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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2023

OR

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

For the transition period from _____ to

Commission file number: 001-39094

PHATHOM PHARMACEUTICALS, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**82-4151574**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
100 Campus Drive, Suite 102 Florham Park, New Jersey	**07932**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (877) 742-8466

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	**PHAT**	**The 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 Section 15(d) of the Act. Yes ☐ No ☒

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

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

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

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

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

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

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

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

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

As of June 30, 2023, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $526.0 million, based on the closing price of the registrant's common stock on the Nasdaq Global Select Market of $14.32 per share.

As of March 4, 2024, the registrant had 58,477,351 shares of common stock ($0.0001 par value) outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain sections of the registrant's definitive proxy statement for the 2024 annual meeting of stockholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Form 10-K are incorporated by reference into Part III of this Form 10-K.

PHATHOM PHARMACEUTICALS, INC.

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PART I

This annual report on Form 10-K contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this annual report, including statements regarding our future results of operations and financial position, business strategy, research and development plans and costs, the timing and likelihood of regulatory filings and approvals, commercialization plans, pricing and reimbursement, the potential to develop future product candidates, the timing and likelihood of success of the plans and objectives of management for future operations, and future results of anticipated product development efforts, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. This annual report on Form 10-K also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other similar expressions. The forward-looking statements in this annual report are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, operating results, business strategy, and short term and long term business operations and objectives. These forward-looking statements speak only as of the date of this annual report and are subject to a number of risks, uncertainties and assumptions, including those described in Part I, Item 1A, “Risk Factors.” The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

This annual report includes trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, trademarks and tradenames referred to in this annual report appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or that the applicable owner will not assert its rights, to these trademarks and tradenames.

We maintain a website at www.phathompharma.com, to which we regularly post copies of our press releases as well as additional information about us. Our filings with the Securities and Exchange Commission, or SEC, are available free of charge through our website as soon as reasonably practicable after being electronically filed with or furnished to the SEC. Information contained in our website does not constitute a part of this report or our other filings with the SEC.

Item 1. Business

Overview

We are a biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal, or GI, diseases. Our approved products, VOQUEZNA®, VOQUEZNA® TRIPLE PAK® and VOQUEZNA® DUAL PAK®, contain vonoprazan, an oral small molecule potassium-competitive acid blocker, or PCAB. PCABs are a novel class of medicines that block acid secretion in the stomach. Vonoprazan is the first gastric anti-secretory agent from a novel class approved in the United States, Europe, or Canada in over 30 years, and has shown rapid, potent, and durable anti-secretory effects. Vonoprazan has also demonstrated clinical benefits over the current standard of care as a single agent in the treatment of erosive gastroesophageal reflux disease, or Erosive GERD, and in combination with antibiotics for the treatment of *Helicobacter pylori*, or *H. pylori*, infection. Takeda Pharmaceutical Company Limited, or Takeda, developed vonoprazan and has received marketing approval in numerous countries in Asia and Latin America as well as Russia. Vonoprazan generated approximately $850 million in net sales in its seventh full year on the market since its approval in Japan in late 2014. In May 2019, we in-licensed the U.S., European, and Canadian rights to vonoprazan from Takeda.

In 2021 we reported positive topline data from two pivotal Phase 3 clinical trials for vonoprazan: one for the treatment of *H. pylori* infection, or PHALCON-HP, and a second for the treatment of Erosive GERD, or PHALCON-EE. These data are supplemented by the extensive existing clinical data generated by Takeda as part of its development program for vonoprazan in Japan and other markets. In September 2021, we submitted two new drug applications, or NDAs, for combination packs that contain vonoprazan for the treatment of *H. pylori* infection in adults, one in combination with amoxicillin and clarithromycin (vonoprazan triple therapy) and the other in combination with amoxicillin alone (vonoprazan dual therapy). In May 2022, the U.S. Food and Drug Administration, or FDA, approved the NDAs for vonoprazan triple therapy, under the brand name VOQUEZNA TRIPLE PAK, and vonoprazan dual therapy, under the brand name VOQUEZNA DUAL PAK. Based on our qualified infectious disease product, or QIDP, designations for VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK, we received an extension of the five years of the new chemical entity, or NCE, exclusivity based on the vonoprazan component in those NDAs. We believe the extended NCE exclusivity should apply to any other approved or future products containing vonoprazan we develop and for which we obtain FDA approval.

While the NDAs for VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK were still under review by the FDA, in March 2022, we submitted an additional NDA for vonoprazan, under the brand name VOQUEZNA, as a treatment for adults for the healing of all grades of Erosive GERD, maintenance of healing of all grades of Erosive GERD, and relief of heartburn associated with Erosive GERD. In August 2022, following approval of VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK but before launch, and while the NDA for VOQUEZNA for Erosive GERD was still under review, we announced that trace levels of a nitrosamine impurity, *N*-nitroso-vonoprazan, or NVP, were present in our initial commercial drug product for VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK. After identifying this impurity, and prior to launching VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK, we submitted supplements to our approved NDAs with the goal of addressing this issue. However, in February 2023, we received complete response letters from the FDA relating both to our Erosive GERD NDA and to the NDA supplements for our approved *H. pylori* NDAs. The complete response letters formalized the FDA's prior request that we provide additional stability data to demonstrate that levels of NVP will remain at or below 96 ng/day, the acceptable daily intake level, or AI, for NVP established by the FDA, throughout the proposed shelf life of the product. No additional deficiencies were cited by the FDA in the complete response letters. In May 2023, we resubmitted our Erosive GERD NDA to the FDA, and in June 2023 we submitted new prior approval supplements to our approved *H. pylori* NDAs. On October 27 and November 1, 2023, the FDA approved, the prior approval supplements to our *H. pylori* NDAs and our Erosive GERD NDA, respectively. As a result, we initiated commercial launch for VOQUEZNA for both the Erosive GERD and *H. pylori* indications, and VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK for treatment of *H. pylori* infection in the fourth quarter of 2023.

VOQUEZNA Commercial Launch Initiated in November 2023

VOQUEZNA® 20 mg & 10 mg tablets
30-count bottles

We are also continuing to develop vonoprazan as a treatment for heartburn symptoms associated with Non-Erosive GERD. In January 2023, we reported positive topline results from PHALCON-NERD-301, a Phase 3 study evaluating the safety and efficacy of vonoprazan for the daily treatment of adults with Non-Erosive GERD, and in August 2023, we announced successful completion of the 20-week extension period of PHALCON-NERD-301. Based on the results of this study, in September 2023, we submitted an NDA seeking approval of vonoprazan as a once-daily treatment for heartburn symptoms associated with Non-Erosive GERD in adults. The FDA has assigned this NDA a Prescription Drug User Fee Act, or PDUFA, target action date of July 19, 2024, and, if approved, we anticipate launching VOQUEZNA for this new indication in the third quarter of 2024. In addition, in 2024 we plan to initiate a Phase 3 trial evaluating the novel dosing regimen of vonoprazan as an as-needed treatment for episodic heartburn relief in patients with Non-Erosive GERD, a dosing regimen not approved in the United States for proton pump inhibitors, or PPIs. This trial would constitute our fourth Phase 3 trial for vonoprazan. In February 2022, we reported positive topline results from PHALCON-NERD-201, a Phase 2 proof-of-concept study evaluating this novel dosing regimen.

While we initially focused on the development of vonoprazan for the treatment of GERD and *H. pylori* infection, we believe there are opportunities to develop vonoprazan in other indications in our licensed territories. For example, we plan to expand the clinical development of vonoprazan in the U.S. into eosinophilic esophagitis, or EoE, the most common type of eosinophilic gastrointestinal disease. EoE is an autoimmune disease with significant unmet need and can result in trouble swallowing, chest pain, vomiting and impaction of food in the esophagus, a medical emergency. There are only two FDA-approved treatments for EoE. Although not approved for this indication, PPIs are often prescribed as a first-line therapy for the treatment of EoE. Given the limited choices of therapies for EoE and vonoprazan's demonstrated potential, we believe EoE is an important indication for future study and we expect to initiate a Phase 2 trial evaluating vonoprazan as a treatment for EoE in adult and adolescent patients later in 2024.

We are independently commercializing VOQUEZNA, VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK in the United States. We plan to evaluate commercial partnerships for vonoprazan in Europe and Canada, expand development of vonoprazan into other indications, dosing regimens and alternative formulations and packaging, and in-license or acquire additional clinical or commercial stage product candidates for the treatment of GI diseases in a capital efficient manner.

GERD and *H. pylori* infection are two of the most common acid-related GI diseases and impact millions of people. The prevalence of GERD is estimated to be 20% of the U.S. population and 15% of the population in the five major countries in Europe (France, Germany, Italy, Spain and the United Kingdom), or collectively, the EU5. GERD is a disease that develops when the reflux of acidic stomach contents causes troublesome symptoms and/or complications. An estimated 17 million adults in the U.S. have Erosive GERD and more than twice that number, or 38 million adults, are believed to suffer from Non-Erosive GERD. *H. pylori* is a bacterial pathogen that infects approximately 35% of the U.S. population and 45% of the EU5 population. As a result of the chronic

inflammation induced by *H. pylori* infection, approximately 20% of infected patients will develop a range of pathologies, including dyspepsia, peptic ulcer disease, gastric cancer, and mucosa-associated lymphoid tissue or MALT, lymphoma.

Over the last thirty years, the proton pump inhibitor, or PPI, class, has been the standard of care for the treatment of acid-related GI diseases. PPIs are generally used as a single agent for the treatment of GERD and in combination with antibiotics for the treatment of *H. pylori* infection. The PPI class includes drugs such as Prilosec (omeprazole), Nexium (esomeprazole), and Prevacid (lansoprazole). Prior to the introduction of generic and over-the-counter, or OTC, alternatives, annual PPI class sales reached approximately $12.5 billion in the United States, with peak sales for individual brands of approximately $3.7 billion for Prilosec, $3.5 billion for Nexium, and $3.4 billion for Prevacid.

While PPIs are the current standard of care and have experienced significant commercial success, they have significant limitations that result in a large unmet medical need. In GERD, PPI therapy is suboptimal for many patients due to the slow onset and insufficient duration of acid control which can lead to inadequate symptom relief. Approximately 15% to 45% of GERD patients remain inadequately treated with PPIs. In the treatment of *H. pylori* infection, the standard of care consists of a combination of a PPI and at least two oral antibiotics. However, increasing antibiotic resistance has resulted in declining eradication rates with PPI-based therapy. We believe these unmet medical needs are in part driven by limitations associated with the mechanism of action and pharmacokinetics of PPIs.

PPIs reduce gastric acid secretion by irreversibly binding to and inhibiting active proton pumps expressed on the parietal cells. Proton pumps of parietal cells become activated during a meal and thus, oral intake of PPIs prior to meal is required ideally to achieve maximal efficacy. PPIs also require activation by gastric acid, but they are unstable in the presence of acid and therefore enteric coating is necessary to protect them from degradation in the stomach when given orally. All these factors, combined with the short circulating half-life of PPIs, limits their efficacy. Additionally, because proton pumps continuously switch between active and inactive states, multiple doses of PPIs are required to inhibit enough proton pumps to achieve a clinical benefit. As a result, PPIs have a relatively slow onset of action and limited potency and duration of effect, which may result in patients experiencing only partial relief, increasing PPI dosage, and/or cycling through multiple PPIs seeking relief.

Vonoprazan has a differentiated mechanism of action from PPIs. Unlike PPIs, vonoprazan:

- is stable in the presence of acid;
- does not require activation by gastric acid;
- is designed to selectively concentrate in the parietal cells in both the resting and stimulated states, bind to the active pumps and remain associated with the active and inactive pumps;
- can be taken independent from meal intake;
- binds to the pumps in a noncovalent and reversible manner; and
- has a long plasma half-life that replenishes the drug at the site of action over the course of the day.

These factors have enabled vonoprazan to demonstrate more rapid and potent acid suppression versus the PPIs esomeprazole and lansoprazole in human subjects two to three hours after oral dosing and maintain target acid inhibition over a 24-hour period in randomized, open-label, crossover clinical trials. In contrast, PPIs require three to five days to reach steady state acid suppression and do not reliably maintain target acid inhibition over a 24-hour period. In addition, vonoprazan demonstrated approximately 10-to-100-fold better acid control compared to lansoprazole and esomeprazole.

Vonoprazan has demonstrated clinical advantages over the PPI lansoprazole in the treatment of Erosive GERD and *H. pylori* infection in completed Phase 3 clinical trials conducted in the United States and Europe, including:

- more complete healing of Erosive GERD in patients with moderate to severe disease after two weeks;
- more durable healing of Erosive GERD in patients with all grades of disease;

- higher *H. pylori* eradication rates in combination with antibiotics compared to standard of care triple therapy; and
- more flexible dosing, including dosing independent of food and time of day.

Moreover, we believe that vonoprazan's anti-secretory mechanism has the potential to contribute to additional clinical advantages over PPIs such as rapid symptom relief through "as needed" dosing in the treatment of patients with Non-Erosive GERD.

Erosive GERD. FDA approval of VOQUEZNA for the healing and maintenance of healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults was based on the results from PHALCON-EE, our Phase 3 clinical trial conducted in the United States and Europe. This trial assessed vonoprazan versus lansoprazole in the healing and maintenance of healing of adult patients with Erosive GERD. In PHALCON-EE, vonoprazan met its primary healing endpoint demonstrating non-inferiority to lansoprazole in the number of patients who showed complete healing of Erosive GERD after eight weeks of treatment. Further, in a pre-specified secondary endpoint, vonoprazan demonstrated superior healing after two weeks of treatment in patients with moderate to severe Erosive GERD compared to lansoprazole. After two weeks of treatment, 70% of patients with moderate to severe Erosive GERD were healed after treatment with vonoprazan versus 53% with lansoprazole (p=0.0008). In the maintenance phase of the trial, both doses of vonoprazan (10 mg and 20 mg) met the primary endpoint of non-inferiority compared to lansoprazole in the number of all patients who maintained healing of Erosive GERD through week 24. Further, both vonoprazan doses also met a pre-specified secondary endpoint demonstrating superiority of maintenance of healing versus lansoprazole (79% for vonoprazan 10 mg, 81% for vonoprazan 20 mg compared to 72% for lansoprazole 15 mg) (p<0.0001 for both non-inferiority comparisons; p=0.0436 for vonoprazan 10 mg superiority comparison; p=0.0272 for vonoprazan 20 mg superiority comparison). Both vonoprazan doses also met the pre-specified secondary endpoint of demonstrating superiority of the percentage of patients with moderate-to-severe disease who maintained healing of Erosive GERD through week 24 (75% vonoprazan 10 mg, 77% vonoprazan 20 mg v. 61% lansoprazole 15 mg) (p=0.0490 for vonoprazan 10 mg superiority comparison; p=0.0196 for vonoprazan 20 mg superiority comparison).

In PHALCON-EE, vonoprazan 20 mg met the secondary endpoint of showing non-inferiority to lansoprazole 30 mg in the mean percentage of 24-hour heartburn free days over the healing period, and both vonoprazan doses met the secondary endpoint of showing non-inferiority to lansoprazole 15 mg in the mean percentage of 24-hour heartburn free days over the maintenance period. Finally, vonoprazan 20 mg was also compared to lansoprazole 30 mg in a superiority test for onset of sustained resolution of heartburn by day three of the healing phase but did not achieve statistical significance (p=0.2196).

Symptomatic Non-Erosive gastroesophageal reflux disease (Non-Erosive GERD). In PHALCON-NERD-301, a Phase 3 study evaluating the efficacy and safety of vonoprazan for the daily treatment of adults with Non-Erosive GERD, both doses of vonoprazan (10 mg and 20 mg) met the primary endpoint evaluating the mean percentage of 24-hour heartburn-free days through week four by demonstrating statistical significance versus placebo (mean 45% vonoprazan 10 mg, 44% vonoprazan 20 mg, compared to 28% for placebo; p<0.0001 for both vonoprazan 10 mg and 20 mg versus placebo). The median percentage of 24-hour heartburn-free days was 48%, 46% and 17% for vonoprazan 10 mg, vonoprazan 20 mg, and placebo, respectively. Patients randomized to vonoprazan 10 mg and 20 mg during the initial 4-week period remained on their blinded treatment assignment for a 20-week extension period. The mean percentage of heartburn free days reported over the 20-week extension period for these patients was 63% for vonoprazan 10 mg and 61% for vonoprazan 20 mg. Additionally, patients randomized to placebo during the initial 4-week period were re-randomized to either vonoprazan 10 mg or 20 mg for the 20-week extension period. For these patients, the mean percentage of heartburn free days reported over the 20-week extension period was 62% for vonoprazan 10 mg and 63% for vonoprazan 20 mg. Based on the results of PHALCON-NERD-301, in September 2023, we submitted an NDA seeking approval of vonoprazan as a daily treatment of heartburn associated with symptomatic Non-Erosive GERD in adults for which the FDA has assigned a PDUFA target action date of July 19, 2024. If approved, we would expect to launch vonoprazan in this new indication in the third quarter of 2024.

In PHALCON-NERD-201, a Phase 2 study evaluating three doses of vonoprazan (10 mg, 20 mg, and 40 mg) as an as needed therapy for relief of episodic heartburn in subjects with Non-Erosive GERD, all three vonoprazan doses successfully met the primary endpoint evaluating the percentage of heartburn episodes completely relieved within three hours with relief sustained for over 24 hours and were statistically significant (p<0.0001) when compared to placebo. Within three hours, vonoprazan 10 mg, 20 mg, and 40 mg achieved complete and sustained relief in 56%, 61% and 70% of evaluable heartburn episodes, respectively, as compared to 27% of episodes for placebo. An evaluable heartburn episode is a heartburn episode for which the participant completes a minimum of one timed assessment after taking study medication.

Based on the positive PHALCON-NERD-201 results, we expect to commence a Phase 3 trial in 2024, our fourth Phase 3 trial for vonoprazan, evaluating VOQUEZNA as an "as needed" treatment for episodic heartburn relief in patients with symptomatic Non-Erosive GERD, a dosing regimen not approved in the United States for PPIs.

H. pylori. The FDA's approval of VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK was based on the results from PHALCON-HP, our Phase 3 clinical trial in the United States and Europe studying two vonoprazan-based treatment regimens for the eradication of *H. pylori* infection, both of which successfully met their primary and all secondary endpoints. The trial studied vonoprazan triple therapy and vonoprazan dual therapy compared to lansoprazole in combination with amoxicillin and clarithromycin, or lansoprazole triple therapy. The objective of the PHALCON-HP trial was to compare eradication rates in all treated subjects as well as in two pre-identified subgroups of patients: those patients with clarithromycin resistant strains of *H. pylori,* and those patients who did not have clarithromycin or amoxicillin resistant strains of *H. pylori.* For regulatory purposes, the primary endpoint of this study was a non-inferiority comparison in the non-resistant subgroup for each of vonoprazan triple therapy and vonoprazan dual therapy compared to lansoprazole triple therapy.

In PHALCON-HP, both vonoprazan-based regimens successfully met their primary endpoints. In the modified intent-to-treat, or mITT, population, *H. pylori* eradication rates were 84.7% for vonoprazan triple therapy and 78.5% for vonoprazan dual therapy compared to 78.8% with lansoprazole triple therapy ($p<0.0001$ and $p=0.0073$, respectively, for non-inferiority). In the pre-specified per protocol population, a subset of the mITT population comprised of patients who were protocol compliant, *H. pylori* eradication rates were 90.4% with vonoprazan triple therapy and 81.2% with vonoprazan dual therapy compared to 82.1% with lansoprazole triple therapy ($p<0.0001$ and $p=0.0155$, respectively, for non-inferiority).

In PHALCON-HP vonoprazan triple therapy and vonoprazan dual therapy also met all secondary endpoints, demonstrating superior eradication rates versus lansoprazole triple therapy in all patients and in the subgroup of patients with clarithromycin resistant strains of *H. pylori*. Among all patients, the *H. pylori* eradication rate of vonoprazan triple therapy was superior to that of lansoprazole triple therapy in both the mITT population (80.8% vs. 68.5%; $p=0.0001$) and the per protocol population (85.7% vs. 70.0%; $p<0.0001$). In the subset of patients with *H. pylori* strains resistant to clarithromycin, the *H. pylori* eradication rate with vonoprazan triple therapy was superior to that of lansoprazole triple therapy in both the mITT population (65.8% vs. 31.9%; $p<0.0001$) and the per protocol population (67.2% vs. 29.0%; $p<0.0001$).

Among all patients, the *H. pylori* eradication rate of vonoprazan dual therapy was superior to that of lansoprazole triple therapy in both the mITT population (77.2% vs. 68.5%; $p=0.0127$) and the per protocol population (81.1% vs. 70.0%; $p=0.0027$). The *H. pylori* eradication rate of vonoprazan dual therapy was also superior to that of lansoprazole triple therapy in the subset of patients with *H. pylori* strains resistant to clarithromycin in both the mITT population (69.6% vs. 31.9%; $p<0.0001$) and the per protocol population (79.5% vs. 29.0%; $p<0.0001$).

Our Management

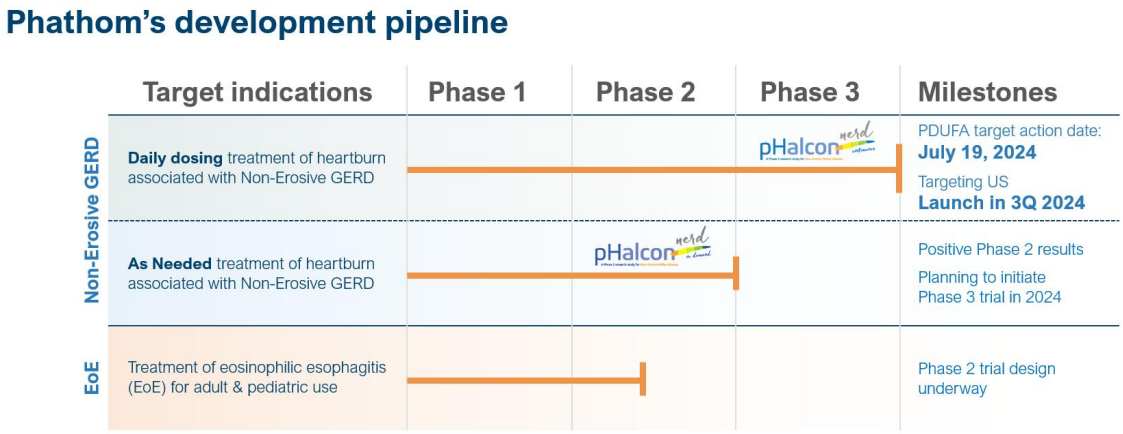
Our management team has deep expertise in developing and commercializing therapeutics, including anti-secretory agents, and direct experience developing vonoprazan at Takeda. Our Chief Executive Officer, Terrie Curran, has more than 25 years of experience in the biopharmaceutical industry. Ms. Curran served as President, Global Inflammation and Immunology (I&I) Franchise and as a member of the Executive Committee at Celgene Corporation from 2017 to 2019. Ms. Curran joined Celgene in 2013 as the U.S. Commercial Head of the I&I Franchise, where she built the capabilities and recruited the teams that executed the successful launch of OTEZLA, which was sold to Amgen in November 2019 for $13.4 billion. Molly Henderson, our Chief Financial and Business Officer, has over 20 years of extensive financial experience in the biopharmaceutical industry. Ms. Henderson previously held the role of Chief Financial Officer at various companies such as UroGen Pharma, Advaxis, Inc., and Iovance Biotherapeutics, Inc. where she oversaw all aspects of the corporate finance strategy, investor relations and capital raising. Martin Gilligan, our Chief Commercial Officer, has more than 30 years in the industry working at both large and small biopharmaceutical companies. His commercial experience includes launching specialty and primary care products, both in the U.S. and globally. Prior to joining Phathom, Mr. Gilligan worked at Celgene Corporation, and was Corporate Vice President in the I&I Franchise, responsible for marketing, market access, early product development, and business development.

Azmi Nabulsi, M.D., M.P.H., our Chief Operating Officer, was Deputy Chief Medical and Scientific Officer at Takeda. Our Chief Development Sciences Officer, Tom Harris, was Senior Vice President and Head of Global Regulatory at Takeda. Both Dr. Nabulsi and

Mr. Harris were extensively involved with the development of vonoprazan at Takeda and continue to lead our ongoing development efforts for VOQUEZNA.

Our Pipeline

The following chart summarizes our current development programs:



Our Strategy

Our mission is to improve the lives of people suffering from GI diseases. Our strategy is initially focused on commercializing and further developing vonoprazan as a first-in-class PCAB in the United States for the treatment of acid-related GI diseases. Key elements of this strategy include:

- ***Successfully commercialize VOQUEZNA, VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK in the U.S***. We have built a first-class commercial infrastructure including a national sales force to support the commercial launch of VOQUEZNA for treatment of Erosive GERD and *H. pylori* infection, and VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK for treatment of *H. pylori* infection, which commenced in the fourth quarter of 2023. Further, subject to FDA approval, we would expect to launch vonoprazan in the U.S. for daily treatment of heartburn associated with symptomatic Non-Erosive GERD in the third quarter of 2024. We believe we can successfully commercialize these products in the United States with a focused sales force targeting prescribers of treatments for GERD and *H. pylori* infection, particularly gastroenterologists and primary care physicians. Through our national sales force we plan to target approximately 52,000 prescribers who, on average, have written close to 1,200 PPI prescriptions annually. We believe we have an opportunity to achieve significant share of voice and exposure to physicians given the scarcity of actively marketed anti-secretory medicines. Given the limitations of PPIs and current unmet need, we believe the commercial opportunity for VOQUEZNA is substantial. Moreover, we believe all our U.S. approved products containing vonoprazan, including VOQUEZNA, should benefit from the 10-year period of non-patent NCE exclusivity that commenced upon approval of our initial products for *H. pylori* infection in May 2022.

- ***Advance the clinical development of vonoprazan as an "as needed" treatment for Non-Erosive GERD.*** In addition to seeking approval of vonoprazan as a daily treatment for Non-Erosive GERD, we are also pursuing the development of vonoprazan as an "as needed" treatment of Non-Erosive GERD. In January 2023, we reported positive topline results for the primary endpoint of PHALCON-NERD-301, a Phase 3 study evaluating the efficacy and safety of vonoprazan for the daily treatment of heartburn associated with Non-Erosive GERD in adults, and in 2024 we plan to initiate a Phase 3 trial studying the novel dosing regimen of vonoprazan as an as needed treatment for episodic heartburn relief in adults with heartburn associated with Non-Erosive GERD, a dosing regimen not approved in the U.S. for PPIs. The pursuit of this novel dosing regimen is supported by the positive topline results we reported in February 2022 for PHALCON-NERD-201, a

Phase 2 study evaluating various doses of vonoprazan and placebo as an as needed treatment for adults with Non-Erosive GERD.

- ***Evaluate commercial partnerships to maximize the vonoprazan opportunity outside of the United States***. To address the opportunity for vonoprazan in Europe and Canada, we plan to evaluate one or more partners with existing commercial infrastructure and expertise in these markets. We believe this strategy could allow us to realize the value of the market opportunity in Europe and Canada while focusing our resources on the U.S. market.

- ***Further expand the development of vonoprazan across indications, including EoE, and alternative formulations and packaging***. We plan to pursue vonoprazan lifecycle extension strategies in areas with clear unmet need, clinical rationale, and commercial justification. For example, based on feedback from the FDA on our proposed development plan to study vonoprazan as a treatment for EoE, we plan to commence a Phase 2 trial studying vonoprazan as a treatment for EoE in adults and adolescent patients later in 2024. Potential indications for development in addition to EoE may include treatment of gastric and duodenal ulcers, and Barrett's esophagus; and alternative formulations and packaging include orally disintegrating tablets and other oral dosage forms for patients with difficulty swallowing, and an intravenous formulation for in-hospital applications. Additionally, we believe that vonoprazan has the ideal profile for an OTC product because of the potential for as needed symptom relief and a well-tolerated safety profile.

- ***In-license or acquire additional clinical or commercial stage product candidates for the treatment of GI diseases in a capital efficient manner***. We intend to take advantage of our management team's GI expertise to opportunistically in-license or acquire additional innovative therapies for diseases treated by gastroenterologists. We plan to leverage our development and planned commercial infrastructure to support multiple assets targeting GI indications.

Acid-Related GI Diseases

Overview

Gastric acid is a digestive fluid formed in the stomach. The highly acidic environment of the stomach causes the unfolding, or denaturing, of food proteins that are subsequently broken down by gastric enzymes. Gastric acid is secreted by the hydrogen potassium ATPase enzyme, which is known as the proton pump. Proton pumps are expressed on the channeled surfaces, or canaliculi, of parietal cells in the stomach, which secrete acid. Proton pumps are continuously synthesized and switch between active and inactive states in response to various stimuli, such as food. When activated, proton pumps increase acid secretion.

GI diseases where treatment is related to acid control, such as GERD, peptic ulcer disease, Zollinger Ellison syndrome, and *H. pylori* infection, are significant medical problems because of their high prevalence, chronic nature and clinical sequelae. GERD results from the effects of acid on compromised mucosal defenses in the gastrointestinal tract. The reflux of gastric acid into the esophagus produces frequent and/or severe heartburn, indigestion, and reflux symptoms. Chronic GERD may damage esophageal tissue and progress to more severe diseases including Erosive GERD, Barrett's esophagus, and esophageal cancer. GERD and related diseases are associated with impaired quality of life and substantial costs to the healthcare system given their chronic nature and sequelae. In *H. pylori* infection, gastric acid limits the effectiveness of antibiotics used to eradicate infection. Chronic *H. pylori* infection can lead to dyspepsia, peptic ulcer disease, gastric cancer, and MALT lymphoma.

Prevalence

The prevalence of GI diseases is high. Approximately 20% of the U.S. population and 15% of EU5 population report chronic heartburn or regurgitation symptoms potentially related to GERD. We estimate that there are approximately 65 million individuals in the United States and 50 million individuals in the EU5 with GERD. In the United States, GERD is the most common gastroenterology-related outpatient diagnosis. Additionally, approximately 35% of the U.S. population and 45% of the EU5 population are infected with *H. pylori*. We estimate that there are approximately 115 million individuals in the United States and 145 million individuals in the EU5 infected with *H. pylori*.

Prevalence of GERD and *H. pylori* Infection

	GERD		*H. pylori* infection	
	Prevalence	Estimated Population	Prevalence	Estimated Population
United States	20%	65 million	35%	115 million
EU5	15%	50 million	45%	145 million

Treatments

Treatments of acid-related GI diseases aim to provide relief of acute symptoms, healing of damaged tissue, and prevention of long-term clinical sequelae associated with chronic acid exposure. Gastric acidity is measured by the pH scale, a logarithmic scale where 7.0 describes a neutral state and lower levels indicate a higher level of acidity. The pH of the stomach typically ranges from 1.5 to 3.5. In patients with acid-related GI diseases, increasing gastric pH has been shown to improve mucosal healing rates and provide more rapid symptom relief for patients. For example, the duration of time that intra-gastric acidity is greater than pH 3.0 correlates with the healing of duodenal and gastric ulcers, and pH greater than 4.0 is correlated with the healing of Erosive GERD. Similarly, in patients with *H. pylori* infection, a more neutral gastric pH of 6.0 to 8.0 preserves antibiotic function and is optimal for successful eradication.

Drug-induced gastric acid suppression is a key component of the management of acid-related GI diseases. Three classes of drugs with distinct mechanisms of action are principally used for treatment in the United States and Europe: antacids, histamine receptor antagonists, or H2RAs, and PPIs.

Antacids

Antacids, first commercially available in the 1930s, directly neutralize gastric acid to raise intra-gastric pH and can alleviate intermittent, mild symptoms of acid-related GI diseases, such as heartburn, but they are only effective for a short duration and require frequent administrations per day. In addition, antacids do not significantly help heal or prevent complications of acid-related diseases. Antacids include commonly known OTC products, such as Alka-Seltzer, Pepto-Bismol, Rolaids, and TUMS.

Histamine Receptor Antagonists (H2RAs)

H2RAs, first commercially available in the 1970s, decrease gastric acid secretion in order to raise gastric pH. H2RAs represented a dramatic improvement over antacids in the control of gastric acid and consequently in the management of acid-related GI diseases. H2RAs are also generally safe and well-tolerated. Among the H2RA class were the first commercial blockbuster drugs, Pepcid (famotidine), Tagamet (cimetidine), and Zantac (ranitidine). Zantac was the world's highest-selling prescription drug in the mid-1990s, with peak global sales of $3.7 billion and U.S. sales of $2.2 billion. Prior to the launch of generic H2RAs and increasing competition from PPIs, the H2RA class achieved sales of approximately $3.5 billion in the United States. H2RAs achieved commercial success despite clinical limitations, including unreliable 24-hour acid control, poor control of post-meal symptoms, and loss of efficacy over time.

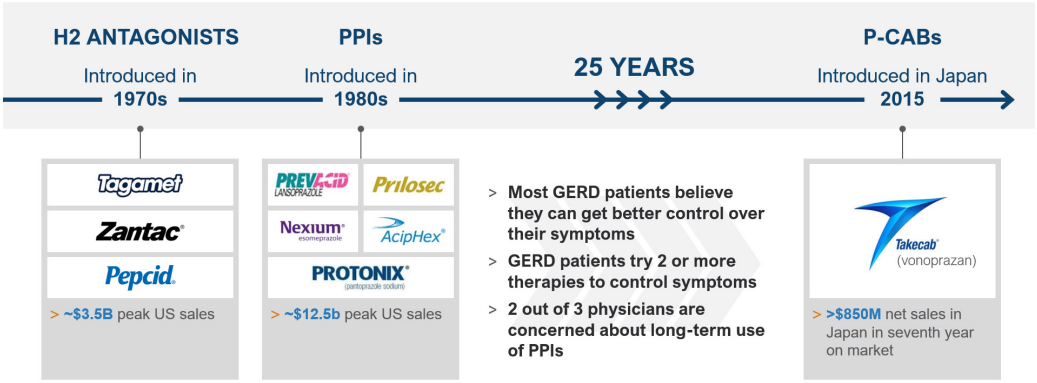
Proton Pump Inhibitors (PPIs)

PPIs, first commercially available in 1989, offered improved acid control over H2RAs. Pharmacodynamic data demonstrated that PPIs maintain gastric pH above target levels for a longer duration than H2RAs. A commonly used benchmark of anti-secretory activity is the percentage of time in a 24-hour period that gastric pH exceeds 4.0, which we refer to as time above pH 4.0, which ranges from 40% to 71% for PPIs versus 33% for H2RAs.

Given this improved pharmacodynamic profile, PPIs demonstrated improved clinical symptom relief and healing over H2RAs. In a meta-analysis of results from 33 randomized clinical trials with over 3,000 GERD patients, a reduction in symptoms was achieved in 83% of patients taking PPIs versus 60% of those on H2RAs. In a second meta-analysis, the eight-week healing rate in patients with Erosive GERD was 82% for PPIs versus 52% for H2RAs.

