partners are not significant. The Company reviews the need for an allowance for credit losses for its receivables based on various factors including payment history and historical bad debt experience. The Company had no allowance for credit losses as of December 31, 2025 or 2024.

***Concentrations of Credit Risk***

Financial instruments that subject the Company to credit risk primarily consist of cash and cash equivalents, restricted cash, and accounts receivable. The Company maintains its cash and cash equivalent balances with high-quality financial institutions and the Company believes that such funds are subject to minimal credit risk. The Company has adopted an investment policy which limits the amounts the Company may invest in certain types of investments, and requires all investments held by the Company to be at least A- rated, thereby reducing credit risk exposure.

Accounts receivable primarily consists of amounts due under the linaclotide collaboration agreement with AbbVie for North America (Note 4). The Company does not obtain collateral for its accounts receivable.

The percentages of revenue recognized from significant collaborative partners of the Company in the years ended December 31, 2025 and 2024 and the account receivable balances, net of any payables due, as of December 31, 2025 and 2024 are included in the following table:

| | Accounts Receivable December 31, | | Revenue Year Ended December 31, | |
|---|---|---|---|---|
| | 2025 | 2024 | 2025 | 2024 |
| **Collaborative Partner:** | | | | |
| AbbVie (North America and Europe) | 99 % | 99 % | 100 % | 99 % |

***Property and Equipment***

Property and equipment, including leasehold improvements, are recorded at cost, and are depreciated when placed into service using the straight-line method based on their estimated useful lives as follows:

| Asset Description | Estimated Useful Life (In Years) |
|---|---|
| Laboratory equipment | 5 |
| Computer and office equipment | 3 |
| Furniture and fixtures | 7 |
| Software | 3 |

Included in property and equipment are certain costs of software obtained for internal use. Costs incurred during the preliminary project stage are expensed as incurred, while costs incurred during the application development stage are capitalized and amortized over the estimated useful life of the software. The Company also capitalizes costs related to specific upgrades and enhancements when it is probable the expenditures will result in additional functionality. Maintenance and training costs related to software obtained for internal use are expensed as incurred.

Leasehold improvements are amortized over the shorter of the estimated useful life of the asset or the lease term.

Costs for capital assets not yet placed into service have been capitalized as construction in process, and will be depreciated in accordance with the above guidelines once placed into service. Maintenance and repair costs are expensed as incurred.

***Intangible Assets***

Intangible assets are comprised of the assembled workforce acquired in the VectivBio Acquisition and are amortized on a straight-line basis over an estimated useful life of five years.

***Impairment of Long-Lived Assets***

The Company regularly reviews the carrying amount of its long-lived assets to determine whether indicators of impairment may exist, which warrant adjustments to carrying values or estimated useful lives. If indications of impairment exist, projected future undiscounted cash flows associated with the asset are compared to the carrying amount to determine whether the asset's value is recoverable. If the carrying value of the asset exceeds such projected undiscounted cash flows, the asset will be written down to its estimated fair value.

***Income Taxes***

The Company provides for income taxes under the asset and liability method. Deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates in effect when the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance to reflect the uncertainty associated with their ultimate realization.

The Company accounts for uncertain tax positions recognized in the consolidated financial statements in accordance with the provisions of Accounting Standards Codification ("ASC") Topic 740, Income Taxes, by prescribing a more-likely-than-not threshold for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. The Company evaluates uncertain tax positions on a quarterly basis and adjusts the level of the liability to reflect any subsequent changes in the relevant facts surrounding the uncertain positions. Any changes to these estimates, based on the actual results obtained and/or a change in assumptions, could impact the Company's income tax provision in future periods. Interest and penalty charges, if any, related to unrecognized tax benefits are classified as income tax expense in the Company's consolidated statements of income.

***Financing Costs***

Financing costs include costs directly attributable to the Company's offerings of its equity securities and its debt financings. Costs attributable to equity offerings are charged as a reduction to stockholders' equity against the proceeds of the offering once the offering is completed. Costs attributable to debt financings are deferred and amortized to interest expense over the term of the debt using the effective interest method. In accordance with ASC Topic 835, Interest, the Company presents on its balance sheet unamortized debt issuance costs related to convertible notes as a direct deduction from the associated debt liability and unamortized debt issuance costs related to revolving credit arrangements as other assets.

***Leases***

The Company's lease portfolio for the year ended December 31, 2025 included: office leases for its current headquarters location and other locations, vehicle leases, and leases for computer and office equipment. The Company determines if an arrangement is a lease at the inception of the contract and determines the classification of its leases at lease commencement. The asset component of the Company's operating leases is recorded as operating lease right-of-use assets, and the liability component is recorded as current portion of operating lease liabilities and operating lease liabilities, net of current portion in the Company's consolidated balance sheets. As of December 31, 2025, the Company did not record any finance leases.

Right-of-use assets and operating lease liabilities are recognized based on the present value of lease payments over the lease term at the lease commencement date. The lease term used to measure the right-of-use asset and operating lease liability may include options to extend the lease when it is reasonably certain that the Company will exercise the option. The Company accounts for lease components and non-lease components together as a single lease component for the asset class of right-of-use real estate assets. The Company uses an incremental borrowing rate based on the information available at lease commencement in determining the present value of lease payments, if an implicit rate of return is not readily determinable. Operating lease right-of-use assets are adjusted for prepaid rent, initial direct costs, and lease incentives.

Right-of-use assets and operating lease liabilities are remeasured upon reassessment events and modifications to leases using the present value of remaining lease payments and estimated incremental borrowing rate at the time of remeasurement, as applicable.

Operating lease cost is recognized on a straight-line basis over the lease term, and includes amounts related to short-term leases. The Company has elected to not recognize lease terms with a term of twelve months or less on its balance sheet for all classes of underlying asset types. The Company recognizes variable lease payments as operating expenses in the period in which the obligation for those payments is incurred. Variable lease payments primarily include common area maintenance, utilities, real estate taxes, insurance, and other operating costs that are passed on from the lessor in proportion to the space leased by the Company.

***Derivative Assets and Liabilities***

In August 2019, the Company issued 0.75% Convertible Senior Notes due 2024 (the "2024 Convertible Notes") and 1.50% Convertible Senior Notes due 2026 (the "2026 Convertible Notes"). In connection with the issuance of the 2024 Convertible Notes and the 2026 Convertible Notes, the Company entered into the Capped Calls (as defined in Note 9, *Debt*, below). The Capped Calls cover the same number of shares of Class A Common Stock that initially underlie the 2024 Convertible Notes and the 2026 Convertible Notes (subject to anti-dilution and certain other adjustments). These instruments meet the conditions outlined in ASC Topic 815, Derivatives and Hedging ("ASC 815") to be classified in stockholders' equity (deficit) and are not subsequently remeasured as long as the conditions for equity classification continue to be met. The Capped Calls related to the 2024 Convertible Notes expired unexercised upon maturity of the 2024 Convertible Notes in June 2024.

***Revenue Recognition***

The Company's revenues are generated primarily through collaborative arrangements and license agreements related to the research and development and commercialization of linaclotide. The terms of the collaborative research and development, license, co-promotion and other agreements contain multiple performance obligations which may include (i) licenses, (ii) research and development activities, including participation on joint steering committees, (iii) the manufacture of finished drug product, API, or development materials for a partner, which are reimbursed at a contractually determined rate, and (iv) education or co-promotion activities by the Company's clinical sales specialists. Non-refundable payments to the Company under these agreements may include (i) up-front license fees, (ii) payments for research and development activities, (iii) payments for the manufacture of finished drug product, API, or development materials, (iv) payments based upon the achievement of certain milestones, (v) payments for sales detailing, promotional support services and medical education initiatives, and (vi) royalties on product sales. The Company receives its share of the net profits or bears its share of the net losses from the sale of linaclotide in the U.S. through its collaboration agreement with AbbVie for North America. The Company has adopted a policy to recognize revenue net of tax withholdings, as applicable.

Collaboration, License, and Other Commercial Agreements

Upon licensing intellectual property to a customer, the Company determines if the license is distinct from the other performance obligations identified in the arrangement. The Company recognizes revenues from the transaction price, including non-refundable, up-front fees allocated to the license when the license is transferred to the customer if the license has distinct benefit to the customer. For licenses that are combined with other promises, the Company assesses the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time. For performance obligations that are satisfied over time, the Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

The Company's license and collaboration agreements include milestone payments, such as development and other milestones. The Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method at the inception of the agreement. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company, 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 the Company recognizes revenue as or when the performance obligations under the contract are satisfied. The Company re-evaluates the probability of achievement of such milestones and any related constraint at each reporting period, and any adjustments are recorded on a cumulative catch-up basis.

Agreements that include the supply of active pharmaceutical ingredient ("API") or drug product for either clinical development or commercial supply at the customer's discretion are generally considered as options. The Company assesses if these options provide a material right to its partner, and if so, they are accounted for as separate performance obligations. If the Company is entitled to additional payments when the customer exercises these options, any additional payments are recorded as revenue when the customer obtains control of the goods, which is typically upon shipment for sales of API and finished drug product.

For agreements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue when the related sales occur in accordance with the sales-based royalty exception.

Net Profit or Net Loss Sharing

In accordance with ASC Topic 808, *Collaborative Arrangements* ("ASC 808"), the Company considers the nature and contractual terms of the arrangement and the nature of the Company's business operations to determine the classification of payments under the Company's collaboration agreements. While ASC 808 provides guidance on classification, the standard is silent on matters of separation, initial measurement, and recognition. Therefore, the Company applies the separation, initial measurement, and recognition principles of ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), as applicable.

The Company's collaborative arrangements revenues generated from sales of LINZESS in the U.S. are considered akin to sales-based royalties. In accordance with the sales-based royalty exception, the Company recognizes its share of the pre-tax commercial net profit or net loss generated from the sales of LINZESS in the U.S. in the period the product sales are earned, as reported by AbbVie, and related cost of goods sold and selling, general and administrative expenses as incurred by the Company and AbbVie. These amounts are partially determined based on amounts provided by AbbVie and involve the use of estimates and judgments, such as product sales allowances and accruals related to prompt payment discounts, chargebacks, governmental and contractual rebates, wholesaler fees, product returns, and co-payment assistance costs, which could be adjusted based on actual results in the future. The Company is highly dependent on AbbVie for timely and accurate information regarding net revenues from sales of LINZESS in the U.S. in accordance with both ASC 808 and ASC 606, and the related costs, in order to accurately report its results of operations. If the Company does not receive timely and accurate information or incorrectly estimates activity levels associated with the collaboration at a given point in time, the Company could be required to record adjustments in future periods.

In accordance with ASC 606-10-55, *Principal Agent Considerations*, the Company records revenue transactions as net product revenue in its consolidated statements of income if it is deemed the principal in the transaction, which includes being the primary obligor, retaining inventory risk, and control over pricing. Given that the Company is not the primary obligor and does not have the inventory risks in the collaboration agreement with AbbVie for North America, it records its share of the net profits or net losses from the sales of LINZESS in the U.S. on a net basis and presents the settlement payments to and from AbbVie as collaboration expense or collaborative arrangements revenue, as applicable. The Company and AbbVie settle the cost sharing quarterly such that the Company's statements of income reflect 50% of the pre-tax net profit or loss generated from sales of LINZESS in the U.S.

Other

The Company's deferred revenue balance consists of advance billings and payments received from collaboration partners in excess of revenue recognized.

***Research and Development Costs***

The Company generally expenses research and development costs to operations as incurred. The Company capitalizes nonrefundable advance payments made by the Company for research and development activities and defers expense recognition until the related goods are received or the related services are performed.

Research and development expenses are comprised of costs incurred in performing research and development activities, including salary, benefits, share-based compensation, and other employee-related expenses; laboratory supplies and other direct expenses; facilities expenses; overhead expenses; third-party contractual costs relating to nonclinical studies and clinical trial activities and related contract manufacturing expenses, development of manufacturing processes and regulatory registration of third-party manufacturing facilities; licensing fees for the Company's product candidates; and other outside expenses.