The PPI class is currently the first-line treatment of acid-related GI diseases. Prior to the introduction and adoption of generic and OTC alternatives, annual PPI class sales reached approximately $12.5 billion in the United States, with peak sales for individual brands of approximately $3.7 billion for Prilosec, $3.5 billion for Nexium, and $3.4 billion for Prevacid. As recently as 2015, the last branded PPI, Dexilant (dexlansoprazole), reached approximately $530 million in sales in the United States despite limited differentiation from other PPIs. While Dexilant demonstrated a modest improvement in time above pH 4.0 compared to other PPIs, the approved dose did not demonstrate consistent superiority in Phase 3 trials against other PPIs for the healing of Erosive GERD and has not been tested against PPIs in other indications. We believe that the commercial success of Dexilant highlights the value to physicians and patients of even incremental improvements over other PPIs.

History of Pharmaceutical Agents for Control of Gastric Acid



PPI Limitations

While PPIs provide clinically meaningful symptom relief and healing for millions of patients suffering from acid-related GI diseases, they are inadequate for many patients. The suboptimal anti-secretory profile of PPIs results in slow onset of symptom relief, breakthrough nighttime or postprandial heartburn, and treatment failure. A recent population-based survey with over 70,000 participants in the United States showed that 55% of patients who reported having GERD symptoms were taking PPIs, with 68% taking them daily, and 54% of those daily PPI users reporting persistent symptoms. This is consistent with earlier studies that have shown that approximately 15% to 45% of GERD patients are inadequately treated with PPIs, experiencing persistent, troublesome symptoms, such as heartburn and regurgitation. In approximately two-thirds of symptomatic GERD patients, reflux symptoms are not adequately controlled after the first dose of a PPI, and nearly 50% of patients still suffer from symptoms three days later. Given these limitations, more than 20% of GERD patients on PPI therapy take their PPI twice daily, which is not FDA approved, or purchase OTC heartburn treatments in addition to their prescription medicine. In a survey of approximately 1,000 GERD patients and 1,000 physicians, approximately one third of GERD patients reported persistent symptoms and were dissatisfied with PPI therapy and 35% of physicians perceived patients as somewhat satisfied to completely dissatisfied with PPI treatment. In addition, in a real world study conducted in 2020 and 2021 evaluating the perspectives and unmet needs of over 400 physicians and patients in the U.S. in the management of acid related disorders, fewer than one-third of the physician participants were satisfied with current treatment options for their patients. Moreover, fewer than 50% of patients in the study reported they were satisfied with their current treatment.

In patients with more severe grades of Erosive GERD, studies with PPIs have reported failure rates of healing of esophageal erosions exceeding 25%. Additionally, recurrence of erosions is common in healed Erosive GERD patients receiving maintenance PPI

therapy. One study reported recurrence in 15% to 23% of patients with less severe Erosive GERD and 24% to 41% of patients with more severe Erosive GERD. We believe that these limitations of PPIs are in part driven by their mechanism of action and pharmacokinetics.

As a result of these PPI limitations, real world data shows that up to 50% of GERD patients treated with a prescription PPI make therapy changes during their treatment journey. Real world data has also identified that 35% of patients treated with a prescription PPI switch to a different PPI after approximately 3 months.

Mechanistic Differences Between PPIs and Vonoprazan

PPIs

After oral dosing, PPIs reach the gastric parietal cells through the bloodstream. PPIs are prodrugs that are converted to their active form in the acidic environment of the secretory canaliculus of the parietal cell but degrade quickly because their active form is unstable in acid. For example, the half-life of omeprazole (Prilosec) is less than 10 minutes at pH 2.0. The active form of a PPI blocks acid production by covalently binding to active proton pumps that have moved to the surface of the secretory canaliculi after activation of the parietal cell with stimuli, such as a meal. Because PPIs bind only to actively secreting pumps, it is generally recommended that they be administered 30 to 60 minutes before a meal to achieve maximal efficacy. Once covalently bound to the proton pumps, the active PPI molecule is no longer available to bind to newly synthesized or activated proton pumps. Furthermore, given the relatively short plasma half-life of most PPIs of one to two hours, resupply of additional PPI molecules from the bloodstream is limited, and newly activated pumps are not inhibited. Due to this profile, PPIs must be dosed over several days to inhibit enough proton pumps to increase gastric pH to a clinically meaningful threshold. Moreover, PPIs have a limited window of efficacy leading to incomplete acid suppression over the 24-hour dosing interval. In addition, PPIs are primarily metabolized by CYP2C19, an enzyme which has significant interpatient metabolic variability based on genotype. As a result, PPI exposure levels in some patients may not achieve target levels, potentially reducing clinical efficacy.

Vonoprazan

Vonoprazan, a PCAB, has a differentiated mechanism of action relative to PPIs. Vonoprazan is designed to selectively concentrate in the parietal cell in both the resting and stimulated states. In contrast to most PPIs, vonoprazan does not require gastric acid for activation, remains stable in the presence of gastric acid, binds to the active proton pumps in a noncovalent and reversible manner, can be taken independent from meals and remains associated with the active and inactive proton pumps, and remains in the secretory canaliculus where it continues to inhibit acid secretion over an extended period. Vonoprazan's prolonged effect is also maintained through a slow dissociation rate from the proton pumps and resupply from the bloodstream due to its approximate seven-hour half-life. These characteristics generally allow vonoprazan to rapidly achieve target 24-hour acid suppression within two to three hours of a single dose, unlike PPIs that require three to five days to achieve stable acid suppression. In addition, vonoprazan is primarily metabolized by CYP3A4/5, an enzyme which has less genetic variability than CYP2C19, and may exhibit more consistent activity than PPIs across U.S. and European populations.

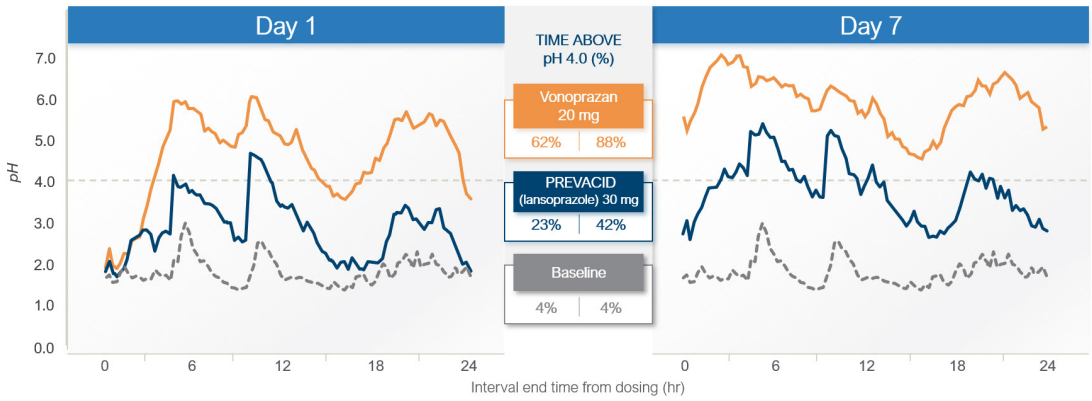
The mechanistic and pharmacologic differences of PPIs and vonoprazan are summarized in the table below:

	PPIs	Vonoprazan
Activation and stability	Prodrugs that require acid for activation yet are unstable in acidic conditions	No activation required and stable in acidic conditions
Binding to proton pump	Irreversibly blocks active proton pumps	Reversibly blocks active proton pumps and remains associated with the active and inactive proton pumps
Half-life	< 2 hours	~7 hours
Onset of action	Steady state anti-secretory effect and complete symptom relief is not achieved for 3 to 5 days (~40% of pumps blocked after a single PPI dose)	Achieved target 24-hour acid suppression within 2 hours of a single dose in a clinical trial in healthy volunteers
Dosing restrictions	Generally administered 30 to 60 minutes before a meal	Dosing independent of meal
Inter-patient variability	Metabolism via CYP2C19	Metabolism via CYP3A4/5

Vonoprazan Pharmacodynamics vs. PPIs

Vonoprazan's more rapid, potent, and durable anti-secretory effects versus the PPI lansoprazole (Prevacid) were demonstrated in a randomized, open-label, crossover clinical trial comparing 20 mg of once daily, or QD, vonoprazan to 30 mg QD of lansoprazole for 7 days in 41 healthy volunteers. As shown below, vonoprazan had a significantly higher 24-hour holding time ratio than lansoprazole for pH>4.0 on Day 1 (62.4% vs. 22.6%) and Day 7 (87.8% vs. 42.3%) and for pH>6.0 on Day 1 (33.1 vs. 7.4) and Day 7 (62.5% vs. 16.4%). Mean 24-hour intragastric pH for vonoprazan and lansoprazole was 4.6 and 2.8, respectively, on Day 1, and 5.9 and 3.8, respectively, on Day 7. Gastric pH levels are measured on a logarithmic scale from 0.0 to 14.0, in which each point represents a 10-fold change in acidity and higher pH values represent less acidity. In this study, vonoprazan maintained an average pH approximately two points higher than lansoprazole at Day 7.

Improved Onset and Potency of pH Control of Vonoprazan vs. Lansoprazole at Day 1 and Day 7



*VONO-103: Mean 0-24 hour gastric pH profiles; study evaluating the PK, PD, safety and tolerability of vonoprazan in comparison to PREVACID (lansoprazole) in 41 healthy adult subjects
[1] Shah SC et al. Gastroenterology. 2021;160:1831–1841

This improved potency and duration of pH control with vonoprazan, as measured by 24-hour pH hold time and time above pH 4.0, was evident not only at Day 1, but also at Day 7 when lansoprazole had reached its steady state (see table below).

24-hr Hold Time > pH 4.0 and Mean pH of Vonoprazan vs. Lansoprazole at Day 1 and Day 7

		Treatment			
	Baseline	Vonoprazan 20 mg QD		Lansoprazole 30 mg QD	
Parameter	Day -1	Day 1	Day 7	Day 1	Day 7
	n=43	n=40	n=40	n=41	n=38
0-24 h pH	1.8	4.6	5.9	2.8	3.8
pH>4 HTR (%)	3.9	62.4	87.8	22.6	42.3

Vonoprazan demonstrated similarly greater time above pH 4.0 versus the PPI esomeprazole (Nexium) in a randomized, open-label, crossover clinical trial comparing 20 mg QD vonoprazan to 20 mg QD of esomeprazole in 20 healthy volunteers. In that trial, greater duration of pH control with vonoprazan, as measured by time above pH 4.0 was observed both on Day 1 and Day 7 (see table below).

24-hr Hold Time > pH 4.0 of Vonoprazan vs. Esomeprazole at Day 1 and Day 7

	Time Above pH 4.0 (%)		
	Baseline	Day 1	Day 7
Vonoprazan 20 mg	11%	71%	86%
Esomeprazole 20 mg	11%	24%	61%

Vonoprazan for the Treatment of Acid-Related GI Diseases

Given the shortcomings of PPI therapy, we believe that there is a significant unmet medical need for a safe and effective anti-secretory agent with rapid, potent, and durable anti-secretary effects. In May 2022, we received FDA approval for VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK, each for the treatment of *H. pylori* infection in adults. In November 2023, we received FDA approval of vonoprazan, under the brand name VOQUEZNA, for the healing and maintenance of healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults, and in September 2023, we submitted an NDA seeking approval of vonoprazan as a once-daily treatment of heartburn associated with symptomatic Non-Erosive GERD in adults. Before we developed and obtained our initial approvals for VOQUEZNA, VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK in the United States, vonoprazan was developed in markets outside of the United States by Takeda through an extensive clinical program, including 19 Phase 3 clinical trials. As of December 2023, an estimate of over 60 million patients have received vonoprazan in Japan and other countries in Asia since its launch. Vonoprazan received marketing approval in Japan in late 2014 and generated approximately $850 million in net sales in its seventh full year on the market in Japan.

Vonoprazan in GERD

Based on the significant unmet medical need, previous Phase 3 trial results from Japan and elsewhere in Asia, and commercial potential, we prioritized the development and commercialization of vonoprazan in GERD, specifically for:

- the healing of Erosive GERD and relief of associated heartburn;
- the maintenance of healing of Erosive GERD and relief of associated heartburn; and

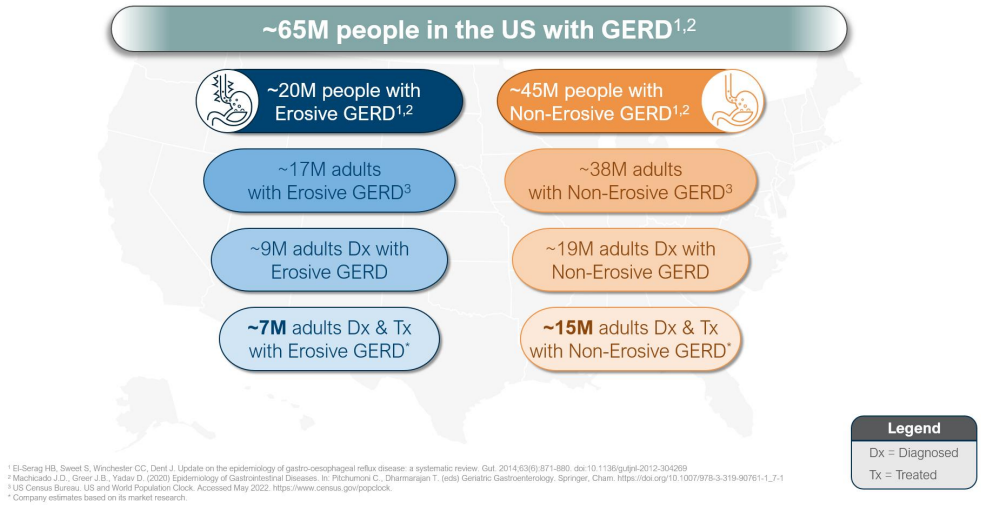
- the daily treatment of heartburn associated with symptomatic Non-Erosive GERD in adults, for which our NDA is currently under review by the FDA.

GERD Disease Overview

GERD is one of the most prevalent diseases of any kind and is the most prevalent GI disease, affecting approximately 20% of the U.S. population and approximately 15% of the European population. We estimate there are approximately 65 million individuals with GERD in the United States and 50 million individuals with GERD in the EU5. GERD is a disease that develops when the reflux of acidic stomach contents into the esophagus causes troublesome symptoms and/or complications. The term covers a spectrum of diseases, the main categories of which are Erosive GERD, or EE, and Non-Erosive reflux disease, or Non-Erosive GERD. These diseases are detailed below:

- ***Erosive GERD***: Approximately 30% of GERD patients have Erosive GERD, which is classified by erosions in the gastric mucosa caused by acidic reflux of stomach contents into the esophagus. Erosive GERD is commonly graded by the Los Angeles (LA) classification system, which characterizes the extent of erosions in the esophagus and is graded on a scale of increasing severity from A to D, with D being the most severe. Approximately 20% to 30% of Erosive GERD patients have moderate-to-severe disease with LA grade C or D erosions. Erosive GERD can have serious consequences. If left untreated, esophagitis may develop into peptic stricture, Barrett's esophagus or esophageal cancer.

- ***Symptomatic Non-Erosive gastroesophageal reflux disease (Non-Erosive GERD)***: Approximately 70% of GERD patients have Non-Erosive GERD, classified by abnormal gastric acid exposure in the esophagus and persistent symptoms.



GERD patients typically present with heartburn and reflux symptoms. Based on these symptoms, patients are typically treated first-line with PPIs prior to a diagnostic endoscopy for specific disease classification of Erosive GERD or Non-Erosive GERD. Clinical guidelines suggest that endoscopy be performed in patients who continue to have symptoms despite a four- to-eight-week course of daily PPIs or have alarm symptoms, including GI bleeding, anemia, weight loss, chest pain, or difficult or painful swallowing. Our market research suggests that most patients are treated empirically based on symptoms rather than based on endoscopic characterization of disease.

GERD Treatment Paradigm

PPIs are currently the most widely used anti-secretory agents available in the United States and Europe for relieving GERD symptoms and healing erosions in gastric mucosa. Our market research suggests that approximately 80% of patients who are

pharmacologically treated receive a PPI, and approximately 85% of PPI use is prescription rather than OTC. The majority of PPI use is chronic, with more than 70% of patients prescribed PPIs for daily use. According to IQVIA Xponent prescription data, approximately 110 million PPI prescriptions are written and filled annually across all indications.

There are few treatment options for GERD patients who are inadequately managed on PPI therapy. In a real world study conducted in 2020 and 2021 evaluating the perspectives and unmet needs of over 400 physicians and patients in the U.S. in the management of acid related disorders, only half of physicians reported that their patients are getting long-lasting relief from a PPI resulting in approximately 25% of patients taking a PPI more than once a day despite patients' concerns about long term side effects of PPI use. A limited number of patients proceed to a surgical procedure, such as Nissen fundoplication. However, this procedure results in postoperative morbidity of 5% to 20%, as well as a two-to six-week recovery period and a median hospital stay of two days.

Our U.S. market research survey reported that 55% to 60% of physicians included in the survey believed that vonoprazan has demonstrated superior efficacy in the healing and maintenance of healed esophageal erosions compared to existing Erosive GERD treatments, provides faster onset of action compared to existing GERD treatments, and has superior duration and magnitude of gastric pH control compared to existing GERD treatments.

Clinical Data for Vonoprazan in GERD

Our Development Program in Erosive GERD

Five Phase 3 clinical trials have been completed comparing vonoprazan to PPIs in Erosive GERD: our healing and maintenance of healing trial in the United States and Europe; a healing trial in Japan; a maintenance of healing trial in Japan; a healing trial in Asia (China, Taiwan, and Korea); and a maintenance of healing trial in Asia. In addition to these Phase 3 trials, several published investigator-sponsored studies have compared vonoprazan to PPIs across dosing regimens and endpoints. Results of these clinical trials are summarized below.

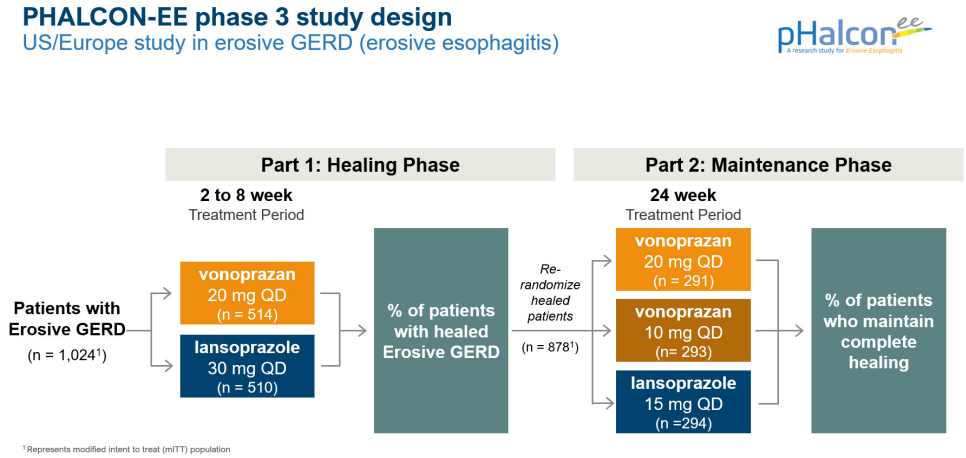
Healing and Maintenance of Healing of Erosive GERD in the United States and Europe (PHALCON-EE)

In October 2021, we announced that vonoprazan successfully met its primary endpoints and key secondary superiority endpoints in PHALCON-EE, our pivotal Phase 3 trial evaluating vonoprazan versus lansoprazole for the treatment of Erosive GERD.

PHALCON-EE was a randomized, double-blind, two-phase, multicenter, Phase 3 trial that enrolled 1,024 patients with EE in the U.S. and Europe. PHALCON-EE was modeled after the successful Phase 3 clinical trials conducted in Japan and Asia with limited differences, including the combination of the healing and maintenance phases into one single study whereas in Japan and Asia separate clinical trials were conducted for each of these indications.

The first phase of the trial, the Healing Phase, evaluated the efficacy and safety of vonoprazan 20 mg QD compared to lansoprazole 30 mg QD for the healing of Erosive GERD for up to eight weeks. In the Healing Phase, patients were assessed via endoscopy to determine complete healing following 2 weeks of treatment and, if complete healing was not achieved, a second endoscopy occurred at 8 weeks of treatment. Patients who achieved complete healing were re-randomized into the second phase of the trial, the Maintenance Phase, where vonoprazan 10 mg and 20 mg were compared to lansoprazole 15 mg to assess maintenance of healing of Erosive GERD via endoscopy following 24 weeks of treatment. Heartburn symptom relief was assessed via secondary endpoints in both the Healing and Maintenance Phases of the study based on twice daily e-diary data collection.

Design of US/EU Phase 3 Clinical Trial for the Healing and Maintenance of Healing of Erosive GERD



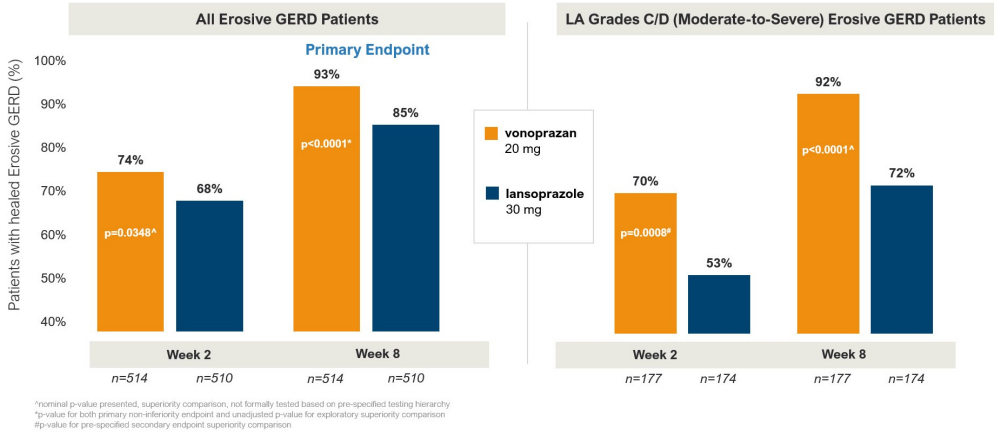
Healing Phase

The primary endpoint analysis of the Healing Phase was non-inferiority of vonoprazan 20 mg compared to lansoprazole 30 mg in the percentage of all patients who have complete healing of Erosive GERD by Week 8. Vonoprazan met the non-inferiority criteria for the primary comparison with a healing rate of 93% compared to 85% for lansoprazole ($p<0.0001$). Based on a prespecified exploratory comparison test, the difference in healing rates in all patients between vonoprazan and lansoprazole was also significant (nominal $p<0.0001$). Non-inferiority analyses are conducted to evaluate whether the effect of an agent is not worse than the active control by more than a specified margin, while superiority analyses are conducted to evaluate whether an agent outperformed a comparator by a statistically significant margin.

Vonoprazan met the secondary superiority endpoint of healing in patients with moderate-to-severe disease, defined as patients with esophageal erosions classified as Grades C or D by the Los Angeles (LA) Classification System, at Week 2, demonstrating significantly faster healing than lansoprazole (70% for vonoprazan 20 mg and 53% for lansoprazole 30 mg) ($p=0.0008$). Vonoprazan also met the secondary endpoint of showing non-inferiority to lansoprazole 30 mg in the mean percentage of 24-hour heartburn free days over the healing period. In additional pre-specified secondary endpoint superiority comparisons, vonoprazan 20 mg healing rates were numerically greater than lansoprazole 30 mg in all patients at Week 2 (nominal $p=0.0348$) and in moderate-to-severe patients by Week 8 (nominal $p<0.0001$), although these superiority comparisons were not tested in the pre-specified testing hierarchy.

Vonoprazan 20 mg was also compared to lansoprazole 30 mg in a superiority test for onset of sustained resolution of heartburn by day 3 but did not achieve statistical significance ($p=0.439$).

Results of US/EU Phase 3 Clinical Trial in the Healing of Erosive GERD



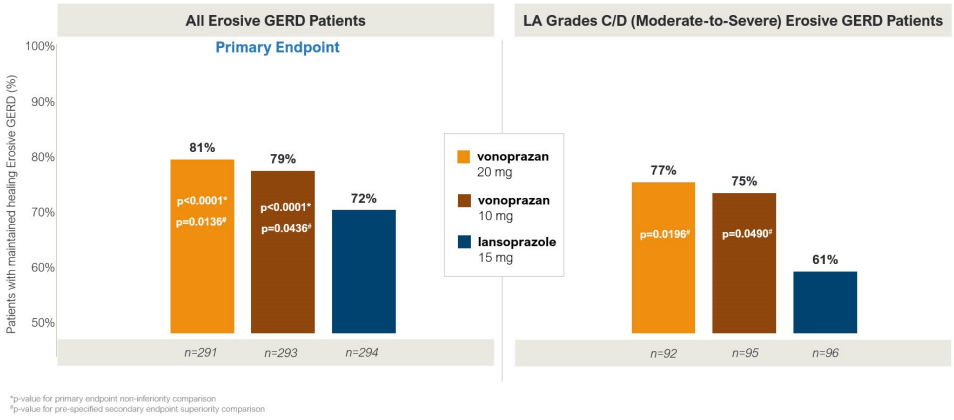
Maintenance Phase

Vonoprazan met the primary and all secondary endpoints in the Maintenance Phase. The primary endpoint of the Maintenance Phase was non-inferiority of vonoprazan 10 mg and 20 mg compared to lansoprazole 15 mg in the percentage of all patients who maintained healing of Erosive GERD through Week 24.

Both vonoprazan doses met the Maintenance Phase primary endpoint of non-inferiority while also meeting the pre-specified secondary comparison demonstrating superiority of maintenance of healing versus lansoprazole (79% for vonoprazan 10 mg, 81% for vonoprazan 20 mg compared to 72% for lansoprazole 15 mg) ($p<0.0001$ for both non-inferiority comparisons; $p=0.0438$ for vonoprazan 10 mg superiority comparison; $p=0.0136$ for vonoprazan 20 mg superiority comparison).

Both vonoprazan doses also met the secondary endpoint of demonstrating superiority of the percentage of patients with moderate-to-severe disease who maintained healing of Erosive GERD through Week 24 (75% vonoprazan 10 mg, 77% vonoprazan 20 mg v. 61% lansoprazole 15 mg) ($p=0.0490$ for vonoprazan 10 mg superiority comparison; $p=0.0196$ for vonoprazan 20 mg superiority comparison). Additionally, both vonoprazan doses also met the secondary endpoint of showing non-inferiority to lansoprazole 15 mg in the mean percentage of 24-hour heartburn free days over the maintenance period.

Results of US/EU Phase 3 Clinical Trial in Maintenance of Healing of Erosive GERD



Healing and Maintenance of Healing of Erosive GERD Clinical Trials in Japan and Asia

The results of PHALCON-EE were consistent with the results of earlier Phase 3 trials of vonoprazan in healing and maintenance of healing of Erosive GERD after which it was modeled. These trials were conducted in Japan as well as other countries in Asia.

In two Phase 3 trials in healing of Erosive GERD comparing vonoprazan 20 mg QD to lansoprazole 30 mg QD for up to eight weeks, one conducted in Japan and the other in several countries in Asia, vonoprazan achieved the primary endpoint of non-inferiority versus lansoprazole on the percent of patients with healed Erosive GERD up to Week 8. Exploratory testing suggested higher healing rates for vonoprazan versus lansoprazole in the moderate to severe patients at Week 2 in both studies.

Similarly, in two Phase 3 trials in maintenance of healing of Erosive GERD comparing two doses of vonoprazan (10 mg and 20 mg QD) to lansoprazole 15 mg QD for 24 weeks, one conducted in Japan and the other in several countries in Asia, both vonoprazan doses achieved the primary endpoint of non-inferiority versus lansoprazole on the percent of patients with recurrence of Erosive GERD during the 24-week maintenance period. In both studies, exploratory testing suggested higher maintenance of healing rates for both vonoprazan doses versus lansoprazole in all patients and in the moderate to severe patients.

Our Development Program in Symptomatic Non-Erosive Gastroesophageal Reflux Disease (Non-Erosive GERD)

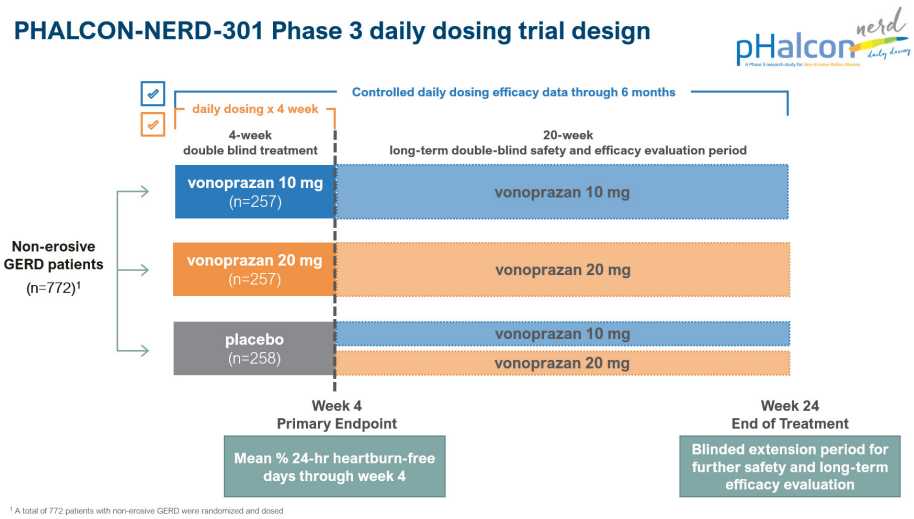
We believe that there is an opportunity to broadly position vonoprazan's use in GERD with an indication in the treatment of heartburn associated with symptomatic GERD in patients without erosions, also known as Non-Erosive GERD, in addition to our current approved indication in Erosive GERD. In fact, we are developing vonoprazan as a treatment for heartburn associated with symptomatic Non-Erosive GERD with both daily and as needed dosing regimens. Non-Erosive GERD patients do not have esophageal erosions that require chronic treatment to prevent recurrence of erosions and their potential sequelae. Moreover, we believe the rapid onset of acid control of vonoprazan may enable as-needed use for the management of heartburn in Non-Erosive GERD patients as an alternative to chronic daily treatment.

Daily Dosing of Vonoprazan for the Treatment of Heartburn Associated with Symptomatic Non-Erosive GERD (PHALCON-NERD-301)

In January 2023, we reported positive topline data from the primary endpoint in PHALCON-NERD-301, our Phase 3 study evaluating the safety and efficacy of vonoprazan 10 mg and 20 mg as a daily dosing (QD) treatment, as compared to placebo (QD), in the relief of heartburn over four weeks in adult participants with symptomatic Non-Erosive reflux disease, or Non-Erosive GERD. In this trial, patients in each vonoprazan treatment group, 10 mg and 20 mg, had a significantly higher mean percentage of 24-hour heartburn-free days (without daytime or nighttime heartburn as assessed by daily diary) compared to placebo after four weeks. This is the same endpoint used in other Phase 3 trials for PPIs that are approved in the U.S. for the treatment of Non-Erosive GERD.

PHALCON-NERD-301 also included a blinded 20-week long-term extension period to further evaluate the safety and efficacy of both doses of vonoprazan after six months of continuous use. A total of 772 patients with Non-Erosive GERD were enrolled, randomized and dosed in the multisite U.S. trial.

Design of PHALCON-NERD-301 Phase 3 Non-Erosive Daily Dosing Clinical Trial

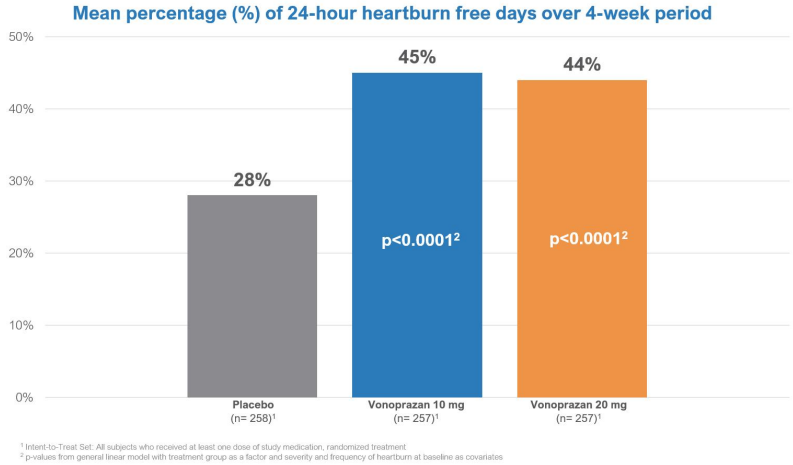


Primary Endpoint of Phase 3 Clinical Trial in the Treatment of Non-Erosive GERD

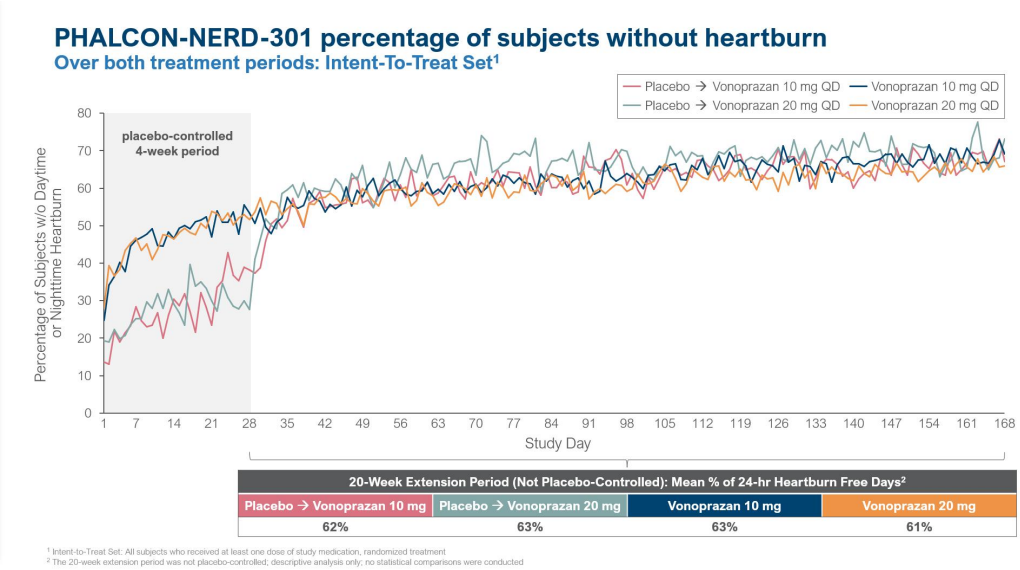
The primary endpoint of the study, measured during the four-week, double-blind, placebo-controlled period, is the mean percentage of 24-hour heartburn free days. The topline results from the study showed both doses of vonoprazan, 20 mg and 10 mg, met the primary endpoint and demonstrated a significantly greater mean percentage of 24-hour heartburn-free days versus placebo (45% vonoprazan 10 mg, 44% vonoprazan 20 mg, 28% for placebo; p<0.0001 for both vonoprazan doses versus placebo). Additionally, the median percentage of 24-hour heartburn-free days was 48%, 46% and 17% for vonoprazan 10 mg, vonoprazan 20 mg, and placebo, respectively.

Vonoprazan was generally well tolerated in the initial four week double-blind, placebo-controlled phase of the trial. The overall adverse events for all vonoprazan arms were comparable to placebo and consistent with what was reported in previous studies. The most commonly reported adverse event was nausea (2.3% vonoprazan 10 mg, 3.1% vonoprazan 20 mg, 0.4% placebo) with no other events reported above 3.0% in either vonoprazan dose arm.

Results of Phase 3 Clinical Trial in the Treatment of Non-Erosive GERD



During the 20-week extension period, patients randomized to vonoprazan 10 mg and 20 mg during the initial 4-week period remained on their blinded treatment assignment. The mean percentage of heartburn free days reported over the 20-week extension period for these patients was 63% for vonoprazan 10 mg and 61% for vonoprazan 20 mg. Additionally, patients who were randomized to placebo during the initial 4-week period were re-randomized to either vonoprazan 10 mg or 20 mg for the 20-week extension period. For these patients, the mean percentage of heartburn free days reported over the 20-week extension period was 62% for vonoprazan 10 mg and 63% for vonoprazan 20 mg. The graph below shows the percentage of subjects without heartburn over the entire 24-week course of the study in the intent-to-treat subject set, which represents subjects who received at least one dose of study medication during randomized treatment.



[1] Intent-to-Treat Set: All subjects who received at least one dose of study medication, randomized treatment
[2] The 20-week extension period was not placebo-controlled; descriptive analysis only; no statistical comparisons were conducted

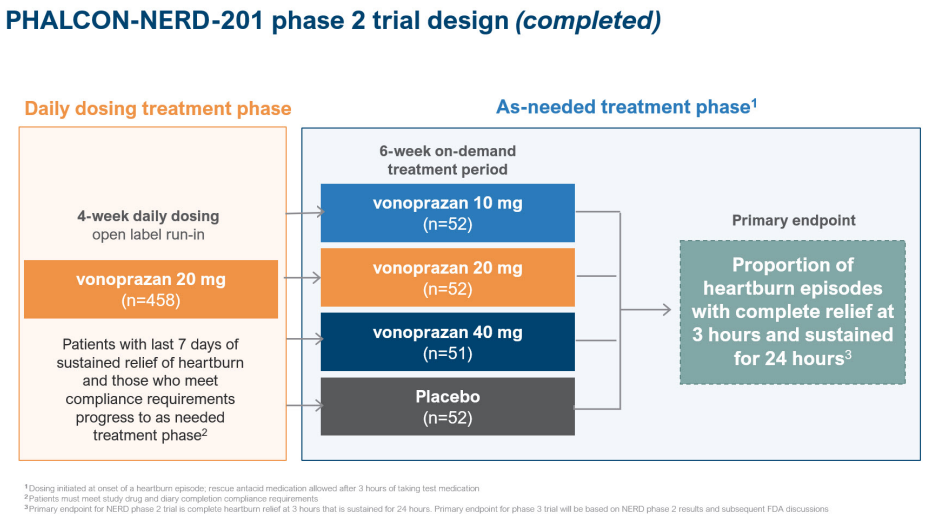
Vonoprazan was generally well tolerated in the 20-week extension period. The most common adverse events reported for the two vonoprazan doses during that period were upper respiratory tract infection, sinusitis, influenza, urinary tract infection, nasopharyngitis, nausea, and gastroenteritis, each reported at or below 5%.

As Needed Dosing of Vonoprazan for the Treatment of Non-Erosive GERD

In February 2022, we announced that vonoprazan (10 mg, 20 mg and 40 mg), successfully met the primary endpoint in PHALCON-NERD-201, a Phase 2 trial evaluating three doses of vonoprazan versus placebo as an as needed treatment of Non-Erosive GERD.

PHALCON-NERD-201 was a Phase 2, randomized, double-blind, multicenter study that enrolled 458 subjects in the U.S. to evaluate the efficacy and safety of vonoprazan 10 mg, 20 mg, and 40 mg administered as needed for relief of episodic heartburn compared to placebo in subjects with Non-Erosive GERD (as confirmed by endoscopy). After an initial four-week vonoprazan 20 mg QD dose open-label run-in period, two hundred and seven subjects without a heartburn episode during the last 7 days of the run-in period and who also met drug and diary compliance requirements were randomized to receive vonoprazan 10 mg, 20 mg, 40 mg or placebo as needed for six weeks. Subjects completed an electronic diary to assess presence and severity of heartburn symptoms and use of rescue antacid (if needed).

Design for PHALCON-NERD Phase 2 Non-Erosive GERD As Needed Dosing Trial

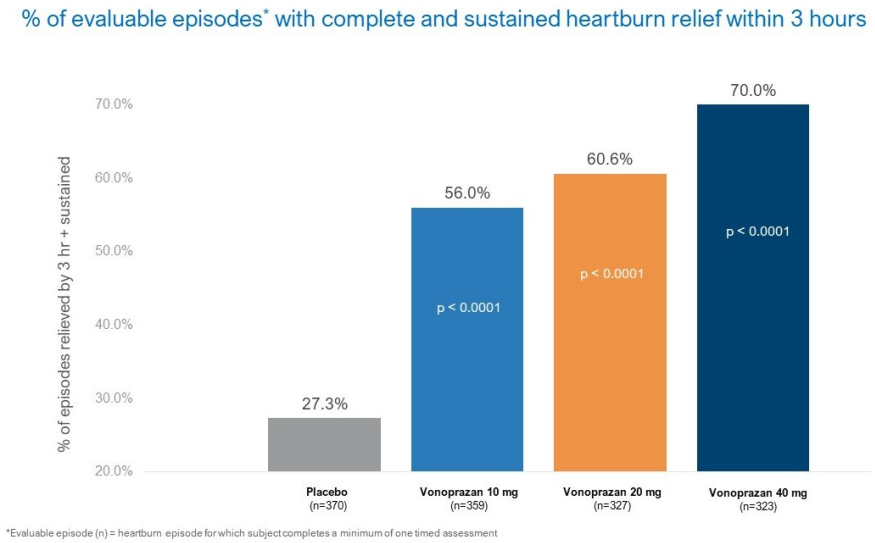


In this Phase 2 proof-of-concept trial, the primary endpoint was the percentage of heartburn episodes completely relieved within three hours and with no further heartburn reported for 24 hours after taking study drug. All three vonoprazan doses met this primary endpoint and were statistically significant ($p<0.0001$) when compared to placebo. Within three hours, vonoprazan 10 mg, 20 mg and 40 mg achieved complete and sustained relief in 56.0%, 60.6% and 70.0% of evaluable heartburn episodes, respectively, as compared to 27.3% of episodes for placebo.

During the PHALCON-NERD open-label daily dosing run-in phase, where all enrolled participants received vonoprazan 20 mg QD for four weeks, the mean percentage of 24-hour heartburn free days observed was 65.4% (median 76.0%).

Based on the following results of PHALCON-NERD-201, we plan to initiate a Phase 3 trial to evaluate the novel dosing regimen of vonoprazan as an as needed treatment for episodic heartburn relief in patients with Non-Erosive GERD, a dosing regimen not approved in the U.S. for PPIs, in 2024.

Results of Phase 2 Non-Erosive GERD As Needed Dosing Trial



Vonoprazan in Combination with Antibiotics for the Treatment of *H. pylori* Infection

Disease Burden and Outcomes

H. pylori is a bacterial pathogen that infects approximately 35% of the U.S. population, 45% of the EU5 population, and more than 50% of the global population. We estimate that there are approximately 115 million individuals in the United States and 145 million individuals in the EU5 infected with *H. pylori*, and we believe there are approximately 2.5 million patients treated for *H. pylori* infection in the United States each year. As a result of the chronic inflammation induced by *H. pylori* infection, approximately 20% of infected patients develop a range of pathologies including dyspepsia, peptic ulcer disease, gastric cancer, and MALT lymphoma. Gastric cancer is the third most common cause of cancer-related death worldwide, and over 80% of gastric cancers are attributed to *H. pylori* infection. Globally there are more than one million new cases of gastric cancer and approximately 782,000 deaths each year. Eradication of *H. pylori* infection has been proven to reduce the incidence of gastric cancer, and the American College of Gastroenterologists, or ACG, guidelines recommend treatment for all patients diagnosed with *H. pylori* infection.

In 2017, the World Health Organization, or WHO, listed *H. pylori* among the 16 antibiotic-resistant bacteria that pose the greatest threat to human health and designated *H. pylori* as a Class 1 carcinogen, meaning that it is a definite known cause of cancer. In 2014, the FDA added *H. pylori* to the agency's list of qualifying pathogens that have the potential to pose a serious threat to public health under the GAIN Act. Despite the importance of *H. pylori* eradication, rates of eradication have fallen from the 1990s to the current rates where it is estimated that about 25% of patients fail first-line therapy. These declining eradication rates are due to multiple factors particularly rising rates of antibiotic resistance, complexity of existing treatment regimens which contributes to suboptimal patient adherence, and insufficient acid suppression. Acid suppression is important because it helps maintain pH levels that can enhance antibiotic effectiveness.

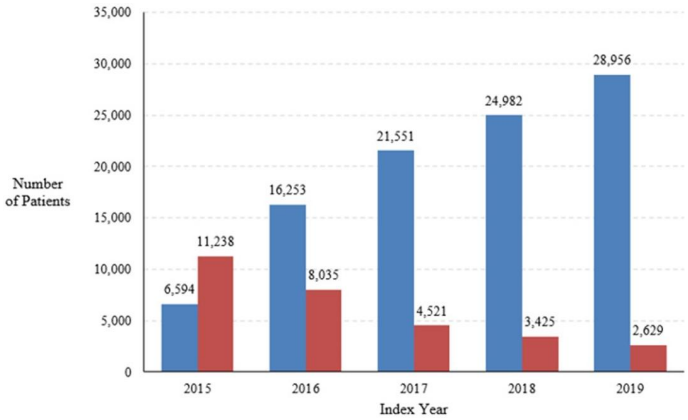
The need for improved treatment options in the U.S. is illustrated by a review of U.S. claims data between 2016 and 2019 for newly diagnosed *H. pylori* patients. The results of this study show not only declining eradication rates and the need for improved treatment, but also a need for improved testing and follow-up. This study showed not only that almost one-third of patients did not receive a treatment that aligned with then-current U.S. clinical treatment guidelines, but also that nearly 22% of patients who received a first-line treatment consistent with treatment guidelines failed to eradicate their *H. pylori* infection, and only 11% of those who failed to receive any subsequent *H. pylori* treatment.

A study evaluating global temporal trends in the efficacy of clarithromycin-based regimens for the treatment of *H. pylori* infection concluded that Vonoprazan-based triple therapy partially mitigated the decline in eradication rates seen with PPI-based triple therapy, likely due to more powerful acid suppression of vonoprazon (Moss et al. Therap Adv Gastroenterol. 2023; 16). The potential of vonoprazan-based treatment regimens can be seen in the results of a retrospective study that compiled real-world health insurance claims data in Japan from 2008 to 2016 for *H. pylori* eradication. Prior to vonoprazan's approval in late 2014, the *H. pylori* eradication rate across Japan fell to below 80% as shown in the figure below. Approximately one year after vonoprazan's launch, the eradication rate increased to greater than 85%. From January 2015 to March 2016, the eradication rate with PPI-containing regimens in Japan was between 78% and 82% while the eradication rate with vonoprazan-containing regimens was 91% across all patients in this analysis.

Results were similar in a real-world study using a different Japanese health insurance claims database. Among patients initiating vonoprazan or a PPI between January 2015 and January 2020 to treat *H. pylori* infection, 93% of vonoprazan-treated patients did not receive a second line of triple therapy compared to 80% of PPI-treated patients.

Following the 2015 launch of vonoprazan in Japan not only did *H. pylori* eradication rates increase, vonoprazan-containing regimens rapidly became the most common first line treatment. One-year post launch, approximately 80% of all treated *H. pylori*-infected patients received vonoprazan-based regimens. In the study of *H. pylori*-infected patients, vonoprazan-based regimens overtook PPI-based regimens as the most common first-line treatment between 2015 and 2019. Within this Japanese database, the number of patients using vonoprazan-based regimens increased from 6,594 to 28,956 patients, while the number of patients using a PPI-based regimen decreased from 11,238 to 2,629, shown in the figure below.

Uptake of Vonoprazan-Based vs. PPI-Based Therapy for First Line Treatment of *H. pylori* Infection in Japan from 2015-2019



This same real-world study utilizing Japanese claims data also shows that improved eradication rates have the potential to result in significant reductions of *H. pylori*-related healthcare costs and healthcare resource utilization. The results of this study showed that vonoprazan was associated with lower healthcare costs and healthcare resource utilization than PPI-based therapy for the treatment of *H. pylori* infection in Japan. Specifically, during the 12 months following initiation of treatment for *H. pylori* infection, all-cause healthcare costs and healthcare resource utilization were significantly lower for patients treated with vonoprazan-based triple therapy compared to a PPI-based triple therapy.

Given the clinical and post-marketing experience in the Japanese market, we believe that vonoprazan-based treatment regimens have the potential not only to restore eradication rates to their 1990s rates in the United States and Europe but also to significantly reduce *H. pylori*-related healthcare costs and healthcare resource utilization.

Current Treatment Paradigm in the United States and Europe

The ACG treatment guidelines for *H. pylori* infection recommend using PPIs in conjunction with antibiotics to improve antibiotic efficacy against *H. pylori* infection. The use of anti-secretory agents enhances the effect of antibiotics in two ways. First, anti-secretory agents increase gastric pH, which in turn increases the stability of the antibiotics. For example, amoxicillin and clarithromycin are chemically unstable at the low pH typically found in the human stomach. Second, several antibiotics, including amoxicillin and clarithromycin, are most potent against *H. pylori* at the time of maximum bacterial replication, which occurs at pH 6.0 to 8.0. *H. pylori* is in a dormant state at lower pH values, which reduces the effectiveness of the antibiotics.

The table below shows the minimum inhibitory concentration of antibiotic required to eradicate 90% of *H. pylori* in vitro, or MIC90. As pH increases, the amount of antibiotic required for 90% eradication decreases substantially.

***H. pylori* MIC_{90} Values as a Function of pH**

	MIC_{90} (mg/L)		
	pH 7.5	pH 6.0	pH 5.5
Ampicillin	0.06	0.25	0.5
Clarithromycin	0.03	0.06	0.25

A triple therapy regimen (PPI, clarithromycin, and either amoxicillin or metronidazole) is the regimen most commonly used in clinical practice for the first-line treatment of *H. pylori* infection. However, *H. pylori* eradication rates with PPI triple therapy in the 1990s have fallen to current levels of <80%, primarily due to increased resistance of *H. pylori* to clarithromycin and metronidazole. A

recent meta-analysis indicates that U.S. resistance rates measured from 2012 to 2016 were 20% for clarithromycin, 29% for metronidazole, and 19% for levofloxacin. Additionally, in a U.S.-based study from 2021, 65.6% of tested *H. pylori* was resistant to at least one antibiotic currently used for treatment, with resistance rates of 33% for clarithromycin and approximately 30% for metronidazole and levofloxacin. These figures represent a marked increase from 2009 to 2011 for both clarithromycin and metronidazole, for which resistance was 9% for clarithromycin, 21% for metronidazole, and 11% for levofloxacin. *H. pylori* resistance to amoxicillin remains low despite its use in most triple therapy regimens; resistance is generally <2% among isolates in the United States and Europe. There is a similar trend of increasing resistance to key antibiotics in Europe.

Given the declining eradication rates for *H. pylori*, bismuth quadruple therapy is recommended as first-line treatment in areas with known high rates of clarithromycin or metronidazole resistance; however, our U.S. market research study reported that physicians prescribe quadruple therapy to only 17% of first-line patients. Due predominantly to considerations of convenience and patient compliance, approximately 75% of physicians surveyed in our market research expressed a preference for convenience, or combination packs compared to individual bottles for both dual and triple therapy. Further, geographic patterns of resistance in the United States are poorly understood and treatment is largely empiric, with susceptibility testing rarely conducted prior to first-line treatment. Our U.S. market research study reported that only 8% and 16% of physicians conduct resistance testing prior to prescribing treatment for first-line and second-line *H. pylori* infection, respectively.

In our U.S. market research study, physicians highlighted the need for more effective and simpler first-line treatment options. For the treatment of *H. pylori* infection, surveyed physicians highlighted the need for improved eradication rates and more convenient dosing as key unmet needs. In fact, on average, 53% and 52% reported a preference to use vonoprazan first line in patients with *H. pylori* infection, and in patients with refractory *H. pylori* infection, respectively.

Our H. pylori Phase 3 Clinical Trial in the United States and Europe – PHALCON-HP

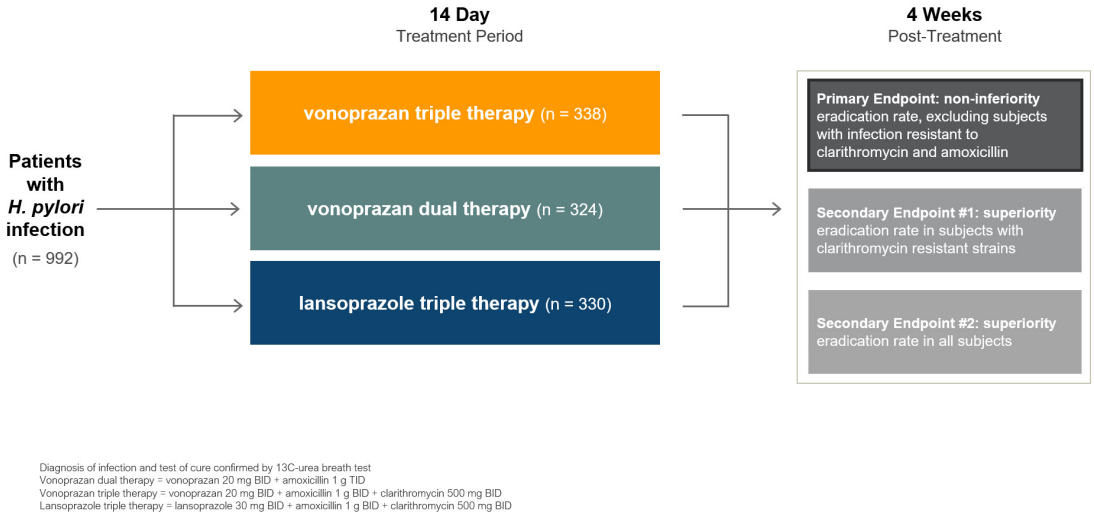
In April 2021, we announced that in PHALCON-HP, our pivotal Phase 3 clinical trial for the eradication of *H. pylori* infection, both vonoprazan-based regimens successfully met their primary endpoints and met all secondary endpoints. The trial studied vonoprazan triple therapy and vonoprazan dual therapy compared to lansoprazole triple therapy. We believe PHALCON-HP was the largest U.S. Phase 3 registration trial ever conducted in *H. pylori* infection, randomizing 992 patients with confirmed *H. pylori* infection.

PHALCON-HP was a randomized, multicenter, Phase 3 trial that enrolled 1,046 patients of which 992 patients with a confirmed *H. pylori* infection were randomized to one of three arms:

- ***vonoprazan dual therapy***: vonoprazan 20 mg BID and amoxicillin 1 g TID for 14 days (n=324);
- ***vonoprazan triple therapy***: vonoprazan 20 mg BID, amoxicillin 1000 mg BID and clarithromycin 500 mg BID for 14 days (n=338); and
- ***PPI triple therapy***: lansoprazole 30 mg BID, amoxicillin 1000 mg BID and clarithromycin 500 mg BID for 14 days (n=330).

The objective of the PHALCON-HP trial was to compare eradication rates in all treated subjects as well as in two pre-identified subgroups of patients: those patients with clarithromycin resistant strains of *H. pylori,* and those patients who did not have clarithromycin or amoxicillin resistant strains of *H. pylori.* For regulatory purposes, the primary endpoint of this study was a non-inferiority comparison in the non-resistant subgroup for each of vonoprazan triple therapy and vonoprazan dual therapy compared to lansoprazole triple therapy. All endpoints measured the percentage of patients with successful eradication of *H. pylori* infection as assessed by ^{13}C-urea breath test four weeks after completion of treatment. The primary analysis in the non-resistant population assessed the non-inferiority of vonoprazan dual therapy compared to lansoprazole triple therapy and vonoprazan triple therapy compared to lansoprazole triple therapy. Secondary analyses for superiority were conducted in all patients and in the subgroup of patients with clarithromycin-resistant *H. pylori* infection. Further efficacy analyses were conducted using the pre-specified per protocol population (n=822), which is comprised of patients who were protocol compliant as defined by FDA established criteria.

Design for PHALCON-HP Phase 3 *H. pylori* Clinical Trial



Diagnosis of infection and test of cure confirmed by 13C-urea breath test
Vonoprazan dual therapy = vonoprazan 20 mg BID + amoxicillin 1 g TID
Vonoprazan triple therapy = vonoprazan 20 mg BID + amoxicillin 1 g BID + clarithromycin 500 mg BID
Lansoprazole triple therapy = lansoprazole 30 mg BID + amoxicillin 1 g BID + clarithromycin 500 mg BID

Primary endpoint analysis

Both vonoprazan-based regimens successfully met their primary endpoints in the subset of patients with *H. pylori* strains that were not shown to be resistant to clarithromycin or amoxicillin. In the mITT population, *H. pylori* eradication rates were 84.7% with vonoprazan triple therapy and 78.5% for vonoprazan dual therapy compared to 78.8% with lansoprazole triple therapy ($p<0.0001$ and $p=0.0073$, respectively, for non-inferiority).

In the per protocol population, *H. pylori* eradication rates were 90.4% with vonoprazan triple therapy and 81.2% with vonoprazan dual therapy compared to 82.1% with lansoprazole triple therapy ($p<0.0001$ and $p=0.0155$, respectively, for non-inferiority).

Secondary endpoint analysis

Vonoprazan triple therapy and vonoprazan dual therapy also met all secondary endpoints, and demonstrated superior eradication rates versus lansoprazole triple therapy in all patients and patients with clarithromycin resistant strains of *H. pylori*. Patients with clarithromycin resistant strains comprised 20.3% of the PHALCON-HP study population.

Vonoprazan triple therapy

The *H. pylori* eradication rate of vonoprazan triple therapy was superior to that of lansoprazole triple therapy among all patients in both the mITT population (80.8% vs. 68.5%; $p=0.0003$) and the per protocol population (85.7% vs. 70.0%; $p<0.0001$).

The *H. pylori* eradication rate of vonoprazan triple therapy was superior to that of lansoprazole triple therapy in the subset of patients with *H. pylori* strains resistant to clarithromycin in both the mITT population (65.8% vs. 31.9%; $p<0.0001$) and the per protocol population (67.2% vs. 29.0%; $p<0.0001$).

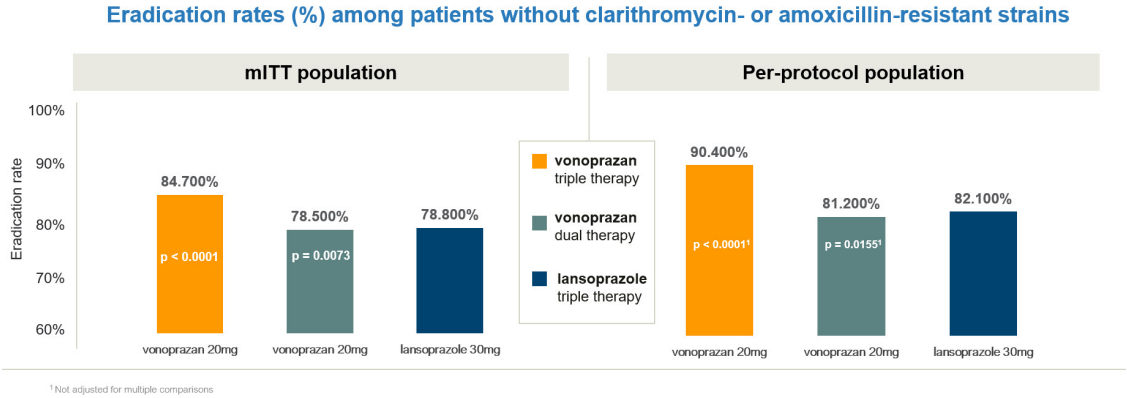
Vonoprazan dual therapy

The *H. pylori* eradication rate of vonoprazan dual therapy was superior to that of lansoprazole triple therapy among all patients in both the mITT population (77.2% vs. 68.5%; $p=0.0127$) and the per protocol population (81.1% vs. 70.0%; $p=0.0027$).

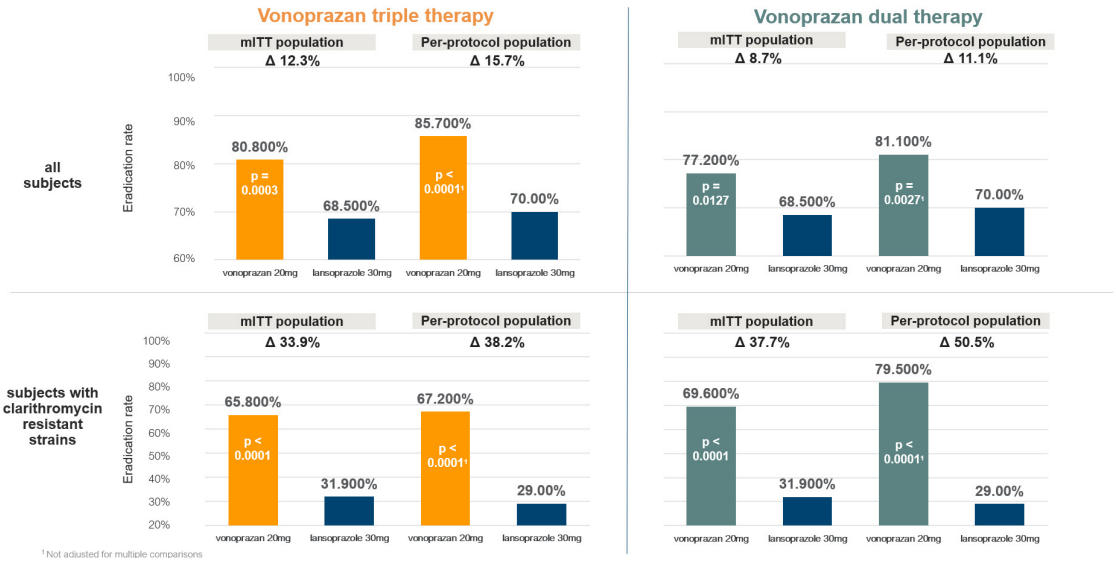
The *H. pylori* eradication rate of vonoprazan dual therapy was superior to that of lansoprazole triple therapy in the subset of patients with *H. pylori* strains resistant to clarithromycin in both the mITT population (69.6% vs. 31.9%; $p<0.0001$) and the per protocol population (79.5% vs. 29.0%; $p<0.0001$).

Results of US/EU Phase 3 Clinical Trial in *H. pylori* Infection

Primary Endpoint Analysis –Subjects without clarithromycin or amoxicillin resistant strains



Secondary Endpoint Analyses – All subject and subjects with clarithromycin resistant strains



Antibiotic resistance and declining eradication rates are significant clinical issues, and we believe that vonoprazan triple therapy and vonoprazan dual therapy have the potential to provide improvements over PPI-based therapies in addressing each of these issues. Vonoprazan dual therapy also has potential to spare the use of clarithromycin, representing an opportunity both for effective treatment and sound antibiotic stewardship through the avoidance of an additional antibiotic. As an alternative to multi-antibiotic drug regimens, vonoprazan dual therapy might also help to limit the spread of resistance among other pathogenic bacteria within populations. In addition, vonoprazan triple therapy and vonoprazan dual therapy will both be available in daily dosing blister cards inclusive of the appropriate antibiotic. We believe this convenience pack has the potential to enhance compliance in a category where full adherence to treatment regimen is often a challenge.

Convenience Packs for H. pylori

In September 2021, we submitted NDAs for vonoprazan triple therapy, or VOQUEZNA TRIPLE PAK and vonoprazan dual therapy, or VOQUEZNA DUAL PAK, for the treatment of *H. pylori* infection in adults, each as a pre-packaged convenience, or

combination pack with either clarithromycin and amoxicillin or amoxicillin alone. On May 3, 2022, the FDA approved both NDAs and in December 2023, both products became available at retail pharmacies in the United States.

VOQUEZNA® Triple Pak® VOQUEZNA® Dual Pak®

Convenience packs have the potential to improve patient adherence and treatment outcomes, and we believe there is a meaningful market opportunity for such a product. In the United States, PrevPac was formerly marketed as a pre-packaged convenience pack of lansoprazole, clarithromycin, and amoxicillin and achieved peak sales of $150 million. In Japan, vonoprazan is marketed both as a stand-alone medicine as well as in pre-packaged convenience packs with either clarithromycin and amoxicillin (Vonosap) or metronidazole and amoxicillin (Vonopion).

Phase 3 Clinical Trial in Japan of Vonoprazan in Combination with Antibiotics to Treat H. pylori Infection

The results of PHALCON-HP were consistent with the results of a Phase 3 clinical trial in *H. pylori*-positive patients completed in Japan. In that trial, patients were treated with either vonoprazan triple therapy (vonoprazan 20 mg BID, amoxicillin 750 mg BID, and clarithromycin (200 mg or 400 mg) BID) or lansoprazole triple therapy (lansoprazole 30 mg BID, amoxicillin 750 mg BID, and clarithromycin (200 mg or 400 mg) BID) for seven days as is customary in Japan. The primary endpoint of the clinical trial was confirmed *H. pylori* eradication determined by ^{13}C-urea breath test. The primary analysis was non-inferiority, and additional analyses of the second line eradication rate and eradication rate in antibiotic-resistant subgroups were also conducted.

Vonoprazan-based triple therapy demonstrated a non-inferior eradication rate of 93% compared to 76% for lansoprazole-based triple therapy ($p<0.0001$). Post hoc analyses suggested that vonoprazan-based triple therapy was superior to lansoprazole-based triple therapy ($p<0.0001$). Patients who were not eradicated on vonoprazan-based triple therapy or lansoprazole-based triple therapy were treated with a different triple therapy regimen of vonoprazan, amoxicillin, and metronidazole. In this second-line setting, the *H. pylori* eradication rate with the different vonoprazan triple therapy was 98%. Exploratory analysis suggested that vonoprazan-based triple therapy had significantly higher eradication rates versus the lansoprazole-based triple therapy in the subgroup of subjects with clarithromycin resistant strains of *H. pylori*.

Summary of Vonoprazan Safety Data

Safety in Clinical Studies

As of December 2023, over 9,000 subjects have been exposed to vonoprazan in completed and ongoing Phase 1 to 3 clinical trials. The doses studied have ranged from 1 to 120 mg with durations up to one year.

In PHALCON-HP, both vonoprazan-based regimens were generally well tolerated with safety results comparable to patients who received lansoprazole triple therapy. The most common adverse events (≥2.0%) reported in the vonoprazan triple therapy, vonoprazan dual therapy, and lansoprazole triple therapy arms, respectively, were diarrhea (4.0%, 5.2%, and 9.6%), dysgeusia (4.3%,

0.6%, and 6.1%), abdominal pain (2.3%, 2.6% and 2.9%), headache (2.6%, 1.4%, 1.4%), vulvovaginal candidiasis (2.3%, 1.4%, 1.2%), hypertension (2.0%, 1.1%, 0.9%), and nasopharyngitis (0.3%, 2.0%, 0.9%). Overall rates of discontinuation due to adverse events were 2.3% for vonoprazan triple therapy-treated patients, 0.9% for vonoprazan dual therapy-treated patients, and 1.2% for lansoprazole triple therapy-treated patients.

Additionally, the safety results for vonoprazan observed in PHALCON-EE were consistent with the results observed in prior clinical studies. In the healing phase of the study, the most common adverse events (≥2%) were abdominal pain (2.1% for vonoprazan and 1.2% for lansoprazole), diarrhea (2.1% for vonoprazan and 2.5% for lansoprazole). Rates of discontinuation due to adverse events in the healing phase were 1% for vonoprazan 20 mg and 2.2% for lansoprazole 30 mg.

In the maintenance phase of the study, the most common adverse events (≥2%) were gastritis (2.7% vonoprazan 10 mg, 6.4% vonoprazan 20 mg, 2.7% lansoprazole), diarrhea (1.0% vonoprazan 10 mg, 2.7% vonoprazan 20 mg, 4.4% lansoprazole), abdominal pain (4.1% vonoprazan 10 mg, 5.4% vonoprazan 20 mg, 2.4% lansoprazole), dyspepsia (3.7% vonoprazan 10 mg, 4.1% vonoprazan 20 mg, 2.7% lansoprazole), gastroesophageal reflux disease (2.4% vonoprazan 10 mg, 3.7% vonoprazan 20 mg, 2.0 lansoprazole), hypertension (3.0% vonoprazan 10 mg, 3.4% vonoprazan 20 mg, 2.0% lansoprazole), liver function test (1.0% vonoprazan 10 mg, 2.0% vonoprazan 20 mg, 3.0% lansoprazole), and nausea (2.0% vonoprazan 10 mg, 1.4% vonoprazan 20 mg, 1.0% lansoprazole). Rates of discontinuation due to adverse events in the maintenance phase were 0.7% for vonoprazan 10 mg, 2.7% for vonoprazan 20 mg, and 0.7% for lansoprazole.

Frequency of serious adverse events, or SAEs, in the healing phase were similar between vonoprazan 20 mg and lansoprazole at 0.6%. In the maintenance phase, SAEs were reported in 4.7% of patients for vonoprazan 20 mg, 3.4% for vonoprazan 10 mg and 2.4% for lansoprazole. Further, this clinical trial was conducted during the 2020-2021 global pandemic, and coronavirus infection was reported in 2.1% of the vonoprazan 20 mg-treated patients and 1.8% of the lansoprazole-treated patients in the healing phase whereas it was reported in 6.1% of the vonoprazan 10 mg-treated patients, 10.1% of the vonoprazan 20 mg-treated patients and 6.7% of the lansoprazole-treated patients in the maintenance phase. There were 2 deaths in the vonoprazan 20 mg-treated patients due to coronavirus infection. None of the coronavirus infection events reported were considered related by the investigator.

In PHALCON-NERD-301, vonoprazan was generally well tolerated in the initial four-week double-blind, placebo-controlled phase of the trial. The overall adverse events for all vonoprazan arms were comparable to placebo and consistent with what was reported in previous studies. The most commonly reported adverse event was nausea (2.3% vonoprazan 10 mg, 3.1% vonoprazan 20 mg, 0.4% placebo) with no other events reported above 3.0% in either vonoprazan dose arm. There was a total of three SAEs reported in the four-week period of the study, one in the vonoprazan 10 mg arm and two in the vonoprazan 20 mg arm. The most common adverse events reported for the two vonoprazan doses during the 20-week extension period were upper respiratory tract infection, sinusitis, influenza, urinary tract infection, nasopharyngitis, nausea, and gastroenteritis, reported at or below 5%.