The Company has certain collaboration agreements pursuant to which it shares or has shared research and development expenses related to linaclotide. The Company records expenses incurred under such linaclotide collaboration arrangements as research and development expense. Under the Company's collaboration agreement with AbbVie for North America, the Company is reimbursed for certain research and development expenses and nets these reimbursements against its research and development expenses as incurred.

Research and development expense includes up-front payment, non-contingent payment, and milestone payment obligations under certain collaboration arrangements. Expense is recognized when the obligation is determined to be probable.

***Restructuring Expenses***

Restructuring expenses are comprised primarily of costs associated with exit and disposal activities in accordance with ASC Topic 420, *Exit or Disposal Cost Obligations*, and ASC Topic 712, *Compensation – Nonretirement Postemployment Benefits*, and include one-time termination benefits and contract-related costs. Such costs are based on estimates of fair value in the period liabilities are incurred. The Company evaluates and adjusts these costs for changes in circumstances as additional information becomes available.

***Selling, General and Administrative Expenses***

The Company expenses selling, general and administrative costs to operations as incurred. Selling, general and administrative expenses consist primarily of compensation, benefits and other employee-related expenses for personnel in the Company's administrative, finance, legal, information technology, business development, commercial, sales, marketing, communications and human resource functions. Other costs include legal costs of pursuing patent protection of the Company's intellectual property, general and administrative related facility costs, insurance costs and professional fees for accounting, tax, consulting, legal and other services.

The Company includes AbbVie's selling, general and administrative cost-sharing payments in the calculation of the net profits and net losses from the sale of LINZESS in the U.S. and presents the net payment to or from AbbVie as collaboration expense or collaborative arrangements revenue, respectively.

***Defined Benefit Pension Obligations***

Pension benefits earned during the year, as well as interest on projected benefit obligations ("PBO"), are accrued. Service costs are recognized within research and development expenses or selling, general and administrative expenses, depending on the function of the plan participant. All other components of net period costs are recognized within other income (expense), net. Prior service costs and credits resulting from changes in plan benefits are recognized in other comprehensive income (loss) in the period in which they occur and then amortized to net periodic benefit costs generally over the average remaining service period of the active participants. Actuarial gains and losses arising from experience adjustments and changes in actuarial assumptions are recognized in other comprehensive income (loss) in the period in which they occur. To the extent such gains and losses exceed 10% of the PBO or the estimated fair value of plan assets, the excess is amortized into net periodic benefit costs, generally over the average remaining service period of the active participants. The Company recognizes a pension plan's funded status as either an asset or liability in its consolidated balance sheets.

***Share-Based Compensation Expense***

The Company grants awards under its share-based compensation programs, including stock awards, restricted stock awards ("RSAs"), restricted stock units ("RSUs") (including both time-based and performance-based RSUs), stock options, and shares issued under the Company's employee stock purchase plan ("ESPP"). Share-based compensation is recognized as expense in the consolidated statements of income based on the grant date fair value over the requisite service period, net of estimated forfeitures. The Company estimates forfeitures over the requisite service period using historical forfeiture activity and records share-based compensation expense only for those awards that are expected to vest.

The Company estimates the fair value of stock options using the Black-Scholes option-pricing model, which requires the use of subjective assumptions including volatility and expected term, among others. The fair value of stock awards, RSAs, and RSUs is based on the market value of the Company's Class A Common Stock on the date of grant, with the exception of performance-based RSUs with market conditions, which are measured using the Monte Carlo simulation method on the date of grant (Note 12). Discounted stock purchases under the Company's ESPP are valued on the first date of the offering period using the Black-Scholes option-pricing model to compute the fair value of the lookback provision plus the purchase discount.

For awards that vest based on service conditions and market conditions, the Company uses a straight-line method to recognize compensation expense over the respective service period. For awards that contain performance conditions, the Company determines the appropriate amount to expense at each reporting date based on the anticipated achievement of performance targets, which requires judgement, including forecasting the achievement of future specified targets. At the date performance conditions are determined to be probable of achievement, the Company records a cumulative expense catch-up, with remaining expense amortized over the remaining service period. Throughout the performance period, the Company re-assesses the estimated performance and updates the number of performance-based awards that it believes will ultimately vest. Discounted stock purchases under the Company's ESPP are recognized over the offering period.

Compensation expense related to modified awards is measured based on the fair value for the awards as of the modification date. Any incremental compensation expense arising from the excess of the fair value of the awards on the modification date compared to the fair value of the awards immediately before the modification date is recognized at the modification date or ratably over the requisite remaining service period, as appropriate.

While the assumptions used to calculate and account for share-based compensation awards represent management's best estimates, these estimates involve inherent uncertainties and the application of management's judgment. As a result, if revisions are made to the Company's underlying assumptions and estimates, the Company's share-based compensation expense could vary significantly from period to period.

***Patent Costs***

Legal and other fees related to patents are charged to selling, general and administrative expenses as incurred.

***Net Income (Loss) Per Share***

Basic net income (loss) per common share is computed by dividing the net income by the weighted average number of common shares outstanding during the period. Diluted net income (loss) per share reflects the potential dilution beyond common shares for basic net income (loss) per share that could occur if securities or other contracts to issue common shares were exercised, converted into common shares, or resulted in the issuance of common shares that would have shared in the Company's earnings.

***Foreign Currency Translation***

For subsidiaries with a different functional currency than the U.S. dollar, assets and liabilities are translated at the exchange rates as of the balance sheet date and income and expense items are translated at the average exchange rates for the reporting period. Adjustments resulting from the translation of the financial statements of foreign subsidiaries are recorded in accumulated comprehensive income (loss), a separate component of stockholders' deficit.

***Comprehensive Income (Loss)***

Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income (loss). Other comprehensive income (loss) includes foreign currency translation adjustments and certain changes in the fair value of pension plan assets and projected benefit obligation attributed to the Company's defined benefit pension plans. Accumulated other comprehensive income (loss) is presented as a separate component of stockholders' deficit.

***Subsequent Events***

The Company considers events or transactions that have occurred after the balance sheet date of December 31, 2025, but prior to the filing of the financial statements with the Securities and Exchange Commission ("SEC") to provide additional evidence relative to certain estimates or to identify matters that require additional recognition or disclosure. Subsequent events have been evaluated through the filing of the financial statements accompanying this Annual Report on Form 10-K.

***New Accounting Pronouncements***

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (the "FASB") or other standard setting bodies that are adopted by the Company as of the specified effective date. Except as set forth below, the Company did not adopt any new accounting pronouncements during the year ended December 31, 2025 that had a material effect on its consolidated financial statements.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* ("ASU 2023-09"). The guidance in ASU 2023-09 improves the transparency of annual income tax disclosures by requiring greater disaggregation of information in the rate reconciliation and income taxes paid disaggregated by jurisdiction. The standard is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. Upon adoption, ASU 2023-09 may be applied prospectively or retrospectively. The Company adopted ASU 2023-09 during the year ended December 31, 2025, on a prospective basis. The expanded disclosures are included in the consolidated financial statements (Note 13).

In November 2024, the FASB issued ASU No. 2024-03, *Disaggregation of Income Statement Expenses* ("ASU 2024-03"). The guidance in ASU 2024-03 requires new financial statement disclosures in tabular format, disaggregating information about prescribed categories underlying any relevant income statement expense captions. The standard is effective for fiscal years beginning after December 15, 2026 and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. Upon adoption, ASU 2024-03 may be applied prospectively or retrospectively. The Company is currently evaluating the impact that the adoption of ASU 2024-03 may have on its disclosures in its consolidated financial statements.

In November 2024, the FASB issued ASU No. 2024-04, *Debt—Debt with Conversion and Other Options (Subtopic 470-20)* ("ASU 2024-04"). The guidance in ASU 2024-04 clarifies the requirements related to accounting for the settlement of a debt instrument as an induced conversion. The standard is effective for fiscal years beginning after December 15, 2025, and interim periods within fiscal years beginning after December 15, 2025, with early adoption permitted as of the beginning of a reporting period if the entity has also adopted ASU 2020-06 for that period. The Company is currently evaluating the impact that the adoption of ASU 2024-04 may have on its disclosures in its consolidated financial statements.

In July 2025, the FASB issued ASU No. 2025-05, *Measurement of Credit Losses for Accounts Receivable and Contract Assets* ("ASU 2025-05"). The guidance in ASU 2025-05 amends ASC Topic 326, *Financial Instruments—Credit Losses*, to provide a practical expedient to simplify estimating expected credit losses for current accounts receivable and current contract assets arising from transactions accounted for under ASC Topic 606, *Revenue from Contracts with Customers*. The practical expedient, if elected, allows entities to assume that current conditions as of the balance sheet date do not change for the remaining life of the asset. The standard is effective for annual fiscal years beginning after December 15, 2025 and interim periods within fiscal years beginning after December 15, 2025, with early adoption permitted. Entities that elect the practical expedient should apply the guidance prospectively. The Company is currently evaluating the impact that the adoption of ASU 2025-05 may have on its consolidated financial statements.

In September 2025, the FASB issued ASU No. 2025-06, *Targeted Improvements to the Accounting for Internal-Use Software* ("ASU 2025-06"). The guidance in ASU 2025-06 amends certain aspects of the accounting for and disclosure of software costs under ASC Subtopic 350-40, *Internal Use Software*. The standard is effective for fiscal years beginning after December 15, 2027 and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. Entities may elect to apply the guidance prospectively, retrospectively, or through a modified prospective transition method. The Company is currently evaluating the impact that the adoption of ASU 2025-06 may have on its consolidated financial statements.

In September 2025, the FASB issued ASU No. 2025-07, *Derivatives Scope Refinements and Scope Clarification for Share-Based Noncash Consideration from a Customer in a Revenue Contract* ("ASU 2025-07"). The guidance in ASU 2025-07 expands the scope exceptions within ASC Topic 815, *Derivatives and Hedging*, to include certain nonexchange-traded contracts with underlyings that are based on operations or activities specific to one of the parties to the contract, including research and development funding arrangements. The standard is effective for annual fiscal years beginning after December 15, 2026 and interim periods within fiscal years beginning after December 15, 2026, with early adoption permitted. Entities should apply the amendments either prospectively for contracts entered into on or after the date of adoption or on a modified retrospective basis through a cumulative-effect adjustment to the opening balance of retained earnings for contracts that exist as of the beginning of the annual reporting period of adoption. The Company is currently evaluating the impact that the adoption of ASU 2025-07 may have on its consolidated financial statements.

In December 2025, the FASB issued ASU No. 2025-11, *Narrow-Scope Improvements* ("ASU 2025-11"). The guidance in ASU 2025-11 amends ASC Topic 270, *Interim Reporting*, to provide clarity on the current interim reporting requirements as well as requires entities to disclose events since the end of the last annual reporting period that have a material impact on the entity through the addition of the disclosure principle. The standard is effective for interim reporting periods within annual reporting periods beginning after December 15, 2027, with early adoption permitted. Upon adoption, ASU 2025-11 may be applied prospectively or retrospectively. The Company is currently evaluating the impact that the adoption of ASU 2025-11 may have on its consolidated financial statements.

In December 2025, the FASB issued ASU No. 2025-12, *Codification Improvements* ("ASU 2025-12"). The guidance in ASU 2025-12 provides incremental improvements to accounting standards for a broad range of topics. The standard is effective for annual fiscal years beginning after December 15, 2026 and interim periods within fiscal years beginning after December 15, 2026, with early adoption permitted. Upon adoption, ASU 2025-12 may be applied prospectively or retrospectively on an issue-by-issue basis. The Company is currently evaluating the impact that the adoption of ASU 2025-12 may have on its consolidated financial statements.

Other recent accounting pronouncements issued, but not yet effective, are not expected to be applicable to the Company or have a material effect on the consolidated financial statements upon future adoption.