In PHALCON-NERD-201, vonoprazan was generally well tolerated. In both phases of the trial, no adverse event was reported in more than three percent of the participants in a treatment group. There was a total of four SAEs in the daily dosing phase, only one of which was related to study drug, and no SAEs in the as needed phase. The safety data for all vonoprazan arms were comparable to placebo and consistent with what was reported in previous studies.

Certain earlier generation PCABs previously under development by other companies may have been discontinued in-part due to their hepatic safety profile. These hepatic safety concerns may be compound-specific and not generalizable to the PCAB class. It is notable that vonoprazan is based on a pyrrole chemical structure and is chemically distinct from previously discontinued PCABs that were based on an imidazole structure. Vonoprazan has had a similar hepatic safety profile to lansoprazole across all clinical studies conducted by Takeda, in which 1.0% of subjects treated with vonoprazan 10 mg or 20 mg and 0.8% of subjects treated with lansoprazole 15 mg or 30 mg had alanine transaminase or ALT or aspartate transaminase or AST elevations greater than three times the upper limit of normal or bilirubin elevations greater than two times the upper limit of normal. Similarly, in the healing phase of PHALCON-EE, transient elevations in ALT or AST greater than 3 times the upper limit of normal were observed in 0.4% of subjects treated with vonoprazan 20 mg and 0.2% of subjects treated with lansoprazole. In the maintenance phase, transient ALT or AST elevations greater than three times the upper limit of normal were observed in 1% of subjects treated with vonoprazan 10 mg, 0.3% of subjects treated with vonoprazan 20 mg, and 2% of subjects treated with lansoprazole.

Vonoprazan Post-Marketing Safety in Japan and Asia

The most recent post-marketing safety report from December 2023 includes a worldwide cumulative estimate of over 60 million patients who have received vonoprazan since its launch in 2015. Based on the post-marketing experience, the clinically significant adverse reactions section of the Japanese prescribing information for vonoprazan was updated to include shock, anaphylaxis, hepatic impairment, skin reactions such as toxic epidermal necrolysis, Steven-Johnson syndrome, and erythema multiforme; and events of pancytopenia, agranulocytosis, leukocytopenia, and thrombocytopenia. The incidence of these reactions was considered extremely rare (less than 1 in 100,000 patients) and a causal relationship to vonoprazan could not be ruled out. Although serious hepatic adverse events have been observed among patients exposed to vonoprazan in Japan in the post-marketing setting, these cases were typically confounded by comorbidities or other concomitant medications and believed to be idiosyncratic reactions. Post-marketing safety data, including the December 2023 post-marketing safety report, has been submitted to the Pharmaceuticals and Medical Devices Agency. Moreover, the final results from the VISION trial, a five-year randomized, open-label, multicenter study conducted by Takeda evaluating the long-term efficacy and safety of vonoprazan compared with the PPI lansoprazole in patients with EE, further demonstrate that the safety profile of vonoprazan is generally comparable to lansoprazole.

Vonoprazan Launch in Japan

Vonoprazan Regulatory Status

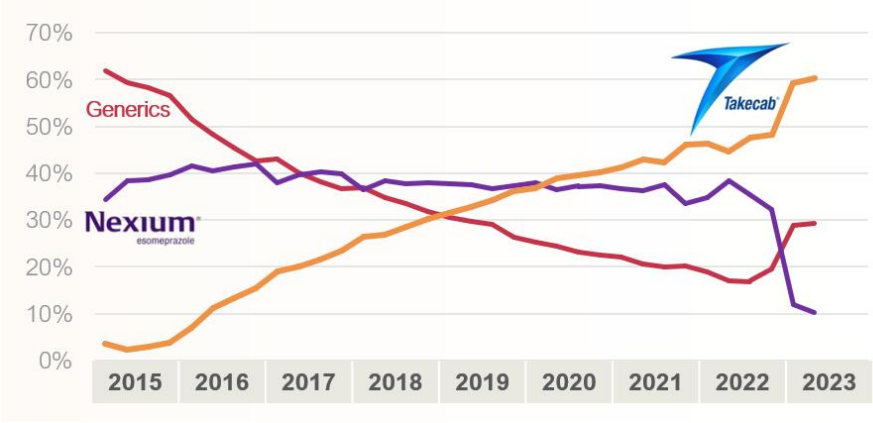
Vonoprazan first received approval in Japan on December 26, 2014, and was launched shortly thereafter in February 2015, as TAKECAB® for the following indications:

- Healing and maintenance of healing of erosive esophagitis;
- Adjunct to antibiotics in *H. pylori* treatment;
- Gastric ulcer;
- Duodenal ulcer;
- Prevention of recurrence of gastric ulcer or duodenal ulcer during low-dose aspirin administration; and
- Prevention of recurrence of gastric ulcer or duodenal ulcer during nonsteroidal anti-inflammatory drug (NSAID) administration.

Vonoprazan was subsequently approved in Japan in February 2016 for the treatment of *H. pylori* in combination packs with antibiotics (Vonosap Pack 400, Vonosap Pack 800, and Vonopion Pack), and has since been approved in numerous other countries in Asia and Latin America as well as Russia.

Vonoprazan Commercialization in Japan

Vonoprazan was approved in Japan in December 2014. In 2021, its seventh full year on the market, vonoprazan generated approximately $850 million in net sales in Japan. Based on sales during the 3-month period ending June 30, 2023, vonoprazan had achieved a 32% market share based on volume and 60% market share based on sales among prescription acid suppression therapies in Japan.



We believe that the market dynamic for anti-secretory agents in Japan is similar to that in the United States. In both countries, the anti-secretory market is largely genericized. Ahead of the vonoprazan launch in Japan, all PPIs, other than Nexium, were available as generics. As of September 2022, generic drugs in Japan represent approximately 80% of the market by volume, compared to the United States where generics are currently approximately 90% of the market by volume. Although vonoprazan and Dexilant are priced at a premium to generic PPIs in Japan and the United States, respectively, both have experienced commercial success.

Vonoprazan Commercial Opportunity and Strategy

The market for prevention and treatment of acid-related GI diseases in the United States and Europe is large. In the U.S., there were approximately 7.8 billion prescription PPI doses dispensed during the 12 months ended December 31, 2023. The PPI volume-based market is dominated by prescriptions products at 93%, with the remaining 7% comprised of over-the-counter products.

Over many decades of use, multiple drug classes and individual drugs have demonstrated the substantial commercial opportunity for therapies treating acid-related GI diseases. H2RAs including Axid, Pepcid, Tagamet, and Zantac provided the first significant improvement in disease management over antacids and as a class reached approximately $3.5 billion in annual sales. After H2RAs, PPIs emerged as the new standard of care. Prior to the introduction of generic and OTC alternatives, annual PPI class sales reached approximately $12.5 billion in the United States, and peak sales for individual brands were approximately $3.7 billion for Prilosec, $3.5 billion for Nexium, and $3.4 billion for Prevacid.

We believe the results of our Phase 3 clinical trials in Erosive GERD and *H. pylori* support the differentiation of our VOQUEZNA-based products from the PPI-based standard of care, which could provide support for broad market access and formulary positioning. For example, following approval of VOQUEZNA, VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK, we believe our interactions with payers highlight the commercial potential of these products. As of February 2024, approximately 60 million commercially covered lives in the United States have access to VOQUEZNA tablets, comprising an estimated 38% of total U.S. commercial lives. We believe our approved VOQUEZNA-based therapies have the potential to improve the standard of care for acid-related GI diseases by providing a safe and effective treatment option for the millions of patients not fully satisfied with their other current treatment options.

In May 2022, we conducted a U.S. market research study with 90 gastroenterologists, 90 primary care physicians and 45 advanced practice providers who treat GERD. Before seeing the vonoprazan clinical data, 82% of these clinicians strongly agreed that PPIs are the most potent class of acid suppressing agents. After review of vonoprazan clinical data and messages, only 34% strongly agreed that PPIs are the most potent class of acid suppressing agents.

Sales and Marketing

We have established robust marketing, sales, and distribution capabilities to support the launch of our approved products and we are independently commercializing VOQUEZNA, VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK in the United States through

an experienced national sales force. We believe we can successfully commercialize our approved products in the United States with a focused sales force targeting high prescribers of PPIs, particularly gastroenterologists and primary care physicians. Our strategy is to target approximately 52,000 high volume PPI prescribers in the treatment of GERD and *H. pylori* infection. According to IQVIA data, of these physicians, each write on average approximately 1,200 PPI prescriptions annually. We are not aware of any anti-secretory product that has been promoted to this core group of prescribers, nor to the broader medical community, for nearly a decade. As a result, we expect our promotional efforts will hold a unique position in the market.

To address the commercial opportunity for vonoprazan in Europe and Canada, we plan to seek one or more partners with existing commercial infrastructure and expertise in these markets.

Additional Vonoprazan Development Opportunities

Eosinophilic Esophagitis and Other Indications

While we are initially focused on the development of vonoprazan for the treatment of GERD and *H. pylori* infection, we believe there are opportunities to expand the use of vonoprazan to other indications in our licensed territories. For example, we plan to expand clinical development of vonoprazan in the U.S. into EoE, the most common type of eosinophilic gastrointestinal disease. EoE is an autoimmune disease with significant unmet need and can result in trouble swallowing, chest pain, vomiting and impaction of food in the esophagus, a medical emergency. There are only two FDA-approved treatments for EoE. Although not approved for this indication, PPIs are often prescribed as a first-line therapy for the treatment of EoE. Vonoprazan demonstrated similar efficacy to PPIs in an investigator-sponsored EoE clinical trial in Japan. In this clinical trial, 112 patients with EoE were treated with vonoprazan, or the PPI rabeprazole or esomeprazole. Of patients treated with vonoprazan, 82% had complete relief of symptoms compared to 70% for esomeprazole and 76-78% for rabeprazole. Similarly, 35% of patients treated with vonoprazan demonstrated complete remission of EoE by histology, compared to 37% for esomeprazole and 31-38% for rabeprazole. Given the limited treatment options for EoE and vonoprazan's demonstrated potential, we believe EoE is an important indication for future study and plan to initiate a Phase 2 trial studying vonoprazan as a treatment for EoE in adults and adolescent patients later in 2024.

In addition to EoE, Barrett's esophagus and Zollinger Ellison syndrome are severe diseases related to acid secretion where PPIs are the current standard of care. The improved acid control of vonoprazan relative to PPIs may lead to use in these indications improved results over PPIs.

Formulations and Packaging

Orally Disintegrating Tablet

An orally disintegrating tablet, or ODT, formulation for vonoprazan is currently being commercialized by Takeda in Japan. We may conduct one or more Phase 1 trials to support potential approval of an ODT formulation. We believe that an ODT formulation represents a meaningful commercial opportunity for patients with difficulty swallowing in adults as well as will provide a more desirable dosing administration options for children. It is estimated peak U.S. sales of the lansoprazole ODT formulation were over $450 million.

Over the Counter Use

We believe that vonoprazan has the ideal profile for an OTC product, including the potential for as needed symptom relief and a well-tolerated safety profile. Sales of OTC heartburn relief products in the United States are substantial, constituting a multi-billion-dollar market.

Competition

The biopharmaceutical industry is characterized by rapidly advancing technologies, intense competition and strong emphasis on proprietary products. We face potential competition from many sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and government agencies and public and private research institutions. In the United States, VOQUEZNA, VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK all compete, and if approved in Europe and/or Canada will compete, with existing therapies and new therapies that may become available in the future.

Some of our competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of treatments and commercializing those treatments. These same competitors may invent technology that competes with vonoprazan. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and subject recruitment for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Outside the U.S., our competitors may obtain regulatory approval for, or initiate commercial launch of, their products more rapidly than we may obtain approval for or launch products containing vonoprazan, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, VOQUEZNA, VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK, are priced at a premium over competitive generic products in the U.S., and our ability to compete may be affected in many cases by insurers or other third-party payers seeking to encourage the use of generic products.

We expect that, for the treatment of *H. pylori* infection, Erosive GERD and, if approved, treatment of heartburn associated with symptomatic Non-Erosive GERD, VOQUEZNA will primarily compete with generic PPIs marketed by multiple pharmaceutical companies in both the prescription and OTC markets. In addition to generic PPI-based triple and quad therapies, we expect VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK will compete with Talicia, a co-formulated capsule comprising generic omeprazole, amoxicillin, and rifabutin for the treatment of *H. pylori* infection, launched in March 2020 by RedHill Biopharma Ltd.

We are aware of other PCABs in development in the United States, as well as a number of other PCABs in territories outside of the United States that if developed and approved in our territories may compete with vonoprazan. In the United States, Daewoong Pharmaceutical Co., Ltd., or Daewoong, is looking for a strategic partner to advance the development of fexuprazan. In addition, Cinclus Pharma AG, or Cinclus, received qualified QIDP designation for linaprazan glurate in combination with antibiotics for the treatment of *H. pylori* infection, completed a Phase 2 dose selection study for Erosive GERD in November 2022, and plans to initiate a Phase 3 study in 2024 for the treatment of Erosive GERD. Finally, Sebela Pharmaceuticals, which acquired development and commercialization rights in United States and Canada to tegoprazan from HK inno.N, a South Korean company, has initiated two Phase 3 studies in the United States, one for Non-Erosive GERD and the other for healing and maintenance of healing of Erosive GERD. The earliest estimated completion date for these studies is during 2024. Outside the United States, in 2022 Daewoong launched fexuprazan in South Korea for the treatment of Erosive GERD under the brand name Fexuclue, has submitted applications for regulatory approval in additional countries in Asia and Latin America, and has out-licensed rights to develop fexuprazan in China to Shanghai Haini, a subsidiary of China's Yangtze River Pharmaceutical Group. Also outside the United States, revaprazan is marketed by Yuhan Corporation in South Korea, and tegoprazan is co-marketed by HK inno.N and Boryung Corp. in South Korea, is also marketed in China, Indonesia, Mexico, Mongolia, Philippines and Singapore and is currently under health authority review in Argentina and Thailand as well as in development by RaQualia Pharma, Inc. in Japan and by Dr. Reddy's in Russia. Additionally, Jeil Pharm has initiated a Phase 3 trial in South Korea of its PCAB candidate, JP-1366, in Erosive GERD, and Cinclus' linaprazan glurate has completed a Phase 2 clinical trial in Europe. To our knowledge, none of these compounds have demonstrated superiority to PPIs in a Phase 3 clinical trial.

Additionally, we are aware of several clinical-stage PPIs in territories outside of the United States that if developed and approved in our licensed territories may compete with vonoprazan. These include Dexa Medica's DLBS-2411, currently launched in the Philippines and in Phase 3 in Indonesia, Sihuan Pharmaceutical's anaprazole, currently in Phase 3 in China, and Eisai's azeloprazole, currently in a Phase 2 in China.

Intellectual Property

Intellectual property, including patents, trade secrets, trademarks and copyrights, is important to our business. Our commercial success depends in part on our ability to obtain and maintain proprietary intellectual property protection for vonoprazan, as well as for future product candidates and novel discoveries, product development technologies, and know-how. Our commercial success also depends in part on our ability to operate without infringing on the proprietary rights of others and to

prevent others from infringing our proprietary rights. Our policy is to develop and maintain protection of our proprietary position by, among other methods, licensing or filing U.S. and foreign patents and applications relating to our technology, inventions, and improvements that are important to the development and implementation of our business.

Our patent portfolio, comprising patents and patent applications exclusively licensed to us, is built with a goal of establishing broad protection that generally includes, for the product candidate compound, claims directed to composition of matter, pharmaceutical compositions or formulations, methods of synthesis, and methods of treatment using such pharmaceutical compositions or formulations. As of December 31, 2023, our patent portfolio covering vonoprazan consists predominantly of exclusively licensed patents and patent applications from Takeda. Subject to the terms of the license agreement we entered into with Takeda on May 7, 2019, or the Takeda License, we have licensed from Takeda exclusive rights in the United States, Europe, and Canada to patents and patent applications covering the composition of matter, formulation, use and/or manufacture of vonoprazan. Our patent portfolio comprises 11 distinct patent families protecting the technology relating to the compound vonoprazan and its synthetic intermediates, methods of synthesizing vonoprazan and related compounds, various formulations of vonoprazan products, as well as methods of treating diseases with vonoprazan and related compounds. As of December 31, 2023, our portfolio consists of approximately 25 issued U.S. patents, 4 pending U.S. applications, 15 issued European patents subsequently validated in individual European countries, 3 pending European applications, 6 issued Canadian patents, and 2 pending Canadian applications. The issued patents and pending applications have nominal expiration dates ranging from 2024 to 2038 without accounting for any available patent term adjustments or extensions. The issued U.S. patent covering the composition of matter of vonoprazan is expected to expire in August 2028, not including patent term extension. The issued U.S. patent covering the formulation of vonoprazan is expected to expire in August 2030, not including patent term extension.

The term of individual patents in our portfolio depends upon the legal term of patents in the countries in which they are obtained. In most countries in which we file, including the United States, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, the term of a patent may be eligible for patent term adjustment, which permits patent term restoration as compensation for delays incurred at the United States Patent and Trademark Office, or USPTO, during the patent prosecution process. In addition, for patents that cover an FDA-approved drug, the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. While the length of the patent term extension is related to the length of time the drug is under regulatory review, patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent per approved drug may be extended under the Hatch-Waxman Act. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We plan to seek any available patent term extension to any issued patents we may be granted in any jurisdiction where such extensions are available; however, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. The relevant patent laws and their interpretation outside of the United States is also uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our technology or product candidates and could affect the value of such intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell or importing products that infringe our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our technology, inventions and improvements. We cannot guarantee that patents will be granted with respect to any of our licensed pending patent applications or with respect to any patent applications we may file in the future, nor can we be sure that any patents that may be granted to us or Takeda in the future will be commercially useful in protecting our products, the methods of use or manufacture of those products. Moreover, issued patents do not guarantee the right to practice our technology in relation to the commercialization of our products. Issued patents only allow us to block potential competitors from practicing the claimed inventions of the issued patents.

Further, patents and other intellectual property rights in the pharmaceutical and biotechnology space are evolving and involve many risks and uncertainties. For example, third parties may have blocking patents that could be used to prevent us from commercializing vonoprazan and any future product candidates and practicing our proprietary technology, and any issued patents may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or could limit the term of patent protection that otherwise may exist for vonoprazan and any future product candidates. In addition,

the scope of the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies that are outside the scope of the rights granted under any issued patents. For these reasons, we may face competition with respect to vonoprazan and any future product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any patent protection for such product may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides.

It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us, and for employees and consultants to enter into invention assignment agreements with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Where applicable, the agreements provide that all inventions to which the individual contributed as an inventor shall be assigned to Phathom, and as such, will become our property. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information.

Further, we have filed for and have received trademark registrations for our company name "Phathom Pharmaceuticals" in the United States, European Union, and other foreign jurisdictions, and are pursuing trademark protection in certain other foreign jurisdictions.

License Agreement with Takeda Pharmaceutical Company Limited

On May 7, 2019, we and Takeda entered into an exclusive license, or the Takeda License, pursuant to which, Takeda granted us an exclusive, sublicensable (with Takeda's reasonable consent) license under certain patents and know how relating to vonoprazan and owned or controlled by Takeda during the term of the Takeda License to commercialize vonoprazan products using specified formulations for all human therapeutic uses in the United States, Europe and Canada, and a non-exclusive license under such patents and know how to develop and manufacture such vonoprazan products anywhere in the world (subject to Takeda's consent as to each country) for the purposes of commercializing the vonoprazan products in the United States, Europe and Canada. We granted Takeda a non-exclusive, royalty-free, sublicensable license under our rights in any patents and know-how that are necessary or useful to enable Takeda to develop and manufacture vonoprazan products anywhere in the world for the purposes of commercialization outside United States, Europe and Canada. We also granted Takeda an exclusive, royalty-free license under our rights in certain patents and know-how owned or controlled by us and necessary for the exploitation of vonoprazan products, in each case for Takeda to commercialize any vonoprazan product outside of the United States, Canada, and Europe and for purposes other than human therapeutic use.

During the term of the Takeda License, we and our affiliates are not permitted to commercialize any pharmaceutical product, other than vonoprazan, that treats acid-related disorders, except for certain generic and OTC competing products in specified circumstances. We will be responsible, at our cost, for the development, manufacture and commercialization of the vonoprazan products. We are required to use commercially reasonable efforts to develop and commercialize the vonoprazan products in our licensed territory.

Under the Takeda License, Takeda has the sole right and authority, with our input, to prepare, file, prosecute, and maintain all Takeda and joint patents on a worldwide basis at its own cost. We are responsible, at our cost, for preparing, filing, prosecuting, and maintaining patents on inventions made solely by us in connection with vonoprazan, subject to input from Takeda. We have the first right to enforce the licensed patent rights with respect to certain infringing products in the United States, Europe and Canada.

We paid Takeda upfront consideration consisting of a cash payment of $25 million, 1,084,000 shares of common stock and a warrant to purchase 7,588,000 shares of common stock, or the Takeda Warrant. We agreed to make milestone payments to Takeda upon achieving certain tiered aggregate annual net sales of licensed products in the United States, Europe and Canada up a total maximum milestone amount of $250 million. We also agreed to make tiered royalty payments in the low double digits to the mid-teens on net sales of licensed products, subject to specified offsets and reductions. Royalties will be payable, on a product-by-product and country-by-country basis from the first commercial sale of such product in such country, until the latest of expiration of

the licensed patents covering the applicable product, expiration of regulatory exclusivity in such country, or 15 years following first commercial sale in such country.

The Takeda License will continue until the expiration of the obligation to pay royalties in all countries and on all products. We may terminate the Takeda License in its entirety without cause upon six months' prior written notice. We and Takeda may terminate the Takeda License in the case of the other party's insolvency, or upon prior written notice within a specified time period for the other party's material uncured breach. Takeda may terminate the Takeda License in its entirety if we challenge the licensed patents, or if we assist any third party in challenging such patents.

Manufacturing

We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of vonoprazan. Vonoprazan is a small molecule that can be manufactured using commercially available technologies.

With respect to any future product candidates, we expect to continue to rely on third-party contract manufacturers to manufacture clinical supplies and commercial quantities of any approved products. Although we rely on contract manufacturers, we have personnel with manufacturing experience to oversee our relationships with Sandoz, Catalent and Evonik.

Sandoz Supply and Packaging Agreement

In December 2020, we entered into a Supply and Packaging Services Agreement with Sandoz GmbH, or the Sandoz Supply Agreement, pursuant to which Sandoz has agreed to supply commercial quantities of amoxicillin capsules and clarithromycin tablets, to package these antibiotics with vonoprazan drug product in finished convenience packs, and to supply us with these convenience packs.

Pursuant to the Sandoz Supply Agreement, we agreed to purchase certain quantities of convenience packs from Sandoz at an agreed upon price per pack. The price per pack is fixed for the first two (2) years following launch of the convenience pack in the United State and may be adjusted thereafter based on Sandoz's cost increases, subject to an annual cap. The Sandoz Supply Agreement sets forth an annual minimum number of convenience packs that we must purchase each year following launch of the convenience pack product, and if we do not meet the minimum order in a given year, we are required to pay Sandoz the amount corresponding to the shortfall. Sandoz has no obligation to supply convenience packs above a maximum number of packs above a certain percentage of our forecasts. We have agreed to purchase convenience packs, amoxicillin capsules and clarithromycin tablets, in each case intended for sale in the United States, exclusively from Sandoz during the five-year period following launch.

The Sandoz Supply Agreement will continue for five years from launch of the convenience pack in the U.S. and may be terminated effective at the end of the initial five-year term upon written notice by either party prior to the end of the third year following launch. In the absence of such notice, the Sandoz Supply Agreement will extend automatically for an additional three-year period, and thereafter as mutually agreed upon by the parties. The Sandoz Supply Agreement may also be terminated at any time upon written notice by either party for uncured material breach following written notice of such breach.

Catalent Commercial Supply Agreement

In July 2021, we entered into a Commercial Supply Agreement, or the Tablet Supply Agreement, with Catalent Pharma Solutions, LLC, or Catalent, pursuant to which Catalent has agreed to supply us with commercial quantities of vonoprazan fumarate tablets.

Pursuant to the Tablet Supply Agreement, as amended, Catalent has agreed to supply us with, and we have agreed to purchase from Catalent, finished vonoprazan tablets at an agreed upon price per unit. The price per unit may be adjusted annually based on increases in costs incurred by Catalent. The Tablet Supply Agreement requires us to purchase a specified percentage of its requirements of finished vonoprazan tablets from Catalent, which percentage is subject to adjustment following January 1, 2027.

Unless terminated earlier, the term of the Tablet Supply Agreement extends for a period of five years from the Commencement Date. The Tablet Supply Agreement will extend automatically for additional two year periods unless terminated by either party upon at least 24 months prior written notice. The Tablet Supply Agreement may also be terminated at any time upon

written notice by either party if the other party has failed to remedy a material breach of the terms of the Tablet Supply Agreement within a specified period following receipt of written notice of such breach.

Evonik Commercial Supply Agreement

In August 2022, we entered into a Commercial Supply Agreement, or the API Supply Agreement, with Evonik Operations GmbH, or Evonik, pursuant to which Evonik has agreed to supply us with commercial quantities of vonoprazan drug substance, or API.

Pursuant to the API Supply Agreement, Evonik has agreed to supply us with, and we have agreed to purchase, certain quantities of API at an agreed upon price which varies based on the volume of product ordered. The price may also be adjusted based on actual changes in costs incurred by Evonik. Subject to pre-existing purchase obligations to Takeda, we have agreed to purchase a percentage of our annual requirements of API from Evonik, for which the percentage of our annual API requirements is subject to adjustment based upon the price of API under the API Supply Agreement.

Unless terminated earlier, the API Supply Agreement has an initial period that expires in August 2027. This initial term will be extended by two additional years if Evonik successfully qualifies a second manufacturing facility to produce API no later than December 31, 2024. The API Supply Agreement may be terminated effective at the end of the initial period on at least 24-months written notice by either party. In the absence of such notice, the API Supply Agreement will extend automatically for additional 2-year periods which may be terminated upon 18 months' notice. The API Supply Agreement may also be terminated at any time upon written notice by either party if the other party has failed to remedy a material breach of the terms of the Supply Agreement within a specified period following receipt of written notice of such breach.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and export and import of products such as those we are developing. A new drug must be approved by the FDA through the NDA process before it may be legally marketed in the United States.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in accordance with Good Laboratory Practice, or GLP, regulations and other applicable regulations;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practice, or GCP, regulations to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current Good Manufacturing Practice, or cGMP, requirements to assure that the facilities,

methods and controls are adequate to preserve the drug's identity, strength, quality and purity, and of selected clinical investigation sites to assess compliance with GCPs; and

- FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the United States.

Once a pharmaceutical candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for certain studies. Prior to beginning the first clinical trial with a product candidate in the United States, a sponsor must submit an IND to the FDA. The sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The sponsor will also include a protocol detailing, among other things, the objectives of the first phase of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the first phase lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns about on-going or proposed clinical trials or non-compliance with specific FDA requirements, and the trials may not begin or continue until the FDA notifies the sponsor that the hold has been lifted. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of one or more qualified investigators in accordance with GCP regulations, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, dosing procedures, subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND as well as any subsequent protocol amendments. While the IND is active, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the drug, findings from animal or in vitro testing suggesting a significant risk to humans exposed to the drug, and any clinically important increased rate of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

Furthermore, an IRB at each institution participating in the clinical trial must review and approve each protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each trial subject or his or her legal representative, monitor the study until completed and otherwise comply with IRB regulations. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- ***Phase 1***: The product candidate is initially introduced into healthy human volunteers or patients with the target disease or condition. These studies test for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain an early indication of its effectiveness.

- ***Phase 2***: The product candidate is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks.

- ***Phase 3***: The product candidate is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of the product's effectiveness for its intended use(s) and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk-benefit ratio of the product candidate and provide, if appropriate, an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase 4 studies, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

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

There are also requirements governing the reporting of ongoing clinical trials and completed trial results to public registries. Sponsors of certain clinical trials of FDA-regulated products are required to register and disclose specified clinical trial information, which is publicly available at www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators and other aspects of the clinical trial is then made public as part of the disclosure.

NDA Review and Approval Process

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, preclinical and other non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once filed, the FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. Under current PDUFA guidelines, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision after the application is submitted.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP

requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP requirements.

After the FDA evaluates an NDA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the NDA identified by the FDA and may require additional clinical trials or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing to support the application. If a Complete Response Letter is issued, the sponsor must resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require a sponsor to conduct Phase 4 testing to further assess a drug's safety and effectiveness after NDA approval, and may require testing and surveillance programs to monitor the safety of approved products which have been commercialized. The FDA may also place other conditions on approval including the requirement for a risk evaluation and mitigation strategy, or REMS, to assure the safe use of the drug, which could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve the NDA without an approved REMS, if required.

Furthermore, the Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, fails to keep a deferral current or fails to submit a request for approval of a pediatric formulation.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. The FDA has a Fast Track designation program that is intended to expedite or facilitate the process for reviewing new drug products that meet certain criteria. Specifically, product candidates are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the application may be eligible for priority review. A Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for Breakthrough Therapy designation to expedite its development and review. A product candidate can receive Breakthrough Therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

Any marketing application for a drug submitted to the FDA for approval, including a product candidate with a Fast Track designation or Breakthrough Therapy designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review. A product candidate is eligible for priority review if it is designed to treat a serious or life-threatening disease or condition, and if approved, would provide a significant improvement in safety or effectiveness compared to available alternatives for such disease or condition. The FDA will attempt to direct additional resources to the evaluation of an application designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of new molecular entity NDAs under its current PDUFA review goals.

In addition, depending on the design of the applicable clinical trials, a product candidate may be eligible for accelerated approval. Drug products intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA will generally require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled confirmatory clinical trials verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit, and may require such confirmatory trials to be well underway prior to granting accelerated approval. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required confirmatory studies in a timely manner, or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast Track designation, Breakthrough Therapy designation, accelerated approval, and priority do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Post-Approval Requirements

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. After approval, some types of changes to the approved product, such as adding new indications, certain manufacturing changes and additional labeling claims, are subject to further FDA review and approval. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP regulations and other laws and regulations. In addition, the FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

Any drug products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the drug, providing the FDA with updated safety and efficacy information, drug sampling and distribution requirements, complying with certain electronic records and signature requirements, and complying with FDA promotion and advertising requirements. The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market and imposes requirements and restrictions on drug manufacturers, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the Internet. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their

products. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labelling.

Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or post-approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical holds on post-approval clinical trials, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties.

Non-Patent Data and Market Exclusivity

Data and market exclusivity provisions under the FDCA can delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a NCE if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or an NDA submitted under Section 505(b)(2), or 505(b)(2) NDA, submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FDCA alternatively provides three years of non-patent market exclusivity for an NDA, or supplement to an existing NDA, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of market exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials.

Additionally, under the GAIN Act, the FDA may designate a product as a QIDP. In order to receive this designation, a drug must qualify as an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by either (1) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens, or (2) a so-called "qualifying pathogen" found on a list of potentially dangerous, drug-resistant organisms established and maintained by the FDA under the law. The FDA interprets QIDP designation to apply to a specific drug product, including a specific dosage form of the product. A sponsor must request such designation before submitting a marketing application, and the FDA will respond to a request for QIDP designation within 60 days of the date the FDA receives the request. The GAIN Act permits the FDA to revoke a QIDP designation if the request for such designation contained an untrue statement of material fact.

The benefits of QIDP designation include potential eligibility for priority review and Fast Track designation, and an extension by an additional five years of any non-patent exclusivity period awarded, such as a five-year NCE exclusivity period awarded for a new chemical entity. This extension is in addition to any pediatric exclusivity extension that may be awarded, and the extension will be awarded only to a drug first approved on or after the date of enactment. The GAIN Act provisions prohibit the grant of an exclusivity extension where the application is a supplement to an application for which an extension is in effect or has expired, is a

subsequent application for a specified change to an approved product, or is an application for a product that does not meet a definition of QIDP based on the uses for which it is ultimately approved.

U.S. Healthcare Fraud and Abuse Laws and Compliance Requirements

In addition to FDA regulation of pharmaceutical products, U.S. federal and state healthcare laws and regulations restrict business practices in the pharmaceutical industry. These laws may impact, among other things, our current and future business operations, including our clinical research activities, and constrain the business or financial arrangements and relationships with healthcare providers and other parties. These laws include anti-kickback and false claims laws, civil monetary penalties laws, and transparency laws regarding drug pricing and payments or other items of value provided to physicians and other healthcare providers.

The federal Anti-Kickback Statute prohibits, among other things, individuals or entities from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation.

The federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws prohibit, among other things, any individual or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payers and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation.

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists, anesthesiology assistants and certified nurse midwives), and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members.

Similar state and local laws and regulations may also restrict business practices in the pharmaceutical industry, such as state anti-kickback and false claims laws, which may apply to business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payers, including private insurers, or by patients themselves; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information or which require tracking gifts and other remuneration and items of value provided to physicians, other healthcare providers and entities; and state and local laws that require the registration of pharmaceutical sales representatives.

Violation of any of such laws or any other governmental regulations that apply may result in significant criminal, civil and administrative penalties including damages, fines, imprisonment, disgorgement, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these

laws, contractual damages, reputational harm, diminished profits and future earnings, disgorgement, exclusion from participation in government healthcare programs and the curtailment or restructuring of our operations.

U.S. Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidate for which we may seek regulatory approval. Sales in the United States will depend, in part, on the availability of sufficient coverage and adequate reimbursement from third-party payers, which include government health programs such as Medicare, Medicaid, TRICARE and the Veterans Administration, as well as managed care organizations and private health insurers. Prices at which we or our customers seek reimbursement for VOQUEZNA, VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK and any future product candidates can be subject to challenge, reduction or denial by third-party payers.

The process for determining whether a third-party payer will provide coverage for a product is typically separate from the process for setting the reimbursement rate that the payer will pay for the product. In the United States, there is no uniform policy among payers for coverage or reimbursement. Decisions regarding whether to cover a product, the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. Third-party payers often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval processes. Therefore, coverage and reimbursement for products can differ significantly from payer to payer. As a result, the coverage determination process is often a time-consuming and costly process that can require manufacturers to provide scientific and clinical support for the use of a product to each payer separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Third-party payers are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product that receives approval. Third-party payers may not consider vonoprazan or any future product candidates to be medically necessary or cost-effective compared to other available therapies, or the rebate percentages required to secure favorable coverage may not yield an adequate margin over cost or may not enable us to maintain price levels sufficient to realize an appropriate return on our investment in drug development. Additionally, decreases in third-party reimbursement for any product or a decision by a third-party payer not to cover a product could reduce physician usage and patient demand for the product.