**3. Net Income Per Share**

The following table sets forth the computation of basic and diluted net income per common share (in thousands, except per share amounts):

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Numerator: | | |
| Net income | $ 24,017 | $ 880 |
| Numerator used in computing net income per share — basic & diluted | $ 24,017 | $ 880 |
| Denominator: | | |
| Weighted average number of common shares outstanding used in computing net income per share — basic | 161,842 | 159,083 |
| Effect of dilutive securities: | | |
| Time-based RSUs | 598 | 425 |
| Performance-based RSUs | 396 | 480 |
| Restricted stock | 147 | 96 |
| Dilutive potential common shares | | |
| Weighted average number of common shares outstanding used in computing net income per share — diluted | 162,983 | 160,084 |
| Net income per share — basic & diluted | $ 0.15 | $ 0.01 |

The dilutive impact of the convertible senior notes is determined using the if-converted method. Under the if-converted method, the convertible senior notes are assumed to be converted into common stock at the beginning of the period (or at the time of issuance, if later). Interest charges are deducted from the numerator, unless the principal amount of the convertible instruments is required to be paid in cash. The dilutive impact of all other types of dilutive securities is determined using the treasury stock method.

On December 15, 2025, the Company elected to settle conversions of the 2026 Convertible Notes through cash payment equal to the principal value and shares of Class A Common Stock for the conversion premium, if any (Note 9). Accordingly, interest expense is added to the numerator and the calculated spread is added to the denominator only for the period the 2026 Convertible Notes were outstanding prior to the settlement method election, to the extent an assumed conversion is dilutive. Interest expense was excluded from the numerator and there was no calculated spread added to the denominator because an assumed conversion would be anti-dilutive.

The outstanding securities set forth in the following table have been excluded from the computation of diluted weighted average shares outstanding, as applicable, as their effect would be anti-dilutive (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Stock options | 3,709 | 4,821 |
| Time-based RSUs | 3,403 | 3,596 |
| Performance-based RSUs | — | 34 |
| 2026 Convertible Notes | 14,277 | 14,934 |
| Total | 21,389 | 23,385 |

There was no dilutive impact of the 2024 Convertible Notes for the year ended December 31, 2024 because the Company had elected prior to the beginning of the period to settle the conversion of 2024 Convertible Notes, if any, with a combination settlement of a cash payment equal to the principal value of converted notes and shares of Class A Common Stock equal to the conversion value in excess of the principal value, if any (Note 9). Accordingly, interest expense was removed from the numerator and there was no calculated spread added to the denominator because the average market price of the Company's Class A Common Stock during the period was not in excess of the conversion price.

## 4. Collaboration, License, and Other Agreements

The Company has linaclotide collaboration agreements with AbbVie for North America and AstraZeneca for China (including Hong Kong and Macau), as well as linaclotide license agreements with Astellas for Japan and with AbbVie for the AbbVie License Territory. The following table provides amounts included in the Company's consolidated statements of income as collaborative arrangements revenue attributable to transactions from these and other agreements (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| **Collaborative Arrangements Revenue** | **2025** | **2024** |
| Linaclotide Collaboration and License Agreements: | | |
| AbbVie (North America) | $ 292,356 | $ 343,154 |
| AbbVie (Europe and other) | 3,633 | 3,236 |
| AstraZeneca (China, including Hong Kong and Macau) | 321 | 364 |
| Astellas (Japan) | 1,685 | 1,673 |
| Other Agreements: | | |
| Asahi Kasei Pharma Corporation (apraglutide) | (1,931) | 2,249 |
| Other | 87 | 734 |
| Total collaborative arrangements revenue | $ 296,151 | $ 351,410 |

Accounts receivable, net, included $46.7 million and $81.9 million primarily related to collaborative arrangements revenue, collectively, as of December 31, 2025 and 2024, respectively. Accounts receivable, net, included $46.2 million and $81.3 million due from the Company's partner, AbbVie, net of $2.7 million and $3.1 million of accounts payable, as of December 31, 2025 and 2024, respectively.

The Company routinely assesses the creditworthiness of its license and collaboration partners. The Company did not experience any material losses related to receivables from its license or collaboration partners during the years ended December 31, 2025 or 2024.

### Linaclotide Agreements

#### *Collaboration Agreement for North America with AbbVie*

In September 2007, the Company entered into a collaboration agreement with AbbVie to develop and commercialize linaclotide for the treatment of IBS-C, CIC, and other GI conditions in North America. Under the terms of this collaboration agreement, the Company received an upfront licensing fee, equity investment, and development and regulatory milestones, and shares equally with AbbVie all development costs as well as net profits or losses from the development and sale of linaclotide in the U.S. In addition, the Company receives royalties in the mid-teens percent based on net sales in Canada and Mexico. AbbVie is solely responsible for the further development, regulatory approval and commercialization of linaclotide in those countries and funding any costs.

During the years ended December 31, 2025 and 2024, the Company incurred $7.5 million and $7.4 million, respectively, in total research and development expenses under the linaclotide collaboration for North America. As a result of the research and development cost-sharing provisions of the linaclotide collaboration for North America, the Company incurred $5.0 million and $8.6 million in incremental research and development costs during the years ended December 31, 2025 and 2024, respectively, to reflect the obligations of each party under the collaboration to bear 50% of the development costs incurred.

The Company and AbbVie began commercializing LINZESS in the U.S. in December 2012. The Company receives 50% of the net profits and bears 50% of the net losses from the commercial sale of LINZESS in the U.S. Net profits or net losses consist of net sales of LINZESS to third-party customers and sublicense income in the U.S. less the cost of goods sold as well as selling, general and administrative expenses. LINZESS net sales are calculated and recorded by AbbVie and may include gross sales net of discounts, rebates, allowances, sales taxes, freight and insurance charges, and other applicable deductions.

The Company evaluated its linaclotide collaboration arrangement for North America and concluded that all development-period performance obligations had been satisfied as of September 2012. The Company has determined that there are three remaining commercial-period performance obligations, which include the sales detailing of LINZESS, participation in the joint commercialization committee, and approved additional trials. The consideration remaining includes cost reimbursements in the U.S. and net profit and loss sharing payments based on net sales in the U.S. Additionally, the Company receives royalties in the mid-teens percent based on net sales in Canada and Mexico. Royalties and net profit and loss sharing payments will be recorded as collaborative arrangements revenue or expense in the period earned, as these payments relate predominantly to the license granted to AbbVie. The Company records royalty revenue in the period earned based on royalty reports from its partner, if available, or based on the projected sales and historical trends. The cost reimbursements received from AbbVie during the commercialization period will be recognized as earned in accordance with the right-to-invoice practical expedient, as the Company's right to consideration corresponds directly with the value of the services transferred during the commercialization period.

Under the Company's linaclotide collaboration agreement for North America, LINZESS net sales are calculated and recorded by AbbVie and include gross sales net of discounts, rebates, allowances, sales taxes, freight and insurance charges, and other applicable deductions, as noted above. These amounts include the use of estimates and judgments, which could be adjusted based on actual results in the future. The Company records its share of the net profits or net losses from the sales of LINZESS in the U.S. less commercial expenses on a net basis, and presents the settlement payments to and from AbbVie as collaboration expense or collaborative arrangements revenue, as applicable. This treatment is in accordance with the Company's revenue recognition policy, given that the Company is not the primary obligor and does not have the inventory risks in the collaboration agreement with AbbVie for North America. The Company relies on AbbVie to provide accurate and complete information related to net sales of LINZESS in accordance with U.S. generally accepted accounting principles in order to calculate its settlement payments to and from AbbVie and record collaboration expense or collaborative arrangements revenue, as applicable.

During the year ended December 31, 2024, the Company recognized a $43.0 million reduction to collaboration revenue, as a result of changes in estimates of sales reserves and allowances associated with governmental and contractual rebates. Excluding the changes in estimates, net income per share – basic and net income per share – diluted would have been $0.21 and $0.19, respectively, for the year ended December 31, 2024.

The following table summarizes collaborative arrangements revenue from the linaclotide collaboration agreement for North America during the years ended December 31, 2025 and 2024 as follows (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Collaborative arrangements revenue related to sales of LINZESS in the U.S. | $ 289,317 | $ 340,394 |
| Royalty revenue | 3,039 | 2,760 |
| Total collaborative arrangements revenue | $ 292,356 | $ 343,154 |

The Company incurred $4.4 million and $39.3 million in total selling, general and administrative costs related to the sale of LINZESS in the U.S. in accordance with the cost-sharing arrangement with AbbVie for the years ended December 31, 2025 and 2024, respectively.

In May 2014, CONSTELLA® became commercially available in Canada and, in June 2014, LINZESS became commercially available in Mexico. The Company records royalties on sales of CONSTELLA in Canada and LINZESS in Mexico in the period earned. The Company recognized $3.0 million and $2.8 million of combined royalty revenues from Canada and Mexico during the years ended December 31, 2025 and 2024, respectively.

***License Agreement with AbbVie (All countries other than the countries and territories of North America, China (including Hong Kong and Macau), and Japan)***

The Company has a license agreement with AbbVie to develop, manufacture and commercialize linaclotide in (i) Europe, and (ii) all other countries other than China (including Hong Kong and Macau), Japan, and the countries and territories of North America, or collectively the "Expanded Territory", for the treatment of IBS-C, CIC and other GI conditions.

Under the license agreement, as amended, AbbVie is obligated to pay the Company, (i) royalties based on sales volume in Europe in the upper-teens percent, and (ii) on a country-by-country and product-by-product basis in the Expanded Territory, a royalty as a percentage of net sales of products containing linaclotide as an active ingredient in the upper-single digits for five years following the first commercial sale of a linaclotide product in a country, and in the low-double digits thereafter. The royalty rate for products in Europe and the Expanded Territory will decrease, on a country-by-country basis, to the lower-single digits, or cease entirely, following the occurrence of certain events. The license agreement also contains certain sales-based milestones and commercial launch milestones, which could total up to $42.5 million.

The Company recognized $3.6 million and $3.2 million of royalty revenue during the years ended December 31, 2025 and 2024, respectively.

***License Agreement for Japan with Astellas***

The Company has a license agreement with Astellas to develop, manufacture, and commercialize linaclotide for the treatment of IBS-C, CIC and other GI conditions in Japan.

Under the license agreement, as amended, Astellas is required to pay royalties to the Company at rates beginning in the mid-single digit percent and escalating to low-double-digit percent, based on aggregate annual net sales in Japan of products containing linaclotide as an active ingredient. These royalty payments are subject to reduction following the expiration of certain licensed patents and the occurrence of generic competition in Japan.

During the years ended December 31, 2025 and 2024, the Company recognized $1.7 million and $1.7 million of royalty revenue, respectively.

***Collaboration Agreement for China (including Hong Kong and Macau) with AstraZeneca***

The Company has a collaboration agreement with AstraZeneca under which AstraZeneca has the exclusive right to develop, manufacture and commercialize products containing linaclotide in the AstraZeneca License Territory.

Under the collaboration agreement, AstraZeneca is required to pay tiered royalties to the Company at rates beginning in the mid-single-digit percent and increasing up to twenty percent based on the aggregate annual net sales of products containing linaclotide in the AstraZeneca License Territory. In addition, AstraZeneca may be required to make milestone payments totaling up to $90.0 million contingent on the achievement of certain sales targets.

During the years ended December 31, 2025 and 2024, the Company recognized $0.3 million and $0.4 million of royalty revenue, respectively.

**Apraglutide Agreements**

***Development and Commercialization Agreement with AKP***

In March 2022, VectivBio entered into a development and commercialization agreement with Asahi Kasei Pharma Corporation (“AKP”) in which VectivBio granted an exclusive license to AKP, with the right to sublicense in multiple tiers, to develop, commercialize and exploit products derived from apraglutide in Japan.

Pursuant to the terms of the development and commercialization agreement with AKP, VectivBio received an upfront payment of JPY 3,000 million ($24.6 million at date of agreement) and development-related payments of JPY 1,600 million in the aggregate ($13.1 million at date of agreement), and is eligible to receive development milestones of JPY 1,000 million ($8.2 million at date of agreement) and up to JPY 19,000 million ($155.8 million at date of agreement) of commercial and sales-based milestone payments. VectivBio is also eligible to receive payments in the commercial period for manufacturing supply equal to cost-plus manufacturing mark-up and tiered royalties of up to a mid-double-digit percentage on product sales continuing until the later of (i) expiration of regulatory exclusivity in Japan, or (ii) expiration of the last valid patent claim that provides exclusivity to apraglutide in Japan (the “Royalty Term”). The development and commercialization agreement will terminate upon the expiration of the Royalty Term.