Medicaid is a joint federal and state program administered by the states for low-income and disabled beneficiaries. Medicare is a federal program that is administered by the federal government covering individuals age 65 and over as well as those with certain disabilities. Under the Medicaid Drug Rebate Program, or MDRP, as a condition of having federal funds being made available to the states for covered outpatient drugs under Medicaid, and, if applicable, Medicare Part B, pharmaceutical manufacturers must enter into an agreement with the Secretary of Health and Human Services to pay a rebate to state Medicaid programs for each unit of covered outpatient drug dispensed to a Medicaid beneficiary and paid for by the state Medicaid program. Medicaid drug rebates are based on pricing data that pharmaceutical manufacturers report on a monthly and quarterly basis to CMS, which is the federal agency that administers the MDRP and Medicare programs. For the MDRP, these data include the average manufacturer price, or AMP, for each drug and, in the case of innovator products, the Best Price, or BP, which represents the lowest price available from the manufacturer to any entity in the United States in any pricing structure, calculated to include all applicable sales and associated rebates, discounts and other price concessions. If a manufacturer becomes aware that its MDRP government price reporting submission for a prior quarter was incorrect or has changed as a result of recalculation of the pricing data, the manufacturer must resubmit the corrected data for up to three years after those data originally were due. If a manufacturer fails to provide information timely or is found to have knowingly submitted false information to the government, the manufacturer may be subject to civil monetary penalties and other sanctions, including termination from the MDRP.

Federal law requires that a manufacturer that participates in the MDRP also participate in the Public Health Service's 340B drug pricing program, or the 340B program, in order for federal funds to be available for the manufacturer's drugs under Medicaid and, if applicable, Medicare Part B. The 340B program is administered by the Health Resources and Services Administration, or HRSA, and requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs used in an outpatient setting. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula,

which is based on the AMP and rebate amount for the covered outpatient drug as calculated under the MDRP. In general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price calculation and discount requirement. Manufacturers must report 340B ceiling prices to HRSA on a quarterly basis, and HRSA publishes them to 340B covered entities. HRSA has finalized regulations regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities for 340B-eligible drugs. HRSA has also finalized an administrative dispute resolution process through which 340B covered entities may pursue claims against participating manufacturers for overcharges, and through which manufacturers may pursue claims against 340B covered entities for engaging in unlawful diversion or duplicate discounting of 340B drugs. In addition, legislation may be introduced that, if passed, would further expand the 340B program, such as adding further covered entities or requiring participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting.

In order to be eligible to have drug products paid for with federal funds under Medicaid and, if applicable, Medicare Part B, and purchased by certain federal agencies and grantees, a manufacturer must also participate in the U.S. Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program. Under the VA/FSS program, a manufacturer must report the Non-Federal Average Manufacturer Price, or Non-FAMP, for its covered drugs to the VA and charge certain federal agencies no more than the Federal Ceiling Price, which is calculated based on Non-FAMP using a statutory formula. These federal agencies are the VA, the U.S. Department of Defense, the U.S. Coast Guard, and the U.S. Public Health Service (including the Indian Health Service). The manufacturer must also pay rebates on products purchased by military personnel and dependents through the TRICARE retail pharmacy program.

We are enrolled or participate in the MDRP, the 340B program, the VA/FSS program, and the TRICARE retail pharmacy program, and have price reporting and payment obligations under these and other programs. Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies, and the courts. We cannot ensure that any submissions we are required to make under these programs will not be found to be incomplete or incorrect.

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

U.S. Healthcare Reform

In the United States, there has been, and continues to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the profitable sale of product candidates.

Among policy makers and payers in the United States, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the Patient Protection and Affordable Care Act, or the Affordable Care Act, was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the pharmaceutical industry. The Affordable Care Act increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; required collection of rebates for drugs paid by Medicaid managed care organizations; required manufacturers to participate in a coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs; implemented a new methodology by which rebates owed by manufacturers under the MDRP are calculated for drugs that are inhaled, infused, instilled, implanted, or injected; expanded eligibility criteria for Medicaid programs; created a new Patient-Centered Outcomes

Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare and Medicaid Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial and political challenges to certain aspects of the Affordable Care Act. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the Affordable Care Act without specifically ruling on the constitutionality of the Affordable Care Act. Thus, the Affordable Care Act will remain in effect in its current form.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, beginning April 1, 2013, Medicare payments to providers were reduced under the sequestration required by the Budget Control Act of 2011, which will remain in effect through 2032, unless additional Congressional action is taken. Additionally, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. On March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap, beginning January 1, 2024. Previously, the rebate was capped at 100% of a drug's AMP.

Moreover, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products.

Most significantly, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the Affordable Care Act in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services, or HHS, to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. The impact of the IRA on the pharmaceutical industry cannot yet be fully determined, but is likely to be significant. Individual states in the U.S. have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs and suppliers will be included in their healthcare programs. Furthermore, there has been increased interest by third-party payers and governmental authorities in reference pricing systems and publication of discounts and list prices.

The likelihood of implementation of additional reform initiatives is uncertain. Moreover, in the coming years, additional legislative and regulatory changes could be made to governmental health programs that could significantly impact pharmaceutical companies and the success of our product candidates.

Foreign Regulation

In order to market any product outside of the United States, we would need to 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 our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical trials or marketing of the product in foreign countries and jurisdictions. Although many of the issues discussed above with respect to the United States apply similarly in the context of the European Union, or EU, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain

FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Regulation and Procedures Governing Marketing Authorization of Medicinal Products in the EU

Non-Clinical Studies and Clinical Trials

Similarly, to the United States, the various phases of non-clinical and clinical research in the EU are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical (pharmaco-toxicological) studies must be conducted in compliance with the principles of good laboratory practice, or GLP, as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products, e.g., radio-pharmaceutical precursors for radio-labeling purposes). In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use, or ICH, guidelines on good clinical practices, or GCP, as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU member states, the sponsor is liable to provide 'no fault' compensation to any study subject injured in the clinical trial.

The regulatory landscape related to clinical trials in the EU has been subject to recent changes. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. Unlike directives, the CTR is directly applicable in all EU member states without the need for member states to further implement it into national law. The CTR notably harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System, which contains a centralized EU portal and database.

While the EU Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, much like the FDA and IRB, respectively, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The CTA must include, 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.

The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed.

The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the EU Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the EU Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date, all clinical trials (including those which are ongoing) will become subject to the provisions of the CTR.

Medicines used in clinical trials must be manufactured in accordance with Good Manufacturing Practice, or GMP. Other national and EU-wide regulatory requirements may also apply.

Marketing Authorizations

In the EU, medicinal product candidates can only be commercialized after obtaining a marketing authorization, or MA. To obtain regulatory approval of a product candidate in the EU, we must submit a MA Application, or MAA. The process for doing this depends, among other things, on the nature of the medicinal product.

There are two types of MAs:

- "Centralized MAs" are issued by the European Commission through the centralized procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, and are valid throughout the EU. The centralized procedure is mandatory for certain types of products, such as (i) medicinal products derived from biotechnological processes, (ii) designated orphan medicinal products, (iii) advanced therapy medicinal products, or ATMPs, such as gene therapy, somatic cell-therapy or tissue-engineered medicines and (iv) medicinal products containing a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions and viral diseases. The centralized procedure is optional for any products containing a new active substance not yet authorized in the EU, or for products that constitute a significant therapeutic, scientific or technical innovation or for which the granting of a MA would be in the interest of public health in the EU.

- "National MAs" are issued by the competent authorities of the EU member states, only cover their respective territory, and are available for product candidates not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in an EU member state, this national MA can be recognized in another member state through the mutual recognition procedure. If the product has not received a national MA in any member state at the time of application, it can be approved simultaneously in various member states through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the competent authorities of each of the member states in which the MA is sought, one of which is selected by the applicant as the reference member state.

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the EU member states make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

MAs have an initial duration of five years. After these five years, the authorization may be renewed for an unlimited period on the basis of a reevaluation of the risk-benefit balance. Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops. In exceptional cases, the CHMP might perform an accelerated review of a MA in no more than 150 days (not including clock stops).

Data and marketing exclusivity

The EU also provides opportunities for market exclusivity. Upon receiving MA, innovative medicinal products generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, the data exclusivity period prevents generic or biosimilar applicants from relying on the pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial MA of the reference product in the EU. The overall 10-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those 10 years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical (or biological) entity, and products may not qualify for data exclusivity.

Pediatric investigation plan

In the EU, MAAs for new medicinal products have to include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMA's Pediatric Committee, or PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to

demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all EU member states and study results are included in the product information, even when negative, the product is eligible for six months' supplementary protection certificate extension (if any is in effect at the time of approval) or, in the case of orphan pharmaceutical products, a two-year extension of the orphan market exclusivity is granted.

Post-Approval Requirements

Similar to the United States, 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 member states. The holder of a MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, or QPPV, who is responsible for the establishment and maintenance of that system, and oversees the safety profiles of medicinal products and any emerging safety concerns. 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, or RMP, describing the risk management system that we 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.

The advertising and promotion of medicinal products is also subject to laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the EU. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another.

Failure to comply with the aforementioned EU and member state laws may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

The aforementioned EU rules are generally applicable in the European Economic Area, or EEA, which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

Coverage and Reimbursement

Outside of the United States, the pricing of pharmaceutical products and medical devices is subject to governmental control in many countries. In the EU, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost effectiveness of a particular therapy to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. Other countries may allow companies to fix their own prices for products, but monitor and control product volumes and issue guidance to physicians to limit prescriptions. Efforts to control prices and utilization of pharmaceutical products and medical devices will likely continue as countries attempt to manage healthcare expenditures. Historically, products launched in the EU do not follow price structures of the United States and generally prices tend to be significantly lower.

Brexit and the Regulatory Framework in the United Kingdom

The United Kingdom, or UK, left the EU on January 31, 2020, following which existing EU medicinal product legislation continued to apply in the United Kingdom during the transition period under the terms of the EU-UK Withdrawal Agreement. The

transition period, which ended on December 31, 2020, maintained access to the EU single market and to the global trade deals negotiated by the EU on behalf of its members. The transition period provided time for the UK and EU to negotiate a framework for partnership for the future, which was then crystallized in the Trade and Cooperation Agreement, or TCA, and became effective on the January 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP inspections of manufacturing facilities for medicinal products and GMP documents issued but does not foresee wholesale mutual recognition of UK and EU pharmaceutical regulations.

EU laws which have been transposed into UK law through secondary legislation continue to be applicable as "retained EU law". However, new legislation such as the EU Clinical Trials Regulation or in relation to orphan medicines will not be applicable. The UK government has passed a new Medicines and Medical Devices Act 2021, which introduces delegated powers in favor of the Secretary of State or an 'appropriate authority' to amend or supplement existing regulations in the area of medicinal products and medical devices. This allows new rules to be introduced in the future by way of secondary legislation, which aims to allow flexibility in addressing regulatory gaps and future changes in the fields of human medicines, clinical trials and medical devices.

As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, is the UK's standalone medicines and medical devices regulator. As a result of the Northern Ireland protocol, different rules will apply in Northern Ireland than in England, Wales, and Scotland, together, Great Britain, or GB; broadly, Northern Ireland will continue to follow the EU regulatory regime, but its national competent authority will remain the MHRA. The MHRA has published a guidance on how various aspects of the UK regulatory regime for medicines will operate in GB and in Northern Ireland following the expiry of the Brexit transition period on December 31, 2020. The guidance includes clinical trials, importing, exporting, and pharmacovigilance and is relevant to any business involved in the research, development, or commercialization of medicines in the UK.

The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, including a 150-day assessment and a rolling review procedure. All existing EU MAs for centrally authorized products were automatically converted or grandfathered into UK MAs, effective in GB (only), free of charge on January 1, 2021, unless the MA holder chooses to opt-out. After Brexit, companies established in the UK cannot use the centralized procedure and instead must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures to obtain an MA to commercialize products in the UK. A new international recognition framework has been in place from January 1, 2024, whereby the MHRA will have regard to decisions on the approval of MAs made by the EMA and certain other regulators when determining an application for a new GB MA.

Data Privacy and Security Laws

As a pharmaceutical company, we are subject to federal, state and foreign data privacy, cybersecurity and data breach notification laws governing the collection, use, disclosure and protection of health-related and other personal information. For example, in the U.S., HIPAA imposes privacy, security and breach reporting obligations upon "covered entities" (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, receive, maintain or transmit protected health information, or PHI, in connection with providing certain services for or on behalf of a covered entity. HIPAA mandates the reporting of certain breaches of protected health information to the HHS to affected individuals and if the breach is large enough, to the media. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured personal health information, 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. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI.

Even when HIPAA does not apply, according to the Federal Trade Commission or the FTC, failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's cybersecurity measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. In addition, certain other federal, state laws, such as the California Consumer Privacy Act, or CCPA, similar state laws in other U.S. states including Colorado, Connecticut, Virginia and Utah, govern the privacy and security of personal information, including health-related information in certain circumstances, some of which are more stringent than HIPAA and many

of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. We are also subject to EU/UK General Data Protection Regulation, or GDPR, which imposes comprehensive data privacy compliance obligations in relation to our collection, processing, sharing, disclosure, transfer and other use of data relating to an identifiable living individual or "personal data", including a principle of accountability and the obligation to demonstrate compliance through policies, procedures, training and audit. Failure to comply with applicable data privacy and security laws can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Human Capital

As of February 29, 2024, we had 452 full-time employees, many of whom hold a Ph.D., M.D. or other advanced degree in their field. None of our employees are represented by labor unions or covered by collective bargaining agreements. We continued to add employees in fiscal year 2023 with a focus on building our in-house sales management and field sales teams. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and developing our existing and new employees, advisors and consultants. We maintain equity and cash incentive plans for, and offer a comprehensive benefit package to, every employee to attract, retain and reward personnel. The purpose of our cash and equity compensation plans is to increase stockholder value and the success of our company by motivating our employees to perform to the best of their abilities and achieve our objectives.

Corporate Information

We were originally incorporated under the laws of the state of Delaware on January 9, 2018 under the name North Bridge IV, Inc. On March 13, 2019, we changed our name to Phathom Pharmaceuticals, Inc. and merged YamadaCo IIA, Inc., a Delaware corporation, or YamadaCo, with and into our company, with Phathom Pharmaceuticals, Inc. as the surviving entity, or the Merger. Our principal executive offices are located at 100 Campus Drive, Suite 102, Florham Park, New Jersey 07932, and our telephone number is (877) 742-8466.

Available Information

Our internet address is www.phathompharma.com. Our investor relations website is located at https://investors.phathompharma.com. We make available free of charge on our investor relations website under "Financials and Filings" our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, our directors' and officers' Section 16 reports and any amendments to those reports as soon as reasonably practicable after filing or furnishing such materials to the SEC. They are also available for free on the SEC's website at www.sec.gov.

We use our investor relations website as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation FD. Investors should monitor such website, in addition to following our press releases, SEC filings and public conference calls and webcasts. Information relating to our corporate governance is also included on our investor relations website. The information in or accessible through the SEC and our website are not incorporated into, and are not considered part of, this filing.

Item 1A. Risk Factors

You should carefully consider the following risk factors, together with the other information contained in this annual report on Form 10-K, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before making a decision to purchase or sell shares of our common stock. We cannot assure you that any of the events discussed in the risk factors below will not occur. These risks could have a material and adverse impact on our business, results of operations, financial condition and growth prospects. If that were to happen, the trading price of our common stock could decline. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations or financial condition. In this section, we first provide a summary of the more significant risks and uncertainties we face and then provide a full set of risk factors and discuss them in greater detail.

SUMMARY RISKS FACTORS

- We have a limited operating history, have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future;
- We may never become profitable or, if we achieve profitability, we may not be able to sustain it;
- We may require additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our commercialization activities, product development programs, or other operations;
- Our Revenue Interest Financing Agreement could limit cash flow available for our operations and expose us to risks that could adversely affect our business, financial condition and results of operations;
- We currently depend entirely on the success of VOQUEZNA, VOQUEZNA TRIPLE PAK and VOQEUZNA DUAL PAK, which were launched in the fourth quarter of 2023. If we are unable to successfully commercialize these products, or are unable to obtain regulatory approval for vonoprazan to treat heartburn associated with symptomatic Non-Erosive GERD, our business will be materially harmed;
- Vonoprazan may not have favorable results in our future clinical trials, or receive additional regulatory approvals on a timely basis, if at all;
- VOQUEZNA, VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK, and any future product candidates are subject to extensive regulation and compliance obligations, which is costly and time consuming, and such regulation may cause unanticipated delays or prevent the receipt of the required approvals to commercialize additional product candidates;
- We may not be successful in our efforts to expand our pipeline by identifying additional indications and formulations for which to investigate vonoprazan in the future. We may expend our limited resources to pursue a particular indication or formulation for vonoprazan and fail to capitalize on product candidates, indications or formulations that may be more profitable or for which there is a greater likelihood of success;
- We currently have limited experience as a company in commercializing products. We may lack the necessary expertise, personnel and resources to successfully commercialize any of our product candidates that have received or may receive regulatory approval, including VOQUEZNA;

- We rely on third parties to conduct our preclinical and clinical trials and perform other tasks for us. 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 obtain additional regulatory approvals for or commercialize vonoprazan and our business could be harmed;

- We currently engage third-party manufacturers for all of our clinical and commercial supplies. The loss of any of these suppliers, or any future single source suppliers, could harm our business;

- We rely on the Takeda License to provide us rights to develop and commercialize vonoprazan in the United States, Europe, and Canada. If the license agreement is terminated, we would lose our rights to develop and commercialize vonoprazan;

- If the scope of any patent protection or non-patent regulatory exclusivity we obtain is not sufficiently broad, or if we lose or fail to obtain any of our patent protection or non-patent regulatory exclusivity, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected;

- The successful commercialization of VOQUEZNA, VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our products could limit our ability to market those products successfully and decrease our ability to generate revenue;

- If we fail to comply with reporting and payment obligations for VOQUEZNA, VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK under the Medicaid Drug Rebate Program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects;

- We are subject to various foreign, federal, and state healthcare and privacy laws and regulations, and our failure to comply with these laws and regulations could harm our results of operations and financial condition;

- We are highly dependent on the services of our key executives and personnel, and if we are not able to retain these members of our management or recruit additional management, clinical and commercial personnel, our business will suffer; and

- The trading price of our securities is likely to be volatile, and purchasers of our securities could incur substantial losses.

Risks Related to Our Limited Operating History, Financial Position and Capital Requirements

We have a limited operating history as a commercial company, which may make it difficult to evaluate the success of our business to date and to assess our future viability.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk.

We received our first regulatory approvals in 2022, and prior to our commercialization of VOQUEZNA, VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK in the fourth quarter of 2023, we had not manufactured products on a commercial scale, or arranged for a third party to do so on our behalf or conducted sales and marketing activities necessary for successful commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer history of successfully developing and commercializing products. We expect our financial condition and operating results to continue to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. We have transitioned from a company with solely a clinical development focus to a company also undertaking commercial activities. We may encounter unforeseen expenses, difficulties, complications and delays, and may not be successful in such a transition.

We have incurred significant operating losses since inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future and may never achieve or maintain profitability.

Since our inception, we have incurred significant operating losses. Our net loss was $201.6 million and $197.7 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $928.7 million. We expect to continue to incur expenses and operating losses for the foreseeable future. It could be several years, if ever, before VOQUEZNA, VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK or other product candidates, if approved, generate significant revenues to offset these expenses and operating losses. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially as we:

- initiate, continue, or complete planned or ongoing clinical trials of vonoprazan, including related support activities;
- make required milestone and royalty payments under license agreements by which we acquired rights to vonoprazan;
- make required royalty payments under the Revenue Interest Financing Agreement, or RIFA, entered into in May 2022, as amended;
- make required payments under the Loan and Security Agreement with Hercules Capital, Inc., entered into in September 2021, as amended;
- initiate clinical trials for VOQUEZNA, vonoprazan or any future product candidates;
- build a portfolio of product candidates through the acquisition or in-license of additional product candidates or technologies;
- pursue regulatory approvals for new indications for vonoprazan and future product candidates that successfully complete clinical trials; and
- incur additional legal, accounting and other expenses in connection with operating as a public company.

To become and remain profitable, we must successfully commercialize one or more product candidates with significant market potential. This will require us to be successful in manufacturing, marketing and selling our currently approved products, particularly VOQUEZNA, and any future product candidates for which we may obtain marketing approval and satisfying any post-marketing requirements. We are only in the early stages of many of these activities and, in some cases, have not yet commenced certain of these activities.

Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, continue our product development efforts, diversify our product candidate pipeline or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations.

The development and commercialization of biopharmaceutical product candidates is capital-intensive. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue to achieve product sales for VOQUEZNA and our other approved products and progress our Non-Erosive GERD development program. In addition, we are required to make milestone and royalty payments to Takeda, from whom we have in-licensed the rights to develop and commercialize vonoprazan in the United States, Europe, and Canada pursuant to the Takeda License. Furthermore, if and to the extent we seek to acquire or in-license additional product candidates in the future, we may be required to make significant upfront payments, milestone payments, and/or royalty payments. If we obtain additional regulatory approvals for vonoprazan or regulatory approval for any future product candidate, we also expect to incur significant additional commercialization expenses related to product manufacturing, marketing, sales and distribution. Because the outcome of any clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of vonoprazan for additional populations, such

as patients with Non-Erosive GERD or EoE, or other product candidates. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

We believe that our existing cash and cash equivalents together with the drawdown of the remaining $160 million under our loan and security agreement, or the Loan Agreement, with Hercules Capital, or Hercules, are sufficient to fund operations for at least the next 12 months and, along with anticipated product revenues, will be sufficient to fund our operations through the end of 2026. In particular, we expect that these funds will allow us to finance the ongoing launch of VOQUEZNA, including for the treatment of heartburn associated with symptomatic Non-Erosive GERD, if approved, VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK, and complete the clinical development of vonoprazan as an as needed treatment for Non-Erosive GERD. We have based these estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop vonoprazan or any future product candidates.

Our future capital requirements will depend on many factors, including:

- the costs of sales and marketing activities in support of the commercial launch of VOQUEZNA, VOQUEZNA TRIPLE PAK, and VOQUEZNA DUAL PAK, or any future product candidate;
- the initiation, type, number, scope, results, costs and timing of our clinical trials of vonoprazan, and preclinical studies or clinical trials of other potential product candidates we may choose to pursue in the future, including feedback received from regulatory authorities;
- the costs and timing of manufacturing for vonoprazan or any future product candidates, including commercial scale manufacturing if any product candidate is approved;
- the costs, timing and outcome of regulatory review of our NDA for vonoprazan for the treatment of heartburn associated with symptomatic Non-Erosive GERD, and the costs, timing and outcome of regulatory review of any future product candidates;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;
- the costs associated with hiring additional personnel and consultants as our business grows particularly commercial personnel;
- the timing and amount of the milestone or other payments we must make to Takeda and any future licensors;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payers and adequate market share and revenue for any approved products;
- patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payers;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements; and
- the costs associated with any products or technologies that we may in-license or acquire.

Conducting clinical trials and preclinical studies is a time consuming, expensive, and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval of future product candidates. In addition, VOQUEZNA, VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK, or any future product candidate, may not achieve commercial success. Our commercial revenues will, for the foreseeable future, be derived exclusively from sales of products containing vonoprazan in the United States.

Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through equity offerings, our Loan Agreement with Hercules, our Revenue Interest Financing Agreement, other debt financings, or other capital sources, including potential collaborations, licenses and other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Our Loan Agreement and our Revenue Interest Financing Agreement include, and any future debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. For example, our Loan Agreement with Hercules contains minimum cash financial covenants.

If we raise funds through future collaborations, licenses and other similar arrangements, we may have to relinquish valuable rights to our future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us and/or that may reduce the value of our common stock.

Risks Related to Commercialization of VOQUEZNA, VOQUEZNA TRIPLE PAK, VOQUEZNA DUAL PAK and Any Future Product Candidates

We may lack the necessary expertise, personnel and resources to successfully commercialize VOQUEZNA, VOQUEZNA TRIPLE PAK, VOQUEZNA DUAL PAK, and any future product candidates that may receive regulatory approval, on our own or together with collaborators.

Until 2023, our operations were primarily limited to organizing and staffing our company, business planning, raising capital, acquiring the rights to, and undertaking clinical trials of, vonoprazan. Although we started developing marketing and distribution capabilities in 2021 in advance of the planned commercialization of VOQUEZNA, VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK, due to approval and launch delays, we did not hire our field force until late 2023. The success of the commercialization of our approved products in the United States and any of our future product candidates that may be approved by the FDA will depend on such marketing, sales and distribution capabilities. Factors that may affect our ability to commercialize our approved products and future product candidates successfully on our own include obtaining access to or persuading adequate numbers of physicians to prescribe our products. Building and maintaining a sales and marketing organization has required, and will continue to require, significant investment, and is time-consuming. Our sales and marketing organization may prove not to be effective. If we are unable to maintain effective sales and marketing capabilities for our approved products including VOQUEZNA, or to find suitable partners for such commercialization, we may have difficulties generating revenue from them.

Following receipt of regulatory approval, we are subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense.

With respect to VOQUEZNA, VOQUEZNA TRIPLE PAK, VOQUEZNA DUAL PAK, and any future product candidates, the FDA, EMA or other comparable regulatory authority may impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly and time-consuming post-approval studies, post-market surveillance or clinical trials to monitor the safety and efficacy of the product. The FDA and comparable regulatory authorities may also require a REMS or similar risk management measures as a condition of approval of any future product candidates, which could include requirements for a

medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, for our approved products or future products that obtain approval, particularly following commercial launch of any such products, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and similar requirements and GCP requirements for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our products, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;
- fines, restitutions, disgorgement of profits or revenues, warning letters, untitled letters or holds on clinical trials;
- refusal by the FDA or comparable foreign regulatory authority to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of our products; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our current products and any future product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of any future product candidates or additional indications for our current products. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, may be subject to enforcement action, and we may not achieve or sustain profitability.

Additionally, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection, revising the eligibility for expedited pathways, etc.) was published on April 26, 2023. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revisions may however have a significant impact on the pharmaceutical industry and our business in the long term.

The commercial success of our current products or any future product candidates will depend upon the degree of market acceptance of such product candidates by physicians, patients, healthcare payers and others in the medical community.

VOQUEZNA, VOQUEZNA TRIPLE PAK, VOQUEZNA DUAL PAK, and any future product candidates, if approved, may not be commercially successful. The commercial success of our current products or any future product candidates will depend significantly on the broad adoption and use of such product by physicians and patients for approved indications. The degree of market acceptance of our current products or any future products, if approved, will depend on a number of factors, including:

- demonstration of clinical efficacy and safety compared to other more-established products;
- the indications for which our current or any future product candidates are approved;
- the limitation of our targeted patient population and other limitations or warnings contained in any FDA-approved labeling or comparable approved labeling;
- acceptance of a new drug for the relevant indication by healthcare providers and their patients;

- the pricing and cost-effectiveness of our products, as well as the cost of treatment with our products in relation to alternative treatments and therapies;
- our ability to obtain and maintain sufficient third-party coverage and adequate reimbursement from government healthcare programs, including Medicare and Medicaid, private health insurers and other third-party payers;
- the willingness of patients to pay all, or a portion of, out-of-pocket costs associated with our products in the absence of sufficient third-party coverage or adequate reimbursement;
- any restrictions on the use of our products, and the prevalence and severity of any adverse effects;
- potential product liability claims;
- the timing of market introduction of our products as well as competitive drugs;
- the effectiveness of our or any of our potential future collaborators' sales and marketing strategies; and
- unfavorable publicity relating to the product.

If our current products or any future product candidates, if approved, does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payers or patients, we may not generate sufficient revenue from that product and may not become or remain profitable. Our efforts to educate the medical community and third-party payers regarding the benefits of our products may require significant resources and may never be successful.

Takeda has the right to develop and commercialize vonoprazan outside of the United States, Europe, and Canada and has received marketing approval for vonoprazan in numerous countries in Asia and Latin America as well as in Russia. We have little or no control over Takeda's commercialization activities with respect to vonoprazan outside of our licensed territories even though those activities could impact our ability to successfully commercialize vonoprazan. For example, Takeda can make statements or use promotional materials with respect to vonoprazan outside of our licensed territories that are inconsistent with our positioning of the product in the United States, Europe, and Canada, and could sell vonoprazan in foreign countries at prices that are dramatically lower than the prices we would charge in our licensed territories. These activities and decisions, while occurring outside of our licensed territories, could harm our commercialization strategy. In addition, product recalls or safety issues with vonoprazan outside our licensed territories could result in serious damage to the brand and impair our ability to successfully market our products containing vonoprazan in our licensed territories.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. If we are found or alleged to have improperly promoted off-label uses, we may become subject to significant liability.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products such as our currently approved products, and any additional product candidates containing vonoprazan and any future product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. For example, the FDA has approved VOQUEZNA for the treatment for healing and maintenance of healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults and, in combination with either amoxicillin, or amoxicillin and clarithromycin, treatment of *H. pylori* infection in adults, and we are not currently permitted to promote this product for any other uses unless and until such uses are approved by the FDA. For any product for which we have obtained a marketing approval, however, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our current products or any product candidates, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

The successful commercialization of our current products or any future product candidate, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing

policies. Failure to obtain or maintain coverage and adequate reimbursement for our products could limit our ability to market those products and decrease our ability to generate revenue.

The availability of coverage and the adequacy of reimbursement by governmental healthcare programs, such as Medicare and Medicaid, private health insurers and other third-party payers are essential for most patients to be able to afford prescription medications such as VOQUEZNA, VOQUEZNA TRIPLE PAK, VOQUEZNA DUAL PAK or any future product candidates that may be approved. Our ability to achieve coverage and acceptable levels of reimbursement for our products by third-party payers will have an effect on our ability to successfully commercialize those products. Even if we obtain coverage for a given product by a third-party payer, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the European Union, or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payers increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payers may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payer may consider our products as substitutable and only offer to reimburse patients for the less expensive product. Even if we are successful in demonstrating improved efficacy or improved convenience of administration with our products, pricing of existing drugs may limit the amount we will be able to charge for our products. These payers may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products and may not be able to obtain a satisfactory financial return on products that we may develop.

There is significant uncertainty related to third-party payer coverage and reimbursement of newly approved products. In the United States, third-party payers, including private and governmental payers, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. Some third-party payers may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payers will decide with respect to the coverage and reimbursement for our products.

Obtaining and maintaining reimbursement status is time consuming, costly and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payers and other governmental payers develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and reimbursement for products exists among third-party payers in the United States. Therefore, coverage and reimbursement for products can differ significantly from payer to payer. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payer separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of our products. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payers in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with the sale of any of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly

prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

If we fail to comply with reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We participate in various governmental programs, such as the Medicaid Drug Rebate Program, that impose extensive drug price reporting and payment obligations on pharmaceutical manufacturers.

Medicaid is a joint federal and state program that is administered by the states for low-income and disabled beneficiaries. Medicare is a federal program that is administered by the federal government covering individuals age 65 and over as well as those with certain disabilities. Under the Medicaid Drug Rebate Program, or MDRP, as a condition of having federal funds being made available to the states for covered outpatient drugs under Medicaid and, if applicable, Medicare Part B, pharmaceutical manufacturers must enter into an agreement with the Secretary of Health and Human Services to pay a rebate to state Medicaid programs for each unit of covered outpatient drug dispensed to a Medicaid beneficiary and paid for by the state Medicaid program. Medicaid drug rebates are based on pricing data that pharmaceutical manufacturers report on a monthly and quarterly basis to the U.S. Centers for Medicare & Medicaid Services, or CMS, which is the federal agency that administers the MDRP and Medicare programs. For the MDRP, these data include the average manufacturer price, or AMP, for each drug and, in the case of innovator products, the Best Price, or BP, which represents the lowest price available from the manufacturer to any entity in the United States in any pricing structure, calculated to include all applicable sales and associated rebates, discounts and other price concessions. If a manufacturer becomes aware that its MDRP government price reporting submission for a prior quarter was incorrect or has changed as a result of recalculation of the pricing data, the manufacturer must resubmit the corrected data for up to three years after those data originally were due. If a manufacturer fails to provide information timely or is found to have knowingly submitted false information to the government, the manufacturer may be subject to civil monetary penalties and other sanctions, including termination from the MDRP.

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

In order to be eligible to have drug products paid for with federal funds under Medicaid and, if applicable, Medicare Part B, and purchased by certain federal agencies and grantees, a manufacturer must also participate in the U.S. Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program. Under the VA/FSS program, a manufacturer must report the Non-Federal Average Manufacturer Price, or Non-FAMP, for its covered drugs to the VA and charge certain federal agencies no more than the Federal Ceiling Price, which is calculated based on Non-FAMP using a statutory formula. These federal agencies are the VA, the U.S. Department of Defense, the U.S. Coast Guard, and the U.S. Public Health Service (including the Indian Health Service). The manufacturer must also pay rebates on products purchased by military personnel and dependents through the TRICARE retail

pharmacy program. If a manufacturer participating in the FSS program fails to provide timely information or is found to have knowingly submitted false information, the manufacturer may be subject to civil monetary penalties.

Individual states continue to consider and have enacted legislation to limit the growth of healthcare costs, including the cost of prescription drugs and combination products. A number of states have either implemented or are considering implementation of drug price transparency legislation that may prevent or limit our ability to take price increases at certain rates or frequencies. Requirements under such laws include advance notice of planned price increases, reporting price increase amounts and factors considered by manufacturers in taking such increases, wholesale acquisition cost disclosure to prescribers, purchasers, and state agencies, and new product notice and reporting. Such legislation could limit the price or payment for certain drugs, and a number of states are authorized to impose civil monetary penalties or pursue other enforcement mechanisms against manufacturers who fail to comply with drug price transparency requirements, including the untimely, inaccurate, or incomplete reporting of drug pricing information. If we are found to have violated state law requirements, we may become subject to penalties or other enforcement mechanisms, which could have a material adverse effect on our business.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by pharmaceutical manufacturers, governmental or regulatory agencies, and the courts, which can change and evolve over time. Such pricing calculations and reporting, along with any necessary restatements and recalculations, could increase costs for complying with the laws and regulations governing the MDRP and other governmental programs, and under the MDRP could result in an overage or underage in Medicaid rebate liability for past quarters. Price recalculations under the MDRP also may affect the ceiling price at which manufacturers are required to offer products under the 340B program. Civil monetary penalties can be applied if we are found to have knowingly submitted any false price or product information to the government, if we fail to submit the required price data on a timely basis, or if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. CMS could also terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid for our covered outpatient drugs. We cannot assure you that our submissions will not be found to be incomplete or incorrect.

We face significant competition, and if our competitors develop technologies or product candidates more rapidly than we do or their technologies are more effective, our ability to develop and successfully commercialize products may be adversely affected.