The Company identified two performance obligations consisting of the (i) exclusive license for the development and commercialization of apraglutide in Japan and (ii) development activities for conducting global trials and sharing of associated development data necessary for obtaining and maintaining regulatory approval in Japan. Each performance obligation was capable of being distinct and distinct in the context of the contract. The initial transaction price was allocated to each performance obligation on a relative standalone selling price basis. The Company assessed that it provided a right to use the license as the license exists (in terms of form and functionality) at the point in time at which it is granted and therefore, was satisfied at the inception of the arrangement. The development activities are being recognized over time as the Company performs development activities related to the global trials. The Company recognizes revenue associated with the development activities using an input method, according to the costs incurred, which in management's judgment, is the best measure of progress towards satisfying the performance obligation. Under the sales-or-usage-based royalty exception, revenue related to sales-based milestone payments and royalty payments will be recognized as the underlying sales occur.

Prior to the VectivBio Acquisition, VectivBio had received the upfront payment of JPY 3,000 million ($24.6 million at date of agreement), development-related payments of JPY 1,100 million ($9.0 million at date of agreement), and development milestones of JPY 500 million ($4.1 million at date of agreement). Upon the acquisition of VectivBio on June 29, 2023, the Company assumed a contract liability for deferred revenue related to the development-related payments at its fair value of $4.3 million.

In April 2024, VectivBio received the final development-related payment of JPY 500 million ($4.1 million at date of agreement).

During the second quarter of 2025, the Company recorded a $2.9 million reduction to cumulative collaborative arrangements revenue due to an increase in estimated development costs in connection with the confirmatory Phase III clinical trial needed to seek U.S. FDA approval for apraglutide.

The Company recognized a net reduction of revenue in the amount of $1.9 million during the year ended December 31, 2025, related to development activities. The Company recognized $2.2 million of revenue during the year ended December 31, 2024. As of December 31, 2025, current deferred revenue of $1.1 million and non-current deferred revenue of $5.3 million is reported within accrued expenses and other current liabilities and other liabilities, respectively, on the consolidated balance sheets. Deferred revenue related to development activities is expected to be recognized over the course of the development activities, which are anticipated to be substantially complete by 2030.

***License Agreement with Ferring***

In August 2012, as subsequently amended and restated in December 2016, GlyPharma entered into an exclusive licensing agreement with Ferring International Center S.A. ("Ferring"), pursuant to which Ferring granted GlyPharma an exclusive, worldwide, sublicensable license under certain patent rights and know-how controlled by Ferring relating to apraglutide and certain know-how controlled by Ferring relating to specified alternate drug compounds, to research, develop, manufacture, make, have made, import, export, use, sell, distribute, promote, advertise, dispose of or offer to sell (i) products containing apraglutide whose manufacture, use or sale is covered by a valid claim of the licensed patents, or licensed products and (ii) products, containing a specified alternate drug compound, or alternate drug products. In April 2021, the license agreement was transferred and assigned to VectivBio AG, a subsidiary of VectivBio.

Under the license agreement, as partial consideration for the rights Ferring granted to it, VectivBio AG is required to pay Ferring a high single-digit percentage royalty on worldwide annual net sales of licensed products and alternate drug products until, on a country-by-country basis and licensed product-by-licensed product or alternate drug product-by-alternate drug product basis, as applicable, the date on which the manufacture, use or sale of such licensed product or alternate drug product, as applicable, ceases to be covered by a valid claim of a patent within the licensed patents in such a country. GlyPharma was also required to issue Ferring a certain number of warrants and Class A preferred shares pursuant to a shareholders' agreement. The equity obligations under the license agreement have been fully performed by GlyPharma.

The Company is also obligated to pay Ferring a specified percentage of the annual consideration VectivBio AG or its affiliates, including the Company, received in connection with sales of licensed product or alternate drug product by any third parties to which VectivBio AG or its affiliates, including the Company, grant a sublicense of any of the rights licensed to VectivBio AG by Ferring under this license agreement. Such percentage is in the high single digits for sales of both licensed products and alternate drug products, and such payments are owed for the duration of the royalty term for licensed products or alternate drug products, as applicable.

On October 2, 2025, Ferring filed a complaint against VectivBio AG, for trade secret misappropriation and correction of patent inventorship and ownership in the U.S. District Court in the Eastern District of Texas. On December 18, 2025, the Company and Ferring entered into an agreement to settle the claims for $12.5 million and amended the terms of the licensing agreement to require VectivBio AG to pay a low single-digit percentage royalty from the end of the seventh year from such first commercial sale through the date on which such licensed product ceases to be covered by a valid claim of a patent. In connection with the settlement, the Company recorded a charge of $12.5 million as selling, general, and administrative expense in the consolidated statements of income during the year ended December 31, 2025. VectivBio AG paid $7.5 million in December 2025 and is obligated to pay the remaining $5.0 million on or by December 31, 2026, subject to accelerated payment in certain circumstances. As of December 31, 2025, the remaining obligation of $5.0 million is recorded in accrued expenses and other liabilities in the consolidated balance sheet.

**Other Collaboration and License Agreements**

***Collaboration and License Option Agreement with COUR***

In November 2021, the Company entered into the collaboration and license option agreement (the "COUR Collaboration Agreement") with COUR Pharmaceutical Development Company, Inc. ("COUR"), pursuant to which the Company was granted an option (the "Option") to acquire an exclusive license to research, develop, manufacture and commercialize, in the U.S., products containing CNP-104 for the treatment of PBC. COUR has initiated a Phase II clinical study to evaluate the safety, tolerability, and pharmacodynamic effects and efficacy of CNP-104 in PBC patients. After reviewing the data from the clinical study for CNP-104, the Company had the right to exercise the Option and pay COUR $35.0 million in exchange for the license, subject to the Company's right to apply a credit against such payment as described below.

In April 2023, the Company and COUR executed an amendment to the COUR Collaboration Agreement, in which the Company agreed to pay a one-time, non-refundable, upfront payment of $6.0 million to COUR in exchange for the right to apply a credit of $6.6 million against future amounts due to COUR in connection with the exercise of the Option, commercial milestones, or royalties. In connection with such payment, COUR also granted the Company a right of first negotiation over certain additional potential research and development programs. The $6.0 million payment was recognized as research and development expense in the second quarter of 2023.

In the third quarter of 2024, the Company received from COUR the topline data from COUR's Phase II clinical study for the treatment of PBC. In September 2024, the Company notified COUR of its decision not to exercise the option to acquire an exclusive license to CNP-104. As a result, the collaboration and license option agreement between the Company and COUR has terminated, and the Company retains no rights and has no obligations related to CNP-104.

**5. Fair Value of Financial Instruments**

The tables below present information about the Company's assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2025 and 2024 and indicate the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value. In general, fair values determined by Level 1 inputs utilize observable inputs such as quoted prices in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are either directly or indirectly observable, such as quoted prices for similar instruments in active markets, interest rates and yield curves. Fair values determined by Level 3 inputs utilize unobservable data points in which there is little or no market data, which require the Company to develop its own assumptions for the asset or liability.

The Company's investment portfolio may include fixed income securities that do not always trade on a daily basis. As a result, the pricing services used by the Company apply other available information as applicable through processes such as benchmark yields, benchmarking of like securities, sector groupings and matrix pricing to prepare valuations. In addition, model processes are used to assess interest rate impact and develop prepayment scenarios. These models take into consideration relevant credit information, perceived market movements, sector news and economic events. The inputs into these models may include benchmark yields, reported trades, broker-dealer quotes, issuer spreads and other relevant data. The Company validates the prices provided by its third-party pricing services by obtaining market values from other pricing sources and analyzing pricing data in certain instances. The Company periodically invests in certain reverse repurchase agreements, which are collateralized by Government Securities and Obligations for an amount not less than 102% of their principal amount. The Company does not record an asset or liability for the collateral as the Company is not permitted to sell or re-pledge the collateral. The collateral has at least the prevailing credit rating of U.S. Government Treasuries and Agencies. The Company uses a third-party custodian to manage the exchange of funds and ensure the collateral received is maintained at 102% of the reverse repurchase agreements principal amount on a daily basis.

The following tables present the assets the Company has measured at fair value on a recurring basis (in thousands):

| | | Fair Value Measurements at Reporting Date Using | | |
|---|---|---|---|---|
| | December 31, 2025 | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| **Assets:** | | | | |
| Cash and cash equivalents: | | | | |
| Money market funds | $ 164,907 | $ 164,907 | $ — | $ — |
| U.S. Treasury securities | 11,479 | — | 11,479 | — |
| Commercial paper | 7,880 | — | 7,880 | — |
| Total assets measured at fair value | $ 184,266 | $ 164,907 | $ 19,359 | $ — |

| | | Fair Value Measurements at Reporting Date Using | | |
|---|---|---|---|---|
| | December 31, 2024 | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| **Assets:** | | | | |
| Cash and cash equivalents: | | | | |
| Money market funds | $ 36,010 | $ 36,010 | $ — | $ — |
| U.S. Treasury securities | 11,044 | — | 11,044 | — |
| Commercial paper | 7,928 | — | 7,928 | — |
| Total assets measured at fair value | $ 54,982 | $ 36,010 | $ 18,972 | $ — |

Cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable, accrued research and development costs, accrued expenses and other current liabilities and current portion of operating lease obligations as of December 31, 2025 and 2024 are carried at amounts that approximate fair value due to their short-term maturities.

**Convertible Senior Notes**

In August 2019, the Company issued $200.0 million aggregate principal amount of its 2026 Convertible Notes (Note 9). The fair value of the 2026 Convertible Notes, which differs from their carrying value, is influenced by interest rates, the price of the Company's Class A Common Stock and the volatility thereof, and the prices for the 2026 Convertible Notes observed in market trading, which are Level 2 inputs.

The estimated fair value of the 2026 Convertible Notes was $189.3 million and $186.6 million as of December 31, 2025 and 2024, respectively.

**Capped Calls with Respect to 2026 Convertible Notes**

In connection with the issuance of the 2026 Convertible Notes, the Company entered into the Capped Calls (as defined in Note 9, *Debt*, below) with certain financial institutions. The Capped Calls cover 14,933,740 shares of Class A Common Stock (subject to anti-dilution and certain other adjustments), which is the same number of shares of Class A Common Stock that initially underlie the 2026 Convertible Notes. The Capped Calls have an initial strike price of approximately $13.39 per share, which corresponds to the initial conversion price of the 2026 Convertible Notes, and have a cap price of approximately $17.05 per share (Note 9). The strike price and cap price are subject to anti-dilution adjustments generally similar to those applicable to the 2026 Convertible Notes. These instruments meet the conditions outlined in ASC 815, to be classified in stockholders' equity and are not subsequently remeasured as long as the conditions for equity classification continue to be met (Note 9).

**Revolving Credit Agreement**

Outstanding borrowings under the revolving credit facility (Note 9) are carried at amounts that approximate fair value based on their nature, terms, credit spreads, and variable interest rates, which are Level 3 inputs.

**6. Leases**

The Company's lease portfolio for the year ended December 31, 2025 included: an office lease for its current headquarters location and other locations, vehicle leases, and leases for computer and office equipment.

The Company's headquarters office lease and vehicle leases require letters of credit totaling $0.6 million to secure the Company's obligations under the lease agreements. The letters of credit are maintained under a subfacility of the revolving credit agreement (Note 9).

Lease cost is recognized on a straight-line basis over the lease term. The components of lease cost for the years ended December 31, 2025 and 2024 are as follows (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Operating lease cost | $ 2,507 | $ 2,507 |
| Short-term lease cost | 354 | 1,520 |
| Total lease cost | $ 2,861 | $ 4,027 |

Supplemental information related to leases for the periods reported is as follows:

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Cash paid for amounts included in the measurement of lease liabilities (in thousands) | $ 3,189 | $ 3,126 |
| Weighted-average remaining lease term of operating leases (in years) | 4.4 | 5.4 |
| Weighted-average discount rate of operating leases | 5.8 % | 5.8 % |

***Summer Street Lease***

In June 2019, the Company entered into a non-cancelable operating lease (the "Summer Street Lease") for approximately 39,000 square feet of office space on the 23rd floor of 100 Summer Street, Boston, Massachusetts, which has been the Company's headquarters since October 2019. The Summer Street Lease terminates on June 11, 2030 and includes a 2% annual rent escalation, free rent periods, a tenant improvement allowance, and an option to extend the term of the lease for an additional five years at a market base rental rate. The extension option is not included in the lease term used for the measurement of the lease, as it is not reasonably certain to be exercised. The lease expense, inclusive of the escalating rent payments and lease incentives, is recognized on a straight-line basis over the lease term.

As of lease commencement, the Company recorded a right-of-use asset and a lease liability using an incremental borrowing rate of 5.8%. As of December 31, 2025, the balances of the right-of-use asset and operating lease liability were $9.3 million and $13.1 million, respectively. As of December 31, 2024, the balances of the right-of-use asset and operating lease liability were $11.0 million and $15.5 million, respectively.

Lease costs recorded during each of the years ended December 31, 2025 and 2024 were $2.5 million.

Future minimum lease payments under the Summer Street Lease as of December 31, 2025 are as follows (in thousands):

| | |
|---|---|
| 2026 | $ 3,252 |
| 2027 | 3,317 |
| 2028 | 3,384 |
| 2029 | 3,451 |
| 2030 | 1,450 |
| Total future minimum lease payments | 14,854 |
| Less: present value adjustment | (1,732) |
| Operating lease liabilities | 13,122 |
| Less: current portion of operating lease liabilities | (3,252) |
| Operating lease liabilities, net of current portion | $ 9,870 |

## 7. Property and Equipment

Property and equipment, net consisted of the following (in thousands):

| | December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Software | $ 214 | $ 1,567 |
| Leasehold improvements | 7,443 | 7,407 |
| Furniture and fixtures | 1,759 | 1,732 |
| Computer and office equipment | 1,997 | 2,154 |
| | 11,413 | 12,860 |
| Less accumulated depreciation and amortization | (8,005) | (8,365) |
| | $ 3,408 | $ 4,495 |

Depreciation expense of property and equipment was $1.1 million and $1.2 million for the years ended December 31, 2025 and 2024, respectively.

## 8. Accrued Expenses and Other Current Liabilities

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

| | December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Accrued compensation and benefits | $ 11,590 | $ 14,547 |
| Accrued litigation settlement | 5,000 | — |
| Accrued interest | 4,437 | 4,771 |
| Deferred revenue | 1,107 | 2,032 |
| Accrued taxes | 927 | 521 |
| Accrued restructuring liabilities | 771 | 560 |
| Other | 9,407 | 4,418 |
| Total accrued expenses and other current liabilities | $ 33,239 | $ 26,849 |

As of December 31, 2025 and 2024, other accrued expenses were comprised primarily of $9.4 million and $4.3 million of uninvoiced vendor liabilities, respectively.

**9. Debt**

***0.75% Convertible Senior Notes due 2024 and 1.50% Convertible Senior Notes due 2026***

In August 2019, the Company issued $200.0 million aggregate principal amount of the 2024 Convertible Notes and $200.0 million aggregate principal amount of the 2026 Convertible Notes, pursuant to separate indentures (each an "Indenture" and together the "Indentures"), between the Company and U.S. Bank National Association, as trustee (the "Trustee"). The Company received net proceeds of $391.0 million from the sale of the 2024 Convertible Notes and 2026 Convertible Notes, after deducting fees and expenses of $9.0 million. The Company used $25.2 million of the net proceeds from the sale of the 2024 Convertible Notes and 2026 Convertible Notes to pay the cost of the Capped Calls, as described below.

In June 2024, the Company repaid the $200.0 million aggregate principal amount of the 2024 Convertible Notes upon maturity. The 2024 Convertible Notes bore cash interest at the annual rate of 0.75% payable on June 15 and December 15 of each year. No conversions were exercised by holders of the 2024 Convertible Notes.

The 2026 Convertible Notes bear cash interest at the annual rate of 1.50%, payable on June 15 and December 15 of each year. The 2026 Convertible Notes will mature on June 15, 2026, unless earlier converted or repurchased.

The initial conversion rate for the 2026 Convertible Notes is 74.6687 shares of Class A Common Stock (subject to adjustment as provided for in the Indenture) per $1,000 principal amount of the 2026 Convertible Notes, which is equal to an initial conversion price of approximately $13.39 per share.

The Company held the option to determine the settlement method for conversions of the 2026 Convertible Notes through payment or delivery, as the case may be, of cash, shares of the Company's Class A Common Stock, or a combination of cash and shares of Class A Common Stock (subject to, and in accordance with, the settlement provisions of the applicable Indenture). The Company has elected to settle conversion of the 2026 Convertible Notes through cash payment equal to the principal value and shares of Class A Common Stock for the conversion premium, if any.

Holders of the 2026 Convertible Notes had the right to convert their 2026 Convertible Notes at their option at any time prior to the close of business on the business day immediately preceding December 15, 2025 upon the occurrence of certain circumstances and no such conversions occurred. On or after December 15, 2025, until the close of business on the second scheduled trading day immediately preceding June 15, 2026, holders may convert their 2026 Convertible Notes, in multiples of $1,000 principal amount, at the option of the holder.

Upon the occurrence of fundamental changes, as described in the Indenture, prior to the maturity date of the 2026 Convertible Notes, holders of such notes may require the Company to repurchase for cash all or a portion of their notes at a repurchase price equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest. If a make-whole fundamental change, as described in the Indenture, occurs and a holder elects to convert its notes in connection with such make-whole fundamental change, such holder may be entitled to an increase in the conversion rate as described in the Indenture.

The Indenture does not contain any financial covenants or restrict the Company's ability to repurchase the Company's securities, pay dividends or make restricted payments in the event of a transaction that substantially increases the Company's level of indebtedness. The Indenture provides for customary events of default. In the case of an event of default arising from specified events of bankruptcy or insolvency, all outstanding notes will become due and payable immediately without further action or notice. If any other event of default under the Indenture occurs or is continuing, the Trustee or holders of at least 25% in aggregate principal amount of the then outstanding notes may declare the principal amount of such notes to be immediately due and payable.

The Company accounts for convertible debt instruments as a single liability measured at amortized cost.

The Company's outstanding balance for the 2026 Convertible Notes consisted of the following (in thousands):

| | 2025 | 2024 |
|---|---|---|
| Principal: | $ 200,000 | $ 200,000 |
| Less: unamortized debt issuance costs | (320) | (1,012) |
| Net carrying amount | $ 199,680 | $ 198,988 |

The outstanding balance of the 2026 Convertible Notes is classified as a current liability and non-current liability as of December 31, 2025 and December 31, 2024, respectively.

In connection with the issuance of the 2026 Convertible Notes, the Company incurred $4.5 million of debt issuance costs, which primarily consisted of initial purchaser's discounts and legal and other professional fees. The debt issuance costs are reflected as a reduction in the carrying value of the 2026 Convertible Notes and recorded as interest expense over the life of the 2026 Convertible Notes.

The Company determined the expected life of the 2026 Convertible Notes was equal to its approximately seven-year term. The effective annual interest rate of the 2026 Convertible Notes for the period from the date of issuance through December 31, 2025 was 1.9%. The effective annual interest rate is computed using the contractual interest and the amortization of debt issuance costs.

The following table sets forth total interest expense recognized related to convertible senior notes (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Contractual interest expense | $ 3,000 | $ 3,688 |
| Amortization of debt issuance costs | 692 | 1,119 |
| Total interest expense | $ 3,692 | $ 4,807 |

***Capped Calls with Respect to 2024 Convertible Notes and 2026 Convertible Notes***

To minimize the impact of potential dilution to the Company's Class A common stockholders upon conversion of the 2024 Convertible Notes and the 2026 Convertible Notes, the Company separately entered into the capped call transactions in August 2019 (the "Capped Calls") in connection with the issuance of the 2024 Convertible Notes and the 2026 Convertible Notes. The Company paid the counterparties $25.2 million to enter into the Capped Calls, of which $25.0 million related to the premium payments and $0.2 million related to transaction costs. These instruments meet the conditions outlined in ASC 815 to be classified in stockholders' equity and are not subsequently remeasured as long as the conditions for equity classification continue to be met.

The Capped Calls in connection with the issuance of the 2024 Convertible Notes, which covered 14,933,740 shares of Class A Common Stock, terminated unexercised upon expiry in June 2024.

The Capped Calls in connection with the 2026 Convertible Notes have an initial strike price of approximately $13.39 per share, which corresponds to the initial conversion price of the 2026 Convertible Notes and is subject to anti-dilution adjustments generally similar to those applicable to the 2026 Convertible Notes. The Capped Calls have a cap price of approximately $17.05 per share, subject to certain adjustments. The Capped Calls cover 14,933,740 shares of Class A Common Stock (subject to anti-dilution and certain other adjustments), which is the same number of shares of Class A Common Stock that initially underlie the 2026 Convertible Notes. Holders of the 2026 Convertible Notes do not have any rights with respect to the Capped Calls.

The Capped Calls are expected generally to reduce the potential dilution to the Class A Common Stock upon conversion of the 2026 Convertible Notes in the event that the market price per share of Class A Common Stock is greater than the strike price of the Capped Calls as adjusted pursuant to the anti-dilution adjustments. If, however, the market price per share of Class A Common Stock exceeds the cap price of the Capped Calls, there would nevertheless be dilution upon conversion of the 2026 Convertible Notes to the extent that such market price exceeds the cap price of the Capped Calls.

***Revolving Credit Facility***

In May 2023, in connection with the VectivBio Acquisition, the Company entered into a credit agreement with Wells Fargo Bank, N.A., as administrative agent (in such capacity, the "Agent"), collateral agent, a letter of credit issuer and a lender, and the other agents, lenders and letter of credit issuers parties thereto (collectively, the "Lenders"). In September 2024, the Company, the Agent and the Lenders entered into the first amendment to the revolving credit agreement (as amended from time to time, the "Revolving Credit Agreement") to, among other things, increase the borrowing capacity from $500.0 million to $550.0 million, extend the maturity date, and increase the Company's permitted maximum consolidated secured net leverage ratio.

The Revolving Credit Agreement provides for a $550.0 million secured revolving credit facility (the "Revolving Credit Facility"), which includes a $10.0 million letter of credit subfacility, and loans made thereunder will mature on the earliest to occur of (i) December 31, 2028 or (ii) the date that is 91 days prior to the stated maturity date of the Company's existing convertible notes then outstanding, unless, in the case of clause (ii), the Company's minimum liquidity equals or exceeds certain agreed levels.

At the Company's election, borrowings under the Revolving Credit Agreement will bear interest at a rate equal to (a) Adjusted Term Secured Overnight Financing Rate ("Adjusted Term SOFR") (as defined in Revolving Credit Agreement) plus the applicable rate (ranging from 1.75% to 3.00%) or (b) the highest of (1) the weighted average overnight Federal funds rate, as published by the Federal Reserve Bank of New York, plus one half of 1.0%, (2) the prime lending rate or (3) the one-month Adjusted Term SOFR plus 1.0% in effect from time to time plus the applicable rate (ranging from 0.75% to 2.00%). The applicable rates are based on the Company's consolidated secured net leverage ratio (as defined under the Revolving Credit Facility) at the time of the applicable borrowing.

The Company pays a quarterly commitment fee of 0.30% to 0.425% on the daily amount by which the commitments under the Revolving Credit Agreement exceed the outstanding loans and letters of credit.

The loans and other obligations under the Revolving Credit Agreement are secured by substantially all of the Company's personal property, including a pledge of all the capital stock of subsidiaries held directly by the Company or any subsidiary that guarantees the Revolving Credit Agreement following the closing date (which pledge, in the case of any foreign subsidiary, is limited to 65% of the voting stock), subject to certain customary exceptions and limitations. The Revolving Credit Agreement generally prohibits any other liens on the assets of the Company and its restricted subsidiaries, subject to certain exceptions as described in the Revolving Credit Agreement.