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. Our competitors have developed, are developing or may develop products, product candidates and processes competitive with VOQUEZNA. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of GI diseases for which we may attempt to develop vonoprazan or any future product candidates. Our competitors include larger and better funded pharmaceutical, biopharmaceutical, biotechnological and therapeutics companies. Moreover, we may also compete with universities and other research institutions who may be active in the indications we are targeting and could be in direct competition with us. We also compete with these organizations to recruit management, scientists and clinical development personnel, which could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites, enrolling patients for clinical trials and in identifying and in-licensing new product candidates. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We expect that, for the treatment of *H. pylori* infection, healing and maintenance of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis and, if approved, treatment of heartburn associated with symptomatic Non-Erosive GERD, VOQUEZNA will primarily compete with generic PPIs marketed by multiple pharmaceutical companies in both the prescription and OTC markets. In addition to generic PPI-based triple and quad therapies, we expect VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK will compete with Talicia, a co-formulated capsule comprising generic omeprazole, amoxicillin, and rifabutin for the treatment of *H. pylori* infection, launched in March 2020 by RedHill Biopharma Ltd.

We are aware of other PCABs in development in the United States, as well as a number of other PCABs in territories outside of the United States that if developed and approved in our territories may compete with vonoprazan. In the United States, Daewoong Pharmaceutical Co., Ltd., or Daewoong is looking for a strategic partner to advance the development of fexuprazan. In addition, Cinclus Pharma AG, or Cinclus, received QIDP designation for linaprazan glurate in combination with antibiotics for the treatment of

H. pylori infection, completed a Phase 2 dose selection study for Erosive GERD in November 2022, and plans to initiate a Phase 3 study in 2024 for the treatment of Erosive GERD. Finally, Sebela Pharmaceuticals, which acquired development and commercialization rights in United States and Canada to tegoprazan from HK inno.N, a South Korean company, has initiated two Phase 3 studies in the United States, one for Non-Erosive GERD and the other for healing and maintenance of healing of Erosive GERD. The earliest estimated completion date for these studies is during 2024. Outside the United States, in 2022 Daewoong launched fexuprazan in South Korea for the treatment of Erosive GERD under the brand name Fexuclue, has submitted applications for regulatory approval in additional countries in Asia and Latin America, and has out-licensed rights to develop fexuprazan in China to Shanghai Haini, a subsidiary of China's Yangtze River Pharmaceutical Group. Also outside the United States, revaprazan is marketed by Yuhan Corporation in South Korea, and tegoprazan is co-marketed by HK inno.N and Boryung Corp. in South Korea, is also marketed in China, Indonesia, Mexico, Mongolia, Philippines and Singapore and is currently under health authority review in Argentina and Thailand as well as in development by RaQualia Pharma, Inc. in Japan and by Dr. Reddy's in Russia. Additionally, Jeil Pharm has initiated a Phase 3 trial in South Korea of its PCAB candidate, JP-1366, in Erosive GERD, and Cinclus' linaprazan glurate has completed a Phase 2 clinical trial in Europe. To our knowledge, none of these compounds have demonstrated superiority to PPIs in a Phase 3 clinical trial.

Additionally, we are aware of several clinical-stage PPIs in territories outside of the United States that if developed and approved in our licensed territories may compete with vonoprazan. These include Dexa Medica's DLBS-2411, currently launched in the Philippines and in Phase 3 in Indonesia, Sihuan Pharmaceutical's anaprazole, currently in Phase 3 in China, and Eisai's azeloprazole, currently in a Phase 2 in China.

In July 2012, the Food and Drug Administration Safety and Innovation Act was passed, which included the Generating Antibiotic Incentives Now Act, or GAIN Act. The GAIN Act is intended to provide incentives for the development of new, qualified infectious disease products. In December 2016, the 21st Century Cures Act was passed, providing additional support for the development of new infectious disease products. These incentives may result in more competition in the market for new antibiotics and may cause pharmaceutical and biotechnology companies with more resources than we have to shift their efforts towards the development of product candidates that could be competitive with vonoprazan or any future product candidates.

Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. We will face competition for our current products and any future product candidates based on many different factors, including the safety and effectiveness of our products, the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration, the scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, more convenient, less expensive or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our current products or any future product candidates. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected.

If the market opportunities for VOQUEZNA, VOQUEZNA TRIPLE PAK, VOQUEZNA DUAL PAK, or any future product candidates are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer.

The precise incidence and prevalence for all the conditions we aim to address with our current products or any future product candidates are unknown. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment of our current products or any future product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, surveys of clinics or market research, and may prove to be incorrect. Further, new trials may change the estimated incidence or prevalence of these diseases. The total addressable market across indications for our current products and any future product candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final label for each of product and any future product candidates approved for sale for these indications, the availability of alternative treatments and the safety, convenience, cost and efficacy of our current products and any future product candidates relative to such alternative treatments, acceptance by the medical community and patient access, drug pricing and reimbursement. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to

treatment with our products or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

We have only recently built out our marketing, sales and distribution infrastructure. If our efforts in developing and maintaining sales, marketing and distribution capabilities are unsuccessful, or if we fail to achieve adequate pricing or reimbursement, we will not be successful in commercializing our current products or any future product candidates.

We have only recently expanded our marketing, sales and distribution capabilities in advance of the launch of VOQUEZNA, VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK. This expansion greatly increased our expenses and was very time consuming for management. We currently market, sell and distribute VOQUEZNA, VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK through our own sales and marketing organization. Our current sales force may not be sufficient in size and may not have adequate expertise in the medical markets we intend to target. Any deficiency in our sales, marketing and distribution capabilities or delay in the future development of such capabilities would adversely impact the commercialization of our products. To the extent that in the future we enter into any collaboration agreements with respect to marketing, sales or distribution for our current products and any future product candidates our product revenue may be lower than if we directly marketed or sold any approved products. We plan on entering into collaboration agreements with respect to marketing, sales and distribution of our products in Europe and Canada. Any revenue we receive in these markets will depend in whole or in part upon the efforts of these third-party collaborators, which may not be successful and are generally not within our control.

If we are unable to enter into these arrangements on acceptable terms or at all, we may not be able to successfully commercialize any approved products. If we are not successful in commercializing any approved products, either on our own or through collaborations with one or more third parties, our future product revenue will suffer, and we may incur significant additional losses.

Our future growth may depend, in part, on our ability to operate in foreign markets, particularly Europe and Canada, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our current products and any future product candidates in foreign markets, particularly Europe and Canada. We are not permitted to market or promote vonoprazan and any future product candidates before we receive regulatory approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for vonoprazan or any future product candidates. To obtain separate regulatory approval in any other countries we must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, commercial sales, pricing and distribution of vonoprazan and any future product candidates. If we obtain regulatory approval of our current products and any future product candidates and ultimately commercialize our products in foreign markets, we would be subject to additional risks and uncertainties, including:

- different regulatory requirements for approval of drugs in foreign countries;
- reduced protection for intellectual property rights;
- the existence of additional third-party patent rights of potential relevance to our business;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, public health emergencies or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling internationally;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- workforce uncertainty in countries where labor unrest is common;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities internationally; and

- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

Risks Related to the Development and Regulatory Approval of Product Candidates

We depend entirely on the success of VOQUEZNA and other products containing vonoprazan. If we do not obtain regulatory approval for vonoprazan for the treatment of heartburn symptoms associated with Non-Erosive GERD, or if we do not successfully commercialize VOQUEZNA for Erosive GERD or, if approved, Non-Erosive GERD, or we experience significant delays in doing so, we may never become profitable.

We expect that a substantial portion of our efforts and expenses over the next few years will be devoted to the commercialization of vonoprazan and the development and regulatory approval of vonoprazan for additional indications; specifically, the ongoing review of the NDA for vonoprazan as a once-daily treatment of heartburn associated with symptomatic Non-Erosive GERD and the planned Phase 3 trial studying for vonoprazan as an as needed treatment for heartburn symptoms associated with Non-Erosive GERD. As a result, our business currently depends heavily on the successful development, regulatory approval and, if approved, commercialization of vonoprazan for this additional indication and dosing regimen. We cannot be certain that we will be able to submit or obtain approval for any additional NDA or NDA supplement, or sNDA, for vonoprazan within the timeframes we expect, that any NDAs or sNDAs we submit will be accepted by the FDA for filing in a timely manner or at all, or that any of our product candidates will receive regulatory approval or will be successfully commercialized even if they receive regulatory approval.

The testing, manufacturing, safety, efficacy, labeling, approval, sale, marketing and distribution of our product candidates are, and will remain, subject to comprehensive regulation by the FDA and similar foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through preclinical studies and clinical trials that the product candidate is safe and effective for use in each target indication. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. Failure to obtain regulatory approval for additional indications for vonoprazan or future product candidates in the United States will prevent us from commercializing and marketing vonoprazan for these indications or our product candidates. The success of vonoprazan for future indications and our product candidates will depend on several additional factors, including:

- completing clinical trials that demonstrate their efficacy and safety;
- receiving marketing approvals from applicable regulatory authorities;
- completing any post-marketing studies required by applicable regulatory authorities;
- maintaining adequate commercial manufacturing capabilities;
- maintaining successful commercial sales, marketing and distribution operations;
- the prevalence and severity of adverse events experienced with vonoprazan and our future product candidates;
- acceptance of VOQUEZNA and our future product candidates by patients, the medical community and third-party payers;
- a continued acceptable safety profile following approval;
- obtaining and maintaining healthcare coverage and adequate reimbursement for VOQUEZNA and our future product candidates;
- competing effectively with other therapies, including with respect to the sales and marketing of our product candidates, if approved; and
- qualifying for, maintaining, enforcing and defending our intellectual property rights and claims.

Many of these factors are beyond our control, including the time needed to adequately complete clinical testing, the regulatory submission process, potential threats to our intellectual property rights and changes in the competitive landscape. It is possible that no new indications for vonoprazan and no future product candidates will ever obtain regulatory approval even if we expend substantial time and resources seeking such approval. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully complete clinical trials, obtain regulatory approval or, if approved, commercialize additional vonoprazan indications or any other product candidates, which would materially harm our business, financial condition and results of operations.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and the results of preclinical studies and early clinical trials are not necessarily predictive of future results.

Clinical drug development is expensive and can take many years to complete, and its outcome is inherently uncertain. Even if we believe the results of our clinical trials are positive, obtaining regulatory approval may not occur on a timely basis, if at all. The results from clinical trials or preclinical studies of a product candidate may not predict the results of later clinical trials of the product candidate, and interim results of a clinical trial are not necessarily indicative of final results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after the product candidate achieved promising results in earlier clinical trials. The results of our trials may not be comparable to those achieved previously, whether as a result of differences in trial design, patient population or otherwise.

For example, in our Phase 3 clinical trial for the treatment of *H. pylor*i infection, the vonoprazan dual therapy arm was not double-blinded because patients in this arm were administered amoxicillin three times daily, versus twice daily for the triple therapy regimens. Both triple therapy regimens were double-blinded. The inability to double-blind the dual therapy arm may impact how regulatory agencies or healthcare payers interpret such results. For example, the EMA has noted that it expects additional analyses of treatment compliance and drop-out rates in the dual therapy arm because it will not be double-blinded.

Further, in July 2019, we received scientific advice from the EMA on our Phase 3 clinical trial of vonoprazan in the healing and maintenance of healing of Erosive GERD. For the healing phase of the study, the EMA recommended that we include an endoscopy to assess healing at Week 4 in addition to the planned endoscopies at Week 2 and Week 8 because the summary of product characteristics for lansoprazole suggests four weeks of treatment to assess healing in Erosive GERD. We decided not to incorporate this change into the study design given the additional burden on study subjects to return for a third endoscopy in an eight-week period. This decision may impact the future summary of product characteristics for vonoprazan or may cause the EMA to require us to conduct additional clinical trials for vonoprazan to support marketing approval.

In addition, Takeda, a third party over which we have no control, has the right to develop and commercialize vonoprazan outside of the United States, Europe, and Canada. Takeda has marketing approval for vonoprazan in certain countries in Asia and Latin America, and Takeda has ongoing clinical trials of vonoprazan in certain indications that we are also pursuing. If such ongoing trials fail to meet their primary endpoints, have serious adverse events or encounter other problems, the development potential of vonoprazan could be materially and adversely affected. In addition, if serious adverse events or other problems occur with patients using vonoprazan marketed outside of our licensed territories, or if the results of ongoing or future clinical trials of vonoprazan conducted by Takeda or others generate negative results or results that conflict with the results of our clinical trials, the FDA or other regulatory authorities may delay, limit, or deny approval of vonoprazan, require us to conduct additional clinical trials as a condition to marketing approval, or withdraw their approval of vonoprazan or otherwise restrict our ability to market and sell vonoprazan, if approved. In addition, treating physicians may be less willing to prescribe vonoprazan due to concerns over such trial results or adverse events, which would limit our ability to commercialize vonoprazan.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the EU Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee

in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the EU Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the EU Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date, all clinical trials (including those which are ongoing) will become subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our developments plans.

It is currently unclear to what extent the United Kingdom, or UK, will seek to align its regulations with the EU. The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation). A decision by the UK not to closely align its regulations with the new approach that has been adopted in the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries.

For the foregoing reasons, our ongoing and future clinical trials and our efforts to obtain additional regulatory approvals for vonoprazan may not be successful. Further, any safety concerns observed in any one of our ongoing or future clinical trials for the targeted indications could limit the prospects for additional regulatory approvals of vonoprazan or any future product candidates in those and other indications, which could have a material adverse effect on our business, financial condition and results of operations.

Any difficulties or delays in the commencement or completion, or termination or suspension, of our ongoing or future clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

Before obtaining marketing approvals from regulatory authorities for the sale of vonoprazan for additional indications or approval of any future product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of vonoprazan in such new indication or of any future product candidates in humans. We do not know whether any ongoing studies will be completed on schedule, if at all, or if any future clinical trials will begin on time. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- the FDA, EMA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials and reaching consensus among the FDA and EMA over the design of the same clinical trial;
- any failure or delay in obtaining regulatory authorizations to commence a trial;
- any failure or delay in reaching an agreement with contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- institutional review boards, or IRBs, or other reviewing bodies refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes to clinical trial protocols;
- clinical sites deviating from trial protocols or dropping out of a trial;
- manufacturing or obtaining sufficient quantities of vonoprazan and any future product candidates;
- inability to obtain and deliver sufficient quantities of vonoprazan and any future product candidates to clinical sites;
- subjects failing to enroll or remain in our trials at the rate we expect, or failing to return for post- treatment follow-up;
- subjects choosing an alternative treatment for the indication for which we are developing vonoprazan and any future product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected drug-related adverse effects;

- occurrence of serious adverse events in trials of the same class of agents conducted by other companies;
- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;
- a facility manufacturing vonoprazan or any future product candidates or any of their components being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of current good manufacturing, or cGMP, regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices, or GCP, or other regulatory requirements;
- third-party contractors not performing data collection or analysis in a timely or accurate manner; or
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted or by the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities may impose a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing, or successful completion of a clinical trial.

Further, conducting clinical trials in foreign countries, as we have done for vonoprazan and may do for any future product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

Moreover, principal investigators for our clinical trials currently serve and may continue to serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the clinical trial. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of vonoprazan or any future product candidates.

If we experience delays in the completion of, or termination of, any clinical trial of vonoprazan or any future product candidates, the commercial prospects of vonoprazan and any future product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues.

In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. We may make

formulation or manufacturing changes to vonoprazan or any future product candidates, in which case we may need to conduct additional preclinical studies to bridge our modified product candidates to earlier versions. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize vonoprazan or any future product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of vonoprazan and any future product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition, and prospects significantly.

We may find it difficult to enroll patients in our clinical trials. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may not be able to initiate or continue clinical trials for vonoprazan or any future product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Subject enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, the risk that enrolled patients will not complete a clinical trial, our ability to recruit clinical trial investigators with the appropriate competencies and experience, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating as well as any drugs under development. We will be required to identify and enroll a sufficient number of patients for each of our clinical trials. Potential patients for any planned clinical trials may not be adequately diagnosed or identified with the diseases which we are targeting or may not meet the entry criteria for such trials. We also may encounter difficulties in identifying and enrolling patients with a stage of disease appropriate for our clinical trials and monitoring such patients adequately during and after treatment. We may not be able to initiate or continue clinical trials if we are unable to locate a sufficient number of eligible patients to participate in the clinical trials required by the FDA or comparable foreign regulatory authorities.

The timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. The eligibility criteria of our clinical trials further limits the pool of available trial participants. If patients are unwilling to participate in our trials for any reason, including the existence of concurrent clinical trials for similar patient or the availability of approved therapies, or we otherwise have difficulty enrolling a sufficient number of patients, the timeline for recruiting patients, conducting trials and obtaining regulatory approval of vonoprazan and any future product candidates may be delayed. Our inability to enroll a sufficient number of patients for any of our future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

Our assumptions used in determining expected clinical trial timelines may not be correct, and we may experience delays in enrollment, which would result in the delay of completion of such trials beyond our expected timelines.

Use of products or product candidates containing vonoprazan or any future product candidates could be associated with side effects, adverse events or other properties or safety risks, which could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon a product candidate, limit the commercial profile of an approved label or result in other significant negative consequences that could severely harm our business, prospects, operating results and financial condition.

As is the case with pharmaceuticals generally, it is likely that there may be side effects and adverse events associated with VOQUEZNA's or vonoprazan's or any future product candidates' use. Results of our ongoing or future clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by vonoprazan and any future 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 FDA or comparable foreign regulatory authorities. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition, and prospects significantly.

Moreover, if vonoprazan or any other future product candidates are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more

acceptable from a risk-benefit perspective, which may limit the commercial expectations for the product candidate, if approved. We may also be required to modify our study plans based on findings in our clinical trials.

It is possible that as we continue to test vonoprazan and any future product candidates in our clinical trials, or as the use of VOQUEZNA and any future product candidates becomes more widespread following any regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. If any such side effects become known later in development or upon approval, such findings may harm our business, financial condition and prospects significantly. Further, if a serious safety issue is identified in connection with use of vonoprazan commercially or in third-party clinical trials in Asia or elsewhere, such issues may adversely affect the development potential of vonoprazan or result in regulatory authorities restricting our ability to develop vonoprazan for additional indications.

If any of our products that receives marketing approval, including VOQUEZNA, is discovered to cause undesirable side effects, a number of potentially significant negative consequences could result, including:

- withdrawal, suspension or limitation by regulatory authorities of approvals of such product;
- seizure of the product by regulatory authorities;
- recall of the product or changes to the manner in which it is administered;
- restrictions on the marketing of the product or the manufacturing process for any component thereof;
- requirement by regulatory authorities of additional warnings on the label, such as a “black box” warning or contraindications;
- requirement that we implement a REMS or create a medication guide outlining the risks of such side effects for distribution to patients;
- commitment to expensive additional safety studies prior to approval or post-marketing studies required by regulatory authorities of such product;
- the product may become less competitive;
- initiation of regulatory investigations and government enforcement actions;
- initiation of legal action against us to hold us liable for harm caused to patients; and
- harm to our reputation and resulting harm to physician or patient acceptance of our products.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, financial condition, and results of operations.

Our current products and any future product candidates are subject to extensive regulation and compliance obligations that are costly and time consuming, and such regulation may cause unanticipated delays or prevent the receipt of the required approvals to commercialize vonoprazan for additional indications or any future product candidates.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our current approved products, including VOQUEZNA, and any future product candidates are subject to extensive regulation by the FDA in the United States and by comparable foreign regulatory authorities in other foreign markets. In the United States, we are not permitted to market vonoprazan for additional indications or any future product candidates until we receive the necessary regulatory approval from the FDA and in the EU, we are not permitted to market any of our approved products or any future product candidates until we receive a marketing authorization from the European Commission or competent authorities of the EU member states. The process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. The ability of the FDA and foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels and the ability to hire and retain key personnel. In addition, approval policies or regulations may change, and the FDA and EMA and comparable

regulatory authorities have substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed. For example, in February 2023, we received complete response letters from the FDA relating to our Erosive GERD NDA and post approval supplement to our approved *H. pylori* NDAs. As a result, the approval of VOQUEZNA for treatment of Erosive GERD was delayed until November 2023, and our ability to launch VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK was delayed until October 2023.

Prior to obtaining approval to commercialize a product candidate in the United States or internationally, we must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for additional regulatory approvals for vonoprazan or for any future product candidates are promising, such data may not be sufficient to support approval by the FDA and comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities, as the case may be, may also require us to conduct additional preclinical studies or clinical trials for vonoprazan or any future product candidates either prior to or post- approval, or may object to elements of our clinical development program.

The FDA, EMA or other comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including:

- such authorities may disagree with the design or implementation of our clinical trials;
- negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance required by the FDA, EMA, or other comparable foreign regulatory agencies for approval;
- serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or in clinical trials conducted by Takeda or others outside of our licensed territories, or by patients using vonoprazan or drugs similar to vonoprazan;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States;
- we may be unable to demonstrate to the satisfaction of such authorities that a product candidate is safe and effective for its proposed indication and that a product candidate's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- such authorities may not agree that the data collected from clinical trials of vonoprazan, including data collected from clinical trials conducted by Takeda and independent investigators outside of our licensed territories, and any future product candidates are acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval, and such authorities may impose requirements for additional preclinical studies or clinical trials;
- such authorities may disagree regarding the formulation, labeling and/or the specifications of vonoprazan and any future product candidates;
- approval may be granted only for indications that are significantly more limited than what we apply for and/or with other significant restrictions on distribution and use;
- such authorities may find deficiencies in the manufacturing processes or facilities of Evonik, Catalent, Sandoz, or any future third-party manufacturers with which we contract for clinical and commercial supplies;
- regulations of such authorities may significantly change in a manner rendering our or any of our potential future collaborators' clinical data insufficient for approval; or
- such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission.

With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, events raising questions about the safety of certain marketed pharmaceuticals may result in increased cautiousness by the FDA, EMA, and other comparable foreign regulatory authorities in reviewing new drugs based on safety, efficacy, or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us or any of our potential future collaborators from commercializing vonoprazan and any future product candidates.

Of the large number of drugs in development, only a small percentage successfully complete the FDA, EMA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain additional regulatory approvals to market vonoprazan and any future product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

With respect to our approvals in the U.S., the FDA has granted approvals, and may grant future approvals, with the requirement that we perform additional costly clinical trials including pediatric trials. Foreign regulatory authorities may also make their approvals contingent on similar requirements. The FDA or other comparable foreign regulatory authority also may approve a product candidate for a more limited indication or patient population than we originally requested, and the FDA or other comparable foreign regulatory authority may not approve the labeling that we believe is necessary or desirable for the successful commercialization of a product. Any delay in obtaining, or inability to obtain, additional regulatory approvals would delay or prevent commercialization of that indication or product candidate and would materially adversely impact our business and prospects.

We may not be successful in our efforts to expand our pipeline by identifying and successfully developing vonoprazan for additional indications and formulations. We may expend our limited resources to pursue a particular indication or formulation for vonoprazan and fail to capitalize on product candidates, indications or formulations that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on specific indications and formulations for VOQUEZNA. As a result, we may fail to generate additional clinical development opportunities for vonoprazan for a number of reasons, including, vonoprazan may in certain indications, on further study, be shown to have harmful side effects, limited to no efficacy, or other characteristics that suggest it is unlikely to receive marketing approval and achieve market acceptance in such additional indications.

For example, we believe the rapid onset of acid suppression observed in clinical studies of vonoprazan may enable as needed use for the management of heartburn symptoms associated with Non-Erosive GERD. However, no proton pump inhibitor has received approval from the FDA for this dosing regimen. We may be incorrect in our belief regarding the potential of vonoprazan as an as needed treatment for Non-Erosive GERD and any future clinical trial we conduct studying as needed dosing of vonoprazan in Non-Erosive GERD patients may not succeed including as a result of our design and enrollment criteria.

Furthermore, research programs to identify additional indications for vonoprazan require substantial technical, financial and human resources. We may also pursue additional formulations and packaging for vonoprazan, such as orally disintegrating tablets and other oral dosage forms for patients with difficulty swallowing, and an intravenous formulation for in-hospital applications. However, we may not successfully develop these additional formulations for chemistry-related, stability-related or other reasons. If we do not accurately evaluate the commercial potential or target market for vonoprazan or any future product candidates, we may relinquish valuable rights to that product candidate through future collaborations, licenses and other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Additionally, we may pursue additional in-licenses or acquisitions of development-stage assets or programs, which entails additional risk to us. Identifying, selecting and acquiring promising product candidates requires substantial technical, financial and

human resources expertise. Efforts to do so may not result in the actual acquisition or license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit.

We enrolled patients in Europe in our Erosive GERD and H. pylori trials. Additionally, we may conduct future clinical trials outside of the United States. However, the FDA and other comparable foreign regulatory authorities may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

We enrolled patients in Europe in our Erosive GERD and *H. pylori* trials, and we may conduct one or more of our future clinical trials outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States and not subject to an IND, acceptance of this data is subject to certain conditions imposed by the FDA. For example, where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless those data are applicable to the United States population and United States medical practice; the trials were performed by clinical investigators of recognized competence; and the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Similar requirements may apply in foreign jurisdictions.

For trials that are conducted only at sites outside of the United States and not subject to an IND, the FDA requires the clinical trial to have been conducted in accordance with GCP and the FDA must be able to validate the data from the clinical trial through an on-site inspection if it deems such inspection necessary. For such trials not subject to an IND, the FDA generally does not provide advance comment on the clinical protocols for the trials, and therefore there is an additional potential risk that the FDA could determine that the trial design or protocol for a non-United States clinical trial was inadequate, which could require us to conduct additional clinical trials. In addition, such foreign trials would be subject to the applicable local laws of the foreign regulatory agency and legal requirements where the trials are conducted. There can be no assurance the FDA will accept data from clinical trials conducted outside of the United States. If the FDA or comparable regulatory authority does not accept data from our clinical trials of vonoprazan and any future product candidates, it would likely result in the need for additional clinical trials, which would be costly and time consuming and delay or permanently halt our development of vonoprazan for additional indications and any future product candidates.

Conducting clinical trials outside the United States also exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research; and
- diminished protection of intellectual property in some countries.

Interim, top-line and preliminary data from clinical trials that we or others announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we or others, such as Takeda, may publicly disclose preliminary or top-line data from clinical trials that are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we or others report may differ from future results of the same clinical trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data previously published. As a result, top-line and preliminary data should be viewed with caution until the final data are available.

From time to time, we or others may also disclose interim data from clinical trials. Interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data

become available. Adverse differences between preliminary, top-line or interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, drug candidate or our business. If the top-line data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, vonoprazan and any future product candidates may be harmed, which could harm our business, operating results, prospects, or financial condition.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA and other government agencies to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, a government agency's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the government agency's ability to perform routine functions. Average review times at the FDA and other government agencies have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies, such as the EMA, may also slow the time necessary for new drugs and or modifications to approved drugs or to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the United States government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations, any resurgence of the virus or emergence of new variants may lead to further inspectional or administrative delays. If a prolonged government shutdown occurs, or if global health concerns hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to Our Reliance on Third Parties

We rely on the Takeda License to provide us rights to develop and commercialize vonoprazan in the United States, Europe, and Canada. If the license agreement is terminated, we would lose our rights to develop and commercialize vonoprazan.

Pursuant to the Takeda License, we have secured an exclusive license from Takeda to commercialize vonoprazan products using specified formulations for all human therapeutic uses in the United States, Europe, and Canada, and a non-exclusive license to develop and manufacture vonoprazan products anywhere in the world (subject to Takeda's consent as to each country) for the purposes of commercializing the vonoprazan products in the United States, Europe, and Canada.

The Takeda License will continue until the expiration of the obligation to pay royalties in all countries and on all products, unless terminated earlier. We may terminate the Takeda License in its entirety without cause upon prior written notice. We and Takeda may terminate the Takeda License in the case of the other party's insolvency or for the other party's material uncured breach. Takeda may terminate the Takeda License in its entirety if we challenge the licensed patents, or if we assist any third party in challenging such patents. In addition, if any of the commercial milestones or other cash payments become due under the terms of the Takeda License, we may not have sufficient funds available to meet our obligations, which would allow Takeda to terminate the

Takeda License. If the license agreement is terminated, we would lose our rights to develop and commercialize products containing vonoprazan, which in turn would have a material adverse effect on our business, operating results and prospects.

We rely on third parties to conduct our clinical trials. Any failure by a third party to conduct the clinical trials according to GCPs and other requirements and in a timely manner may delay or prevent our ability to seek or obtain additional regulatory approvals for vonoprazan and regulatory approvals for any future product candidates.

We are dependent on third parties to conduct our preclinical and clinical trials. Specifically, we have used and relied on, and intend to continue to use and rely on, medical institutions, clinical investigators, CROs and consultants to conduct our clinical trials in accordance with our clinical protocols and regulatory requirements. These CROs, investigators and other third parties will play a significant role in the conduct and timing of these trials and subsequent collection and analysis of data. While we have agreements governing the activities of our third-party contractors, we have limited influence over their actual performance. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for vonoprazan and any future product candidates that reach clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs or trial sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP or similar regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

CROs, investigators or other third parties may not devote adequate time and resources to such trials or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, or otherwise performs in a substandard manner, our clinical trials may be extended, delayed, or terminated. In addition, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA or comparable regulatory authority concludes that the financial relationship may have affected the interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any NDA or similar marketing application we submit by the FDA or by comparable regulatory authority. Any such delay or rejection could prevent us from commercializing vonoprazan for additional indications and any future product candidates.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties or do so on commercially reasonable terms. Switching or adding additional CROs, investigators and other third parties 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, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, investigators and other third parties, we may encounter challenges or delays in the future and these delays or challenges may have a material adverse impact on our business, financial condition and prospects.

We currently rely on, and expect to rely on for the foreseeable future, Evonik and Catalent for the manufacture of vonoprazan drug substance and drug product for clinical development and commercial sale, and we expect to rely on Sandoz for commercial supplies of VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK and the amoxicillin and clarithromycin in those products. This reliance on third parties increases the risk that we will not have sufficient quantities of finished product which could delay, prevent or impair our development or commercialization efforts.

We do not own or operate manufacturing facilities and have no plans to build our own clinical or commercial scale manufacturing capabilities. We have entered into an agreement with Catalent for the supply of finished drug product, an agreement with Evonik for the supply of drug substance, and an agreement with Sandoz for commercial supply of amoxicillin, clarithromycin

and finished convenience packs containing VOQUEZNA and one or both of those antibiotics. As a result, we currently rely, and expect to continue to rely, on third parties for the manufacture of vonoprazan and supply of related raw materials for clinical development and commercial sale. If Catalent, Evonik or Sandoz fails to fulfill its obligations under its respective supply agreement, or if any of the vonoprazan drug product or drug substance supplied by Catalent or Evonik cannot be utilized due to quality or cGMP or similar concerns, adverse findings during regulatory inspections or other reasons, our development plans and commercialization of vonoprazan, if approved, could be significantly delayed or otherwise adversely affected. The facilities used by Catalent and Evonik to manufacture vonoprazan and by Sandoz to manufacture amoxicillin and clarithromycin and to package the antibiotics and vonoprazan must be approved by the FDA and foreign regulatory authority pursuant to inspections that may be conducted after we submit marketing authorizations to the FDA and comparable foreign regulatory authorities. We do not control the manufacturing process of, and are completely dependent on, Catalent, Evonik and Sandoz for compliance with applicable cGMP or similar requirements. If Catalent, Evonik, Sandoz, or any other third-party manufacturer we contract with in the future, cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, including requirements related to the manufacturing of high potency compounds, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over Catalent's, Evonik's, Sandoz's, or any other third-party manufacturer's ability to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve of facilities of the third-party manufacturer for the manufacture of vonoprazan or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to continue to develop, obtain additional regulatory approvals for or continue to market our current products.

Our failure, or Catalent's, Evonik's, Sandoz's or any other third-party manufacturer's failure, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

Our or Catalent's, Evonik's or Sandoz's failure, or the failure of any future third-party manufacturer, to execute on our manufacturing requirements, to do so on commercially reasonable terms and comply with cGMP or similar foreign requirements, could adversely affect our business in a number of ways, including:

- an inability to initiate and continue clinical trials of vonoprazan or any future product candidates;
- delay in submitting regulatory applications, or receiving marketing approvals for new indications for vonoprazan or for any future product candidates;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease development or to recall batches of our current products and any future product candidates; and
- an inability to meet commercial demands for our current products or any future product candidates.

Reliance on third-party manufacturers entails additional risks, including:

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- breach of the manufacturing agreement by the third party;
- failure to manufacture our product according to our specifications;
- failure to manufacture our product according to our schedule or at all;
- misappropriation of our proprietary information, including our trade secrets and know-how; and
- termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Our current products, including VOQUEZNA, and any product candidates that we may develop, may compete with other product candidates and products for access to manufacturing facilities. Moreover, there may be a limited number of manufacturers that operate under cGMP or similar regulations and that might be capable of manufacturing for us.

Any performance failure on the part of Catalent, Evonik, Sandoz or any future manufacturers could delay clinical development or additional marketing approvals, and any related remedial measures may be costly or time consuming to implement. We do not currently have arrangements in place for redundant supply or a second source for all required raw materials used in the manufacture of our current products. If Catalent, Evonik, or Sandoz cannot perform as agreed, we may be required to replace them and we may be unable to replace them on a timely basis or at all. Further, Catalent, Evonik, Sandoz and any other third-party manufacturers we may use may experience manufacturing or shipping difficulties due to resource constraints or as a result of natural disasters, labor disputes, unstable political environments, or public health emergencies such as the COVID-19 pandemic or ongoing hostilities in the Ukraine and the Middle East. If Catalent, Evonik, Sandoz or other third-party manufacturers were to encounter any manufacturing or shipping difficulties or delays due to these factors, our ability to provide vonoprazan to patients in clinical trials, or to provide product for treatment of patients if approved, would be jeopardized.

Our current and anticipated future dependence upon others for the manufacture of our current products or any future product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

Our reliance on third parties, including Sandoz, Catalent and Evonik, requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely, and expect to continue to rely, on Sandoz, Catalent and Evonik to manufacture our current approved products and to perform quality testing, we must, at times, share our proprietary technology and confidential information, including trade secrets, with them. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements, consulting agreements or other similar agreements with our advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are intentionally or inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets and despite our efforts to protect our trade secrets, a competitor's discovery of our proprietary technology and confidential information or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations and prospects.

We may seek to enter into collaborations, licenses and other similar arrangements and may not be successful in doing so, and even if we are, we may not realize the benefits of such relationships.

We may seek to enter into collaborations, joint ventures, licenses and other similar arrangements for the development or commercialization of our current products or any future product candidates due to, for example, capital costs required to develop or commercialize our current products or any future product candidates, or manufacturing constraints. We may not be successful in our efforts to establish such collaborations because, among other reasons, third parties may not view our current products or future product candidates as having the requisite potential to demonstrate safety and efficacy or significant commercial opportunity. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process can be time consuming and complex. Further, any future collaboration agreements may restrict us from entering into additional agreements with potential collaborators. Following a strategic transaction or license, we may not achieve an economic benefit that justifies such transaction.