Under the terms of the Revolving Credit Agreement, the Company will be able to request an increase in the commitments or the addition of a term loan secured by a pari passu lien on the collateral of up to an additional amount equal to the greater of $200.0 million and 100% of the trailing twelve-month Consolidated Adjusted EBITDA (as defined in the Revolving Credit Agreement) upon satisfaction of customary conditions, including receipt of commitments from either new lenders or increased commitments from existing lenders.

The Revolving Credit Agreement contains certain customary covenants applicable to the Company and its Restricted Subsidiaries (as defined in the Revolving Credit Agreement). The Company is required to maintain a maximum consolidated secured net leverage ratio of 3.50 to 1.00 until the end of the final quarter of 2025 (the "Initial Period"), (ii) 3.25 to 1.00 until the end of the first quarter of 2026 (the "Interim Period") and (iii) 3.00 to 1.00 thereafter, and a minimum interest coverage ratio of 3.00 to 1.00, in each case at the end of each fiscal quarter. The Revolving Credit Agreement allows the Company to elect to increase the permitted maximum consolidated secured net leverage ratio to (i) 4.00 to 1.00 during the Initial Period, (ii) 3.75 to 1.00 during the Interim Period and (iii) 3.50 to 1.00 thereafter, in each case for up to four fiscal quarters in the event it consummates an acquisition for consideration in excess of $50.0 million, subject to certain limitations on how often this election can be made. As of December 31, 2025, the Company was in compliance with all covenants under the Revolving Credit Agreement.

In connection with the initial execution of the Revolving Credit Agreement during the second quarter of 2023 and the amendment executed in the third quarter of 2024, the Company incurred $2.9 million and $2.2 million of debt issuance costs, respectively, which consisted primarily of lender fees. The debt issuance costs are classified as other assets and are amortized on a straight-line basis over the term of the Revolving Credit Agreement. The Company had unamortized capitalized debt issuance costs of $2.9 million and $3.9 million as of December 31, 2025 and 2024, respectively.

The outstanding principal balance on the Revolving Credit Facility was $385.0 million as of December 31, 2025 and 2024.

The following table sets forth total interest expense recognized related to Revolving Credit Agreement (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Contractual interest expense | $ 27,341 | $ 27,643 |
| Amortization of debt issuance costs | 976 | 785 |
| Other financing costs | 737 | 50 |
| Total interest expense | $ 29,054 | $ 28,478 |

**10. Commitments and Contingencies**

***Commitments with AbbVie***

The Company and AbbVie are jointly obligated to make minimum purchases of linaclotide API for the territories covered by the Company's collaboration with AbbVie for North America. Currently, AbbVie fulfills all such minimum purchase commitments.

Under the collaboration agreement with AbbVie for North America, the Company shares all development and commercialization costs related to linaclotide in the U.S. with AbbVie. The actual amounts that the Company pays to AbbVie or that AbbVie pays to the Company will depend on numerous factors outside of the Company's control, including the success of certain clinical development efforts with respect to linaclotide, the content and timing of decisions made by the regulators, the reimbursement and competitive landscape around linaclotide and the Company's other product candidates, and other factors.

***Other Funding Commitments***

As of December 31, 2025, the Company has ongoing studies in various pre-clinical and clinical trial stages. The Company's most significant clinical trial expenditures are to contract research organizations and contract manufacturing organizations. These contracts are generally cancellable, with notice, at the Company's option and do not have any significant cancellation penalties.

The Company has entered into a manufacturing supply agreement for apraglutide, which includes certain minimum purchase commitments. The future minimum purchase commitments under this agreement range from $1.0 million to $3.9 million per year through 2030.

***Guarantees***

As permitted under Delaware law, the Company indemnifies its directors and certain of its officers for certain events or occurrences while such director or officer is, or was, serving at the Company's request in such capacity. The maximum potential amount of future payments the Company could be required to make is unlimited; however, the Company has directors' and officers' insurance coverage that is intended to limit its exposure and enable it to recover a portion of any future amounts paid.

The Company enters into certain agreements with other parties in the ordinary course of business that contain indemnification provisions. These typically include agreements with business partners, contractors, landlords, clinical sites and customers. Under these provisions, the Company generally indemnifies and holds harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of the Company's activities. These indemnification provisions generally survive termination of the underlying agreements. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is unlimited. However, to date the Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. As a result, the estimated fair value of these obligations is minimal. Accordingly, the Company did not have any liabilities recorded for these obligations as of December 31, 2025 and 2024.

***Litigation***

From time to time, the Company is involved in various legal proceedings and claims, either asserted or unasserted, which arise in the ordinary course of business. While the outcome of these other claims cannot be predicted with certainty, management does not believe that the outcome of any of these ongoing legal matters, individually and in aggregate, will have a material adverse effect on the Company's consolidated financial statements.

For details regarding the Ferring legal matter, refer to Note 4, *Collaboration, License and Other Agreements.*

**11. Stockholders' Equity**

**Preferred Stock**

The Company's preferred stock may be issued from time to time in one or more series, with each such series to consist of such number of shares and to have such terms as adopted by the board of directors. Authority is given to the board of directors to determine and fix such voting powers, full or limited, or no voting powers, and such designations, preferences and relative participating, optional or other special rights, and qualifications, limitation or restrictions thereof, including without limitation, dividend rights, conversion rights, redemption privileges and liquidation preferences.

**Common Stock**

The Company has one class of common stock ("Class A Common Stock"). Class A Common Stock is entitled to one vote per share. The Company has reserved, out of its authorized but unissued shares of Class A Common Stock, sufficient shares to effect the conversion of the 2026 Convertible Notes pursuant to the terms thereof (Note 9).

The Company's stockholders are entitled to dividends if and when declared by the board of directors.

**12. Employee Stock Benefit Plans**

The Company has several share-based compensation plans under which stock options, RSAs, RSUs, and other share-based awards are available for grant to employees, officers, directors and consultants of the Company.

The following table summarizes share-based compensation expense by award type (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Time-based RSUs | $ 13,486 | $ 21,425 |
| Performance-based RSUs | 2,767 | 6,422 |
| Restricted stock awards | 654 | 1,492 |
| Employee stock purchase plan | 184 | 451 |
| Stock options | 99 | — |
| Stock awards | 60 | 60 |
| Total share-based compensation expense | $ 17,250 | $ 29,850 |

The following table summarizes the share-based compensation expense reflected in the consolidated statements of income (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Share-based compensation expense: | | |
| Research and development | $ 5,447 | $ 7,552 |
| Selling, general and administrative | 11,704 | 22,298 |
| Restructuring | 99 | — |
| Total share-based compensation expense included in operating expenses | 17,250 | 29,850 |
| Income tax expense | 2,519 | 3,414 |
| Total share-based compensation expense, net of tax | $ 14,731 | $ 26,436 |

Restructuring expenses include modifications to share-based awards held by employees impacted by certain workforce reductions (Note 15).

**Stock Benefit Plans**

As of December 31, 2025, the Company has the following active stock benefit plans pursuant to which awards are currently outstanding: the Amended and Restated 2019 Equity Incentive Plan (the "A&R 2019 Equity Plan"), the 2019 Equity Incentive Plan (the "2019 Equity Plan"), the Amended and Restated 2010 Employee Stock Purchase Plan (the "2010 Purchase Plan") and the Amended and Restated 2010 Employee, Director, and Consultant Equity Incentive Plan (the "2010 Equity Plan"). As of December 31, 2025, there were 9,920,123 shares available for future grant under the A&R 2019 Equity Plan and the 2010 Purchase Plan.

*A&R 2019 Equity Plan*

During 2023, the Company's stockholders approved the A&R 2019 Equity Plan under which stock options, RSAs, RSUs, and other stock-based awards may be granted to employees, officers, directors, or consultants of the Company. Under the A&R 2019 Equity Plan, 6,000,000 shares of Class A Common Stock were initially reserved for issuance. Subsequent to the approval of the A&R 2019 Equity Plan, shares available for grant under the 2019 Equity Plan are made available for grant under the A&R 2019 Equity Plan and awards that are returned to the A&R 2019 Equity Plan, 2019 Equity Plan and 2010 Equity Plan as a result of their expiration, cancellation, termination or repurchase are automatically made available for future grant under the A&R 2019 Equity Plan. As of December 31, 2025, 6,185,663 shares were available for future grant under the A&R 2019 Equity Plan.

*2019 Equity Plan*

During 2019, the Company's stockholders approved the 2019 Equity Plan under which stock options, RSAs, RSUs, and other stock-based awards may be granted to employees, officers, directors, or consultants of the Company. Under the 2019 Equity Plan, 10,000,000 shares of Class A Common Stock were initially reserved for issuance. Prior to the approval of the A&R 2019 Equity Plan, awards that were returned to the 2010 Equity Plan as a result of their expiration, cancellation, termination or repurchase were automatically made available for issuance under the 2019 Equity Plan and awards that expired, cancelled, terminated, or were repurchased under the 2019 Equity Plan were no longer available for future grant. As of December 31, 2025, there were no shares available for future grant under the 2019 Equity Plan.

*2010 Purchase Plan*

During 2010, the Company's stockholders approved the 2010 Purchase Plan, which gives eligible employees the right to purchase shares of common stock at the lower of 85% of the fair market value on the first or last day of an offering period. Each offering period is six months. There were 400,000 shares of common stock initially reserved for issuance pursuant to the 2010 Purchase Plan. The number of shares available for future grant under the 2010 Purchase Plan may be increased on the first day of each fiscal year by an amount equal to the lesser of: (i) 1,000,000 shares, (ii) 1% of the Class A shares of common stock outstanding on the last day of the immediately preceding fiscal year, or (iii) such lesser number of shares as is determined by the board of directors. As of December 31, 2025, there were 3,734,460 shares available for future grant under the 2010 Purchase Plan.

*2010 Equity Plan*

The 2010 Equity Plan provided for the granting of stock options, RSAs, RSUs, and other share-based awards to employees, officers, directors, consultants, or advisors of the Company. As of December 31, 2025, there were no shares available for future grant under the 2010 Equity Plan.

**Restricted Stock Awards**

RSAs are granted to non-employee members of the board of directors under restricted stock agreements in accordance with the terms of the Company's equity plans and the Company's non-employee director compensation policy, effective May 2019. Annual restricted stock grants to each non-employee member of the board of directors vest in full on the date immediately preceding the next annual meeting of stockholders, provided the individual continues to serve on the Company's board of directors through each vest date. Initial restricted stock grants to new non-employee members of the board of directors vest annually over a three-year period from the date of grant provided the individual continues to serve on the Company's board of directors through each vest date.

A summary of restricted stock activity for the year ended December 31, 2025 is presented below:

| | Number of Shares | Weighted-Average Grant Date Fair Value |
|---|---|---|
| Unvested as of December 31, 2024 | 194,488 | $ 5.70 |
| Granted | 360,000 | 0.80 |
| Vested | (194,488) | 5.70 |
| Forfeited | (45,000) | 0.80 |
| Unvested as of December 31, 2025 | 315,000 | $ 0.80 |

The weighted-average grant date fair value per share of RSAs granted during the years ended December 31, 2025 and 2024, was $0.80 and $5.70, respectively. The total fair value of RSAs that vested during the years ended December 31, 2025 and 2024 was $0.1 million and $1.0 million, respectively.

**Restricted Stock Units**

RSUs granted under the Company's equity plans represent the right to receive one share of the Company's Class A Common Stock pursuant to the terms of the applicable award agreement. Shares of the Company's Class A Common Stock are delivered to the employee upon vesting, subject to payment of applicable withholding taxes.

*Time-based RSUs*

Time-based RSUs generally vest over a two-to-four-year period on the approximate anniversary of the date of grant until fully vested, provided the individual remains in continuous service with the Company through each vesting date. The fair value of all time-based RSUs is based on the market value of the Company's Class A Common Stock on the date of grant. Compensation expense, including the effect of estimated forfeitures, is recognized over the applicable service period.