Even if we are successful in our efforts to establish such collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such collaborations if, for example, development or approval of a product candidate is delayed, the safety of a product candidate is questioned or sales of an approved product candidate are unsatisfactory.

In addition, any potential future collaborations may be terminable by our strategic partners, and we may not be able adequately to protect our rights under these agreements. Furthermore, strategic partners may negotiate for certain rights to control

decisions regarding the development and commercialization of vonoprazan and any future product candidates and may not conduct those activities in the same manner as we do. Any termination of collaborations we enter into in the future, or any delay in entering into collaborations, could delay or impair the further development and commercialization of vonoprazan or the development and commercialization of any future product candidates and reduce their competitiveness if they reach the market, which could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Business Operations and Industry

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- the timing and cost of, and level of investment in, research, development, regulatory approval and commercialization activities relating to our current products, or any future product candidates, which may change from time to time;
- coverage and reimbursement policies with respect to our current products, or any future product candidates, and potential future drugs that compete with such products, if approved;
- the cost of manufacturing of our current products or any future product candidates, which may vary depending on the quantity of production and the terms of our agreements with Catalent, Evonik, Sandoz and any future third-party manufacturers;
- business interruptions resulting from geopolitical actions, including war, such as the ongoing hostilities in the Ukraine or the Middle East, and terrorism, or natural disasters such as earthquakes, typhoons, floods and fires or public health emergencies or pandemics such as the COVID-19 pandemic;
- the timing and amount of the milestone or other payments we will be required to pay to Takeda pursuant to the Takeda License;
- expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies;
- the level of demand for any approved products, which may vary significantly;
- future accounting pronouncements or changes in our accounting policies; and
- the timing and success or failure of additional clinical trials for vonoprazan or preclinical studies or clinical trials for any future product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

Our business is subject to risks arising from epidemic diseases, such as the COVID-19 pandemic.

A public health pandemic, such as COVID-19, has the potential to impact worldwide economic activity and poses the risk that we or our employees, contractors, including our CROs, suppliers, and other partners may be prevented from conducting business activities for an indefinite period of time, including due to spread of the disease within these groups or due to shutdowns that may be requested or mandated by governmental authorities. In March 2020, due to efforts to combat the COVID-19 pandemic, we

announced a temporary pause in randomization of new patients in our Phase 3 trials and did not recommence randomizations in either trial until June 2020. While it is not possible at this time to estimate the full impact that a future public health pandemic could have on our business, measures taken by the governments of countries affected could, in addition to disrupting our commercial activities and clinical trials, disrupt the supply chain and the manufacture or shipment of drug substance and finished drug product of vonoprazan for use in our clinical trials or in commercial distribution, which could delay our ongoing clinical trials and increase development costs, or impair our ability to successfully commercialize our approved products, and in either case have a material adverse effect on our business, financial condition and results of operations. The COVID-19 pandemic and mitigation measures had an adverse impact on global economic conditions and mitigation measures regarding any future public health pandemic could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed. The extent to which a future public health pandemic impacts our results will depend on future developments that are highly uncertain and cannot be predicted.

Our indebtedness may limit our flexibility in operating our business and adversely affect our financial health and competitive position, and all of our obligations under our indebtedness are secured by substantially all of our assets, excluding our intellectual property and certain other assets. If we default on these obligations, our lenders could foreclose on our assets.

In September 2021, we entered into, and in December 2023 we increased the amounts available under and extended the maturity date of, a Loan Agreement with Hercules. We borrowed $100 million at the inception of the Loan Agreement, $40 million in December 2023, and may be eligible to borrow up to an additional $160 million. All obligations under the Loan Agreement are secured by a first priority lien on substantially all of our assets, including intellectual property and certain other assets. As a result, if we default on any of our obligations under the Loan Agreement, Hercules could foreclose on its security interest and liquidate some or all of the collateral, which would harm our business, financial condition and results of operations and could require us to reduce or cease operations.

In order to service our current indebtedness and any additional indebtedness we may incur in the future, we need to generate cash from our operating activities or other financings. Our ability to generate cash is subject, in part, to our ability to successfully execute our business strategy, as well as general economic, financial, competitive, regulatory and other factors beyond our control. Our business may not be able to generate sufficient cash flow from operations, and future borrowings or other financings may not be available to us in an amount sufficient to enable us to service our indebtedness and fund our other liquidity needs. To the extent we are required to use cash from operations or the proceeds of any future financing to service our indebtedness instead of funding working capital or other general corporate purposes, we will be less able to plan for, or react to, changes in our business, industry and in the economy generally. This could place us at a competitive disadvantage compared to our competitors that have less indebtedness.

The Loan Agreement contains customary affirmative and negative covenants that limit our ability to engage in certain transactions that may be in our long-term best interest. The affirmative covenants include, among others, covenants requiring us to maintain certain levels of cash subject to a control agreement in favor of Hercules, and commencing on September 30, 2024, certain levels of trailing three-month net product revenue from the sale of VOQUEZNA and other products containing vonoprazan, deliver certain financial reports, maintain insurance coverage and satisfy certain requirements regarding our operating accounts. The negative covenants include, among others, limitations on our ability to incur additional indebtedness and liens, merge with other companies or consummate certain changes of control, acquire other companies, engage in new lines of business, make certain investments, pay dividends, transfer or dispose of assets, amend certain material agreements or enter into various specified transactions.

While we believe we are currently in compliance with the covenants contained in the Loan Agreement, we may breach these covenants in the future. Our ability to comply with these covenants may be affected by events and factors beyond our control. In the event that we breach one or more covenants, the lenders may choose to declare an event of default and require that we immediately repay all amounts outstanding under the applicable agreement, terminate any commitment to extend further credit and foreclose on the collateral. The occurrence of any of these events could have a material adverse effect on our business, financial condition and results of operations.

Our Revenue Interest Financing Agreement could limit cash flow available for our operations and expose us to risks that could adversely affect our business, financial condition and results of operations.

In May 2022, we entered into a Revenue Interest Financing Agreement with the Initial Investors pursuant to which we can receive up to $260.0 million in funding from the Initial Investors, and in October 2022, we entered into the Joinder Agreement under which we can receive up to $40 million from the Additional Investor, bringing the total funding available under the Revenue Interest Financing Agreement to up to $300 million. Under the terms of the Revenue Interest Financing Agreement and Joinder Agreement, we received $100 million at the initial closing and received an additional $175 million in November 2023 following FDA approval of vonoprazan for treatment of Erosive GERD. In addition, we are eligible for $25 million in additional funding for achievement of a sales milestone.

Under the Revenue Interest Financing Agreement, the investors are entitled to receive a 10% royalty on net sales of products containing vonoprazan. The royalty rate is subject to a step-down on net sales exceeding certain annual thresholds and if we receive FDA approval for vonoprazan for an indication relating to the treatment of heartburn associated with Non-Erosive GERD. The investors' right to receive royalties on net sales will terminate when the investors have aggregate payments equal to 200% of the Investment Amount.

If the investors have not received aggregate payments of at least 100% of the Investment Amount by December 31, 2028, and at least 200% of the Investment Amount by December 31, 2037, each a Minimum Amount, then we will be obligated to make a cash payment to the investors in an amount sufficient to gross the investors up to the applicable Minimum Amount.

Pursuant to the Revenue Interest Financing Agreement, we also agreed to specified affirmative and negative covenants, including covenants to use commercially reasonable efforts to promote products containing vonoprazan in the United States and covenants requiring us to maintain certain levels of cash. The Revenue Interest Financing Agreement also contains representations and warranties, other covenants, indemnification obligations, and other provisions customary for transactions of this nature. In the event of an event of default under the Revenue Interest Financing Agreement, the investors may be entitled to foreclose on the pledged collateral which includes the applicable royalty under the Royalty Interest Financing Agreement from net sales of VOQUEZNA and other products containing vonoprazan.

Our future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel.

We are highly dependent on the management, commercial, development, clinical, and financial experience of our senior management. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals. Competition for qualified personnel in the biopharmaceutical field is intense, and our future success depends upon our ability to attract, retain and motivate highly skilled commercial, scientific, technical and managerial employees. We face competition for personnel from other biopharmaceutical companies and other organizations. If our recruitment and retention efforts are unsuccessful in the future, it may be difficult for us to implement business strategy, which could harm our business. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating and implementing our development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede achievement of our commercial and development objectives, our ability to raise additional capital and our ability to implement our business strategy.

We have substantially increased the size of our organization over the past year, and we may encounter difficulties in managing our growth and expanding our operations successfully.

Our number of employees increased substantially in 2023 to prepare for the commercialization of VOQUEZNA, VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK. This expansion of our operations has resulted in a significant increase in our commercial organization, which may divert our management and business development resources from our clinical development group. To manage our recent growth and anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the

limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We are subject to various foreign, federal, and state healthcare laws and regulations, and our failure to comply with these laws and regulations could harm our results of operations and financial condition.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payers, patient organizations and customers expose us to broadly applicable foreign, federal and state fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any products for which we obtain marketing approval. Such laws include, but are not limited to:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, or order, or arranging for or recommending the purchase, lease, or order of any good, facility, item or service, for which payment may be made, in whole or in part, under any U.S. federal healthcare program, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;
- the U.S. civil and criminal federal false claims laws, including the civil False Claims Act, which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making or causing to be made a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation;
- the U.S. federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS, information related to certain payments and other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) , certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists, anesthesiology assistants and certified nurse midwives)and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payers, including private insurers, or by the patients themselves; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information or which require tracking gifts and other remuneration and items of value provided to physicians, other healthcare providers and entities.

We may also be subject to additional regulation in the conduct of our business. For example, we may be subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof.

Ensuring that our internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, imprisonment, contractual damages, reputational harm, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, diminished profits and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly, time consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusion from government funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

Enacted and future legislation and healthcare reform measures may increase the difficulty and cost for us to commercialize vonoprazan and any future product candidates and may affect the prices we may set.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system, including cost-containment measures, that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, in March 2010, the Patient Protection and Affordable Care Act, the Affordable Care Act, was enacted in the United States, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the pharmaceutical industry. Among other things, the Affordable Care Act includes:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, which is apportioned among these entities according to their market share in certain government healthcare programs;
- a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the AMP for branded and generic drugs, respectively;
- a methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- an extension of a manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of the entities eligible for discounts under the 340B drug pharmaceutical pricing program;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and

- establishment of a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial and political challenges to certain aspects of the Affordable Care Act. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the Affordable Care Act without specifically ruling on the constitutionality of the Affordable Care Act. Thus, the Affordable Care Act will remain in effect in its current form.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, beginning April 1, 2013, Medicare payments to providers were reduced under the sequestration required by the Budget Control Act of 2011, which will remain in effect through 2032, unless additional Congressional action is taken. Additionally, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. On March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap, beginning January 1, 2024. Previously, the rebate was capped at 100% of a drug's AMP.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. At the federal level, such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products.

Most significantly, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the Affordable Care Act in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services, or HHS, to implement many of these provisions through guidance, as opposed to regulation, for the initial years HHS has and will continue to issue and update guidance as these programs are implemented. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. The impact of the IRA on the pharmaceutical industry cannot yet be fully determined, but is likely to be significant. The likelihood of implementation of these and other reform initiatives is uncertain. In the coming years, additional legislative and regulatory changes could be made to governmental health programs that could significantly impact pharmaceutical companies and the success of our product candidates.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. Furthermore, there has been increased interest by third party payers and governmental authorities in reference pricing systems and publication of discounts and list prices. These reforms could reduce the ultimate demand for vonoprazan and any future product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

We expect that these healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize vonoprazan and any future product candidates, if approved.

We and any of our third-party manufacturers or suppliers may use potent chemical agents and hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly.

We and any of our third-party manufacturers or suppliers will use biological materials, potent chemical agents and may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety of the environment. Our operations and the operations of our third-party manufacturers and suppliers also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. In the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

Although we maintain workers' compensation insurance for certain costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work- related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for toxic tort claims that may be asserted against us in connection with our storage or disposal of biologic, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations, which have tended to become more stringent over time. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could materially adversely affect our business, financial condition, results of operations and prospects.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our products.

We are exposed to potential product liability risks that are inherent in the development, manufacturing, marketing, and use of pharmaceutical products. The current and future use of product candidates by us in clinical trials, and the sale of VOQUEZNA, VOQUEZNA TRIPLE PAK, VOQUEZNA DUAL PAK, and any other approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies, or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend or settle, and could compromise the market acceptance of our product candidates or any prospects for the commercialization of our products and, if approved, product candidates.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease the commercialization of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;

- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant negative financial impact;
- the inability to commercialize our current products and any future product candidates; and
- a decline in our stock price.

Although we maintain product liability insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts in which case our business operations could be impaired. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses.

We and others, including any of our potential future collaborators, will be required to report to regulatory authorities if any of our approved products cause or contribute to adverse medical events, and any failure to do so would result in sanctions that would materially harm our business.

The FDA and foreign regulatory authorities will require that we and Takeda (with respect to products containing vonoprazan) and any of our potential future collaborators, report certain information about adverse medical events for our approved products if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We, Takeda and any of our potential future collaborators or CROs may fail to report adverse events within the prescribed timeframe. If we, Takeda or any of our potential future collaborators or CROs fail to comply with such reporting obligations, the FDA or a foreign regulatory authority could take action, including criminal prosecution, the imposition of civil monetary penalties, seizure of our products or delay in approval of future products.

Compliance with applicable data protection, privacy and security laws, regulations, standards and other requirements involves significant expenditure and resources, and any actual or perceived failures by us, our partners or vendors to comply could adversely affect our business, results of operations, and financial condition.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous federal, state and foreign laws, regulations, standards and other requirements governing the collection, use, disclosure, retention, security and other processing of personal data, such as information that we may collect in connection with our marketing activities in the U.S. and clinical trials in the U.S. and abroad. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer, use, share and otherwise process personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws, regulations or standards, our internal policies and procedures or our contracts relating to privacy, security or our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties, material penalties, significant legal liability, changes in how we operate and damage to our reputation, any of which could have a material adverse effect on our operations, financial performance and business.

As our operations and business grow, we may become subject to or affected by new or additional data protection, privacy and security laws, regulations, standards and other requirements, and face increased scrutiny or attention from regulatory authorities. In the U.S., HIPAA imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. While we are not a covered entity under HIPAA, we interact with healthcare providers regulated by HIPAA as covered entities. Certain states have also adopted comprehensive and health-specific privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation

by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, California enacted the CCPA on June 28, 2018, which went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of covered businesses handling personal information about California residents. It provides for civil penalties for violations, as well as a private right of action and statutory damages for certain data breaches. The CPRA amended the CCPA effective January 1, 2023, imposing additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, and opt outs for certain uses of sensitive data. It also created a new California data protection agency authorized to issue substantive regulations, which will likely result in increased privacy and cybersecurity enforcement. Similar laws are already in effect in other states including Virginia, Connecticut, Colorado and Utah, and have been enacted or proposed in other states and at the federal level, reflecting a trend toward more stringent regulation in the United States of the collection, use, disclosure and other processing of personal information. The enactment of such laws creates the potential for a patchwork of overlapping, but different and potentially conflicting, requirements that may make compliance challenging. In the event that we become subject to HIPAA, the CCPA and similar state privacy laws, compliance will likely involve significant expenditure and resources, and any failure or perceived failure to comply with the requirements of these laws could adversely affect our business, results of operations and financial condition.

Furthermore, the FTC and many state Attorneys General continue to enforce federal and state consumer protection laws against in relation to a variety of data privacy and security issues, such as promises made in privacy policies or failures to appropriately protect information about individuals, as unfair or deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act or similar state laws. The FTC expects a company's cybersecurity measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities.

Given our past sponsorship of clinical trials at sites in Europe, we are also subject to the European Union General Data Protection Regulation, or the EU GDPR, and to the United Kingdom General Data Protection Regulation and Data Protection Act 2018, or collectively, the UK GDPR,(the EU GDPR and UK GDPR together referred to as the "GDPR") which impose comprehensive data privacy compliance obligations in relation to processing the personal data of individuals within the EEA and UK. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million / GBP 17.5 million or up to 4% of the annual global revenues of the noncompliant company, whichever is greater.

In addition, the GDPR increases the scrutiny of transfers of personal data from the EEA and UK to the United States and other jurisdictions that the European Commission does not recognize as having "adequate" data protection laws. Case law from the Court of Justice of the European Union, or CJEU, states that reliance on the standard contractual clauses – a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism – alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. On October 7, 2022, President Biden signed an Executive Order on 'Enhancing Safeguards for United States Intelligence Activities' which introduced new redress mechanisms and binding safeguards to address the concerns raised by the CJEU in relation to data transfers from the EEA to the United States and which formed the basis of the new EU-US Data Privacy Framework, or DPF, as released on December 13, 2022. The European Commission adopted its Adequacy Decision in relation to the DPF on July 10, 2023, rendering the DPF effective as an EU GDPR transfer mechanism to U.S. entities self-certified under the DPF. On October 12, 2023, the UK Extension to the DPF came into effect (as approved by the UK Government), as a UK GDPR data transfer mechanism to U.S. entities self-certified under the UK Extension to the DPF. In the future, as applicable, we expect to rely on the DPF to transfer certain personal data from the EEA to the United States and on the UK Extension to the DPF to transfer certain personal data from the UK to the United States. In the past we have relied on EU standard contractual clauses and the UK Addendum to the EU standard contractual clauses as relevant to transfer personal data outside the EEA and the UK with respect to third party transfers. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue. In particular, we expect the DPF Adequacy Decision to be challenged and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As the regulatory guidance and enforcement landscape in relation to data transfers continue to develop, we could suffer additional costs, complaints and/or regulatory investigations or fines, we may have to stop using certain tools and vendors and make other operational changes, we have had to and will have to implement revised standard contractual clauses for existing customer and vendor arrangements within required time frames, and/or if we are otherwise unable to transfer personal data

between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Our internal information systems, or those of any of our CROs, contract manufacturers, service providers, other contractors or consultants or potential future collaborators, may fail or suffer cybersecurity incidents or breaches, which could result in a material disruption of our product development programs.

The United States federal and various state and foreign governments have adopted or proposed requirements regarding the collection, distribution, use, security, and storage of personally identifiable information and other data relating to individuals, and federal and state consumer protection laws are being applied to enforce regulations related to the online collection, use, and dissemination of data. Despite the implementation of cybersecurity measures, our internal information systems and those of our current and any future CROs, contract manufacturers, and other service providers, contractors, consultants and collaborators are vulnerable to numerous and evolving cybersecurity risks that threaten the confidentiality, integrity and availability of our information systems and confidential Information, including from diverse threat actors, such as state-sponsored organizations, opportunistic hackers and hacktivists, as well as through diverse attack vectors, such as social engineering/phishing, malware (including ransomware), malfeasance by insiders, human or technological error, and as a result of malicious code embedded in open-source software, or misconfigurations, 'bugs' or other vulnerabilities in commercial software that is integrated into our (or our suppliers' or service providers') IT systems, products or services, alongside damage from natural disasters, terrorism, war and telecommunication and electrical failures. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives, expertise, technique and tools – including artificial intelligence – to circumvent security controls, evade detection and remove forensic evidence. For example, on February 22, 2024, UnitedHealth Group, or UHG, disclosed that a suspected nation-state associated cyber security threat actor had gained access to some of the information technology systems at Change Healthcare, one of UHG's affiliates that provides numerous services to the healthcare industry such as payment systems, claims submission, benefits verification, and prior authorization. This breach has, among other things, disrupted the processing of transactions under our patient co-pay assistance card program, and the ability of certain pharmacies to fill prescriptions, including prescriptions for VOQUEZNA. At present, UHG is unable to estimate the duration or extent of the disruption. If this disruption persists, it could have a material adverse effect on our business and financial condition.

We also face increased cybersecurity risks due to our reliance on internet technology and the increased number of our employees (and employees of our vendors, contractors and other organizations with whom we have formed strategic relationships) who are working remotely, which may create additional opportunities for threat actors to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience cybersecurity incidents or data breaches that may remain undetected for an extended period. If such an event were to occur and cause interruptions in our operations, result in the unauthorized access to, disclosure, loss, processing or other compromise of, personal information or individually identifiable health information (violating certain privacy laws such as GDPR) or confidential information, or jeopardize the confidentiality, integrity, or availability of our information systems or any information residing therein, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions. Some of the federal, state and foreign government requirements include obligations of companies to notify individuals of certain cybersecurity breaches involving particular personal information, which could result from breaches experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships. Even though we may have contractual protections with such vendors, contractors, or other organizations, notifications and follow-up actions related to a cybersecurity breach could impact our reputation, cause us to incur significant costs, including legal expenses, harm customer confidence, hurt our expansion into new markets, cause us to incur remediation costs, or cause us to lose existing customers. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We also rely on third parties to manufacture vonoprazan and any future product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. There can no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our information systems and personal or confidential Information. To the extent that any disruption or cybersecurity incident were to jeopardize the confidentiality, integrity, or availability of our information systems, or result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary

information, we could incur liability, the further development and commercialization of vonoprazan and any future product candidates could be delayed, and we could be subject to significant fines, penalties or liabilities for any noncompliance to certain privacy and cybersecurity laws.

Our employees and independent contractors, including principal investigators, CROs, consultants and vendors, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees and independent contractors, including principal investigators, CROs, consultants and vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate: (i) the laws and regulations of the FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies, (ii) manufacturing standards, including cGMP and similar requirements, or (iii) federal and state healthcare, security, fraud and abuse laws, data privacy and cybersecurity laws, and other similar non-U.S. laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials, or illegal misappropriation of product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other U.S. federal healthcare programs or healthcare programs in other jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We could face criminal liability and other serious consequences for violations, which could harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, and anti-corruption and anti-money laundering laws and regulations, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, clinical research organizations, contractors and other collaborators and partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We have engaged, and may engage in the future, third parties for clinical trials outside of the United States, and may engage third parties to sell our products abroad once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, clinical research organizations, contractors and other collaborators and partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may

result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of intellectual property, products or technologies, similar to our approach in in-licensing and acquiring our current product candidates. Any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our financial condition, liquidity and results of operations. Additional potential transactions that we may consider in the future include a variety of business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits of the acquisition. Accordingly, although we may not undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

Risks Related to Our Intellectual Property

Our success depends on our ability to protect our intellectual property and our proprietary technologies.

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for our current products containing vonoprazan and any future product candidates, proprietary technologies and their uses as well as our ability to operate without infringing upon the proprietary rights of others. If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate for our technology or vonoprazan or any future product candidates, our competitive position could be harmed. We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to vonoprazan or any future product candidates, proprietary technologies and their uses that are important to our business. We do not currently own any issued patents or pending patent applications. We also seek to protect our proprietary position by acquiring or in-licensing relevant issued patents or pending patent applications from third parties. We have in-licensed from Takeda a number of United States, European, and Canadian patents and patent applications relating to the compound vonoprazan as well as the use and manufacture of vonoprazan products.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our future patent applications or the patent applications of our current and future licensors will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents if issued will not be infringed, designed around or invalidated by third parties.

Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. These uncertainties and/or limitations in our ability to properly protect the intellectual property rights relating to vonoprazan and any future product candidates could have a material adverse effect on our financial condition and results of operations.

We cannot be certain that the claims in our licensor's U.S. pending patent applications, corresponding international patent applications and patent applications in certain foreign countries will be considered patentable by the United States Patent and Trademark Office, or USPTO, courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our licensor's issued patents will not be found invalid or unenforceable if challenged.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting vonoprazan and any future product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or block our ability to make, use and sell vonoprazan and any future product candidates;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing products.

The patent prosecution process is also expensive and time consuming, and we and our licensor may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we and our licensor will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances such as under the Takeda License, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, directed to technology that we license from third parties. We may also require the cooperation of our licensors in order to enforce the licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

We cannot be certain that patent prosecution and maintenance activities by our licensors have been or will be conducted in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. If they fail to do so, this could cause us to lose rights in any applicable intellectual property that we in-license, and as a result our ability to develop and commercialize products or product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products.

In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties, including our rights in vonoprazan licensed from Takeda, or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are a party to the Takeda License under which we are granted rights to intellectual property that are important to our business and we may enter into additional license agreements in the future with other third parties. The Takeda License imposes, and we expect that any future license agreements where we in-license intellectual property, will impose on us, various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to bankruptcy-related proceedings, the licensor

may have the right to terminate the license, in which event we would not be able to market products covered by the license. Additionally, if a future license agreement includes a sublicense from a third party who is not the original licensor of the intellectual property at issue, then we must rely on our direct licensor to comply with its obligations under the primary license agreements under which such licensor obtained rights in the applicable intellectual property, where we may have no relationship with the original licensor of such rights. If such a licensor fails to comply with its obligations under its upstream license agreement, the original third-party licensor may have the right to terminate the original license, which may terminate our sublicense. If this were to occur, we would no longer have rights to the applicable intellectual property unless we are able to secure our own direct license with the owner of the relevant rights, which we may not be able to do on reasonable terms, or at all, which may impact our ability to continue to develop and commercialize vonoprazan and any future product candidates incorporating the relevant intellectual property.

We may need to obtain further licenses from third parties to advance our research or allow commercialization of vonoprazan and any future product candidates, and we cannot provide any assurances that third-party patents do not exist which might be enforced against vonoprazan and any future product candidates in the absence of such a license. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of vonoprazan and any future product candidates, and what activities satisfy those diligence obligations;
- our right to transfer or assign the license; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize the affected product candidates, which would have a material adverse effect on our business.

In addition, certain of our agreements may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities. For example, if we choose to sublicense or assign to any third parties our rights under our existing license agreement with Takeda with respect to any licensed product, we may be required to wait for a certain period or until the occurrence of certain funding or development milestones.

If the scope of any patent protection or non-patent regulatory exclusivity we obtain is not sufficiently broad, or if we lose or fail to obtain any of our patent protection or non-patent regulatory exclusivity, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our in-licensed pending and future patent applications may not result in patents being issued which protect vonoprazan or any future product candidates or which effectively prevent others from commercializing competitive product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own in the future or license currently issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any future patents that we own or license, now or in the future, may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether vonoprazan or any future product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our future patents or the patents of our current and future licensors by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our future patents or the patents of our current and future licensors may not cover vonoprazan or any future product candidates or may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant review, or PGR, and inter partes review, or IPR, or other similar proceedings in the USPTO or foreign patent offices challenging our patent rights. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our predecessors and the patent examiner were unaware during prosecution. There is no assurance that all potentially relevant prior art relating to our in-licensed patents and patent applications has been found. There is also no assurance that there is not prior art of which we, our predecessors or licensors are aware, but which we do not believe affects the validity or enforceability of a claim in our in-licensed patents and patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize vonoprazan or any future product candidates and compete directly with us, without payment to us. It is possible that defects of form in the preparation or filing of our or our current and future licensors' patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If there are material defects in the form, preparation, prosecution, or enforcement of our future patents or future patent applications or our current and future licensors' patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents.

Any loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of vonoprazan or any future product candidates, which could materially and adversely impact our business. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our future patents and future patent applications or the patents and patent applications of our current and future licensors is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize vonoprazan or any future product candidates.

In addition to patent exclusivity, the successful commercialization of our products also depends, in part, on our ability to obtain and maintain periods of non-patent exclusivity during which time the FDA is precluded from accepting new drug applications, or NDAs, submitted under Section 505(b)(2) of the FDCA or abbreviated new drug applications, or ANDAs, for certain competitive products. In May 2021, FDA granted qualified infectious disease product, or QIDP, designations to vonoprazan tablets in combination with both amoxicillin capsules and clarithromycin tablets, and with amoxicillin capsules alone, respectively, for the treatment of *H. pylori* infection. On May 3, 2022, the FDA approved our NDAs for these products, branded as VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK, respectively. Because these approvals were for QIDP-designated drugs containing the active moiety,

vonoprazan, which had not previously been approved, the FDA granted five-years of NCE exclusivity, which was extended by an additional five-years pursuant to the GAIN Act, resulting in a total of ten-years of NCE exclusivity, until May 3, 2032.

In November 2023, we received approval for VOQUEZNA, which also contains vonoprazan. NCE exclusivity protects against the submission and the FDA's acceptance of a 505(b)(2) NDA or ANDA referencing that NCE for the duration of the exclusivity period, and the FDA interprets this form of exclusivity to attach to the active moiety such that the submission and the FDA's acceptance of ANDAs and 505(b)(2) NDAs for a drug with that active moiety may not occur until the innovator's exclusivity has expired, whether or not FDA has approved other versions of the drugs entitled to exclusivity, and regardless of the specific listed drug product to which the ANDA or 505(b)(2) application refers. Consequently, we believe that VOQUEZNA, because it contains vonoprazan, should benefit from the same extended period of NCE exclusivity granted in connection with our NDAs for VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PACK, until May 3, 2032.

The FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," referred to as the Orange Book, identifies that VOQUEZNA benefits from the same five-year period of NCE exclusivity as VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK, but does not currently identify the GAIN Act extension of an additional five-years of NCE exclusivity to which we believe it is entitled. We informally requested that the FDA correct the VOQUEZNA listings to reflect the same extended NCE exclusivity period as VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK. However, the FDA so far declined to update those listings. We are therefore further engaging with the FDA regarding VOQUEZNA's Orange Book listings and the application to VOQUEZNA of the extended NCE exclusivity tied to vonoprazan. If the FDA ultimately concludes that the GAIN Act extension of NCE exclusivity granted in connection with our VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK NDAs does not extend to our VOQUEZNA NDA, there is the potential we could be subject to competition much earlier than we currently anticipate. If this occurs, it would have a material adverse effect on our business and financial condition.

The patent protection and patent prosecution for vonoprazan or any future product candidates may be dependent on third parties.

We may rely on third parties to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property under certain current and future license agreements, such as the Takeda License. Under such arrangements, we may not have primary control over these activities for certain of licensed patents or patent applications and other intellectual property rights. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. In addition, our current and future licensors may not be fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, which could compromise such patent rights. We may in the future enter into license agreements where the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. If any of our licensors or any of our future licensors or future collaborators fail to appropriately prosecute and maintain patent protection for patents covering VOQUEZNA or any future product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

In addition, even where we have the right to control prosecution of patent applications or enforcement of patents we have acquired or licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions of our predecessors or licensors and their counsel that took place prior to us assuming control over such activities.

Third parties may retain certain rights to the technology that they license to us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. For example, under the Takeda License, Takeda retained the rights to the inventions in all countries other than the United States, Europe, and Canada. Takeda also retained the right to develop certain drug products that contain vonoprazan where vonoprazan is not the only active pharmaceutical ingredient. It is difficult to monitor whether our predecessors or licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

If we are limited in our ability to utilize acquired or licensed technologies, or if we lose our rights to critical in-licensed technology, we may be unable to successfully develop, out-license, market and sell our products, which could prevent or delay new product introductions. Our business strategy depends on the successful development of licensed and acquired technologies into commercial products. Therefore, any limitations on our ability to utilize these technologies may impair our ability to develop, out-license or market and sell our product candidate.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to develop products that are similar to VOQUEZNA or any future product candidates but that are not covered by the claims of the patents that we own in the future or license;
- we or our current and future licensors or predecessors might not have been the first to make the inventions covered by the issued patents or patent applications that we own in the future or license;
- we or our current and future licensors or predecessors might not have been the first to file patent applications covering certain of the claimed inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that the pending patent applications we own or license will not lead to issued patents;
- issued patents that we own in the future or license may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, it could significantly harm our business, results of operations and prospects.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.

Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import VOQUEZNA and any future product candidates and products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, oppositions, reexaminations, IPR proceedings and PGR proceedings before the USPTO and/ or foreign patent offices. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of VOQUEZNA and any future product candidates.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that VOQUEZNA and any future product candidates may be subject to claims of infringement of the patent rights of third parties. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published we may be unaware of third-party patents that may be infringed by commercialization of VOQUEZNA and any future product candidates, and we cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that VOQUEZNA and any future product candidates may infringe. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Any claims of patent infringement asserted by third parties would be time consuming and could:

- result in costly litigation that may cause negative publicity;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing, or continuing to commercialize, VOQUEZNA (and/or other approved products containing vonoprazan), and any future product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- subject us to significant liability to third parties; or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in our competitors gaining access to the same technology.

Although no third party has asserted a claim of patent infringement against us as of the date of this annual report, others may hold proprietary rights that could prevent VOQUEZNA and any future product candidates from being marketed.

Any patent-related legal action against us claiming damages and seeking to enjoin activities relating to VOQUEZNA and any future product candidates or processes could subject us to potential liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or develop VOQUEZNA and any future product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or our future strategic partners were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign VOQUEZNA and any future product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing VOQUEZNA and any future product candidates, which could harm our business, financial condition and operating results.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

We may not be successful in obtaining or maintaining necessary rights to our current products and any future product candidates through acquisitions and in-licenses.

Because our development programs may in the future require the use of proprietary rights held by other third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our current products, including VOQUEZNA, and any future product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of that program and our business and financial condition could suffer.

We may be involved in lawsuits to protect or enforce our future patents or the patents of our current and future licensors, which could be expensive, time consuming and unsuccessful. Further, our future issued patents or the patents of our current and future licensors could be found invalid or unenforceable if challenged in court.

Competitors may infringe our intellectual property rights or those of our current and future licensors. To prevent infringement or unauthorized use, we and/or any such licensors may be required to file infringement claims, which can be expensive and time consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we own or license is not valid, is unenforceable and/or is not infringed. If we or any of our current and future licensors were to initiate legal proceedings against a third party to enforce a patent directed at VOQUEZNA and any future product candidates, the defendant could counterclaim that our patent or the patent of our current or future licensor is invalid and/or unenforceable in whole or in part. In patent litigation, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description, non-enablement, or obviousness-type double patenting. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution.

If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. In addition, if the breadth or strength of protection provided by our future patents and future patent applications or those of our current and future licensors is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Such a loss of patent protection would have a material adverse impact on our business.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common shares to decline.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs or intellectual property could be

diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

Derivation or interference proceedings may be necessary to determine priority of inventions, and an unfavorable outcome may require us to cease using the related technology or to attempt to license rights from the prevailing party.

Derivation or interference proceedings provoked by third parties or brought by us or declared by the USPTO or similar proceedings in foreign patent offices may be necessary to determine the priority of inventions with respect to our future patents or future patent applications or those of our current and future licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of such proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with such proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our commercial activities, clinical trials, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us continue commercializing our current products and bring any future product candidates to market.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our future patent applications or those of our current and future licensors and the enforcement or defense of our future issued patents or those of our current and future licensors.

On September 16, 2011, the Leahy-Smith America Invents Act, or Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first inventor to file" system in which, assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether a third party was first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013 but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we may not be certain that we or our current and future licensors are the first to either (1) file any patent application related to VOQUEZNA and any future product candidates or (2) invent any of the inventions claimed in the patents or patent applications.