A summary of time-based RSU activity for the year ended December 31, 2025 is as follows:

| | Number of RSUs | Weighted-Average Grant Date Fair Value |
|---|---|---|
| Outstanding as of December 31, 2024 | 5,351,507 | $ 10.89 |
| Granted | 4,017,510 | 1.65 |
| Vested and released | (1,878,766) | 10.47 |
| Forfeited | (2,053,525) | 8.36 |
| Outstanding as of December 31, 2025 | 5,436,726 | $ 4.87 |

The weighted-average grant date fair value per share of time-based RSUs granted during the years ended December 31, 2025 and 2024 was $1.65 and $11.53, respectively. The total fair value of time-based RSUs that vested during the years ended December 31, 2025 and 2024 was $3.6 million and $22.0 million, respectively.

*Performance-based RSUs*

Performance-based RSUs ("PSUs") are granted to certain executives. PSUs currently outstanding vest upon the achievement of specified performance criteria over a three-year performance period, generally subject to the executive remaining in continuous service with the Company through the applicable vesting dates. The performance criteria applicable to the PSUs granted in 2025 consisted of relative total shareholder return goals (the "Relative TSR PSUs"). The performance criteria applicable to the PSUs granted in 2024 consisted of an equal weighting of (i) Relative TSR PSUs and (ii) achieving specified stock price targets (the "Absolute TSR PSUs").

The Relative TSR PSUs and Absolute TSR PSUs are valued using the Monte Carlo simulation method on the date of grant. The weighted average assumptions used to estimate the fair value of Relative TSR PSUs and Absolute TSR PSUs were as follows for the years ended December 31, 2025 and 2024:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2025 | 2024 | |
| | Relative TSR PSUs | Relative TSR PSUs | Absolute TSR PSUs |
| Fair value of common stock | $ 0.76 | $ 12.41 | $ 12.41 |
| Expected volatility | 74.1 % | 38.0 % | 38.0 % |
| Expected term (in years) | 2.8 | 3.0 | 3.0 |
| Risk-free interest rate | 3.8 % | 4.2 % | 4.2 % |
| Expected dividend yield | — % | — % | — % |

A summary of PSU activity for the year ended December 31, 2025 is as follows:

| | Number of PSUs | Weighted-Average Grant Date Fair Value |
|---|---|---|
| Outstanding as of December 31, 2024 | 1,108,506 | $ 13.91 |
| Granted | 1,017,777 | 0.17 |
| Vested and released | (260,063) | 13.27 |
| Forfeited | (228,622) | 10.40 |
| Outstanding as of December 31, 2025 | 1,637,598 | $ 5.15 |

The weighted-average grant date fair value per share of PSUs granted during the years ended December 31, 2025 and 2024 was $0.17 and $14.91, respectively. The total fair value of PSUs that vested during the years ended December 31, 2025 and 2024 was $1.0 million and $9.8 million, respectively.

**Stock Options**

Stock options granted under the Company's equity plans represent the right to purchase one share of the Company's Class A Common Stock pursuant to the terms of the applicable award agreement. Shares of the Company's Class A Common Stock are delivered to the employee upon exercise, subject to payment of applicable withholding taxes.

The Company ceased granting stock options during the year ended December 31, 2020. Stock options previously granted under the Company's equity plans generally have a ten-year term and vest over a period of four years, provided the individual continues to serve at the Company through the vesting dates. Options granted under all equity plans are exercisable at a price per share not less than the fair market value of the underlying common stock on the date of grant. The estimated fair value of options, including the effect of estimated forfeitures, is recognized over the requisite service period, which is typically the vesting period of each option.

The following table summarizes stock option activity under the Company's share-based compensation plans:

| | Number of Stock Options | Weighted-Average Exercise Price[1] | Weighted-Average Contractual Life | Aggregate Intrinsic Value |
|---|---|---|---|---|
| | | | (in years) | (in thousands) |
| Outstanding as of December 31, 2024 | 4,540,264 | $ 12.37 | 1.97 | $ — |
| Granted | — | — | — | — |
| Exercised | — | — | — | — |
| Cancelled | (1,141,155) | 13.46 | — | — |
| Outstanding as of December 31, 2025 | 3,399,109 | 12.00 | 1.31 | — |
| Vested or expected to vest as of December 31, 2025 | 3,399,109 | 12.00 | 1.31 | — |
| Exercisable as of December 31, 2025 | 3,399,109 | $ 12.00 | 1.31 | $ — |

(1) Amounts relating to stock options granted prior to the separation of the Company's soluble guanylate cycle business, and certain other assets and liabilities, into Cyclerion Therapeutics, Inc. (the "Separation") on April 1, 2019 have not been adjusted to reflect the effect of the Separation on the Company's stock price.

The total intrinsic value of options exercised during the year ended December 31, 2024 was $2.0 million. The intrinsic value was calculated as the difference between the fair value of the Company's Class A Common Stock at the date of exercise and the exercise price of the option issued.

The following table sets forth the Company's unrecognized share-based compensation expense, net of estimated forfeitures, as of December 31, 2025, by type of award and the weighted-average period over which that expense is expected to be recognized:

| | Unrecognized Expense, Net of Estimated Forfeitures | Weighted-Average Remaining Recognition Period |
|---|---|---|
| | (in thousands) | (in years) |
| Type of award: | | |
| Time-based RSUs | $ 12,891 | 2.42 |
| Performance-based RSUs | 925 | 1.61 |
| Restricted stock awards | 111 | 0.44 |

The total unrecognized share-based compensation cost will be adjusted for future changes in estimated forfeitures.

## 13. Income Taxes

The Company is subject to U.S. federal, state, and foreign income taxes. The components of income before income taxes during the years ended on December 31, 2025 and 2024 consisted of the following (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| United States | $ 161,155 | $ 167,091 |
| Foreign | (91,130) | (101,893) |
| Income before income taxes | $ 70,025 | $ 65,198 |

The components of the provision for (benefit from) income taxes during the years ended December 31, 2025 and 2024 consisted of the following (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Current taxes: | | |
| Federal | $ — | $ — |
| State | 4,374 | (4,487) |
| Foreign | 833 | 754 |
| Total current taxes | 5,207 | (3,733) |
| | | |
| Deferred taxes: | | |
| Federal | 39,071 | 32,584 |
| State | 1,730 | 35,467 |
| Foreign | — | — |
| Total deferred taxes | 40,801 | 68,051 |
| Income tax expense | $ 46,008 | $ 64,318 |

During the year ended December 31, 2025, the Company recorded income tax expense of $46.0 million, comprised of non-cash tax expense of $40.9 million and cash tax expense of $5.1 million, primarily for state income taxes in certain states in which state taxable income exceeded available net operating losses. During the year ended December 31, 2024, the Company recorded income tax expense of $64.3 million, comprised of non-cash tax expense of $57.8 million and cash tax expense of $6.5 million for state income taxes in certain states in which state taxable income exceeded available net operating losses. Due to the Company's ability to utilize its net operating losses to offset federal taxable income and taxable income in many states, the majority of the Company's tax provision is a non-cash tax expense until the Company's net operating losses have been fully utilized.

A reconciliation of income taxes computed using the U.S. federal statutory rate of 21% to that reflected in the consolidated statements of income, after the adoption of ASU 2023-09, is as follows (in thousands, except percentages):

| | Year Ended December 31, 2025 | |
|---|---|---|
| | Amount | Percent |
| Income tax expense using U.S. federal statutory rate | $ 14,705 | 21.0% |
| State income taxes, net of federal benefit [1] | 4,823 | 6.9% |
| Foreign tax effects | | |
| Switzerland | | |
| Statutory tax rate difference | 12,403 | 17.7% |
| Change in valuation allowance | 6,624 | 9.5% |
| Other | 90 | 0.1% |
| Other foreign jurisdictions | 213 | 0.3% |
| Nontaxable or nondeductible items | | |
| Limitation on executive compensation | (461) | (0.7)% |
| Stock compensation | 6,389 | 9.1% |
| Other | 152 | 0.2% |
| Tax credits | — | 0.0% |
| Change in valuation allowance | 428 | 0.6% |
| Change in unrecognized tax benefits | 686 | 1.0% |
| Other adjustments | (44) | (0.1)% |
| Income tax expense and effective tax rate | $ 46,008 | 65.6% |

(1) State taxes in California, Colorado, Florda, Illinois, Massachusetts, New Jersey, New York, New York City and Pennsylvania comprised the majority of the tax effect in this category.

A reconciliation of income taxes computed using the U.S. federal statutory rate of 21% to that reflected in the consolidated statements of income, prior to the adoption of ASU 2023-09, is as follows (in thousands):

| | Year Ended December 31, 2024 |
|---|---|
| Income tax expense (benefit) using U.S. federal statutory rate | $ 13,692 |
| Foreign tax rate differential | 8,111 |
| Permanent differences | 788 |
| State income taxes, net of federal benefit | 10,992 |
| Executive compensation - Section 162(m) | 2,683 |
| Excess tax benefits | 749 |
| Tax credits | (1,244) |
| Expiring net operating losses and tax credits | 1,187 |
| Effect of change in state tax rate on deferred tax assets and deferred tax liabilities | 1,538 |
| Change in the valuation allowance | 25,564 |
| Other | 258 |
| Income tax expense | $ 64,318 |

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the financial reporting and tax bases of assets and liabilities. These differences are measured using the enacted statutory tax rates that are expected to be in effect for the years in which differences are expected to reverse. Deferred tax assets and liabilities were determined based on the difference between financial statement and tax bases using enacted tax rates in effect for the year in which the differences are expected to reverse.

| | December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Deferred tax assets: | | |
| Net operating loss carryforwards | $ 155,036 | $ 146,978 |
| Tax credit carryforwards | 56,980 | 58,494 |
| Capitalized research and development | 1,528 | 22,350 |
| Share-based compensation | 5,710 | 9,508 |
| Basis difference on collaboration agreement for North America with AbbVie | 3,787 | 3,585 |
| Accruals and reserves | 2,010 | 3,804 |
| Basis difference on Convertible Notes | 240 | 714 |
| Intangible assets | 3,615 | 3,411 |
| Operating lease liability | 3,255 | 3,892 |
| Other | 588 | 1,452 |
| Total deferred tax assets | 232,749 | 254,188 |
| Deferred tax liabilities: | | |
| Fixed assets | (692) | (898) |
| Operating lease right-of-use asset | (2,317) | (2,777) |
| Total deferred tax liabilities | (3,009) | (3,675) |
| Net deferred tax asset | 229,740 | 250,513 |
| Valuation allowance | (126,307) | (106,279) |
| Net deferred tax asset | $ 103,433 | $ 144,234 |

On a periodic basis, the Company reassesses the valuation allowance on its deferred income tax assets, weighing positive and negative evidence to assess the recoverability of the deferred tax assets. As of December 31, 2025 and 2024, the Company maintained a valuation allowance of $126.3 million and $106.3 million, respectively, on deferred tax assets not expected to be realized, related primarily to deferred tax assets acquired in the VectivBio Acquisition comprised primarily of net operating loss carryforwards in Switzerland, as well as certain state net operating losses and state tax credits that are expected to expire prior to utilization.

The valuation allowance increased by $20.0 million during the year ended December 31, 2025, primarily to offset foreign net operating losses incurred in Switzerland.

The valuation allowance increased by $20.6 million during the year ended December 31, 2024 primarily to offset the foreign net operating losses incurred in Switzerland, to offset certain state net operating losses that are expected to expire prior to utilization, and to offset certain US tax credits that are expected to expire prior to utilization.

Subject to the limitations described below, as of December 31, 2025, the Company had federal net operating loss carryforwards of $190.3 million, of which $60.6 million is subject to expiration between 2036 and 2037 and $129.6 million may be carried forward indefinitely. As of December 31, 2025, the Company had state net operating loss carryforwards of $286.5 million to offset future state taxable income, which is subject to expiration at various dates through 2040. The Company also had tax credit carryforwards of $59.7 million as of December 31, 2025 to offset future federal and state income taxes, which is subject to expiration at various dates through 2045. The Company had foreign net operating loss carryforwards of $798.6 million, which are subject to expiration at various dates through 2032.

Utilization of federal and state net operating loss carryforwards and research and development credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that could occur in the future in accordance with Section 382 of the Internal Revenue Code of 1986 (“IRC Section 382”) and with Section 383 of the Internal Revenue Code of 1986, as well as similar state provisions. These ownership changes may limit the amount of net operating loss carryforwards and research and development credit carryforwards that can be utilized annually to offset future taxable income and taxes, respectively. In general, an ownership change, as defined by IRC Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period.

The following table summarizes the changes in the Company's unrecognized income tax benefits for the years ended December 31, 2025 and 2024 (in thousands):

| | December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Balance at the beginning of the period | $ 11,585 | $ 98,218 |
| Increases based on tax positions related to the current period | 4,359 | 4,093 |
| Decreases for tax positions in prior periods | (4,093) | (90,726) |
| Balance at the end of the period | $ 11,851 | $ 11,585 |

The Company had gross unrecognized tax benefits of $11.9 million and $11.6 million as of December 31, 2025 and 2024, respectively. Of the $11.9 million of total unrecognized tax benefits as of December 31, 2025, $7.8 million would, if recognized, affect the Company's effective tax rate, and the remaining amount would not affect the Company's effective tax rate, as it relates to a temporary timing difference. Reserves for uncertain tax positions of $13.1 million and $11.8 million are recorded in other liabilities on the Company's consolidated balance sheets as of December 31, 2025 and 2024, respectively.

The Company recognizes interest and penalties, if any, related to uncertain tax positions in income tax expense. The Company recognized $0.9 million and $0.8 million of interest and penalties related to uncertain tax positions during the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025 and 2024, $6.0 million and $5.1 million of interest and penalties have been accrued, respectively.

The statute of limitations for assessment by the Internal Revenue Service ("IRS") and state tax authorities is open for tax years ended December 31, 2022 through the present, although net operating losses generated from years prior to 2022 could be subject to examination and adjustments to the extent utilized in future years. There are currently no federal or state income tax audits in progress. The statute of limitations for assessment for foreign jurisdictions is open for tax years ended December 31, 2021 through the present.

The Company made the following income tax payments (net of refunds received) during the year ended December 31, 2025 (in thousands):

| | Year Ended December 31, |
|---|---|
| | 2025 |
| US federal | $ * |
| US state and local | |
| California | 1,642 |
| Illinois | * |
| Maryland | 281 |
| New Jersey | 206 |
| New York | * |
| Wisconsin | 218 |
| Other | 983 |
| | 3,330 |
| Foreign | |
| Belgium | 213 |
| Total income tax payments (net of refunds received) | $ 3,543 |

* The amount of income taxes paid during the year does not meet the 5% disaggregation threshold.

**14. Retirement Plans**

Defined Contribution Retirement Plans

The Ironwood Pharmaceuticals, Inc. 401(k) Savings Plan is a defined contribution plan in the form of a qualified 401(k) plan in which substantially all employees are eligible to participate upon employment. Subject to certain IRS limits, eligible employees may elect to contribute from 1% to 100% of their compensation. Company contributions to the plan are at the sole discretion of the Company. During the years ended December 31, 2025 and 2024, the Company provided a matching contribution equal to the greater of: (a) 100% of employee contributions on the first 3% of eligible compensation and 50% of employee contributions on the next 3% of eligible compensation; or (b) 75% of the first $10,000 of employee contributions. During the years ended December 31, 2025 and 2024, the Company recorded $1.2 million and $2.4 million of expense, respectively, related to its 401(k) company match.

Defined Benefit Retirement Plans

The Company maintains a defined benefit plan for employees in Switzerland, as required by local laws. The pension plan provides employees retirement benefits and risk insurance for death and disability. The contributions of employers and employees in general are defined in percentages of the insured's salary. The retirement pension is calculated based on the old-age credit balance on retirement multiplied by the fixed conversion rate. The employee has the option to withdraw the capital on demand. As is customary with Switzerland pension plans, the assets of the plan are invested in a collective fund with multiple employers. The Company has no investment authority over the assets of the plan, which are held and invested by a Switzerland-based financial services provider. The investment strategy of the Swiss Plan is managed by an independent asset manager with the objective of achieving a consistent long-term return which will provide sufficient funding for future pension obligations while limiting risk. The Company updates the estimates used to measure employee benefit obligations in the fourth quarter and upon a remeasurement event to reflect the updated actuarial assumptions.

The defined benefit plan in Switzerland is comprised of a basic plan as of December 31, 2025 and 2024.

During each of the years ended December 31, 2025 and 2024, the Company recognized service cost expense in the amount of $1.0 million. Additionally, during the year ended December 31, 2024, the Company recognized a $2.1 million curtailment due to terminations, which reduced net periodic pension cost.

During the year ended December 31, 2025, the Company recognized an increase in accumulated other comprehensive income of $0.8 million, primarily due to actuarial gains. During the year ended December 31, 2024, the Company recognized decrease in accumulated other comprehensive income of $1.1 million, primarily due to the amortization of previously unrecognized actuarial losses.

During the year ended December 31, 2025, employer contributions and employee contributions were $0.7 million and $0.7 million, respectively, and benefits paid, inclusive of settlements, and net of deposits from pension plan assets totaled $6.8 million. During the year ended December 31, 2024, employer contributions and employee contributions were $0.8 million and $0.8 million, respectively, and benefits paid, inclusive of settlements, and net of deposits from pension plan assets totaled $18.1 million. The Company estimates future benefit payments from 2026 to 2030 to range from $0.8 million to $1.2 million per year, and from 2031 and thereafter to be $4.6 million.

As of December 31, 2025, the total fair value of pension plan assets was $13.0 million and the fair value of projected benefit obligations was $15.5 million, resulting in a net liability status of $2.5 million recorded as other liabilities. As of December 31, 2024, the total fair value of pension plan assets was $15.7 million and the fair value of projected benefit obligations was $18.5 million, resulting in a net liability status of $2.8 million recorded as other liabilities. The discount rate used in determining the projected benefit obligation as of December 31, 2025 and 2024 were 1.30% and 1.00%, respectively. The accumulated benefit obligation was $15.0 million and $17.9 million as of December 31, 2025 and 2024, respectively.

The pension plan assets are predominantly comprised of Level 2 assets in the fair value hierarchy, primarily consisting of fixed income, equities and real estate, except for certain mortgage-backed securities valued at $1.8 million and $1.9 million as of December 31, 2025 and 2024, respectively, which are Level 3 assets in the fair value hierarchy.

## 15. Workforce Reductions and Restructuring

In June 2023, the Company commenced the elimination of certain positions in connection with the VectivBio Acquisition. The majority of the eliminations were substantially completed during the year ended December 31, 2023. The Company recorded $0.2 million and $2.6 million of restructuring expenses, which are primarily comprised of employee severance, benefits and related costs, during the year ended December 31, 2025 and 2024, respectively.

In January 2025, following an analysis of its strategy and core business needs, and in an effort to streamline focus and support the continued development of the Company's pipeline, the Company commenced a reduction in the Company's workforce of approximately 50%, primarily consisting of field-based sales employees. The reduction in workforce was substantially completed during the first quarter of 2025. During the year ended December 31, 2025, the Company recorded $17.6 million of restructuring expenses, primarily comprised of severance, benefits, and related costs.

In August 2025, the Company eliminated certain positions supporting apraglutide commercialization efforts, in consideration of delays in development timelines. The reduction in workforce was comprised of 10 positions and was completed during the third quarter of 2025. During the year ended December 31, 2025, the Company recorded $2.4 million of restructuring expenses, primarily comprised of severance, benefits, and related costs.

The following table summarizes the accrued liabilities activity recorded in connection with the reductions in workforce and related restructuring activities during the year ended December 31, 2025 and 2024, respectively (in thousands):

| | Amounts Accrued at December 31, 2024 | Charges | Amount Paid | Adjustments | Amounts Accrued at December 31, 2025 |
|---|---|---|---|---|---|
| January 2025 field-based sales employees reduction | $ — | $ 18,011 | $ (17,576) | $ (363) | $ 72 |
| August 2025 commercial-related workforce reduction | — | 2,224 | (1,312) | (222) | 690 |
| VectivBio Acquisition-related workforce reduction | 615 | 415 | (923) | (96) | 11 |
| Total | $ 615 | $ 20,650 | $ (19,811) | $ (681) | $ 773 |

| | Amounts Accrued at December 31, 2023 | Charges | Amount Paid | Adjustments | Amounts Accrued at December 31, 2024 |
|---|---|---|---|---|---|
| Headquarters-based workforce reduction | $ 270 | $ — | $ (270) | $ — | $ — |
| VectivBio Acquisition-related workforce reduction | 8,102 | 2,612 | (9,990) | (109) | 615 |
| Total | $ 8,372 | $ 2,612 | $ (10,260) | $ (109) | $ 615 |

## 16. Segment Reporting

The Company operates in one reportable business segment—human therapeutics. The human therapeutics segment revenues are generated primarily through collaborative arrangements and license agreements related to research and development and commercialization of linaclotide. The accounting policies of the human therapeutics segment are the same as those described in the summary of significant accounting policies.

The Company has identified the Chief Executive Officer and the Chief Financial Officer as the chief operating decision-maker ("CODM"). The CODM uses consolidated net income (loss) to understand and evaluate the Company's operating performance and trends, to prepare and approve the annual budget, and to develop short-term and long-term operating plans. Revenues, costs and expenses, other income (expense), and income tax expense are provided to the CODM as presented in the statement of income (loss). Total assets are not reviewed by the CODM when evaluating the segment's performance.

**17. Selected Quarterly Financial Data (Unaudited)**

The following table contains quarterly financial information for the years ended December 31, 2025 and 2024. The Company believes that the following information reflects all normal recurring adjustments necessary for a fair presentation of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period.

| | First Quarter | Second Quarter | Third Quarter | Fourth Quarter | Total Year |
|---|---|---|---|---|---|
| | (in thousands, except per share data) | | | | |
| **2025** | | | | | |
| Total revenues | $ 41,143 | $ 85,239 | $ 122,060 | $ 47,709 | $ 296,151 |
| Total cost and expenses | 70,251 | 39,918 | 46,576 | 40,904 | 197,649 |
| Other income (expense), net | (7,164) | (7,499) | (7,464) | (6,350) | (28,477) |
| Net income (loss) | (37,386) | 23,599 | 40,080 | (2,276) | 24,017 |
| Comprehensive income (loss) | (38,015) | 21,279 | 40,392 | (1,622) | 22,034 |
| Net income (loss) per share—basic [(1)] | (0.23) | 0.15 | 0.25 | (0.01) | 0.15 |
| Net income (loss) per share—diluted [(1)] | (0.23) | 0.14 | 0.23 | (0.01) | 0.15 |

(1) The summation of quarterly basic and diluted net income per share does not equate to the calculation for the full fiscal year, as quarterly calculations are performed on a discrete basis.

| | First Quarter | Second Quarter | Third Quarter | Fourth Quarter | Total Year |
|---|---|---|---|---|---|
| | (in thousands, except per share data) | | | | |
| **2024** | | | | | |
| Total revenues | $ 74,877 | $ 94,396 | $ 91,592 | $ 90,545 | $ 351,410 |
| Total cost and expenses | 63,857 | 69,419 | 65,956 | 59,054 | 258,286 |
| Other income (expense), net | (6,062) | (6,101) | (8,267) | (7,496) | (27,926) |
| Net income (loss) | (4,162) | (860) | 3,646 | 2,256 | 880 |
| Comprehensive income (loss) | (2,053) | (408) | 2,064 | 5,231 | 4,834 |
| Net income (loss) per share—basic [(1)] | (0.03) | (0.01) | 0.02 | 0.01 | 0.01 |
| Net income (loss) per share—diluted [(1)] | (0.03) | (0.01) | 0.02 | 0.01 | 0.01 |

(1) The summation of quarterly basic and diluted net income per share does not equate to the calculation for the full fiscal year, as quarterly calculations are performed on a discrete basis.