The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including PGR, IPR, and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our future patent applications or those of our current and future licensors and the enforcement or defense of our future issued patents or those of our current and future licensors, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In 2012, the European Patent Package, or EU Patent Package, regulations were passed with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court, or UPC, for litigation involving European patents. Implementation of the EU Patent Package occurred on June 1, 2023. Under the UPC, all European patents, including those issued prior to ratification of the European Patent Package, will by default automatically fall under the jurisdiction of the UPC. The UPC will

provide our competitors with a new forum to centrally revoke our European patents, and allow for the possibility of a competitor to obtain pan-European injunctions. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates and, resultantly, on our business, financial condition, prospects and results of operations. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by the UPC. Under the EU Patent Package as currently proposed, we will have the right to opt our patents out of the UPC over the first seven years of the court's existence, but doing so may preclude us from realizing the benefits of the new unified court. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC.

Changes in U.S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect our current products and any future product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our future patents or in third-party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us. Evolving judicial interpretation of patent law could also adversely affect our business. For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce the existing licensed patents and the patents we might obtain or license in the future.

We may be subject to claims challenging the inventorship or ownership of our future patents, the patents of our current and future licensors, or other intellectual property.

We may also be subject to claims that former employees or other third parties have an ownership interest in our future patents, the patents of our current and future licensors or other intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

Patent terms may be inadequate to protect our competitive position on VOQUEZNA and any future product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our current products including VOQUEZNA and any future product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of product candidates, patents protecting our current products and any future product candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain patent term extension for our current products and any future product candidates, our business may be materially harmed.

Based on the first marketing approval by the FDA for vonoprazan, we believe one or more of our U.S. patents or those of our current and future licensors, may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term

Restoration Act of 1984, or the Hatch-Waxman Amendments. The Hatch- Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. A maximum of one patent may be extended per FDA approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of vonoprazan and any future product candidates. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

We may not be able to protect our intellectual property rights throughout our licensed territories.

Although we have issued patents and pending patent applications in the United States and certain other countries in which we intend to commercialize our products, filing, prosecuting and defending patents in all relevant countries throughout our licensed territories could be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with VOQUEZNA or any future product candidates, and our patents, the patents of our current and future licensors or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our intellectual property rights or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our future patents or the patents of our current and future licensors at risk of being invalidated or interpreted narrowly and our future patent applications or the patent applications of our current and future licensors at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by regulations and governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our future patents and/or future applications and those of our current and future licensors. We have systems in place to remind us to pay these fees, and we rely on third parties to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ

reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition, we rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. We may need to share our trade secrets and proprietary know-how with current or future partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and other countries.

Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position would be harmed. If we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to protect our trade secret information may be jeopardized.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is common in the biopharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of vonoprazan and any future product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other biopharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We intend to use registered or unregistered trademarks or trade names to brand and market ourselves and our products. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks,

trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

Any collaboration arrangements that we have or may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our products.

The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators and partners. Under the Takeda License, for example, Takeda had certain obligations with respect to assisting with the transition of information and materials to us as well as providing clinical and commercial supply of the vonoprazan product. Collaborations and partnerships are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our products or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our current or future products or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future products;
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Intellectual property discovered through government funded programs may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

We may acquire or license in the future intellectual property rights that have been generated through the use of U.S. government funding or grant. Pursuant to the Bayh-Dole Act of 1980, the U.S. government has certain rights in inventions developed with government funding. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also

referred to as "march-in rights"). The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property.

Risks Related to Our Common Stock

The trading price of the shares of our common stock has been, and is likely to continue to be, highly volatile, and purchasers of our common stock could incur substantial losses.

The stock market in general and the market for stock of biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price at which they paid. Our common stock has a limited trading history and the market price has fluctuated widely, and may in the future fluctuate widely, depending upon many factors such as those discussed in this "Risk Factors" section and many others, some of which are beyond our control, including the following:

- a relatively low-volume trading market for our shares of common stock that could cause trades of small blocks of shares to have a significant impact on the price of our shares of common stock;
- market conditions in the biopharmaceutical sector and issuance of securities analysts' reports or recommendations;
- establishment of short positions by holders or non-holders of our common stock;
- an inability to obtain additional funding;
- sales of our stock by insiders and stockholders, including Takeda;
- our ability to enroll patients in our ongoing and any future clinical trials;
- results of our clinical trials and preclinical studies, the results of clinical trials conducted by Takeda and others for vonoprazan, and the results of trials of our competitors or those of other companies in our market sector;
- additional regulatory approvals of vonoprazan and approvals of any future product candidates, or limitations to specific label indications or patient populations for use of any approved products, or changes or delays in the regulatory review process;
- any termination or loss of rights under the Takeda License;
- regulatory developments in the United States and foreign countries;
- changes in the structure of healthcare payment systems, especially in light of reforms to the U.S. healthcare system;
- the success or failure of our efforts to acquire, license or develop additional product candidates;
- innovations or new products developed by us or our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;

- manufacturing, supply or distribution delays or shortages;
- any changes to our relationship with any manufacturers, suppliers, licensors, future collaborators or other strategic partners;
- achievement of expected product sales and profitability;
- variations in our financial results or those of companies that are perceived to be similar to us;
- general economic, industry and market conditions, public health emergencies or other events or factors, many of which are beyond our control;
- additions or departures of key personnel;
- intellectual property, product liability or other litigation against us;
- changes in our capital structure, such as future issuances of securities and the incurrence of additional debt; and
- changes in accounting standards, policies, guidelines, interpretations or principles.

In addition, in the past, stockholders have initiated class action lawsuits against biopharmaceutical companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources, which could have a material adverse effect on our business, financial condition and results of operations.

Our executive officers, directors and principal stockholders, if they choose to act together, have the ability to control or significantly influence all matters submitted to stockholders for approval. Furthermore, many of our current directors were appointed by our principal stockholders.

Our executive officers, directors and greater than 5% stockholders, in the aggregate, own a majority of our outstanding common stock. As a result, such persons acting together have the ability to control or significantly influence all matters submitted to our board of directors or stockholders for approval, including the appointment of our management, the election and removal of directors and approval of any significant transaction, as well as our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

We do not currently intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation, if any, in the price of our common stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, under the terms of the Loan Agreement, we are prohibited from paying any cash dividends without the consent of the lenders. Any return to stockholders will therefore be limited to the appreciation of their stock. Shares of our common stock may not appreciate in value or even maintain the price at which stockholders have purchased their shares.

Sales of a substantial number of shares of our common stock by our existing stockholders, including Takeda, in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities.

As of December 31, 2023, Takeda owned 7,459,286 shares of common stock that are eligible for sale in the public market to the extent permitted by Rule 144 under the Securities Act. In addition, as of December 31, 2023, up to 9,378,875 shares of common

stock that are either subject to outstanding options, warrants or other rights or reserved for future issuance under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, exercise limitations, and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Further, we filed a registration statement, which became effective on November 17, 2023, registering the resale of up to 5,827,415 shares of common stock held by Frazier Life Sciences IX, L.P., or Frazier. As a result of the registration statement, Frazier is able to freely sell some or all of its shares of our common stock. Any sales by these stockholders could have a material adverse effect on the trading price of our common stock.

We are an emerging growth company and a smaller reporting company, and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting company may make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the completion of our IPO. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, our annual gross revenues exceed $1.235 billion or we issue more than $1 billion of non-convertible debt in any three- year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, unless the SEC, determines the new rules are necessary for protecting the public;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

Investors may find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700 million measured on the last business day of our second fiscal quarter.

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could significantly reduce the value of our shares to a potential acquiror or delay or prevent changes in control or changes in our management without the consent of our board of directors. The provisions in our charter documents include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors, unless the board of directors grants such right to the stockholders, to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the required approval of at least 66-2/3% of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;
- the required approval of at least 66-2/3% of the shares entitled to vote to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- an exclusive forum provision providing that the federal district courts will be the exclusive forum for actions and proceedings a cause of action arising under the Securities Act of 1933, as amended, and that the Court of Chancery of the State of Delaware will be the exclusive forum for certain other actions and proceedings;
- the requirement that a special meeting of stockholders may be called only by the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf under Delaware statutory or common law, including any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided, that, this provision would not apply to suits brought to enforce a duty or liability created by the Securities Act or the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. The choice of forum provisions in our amended and restated certificate of incorporation may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. By agreeing to these provisions, however, stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the choice of forum provisions in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

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

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward and, subject to limitations, offset future taxable income, if any, until such unused losses expire (if at all).

Under prevailing U.S. tax law, federal net operating loss, or NOL, carryforwards generated in periods after December 31, 2017, may be carried forward indefinitely but may only be used to offset 80% of our taxable income annually. Our NOL carryforwards are subject to review and possible adjustment by the Internal Revenue Service, or the IRS, and state tax authorities. Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, our federal NOL carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50 percentage points. Our ability to utilize our NOL carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes, including changes in connection with our IPO or future offerings. Similar rules may apply under state tax laws. We have not yet determined the amount of the cumulative change in our ownership resulting from our IPO or other transactions, or any resulting limitations on our ability to utilize our NOL carryforwards and other tax attributes. If we earn taxable income, such limitations could result in increased future tax liability to us and our future cash flows could be adversely affected. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

Recent U.S. tax legislation may materially adversely affect our financial condition, results of operations and cash flows.

The Tax Cuts and Jobs Act of 2017 has significantly changed the U.S. federal income taxation of U.S. corporations, including by reducing the U.S. corporate income tax rate and revising the rules governing NOLs. Many of these changes became effective beginning in 2018, without any transition periods or grandfathering for existing transactions. The legislation is unclear in many respects and may continue to be subject to potential amendments and technical corrections, as well as interpretations and implementing regulations by the U.S. Treasury Department and the IRS, which have lessened or increased certain adverse impacts of the legislation and may do so in the future. We continue to work with our tax advisors to determine the full impact that the recent tax legislation as a whole will have on us. We urge our investors to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our common stock.

General Risk Factors

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business

interruptions, for which we are predominantly self-insured. We rely, and expect to continue to rely, on third-party manufacturers to produce vonoprazan, including VOQUEZNA, VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK and any future product candidates. Our ability to obtain clinical supplies of vonoprazan and any future product candidates could be disrupted if the operations of these suppliers were affected by a manmade or natural disaster or other business interruption. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Our failure to meet the continued listing requirements of the Nasdaq could result in a delisting of our common stock.

If we fail to satisfy the continued listing requirements of the Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, any action taken by us to restore compliance with listing requirements may not allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements.

We incur significant costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory "say on pay" voting requirements that will apply to us when we cease to be an emerging growth company. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The costs we incur as a public company will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage in the future. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

If securities or industry analysts do not publish research or reports or publish unfavorable research or reports about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. If securities or industry analysts do not continue coverage of our company, the trading price for our stock would be negatively impacted. In addition, if one or more of the analysts who covers us downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Pursuant to Section 404 of Sarbanes-Oxley, our management is required to report upon the effectiveness of our internal control over financial reporting. When we lose our status as an "emerging growth company" and reach an accelerated filer threshold, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we are in the process of implementing additional financial and management controls, reporting systems and procedures; and hiring additional accounting and finance staff. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

There could be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begin its Section 404 reviews, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us, because we, like many other biotechnology and pharmaceutical companies, have recently experienced significant stock price volatility. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 1C. Cybersecurity Risk Management and Strategy

We have developed and implemented a cybersecurity risk management program intended to protect the confidentiality, integrity, and availability of our critical systems and information. Our cybersecurity risk management program includes a cybersecurity incident response plan.

We design and assess our program based on the National Institute of Standards and Technology Cybersecurity Framework, or NIST CSF. This means that we use the NIST CSF as a guide to help us identify, assess, and manage cybersecurity risks relevant to our business. It does not, however, mean that we meet any technical standards, specifications, or requirements.

Our cybersecurity risk management program is part of our overall enterprise risk management program and shares similar governance processes and reporting channels that apply across the enterprise risk management program to financial, legal, compliance, and other operational risk areas. However, there can be no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems and information.

Our cybersecurity risk management program includes:

- risk assessments designed to help identify material cybersecurity risks to our critical systems, information, products, services, and our broader enterprise IT environment;
- an internal team responsible for, inter alia, managing (1) our cybersecurity risk assessment processes, (2) our security controls, and (3) our response to cybersecurity incidents;
- the use of external service providers with subject matter expertise, where appropriate, to assess, test or otherwise assist with aspects of our security controls;
- cybersecurity awareness training of our employees, incident response personnel, and senior management;
- a cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents; and
- a third-party risk management evaluation process for service providers, suppliers, and vendors with access to our information systems or data.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition.

Cybersecurity Governance

Our Board considers cybersecurity risk as part of its risk oversight function and has delegated to the Audit Committee (Committee) oversight of cybersecurity and other information technology risks. The Committee oversees management's implementation of our cybersecurity risk management program. The Committee receives periodic reports from management on our cybersecurity risks. In addition, management is required to update the Committee, as necessary, regarding any material cybersecurity incidents.

The Committee reports to the full Board regarding its activities, including those related to cybersecurity. The full Board also receives briefings from management on our cyber risk management program.

Our management team, including our Chief Financial and Business Officer, is responsible for assessing and managing our material risks from cybersecurity threats. The team has primary responsibility for our overall cybersecurity risk management program and supervises both our internal IT personnel who in turn manage our retained external cybersecurity consultants. Our

management team's experience includes significant responsibility for developing and maintaining cybersecurity risk management programs and for managing cybersecurity risks prior to joining us.

Our management team supervises efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include briefings from internal IT personnel; threat intelligence and other information obtained from governmental, public or private sources, including external consultants engaged by us; and alerts and reports produced by security tools deployed in our internal IT environment.

Item 2. Properties

Our corporate offices are located in Buffalo Grove, Illinois, and Florham Park, New Jersey. We believe that our facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms, if required.

For additional information, see Note 5, Lease Commitments included in Item 15 of this Annual Report on Form 10-K.

Item 3. Legal Proceedings

We are not currently subject to any material legal proceedings. From time to time, we may be involved in legal proceedings or subject to claims incident to the ordinary course of business. Regardless of the outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock has been publicly traded on the Nasdaq Global Select Market under the symbol "PHAT" since our initial public offering on October 25, 2019, which was completed at a price to the public of $19.00 per share. Prior to our initial public offering, there was no public market for our common stock.

Holders of Common Stock

As of March 4, 2024, there were 58,477,351 shares of our common stock outstanding held by approximately 46 holders of record of our common stock. This number was derived from our shareholder records and does not include beneficial owners of our common stock whose shares are held in the name of various dealers, clearing agencies, banks, brokers and other fiduciaries.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors the board of directors deems relevant, and subject to the restrictions contained in any future financing instruments. In addition, under the terms of our Loan Agreement, we are prohibited from paying any cash dividends without the consent of the lenders.

Securities Authorized for Issuance Under Equity Compensation Plans

See Item 12 of Part III of this annual report on Form 10-K for information about our equity compensation plans which is incorporated by reference herein.

Performance Graph

Not applicable.

Unregistered Sales of Equity Securities

Not applicable.

Use of Proceeds from Registered Securities

Not applicable.

Issuer Repurchases of Equity Securities

None.

Item 6. [Reserved]

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes included elsewhere in this annual report. This discussion and analysis contains forward-looking statements based upon our current beliefs, plans and expectations that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Risk Factors" or in other parts of this annual report.

Overview

We are a biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal, or GI, diseases. Our approved products, VOQUEZNA®, VOQUEZNA® TRIPLE PAK® and VOQUEZNA® DUAL PAK®, contain vonoprazan, an oral small molecule potassium-competitive acid blocker, or PCAB. PCABs are a novel class of medicines that block acid secretion in the stomach. Vonoprazan is the first gastric anti-secretory agent from a novel class approved in the United States, Europe, or Canada in over 30 years, and has shown rapid, potent, and durable anti-secretory effects. Vonoprazan has also demonstrated clinical benefits over the current standard of care as a single agent in the treatment of erosive gastroesophageal reflux disease, or Erosive GERD, and in combination with antibiotics for the treatment of *Helicobacter pylori*, or *H. pylori*, infection. Takeda Pharmaceutical Company Limited, or Takeda, developed vonoprazan and has received marketing approval in numerous countries in Asia and Latin America as well as Russia. Vonoprazan generated approximately $850 million in net sales in its seventh full year on the market since its approval in Japan in late 2014. In May 2019, we in-licensed the U.S., European, and Canadian rights to vonoprazan from Takeda.

In 2021 we reported positive topline data from two pivotal Phase 3 clinical trials for vonoprazan: one for the treatment of *H. pylori* infection, or PHALCON-HP, and a second for the treatment of Erosive GERD, or PHALCON-EE. These data are supplemented by the extensive existing clinical data generated by Takeda as part of its development program for vonoprazan in Japan and other markets. In September 2021, we submitted two new drug applications, or NDAs, for combination packs that contain vonoprazan for the treatment of *H. pylori* infection in adults, one in combination with amoxicillin and clarithromycin (vonoprazan triple therapy) and the other in combination with amoxicillin alone (vonoprazan dual therapy). In May 2022, the U.S. Food and Drug Administration, or FDA, approved the NDAs for vonoprazan triple therapy, under the brand name VOQUEZNA TRIPLE PAK, and vonoprazan dual therapy, under the brand name VOQUEZNA DUAL PAK. Based on our qualified infectious disease product, or QIDP, designations for VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK, we received an extension of five years of new chemical entity, or NCE, exclusivity based on the vonoprazan component in those NDAs. We believe the extended NCE exclusivity should apply to any other approved or future products containing vonoprazan we develop and for which we obtain FDA approval.

While the NDAs for VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK were still under review by the FDA, in March 2022, we submitted an additional NDA for vonoprazan, under the brand name VOQUEZNA, as a treatment for adults for the healing of all grades of Erosive GERD, maintenance of healing of all grades of Erosive GERD, and relief of heartburn associated with Erosive GERD. In August 2022, following approval of VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK but before launch, and while the NDA for VOQUEZNA for Erosive GERD was still under review, we announced that trace levels of a nitrosamine impurity, *N*-nitroso-vonoprazan, or NVP, were present in our initial commercial drug product for VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK. After identifying this impurity, and prior to launching VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK, we submitted supplements to our approved NDAs with the goal of addressing this issue. However, in February 2023, we received complete response letters from the FDA relating both to our Erosive GERD NDA and to the NDA supplements for our approved *H. pylori* NDAs. The complete response letters formalized the FDA's prior request that we provide additional stability data to demonstrate that levels of NVP will remain at or below 96 ng/day, the acceptable daily intake level (AI) for NVP established by the FDA, throughout the proposed shelf life of the product. No additional deficiencies were cited by the FDA in the complete response letters. In May 2023, we resubmitted our Erosive GERD NDA to the FDA, and in June 2023 we submitted new prior approval supplements to our approved *H. pylori* NDAs. On October 27 and November 1, 2023, the FDA approved the prior approval supplements to our *H. pylori* NDAs and our Erosive GERD NDA, respectively. As a result, we initiated commercial launch for VOQUEZNA for both the Erosive GERD and *H. pylori* indications, and VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK for treatment of *H. pylori* infection in the fourth quarter of 2023.

We are also continuing to develop vonoprazan as a treatment for heartburn symptoms associated with Non-Erosive GERD. In January 2023, we reported positive topline results from PHALCON-NERD-301, a Phase 3 study evaluating the safety and efficacy of vonoprazan for the daily treatment of adults with Non-Erosive GERD, and in August 2023, we announced successful completion of the 20-week extension period of PHALCON-NERD-301. Based on the results of this study, in September 2023, we submitted an NDA

seeking approval of vonoprazan as a once-daily treatment for heartburn symptoms associated with Non-Erosive GERD in adults. The FDA has assigned this NDA a Prescription Drug User Fee Act, or PDUFA, target action date of July 19, 2024, and if approved, we anticipate launching vonoprazan for this new indication in the third quarter of 2024. In addition, in 2024 we plan to initiate a Phase 3 trial evaluating the novel dosing regimen of vonoprazan as an "as-needed" treatment for episodic heartburn relief in patients with Non-Erosive GERD, a dosing regimen not approved in the United States for PPIs. This trial would constitute our fourth Phase 3 trial for vonoprazan. In February 2022, we reported positive topline results from PHALCON-NERD-201, a Phase 2 proof-of-concept study evaluating this novel dosing regimen. We plan to expand the clinical development of vonoprazan in the U.S. into eosinophilic esophagitis, or EoE, the most common type of eosinophilic gastrointestinal disease. Given the limited treatment options for EoE and vonoprazan's demonstrated potential, we believe EoE is an important indication for future study and expect to initiate a Phase 2 trial evaluating vonoprazan as a treatment for EoE in adult and adolescent patients later in 2024.

We are independently commercializing VOQUEZNA, VOQUEZNA TRIPLE PAK, and VOQUEZNA DUAL PAK in the United States. We plan to evaluate commercial partnerships for vonoprazan in Europe and Canada, expand development of vonoprazan into other indications, dosing regimens and alternative formulations and packaging, and in-license or acquire additional clinical or commercial stage product candidates for the treatment of GI diseases in a capital efficient manner.

We commenced our operations in 2018 and have devoted substantially all of our resources to date to organizing and staffing our company, business planning, raising capital, in-licensing our initial and approved product candidate, vonoprazan, meeting with regulatory authorities, conducting our Phase 3 clinical trials of vonoprazan, preparing applications for regulatory approval for vonoprazan and preparing our commercial launch. Our operations to date have been funded primarily through the issuance of convertible promissory notes, commercial bank debt, the proceeds from our initial public offering, our follow-on public offering, our ATM offering, and our Revenue Interest Financing Agreement. From our inception through December 31, 2023, we have raised aggregate gross proceeds of $90.3 million from the issuance of convertible promissory notes, $140 million of debt, net proceeds from our initial public offering of $191.5 million from the sale of 10,997,630 shares of common stock, which included the exercise in full by the underwriters of their option to purchase 1,434,473 additional shares at a public offering price of $19.00 per share, after deducting underwriting discounts, commissions and offering costs, and net proceeds of $88.6 million from the sale of 2,250,000 shares of common stock at a public offering price of $39.48 per share after deducting underwriting discounts and commissions, and an additional $0.2 million in offering costs, net proceeds of $268.1 million from the Revenue Interest Financing Agreement, net proceeds of $38.7 million from the sale of 3,929,116 shares under the ATM Offering and net proceeds of $141.4 million from the sale of 12,793,750 shares of common stock, which included the exercise in full by the underwriters of their option to purchase 1,668,750 shares, at a price of $11.75 per share, after deducting underwriting discounts and commissions. As of December 31, 2023, we had cash and cash equivalents of $381.4 million. Based on our current operating plan, we believe that our existing cash and cash equivalents together with the drawdown of the remaining $160 million under our Loan Agreement with Hercules together with anticipated product revenues, are sufficient to fund operations for at least the next twelve months and will be sufficient to fund our operations through the end of 2026.

Since inception, we have incurred significant operating losses. Our net loss was $201.6 million and $197.7 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $928.7 million. We expect to continue to incur operating losses for the foreseeable future. It could be several years, if ever, before VOQUEZNA, VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK or other product candidates, if approved, generate significant revenues to offset these operating losses. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. The net losses we incur may fluctuate significantly from quarter to quarter and year to year.

We have generated limited revenue to date, until such time as we can generate significant revenue from sales of our approved products containing vonoprazan, we expect to finance our cash needs through equity offerings, our Loan Agreement, our Revenue Interest Financing Agreement, additional debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all, and this risk could be exacerbated by the impact of ongoing conflicts throughout the world and global economic conditions. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

License Agreement with Takeda

On May 7, 2019, we and Takeda entered into an exclusive license, or the Takeda License, pursuant to which we in-licensed the U.S., European, and Canadian rights to vonoprazan fumarate. During the term of the Takeda License, we and our affiliates are not permitted to commercialize any pharmaceutical product, other than vonoprazan, that treats acid-related disorders, except for certain generic and OTC competing products in specified circumstances. We will be responsible at our cost for the development, manufacture and commercialization of vonoprazan products. We are required to use commercially reasonable efforts to develop and commercialize the vonoprazan products in our licensed territory.

Under the Takeda License, Takeda has the sole right and authority, with our input, to prepare, file, prosecute, and maintain all Takeda and joint patents on a worldwide basis at its own cost. We are responsible, at our cost, for preparing, filing, prosecuting, and maintaining patents on inventions made solely by us in connection with vonoprazan, subject to input from Takeda.

We paid Takeda upfront consideration consisting of a cash fee of $25 million, 1,084,000 shares of our common stock, a warrant to purchase 7,588,000 shares of our common stock at an exercise price of $0.00004613 per share, or the Takeda Warrant, and issued Takeda a right to receive an additional common stock warrant, or the Takeda Warrant Right, if Takeda's fully-diluted ownership of the Company represented less than a certain specified percentage of the fully-diluted capitalization, including shares issuable upon conversion of then outstanding convertible promissory notes, calculated immediately prior to the closing of our IPO. The Takeda Warrant Right expired without effect since no fair value had been allocated to it upon completion of our IPO, and no additional warrant was issued. We agreed to make milestone payments to Takeda upon achieving certain tiered aggregate annual net sales of licensed products in the United States, Europe and Canada up to a total maximum milestone amount of $250 million. We also agreed to make tiered royalty payments at percentages in the low double digits on net sales of licensed products, subject to specified offsets and reductions. Royalties will be payable, on a product-by-product and country-by-country basis from the first commercial sale of such product in such country, until the latest of expiration of the licensed patents covering the applicable product, expiration of regulatory exclusivity in such country, or 15 years following first commercial sale in such country.

Components of Results of Operations

Revenue

We began to recognize revenue from product sales, net of rebates, chargebacks, discounts, and other adjustments, in November 2023 in conjunction with the commercial launch of VOQUEZNA, VOQUEZNA TRIPLE PAK, and VOQUEZNA DUAL PAK in the United States.

Cost of Revenue

Cost of revenue includes the cost of producing and distributing inventories that are related to product sales. This also includes royalties payable to Takeda, pursuant to the Takeda License Agreement (Refer to Note 4 for further details). In addition, shipping and handling costs for product sales are recorded as incurred. Finally, cost of revenue may also include costs related to excess or obsolete inventory adjustment charges.

Operating Expenses

Research and Development

To date, our research and development expenses have related to the development of vonoprazan. Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

Research and development expenses include:

- salaries, payroll taxes, employee benefits, and stock-based compensation charges for those individuals involved in research and development efforts;

- external research and development expenses incurred under agreements with CROs, and consultants to conduct and support our ongoing clinical trials of vonoprazan; and
- costs related to the manufacturing of vonoprazan for our clinical trials.

We plan to continue to invest in our research and development expenses for the foreseeable future as we continue the development of vonoprazan. We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future clinical trials and nonclinical studies of vonoprazan or any future product candidates due to the inherently unpredictable nature of clinical and preclinical development. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

Our future clinical development costs may vary significantly based on factors such as:

- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses evaluated in the trials;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the phase of development of the product candidate; and
- the efficacy and safety profile of the product candidate.

Selling, General and Administrative

Selling, general and administrative expenses consist of salaries and employee-related costs, including stock-based compensation, for personnel in commercial, executive, finance, accounting, legal, human resources and other administrative functions, legal fees relating to intellectual property and corporate matters, and professional fees for accounting and consulting services. We anticipate that our general and administrative expenses will increase in the future to support our continued research and development activities and commercialization activities. We also anticipate increased expenses related to audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums, and investor relations costs associated with operating as a public company.

Interest Income

Interest income consists of interest on our money market funds.

Interest Expense

Beginning on May 3, 2022, interest expense includes interest on the Revenue Interest Financing Agreement, which is based on the imputed effective rate derived from expected future payments and the carrying value of the obligation. We recalculate the effective interest rate each period based on the current carrying value and the revised estimated future payments. Changes in future payments from previous estimates are included in current and future financing expense.

Beginning on December 14, 2023, interest expense under the Hercules Loan consists of (i) cash interest at a variable annual rate equal to the greater of (a) 9.85% and (b) the Prime Rate (as reported in the Wall Street Journal) plus 1.35% and provided that the cash interest rate shall be capped at 10.35% and upon Company achieving the certain milestones, the cash interest shall be decreased by 0.35%, (ii) payment-in-kind interest at a per annum rate of interest equal to 2.15%, and (iii) amortization of the Hercules Loan Agreement debt discount recorded in connection with the fair value of warrants issued to the lenders, the debt issuance costs incurred, and the obligation to make a final payment.

From September 17, 2021 through December 13, 2023, interest expense under the Hercules Loan consisted of (i) cash interest at a variable annual rate equal to the greater of (a) 5.50% and (b) the Prime Rate (as reported in the Wall Street Journal) plus 2.25% or the Interest Rate, (ii) payment-in-kind interest at a per annum rate of interest equal to 3.35%, and (iii) amortization of the Hercules Loan Agreement debt discount recorded in connection with the fair value of warrants issued to the lenders, the debt issuance costs incurred, and the obligation to make a final payment.

Results of Operations

Comparison of the years ended December 31, 2023 and 2022

The following table summarizes our results of operations for the years ended December 31, 2023 and 2022 (in thousands):

	Years Ended December 31,		
	2023	**2022**	**Change**
Product revenue, net	$ 682	$ —	$ 682
Cost of revenue	167	—	167
Gross profit	515	—	515
Operating expenses:			
Research and development	49,899	71,441	(21,542)
Selling, general and administrative	117,928	100,999	16,929
Total operating expenses	167,827	172,440	(4,613)
Loss from operations	(167,312)	(172,440)	5,128
Other income (expense):			
Interest income	7,876	2,132	5,744
Interest expense	(41,968)	(27,305)	(14,663)
Other expense	(188)	(110)	(78)
Total other expense	(34,280)	(25,283)	(8,997)
Net loss	$ (201,592)	$ (197,723)	$ (3,869)

Revenue. Product revenues were $0.7 million for the year ended December 31, 2023 related to sales of VOQUEZNA which was launched in the fourth quarter of 2023.

Cost of Revenue. Cost of revenue was $0.2 million for the year ended December 31, 2023. In periods prior to receiving FDA approval for VOQUEZNA, we recognized inventory and related costs associated with the manufacture of VOQUEZNA as research and development expense and as such, the cost of goods sold and related gross margins are not necessarily indicative of future costs of goods sold and gross margin. Therefore, the manufacturing costs related to the inventory build-up incurred before FDA approval

were already expensed in a prior period and are therefore excluded from the cost of goods sold for the year ended December 31, 2023. These previously expensed costs were not material for the year ended December 31, 2023.

Research and Development Expenses. Research and development expenses were $49.9 million and $71.4 million for the years ended December 31, 2023 and 2022, respectively. The decrease of $21.5 million consisted of a reduction of $24.8 million of clinical study related expenses, $4.6 million of chemistry manufacturing and controls, or CMC, costs related to vonoprazan and $1.8 million related to consulting and other research expenses, partially offset by increases of $7.8 million of personnel-related expenses and $1.9 million of regulatory expenses.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $117.9 million and $101.0 million for the years ended December 31, 2023 and 2022, respectively. The increase of $16.9 million was due to increases of $31.1 million in personnel-related expenses and $0.6 million of legal and other expenses, offset by decreases of $13.3 million of professional services expenses for commercial, medical affairs and other services, $1.1 million of insurance expense and $0.4 million in consulting expense.

Other Income (Expense). Other expense of $34.3 million for the year ended December 31, 2023 consisted of $42.0 million of interest expense under the Hercules Loan and Revenue Interest Financing Agreements, partially offset by $7.9 million of interest income on deposits. Other expense of $25.3 million for the year ended December 31, 2022 consisted of $27.4 million of interest expense under the Hercules Loan and Revenue Interest Financing Agreements, partially offset by $2.1 million of interest income on deposits.

Liquidity and Capital Resources

We have incurred net losses and negative cash flows from operations since our inception and anticipate we will continue to incur net losses for the foreseeable future. As of December 31, 2023, we had cash and cash equivalents of $381.4 million.

Loan Agreement with Hercules

On September 17, 2021, or the Closing Date, we entered into a Loan and Security Agreement, as amended, the Loan Agreement, with Hercules Capital, Inc. (in such capacity, the Agent or Hercules), as administrative agent and collateral agent and as a lender and the other financial institutions that from time to time become parties to the Loan Agreement as lenders (collectively, the Lenders).

The Loan Agreement provides for term loans in an aggregate principal amount of up to $200 million, or the Term Loan, under multiple tranches. The tranches consist of (i) a first tranche consisting of term loans in an aggregate principal amount of $100 million, all of which was funded on the Closing Date, or the First Advance, (ii) a second tranche consisting of up to an additional $50 million, (iii) a third and fourth tranches consisting of an additional total $50 million, which became available to us in May 2022.

On September 27, 2022, we entered into an amendment to the Loan Agreement, or the Second Loan Amendment, pursuant to which the date the second tranche of funding of $50 million will remain available to the Company has been moved until May 15, 2023, rather than December 15, 2022.

On May 9, 2023, we entered into the Third Amendment to Loan and Security Agreement, or the Third Loan Amendment, with the lenders, pursuant to which, among other things, (i) the second tranche availability was extended from through May 15, 2023, to through December 15, 2023, and became available on October 1, 2023, (ii) the third tranche availability was extended from through September 30, 2023, to through December 15, 2023, and became available on October 1, 2023, (iii) the effective date of the Performance Covenants was amended to provide an option to extend the covenant trigger date to May 15, 2024, subject to the achievement of the FDA approval of vonoprazan for Erosive GERD or the EE Milestone, prior to February 15, 2024, and (iv) the warrant agreement with Hercules was amended as described below. On November 1, 2023 the EE Milestone was achieved and the covenant trigger date was extended to May 15, 2024. In connection with the Third Loan Amendment, a tranche extension amendment fee of $150,000 and a covenant extension amendment fee of $100,000 was paid to the Agent. These fees have been

recorded as debt discount and are being amortized to interest expense using the effective interest method over the remaining term of the Term Loan.

On December 14, 2023, we entered into a Fourth Amendment to Loan and Security Agreement, or the Fourth Loan Amendment, with the lenders, pursuant to which, among other things, (i) increases the aggregate principal amount of the term loans from $200 million to $300 million; (ii) provides for the possibility of accessing the $200 million commitment through five additional tranches referred to as tranches 2 through 6, which are available subject to certain milestones and conditions: (a) Tranche 2: $50 million, $40 million of which was funded on December 14, 2023, available through March 15, 2024, (b) Tranche 3: $25 million available through June 15, 2024, (c) Tranche 4: $25 million available through December 15, 2024, (d) Tranche 5: $50 million available, subject to the achievement of a specified revenue milestone, through June 30, 2025, and (e) Tranche 6: $50 million available, subject to the achievement of a specified revenue milestone, through December 31, 2025; (iii) extends the interest only period and the maturity date from October 2026 to December 2027, (iv) reduces the cash interest rate from 10.75% (floating annual rate equal to the greater of (a) 5.50% and (b) the Prime Rate (as reported in the Wall Street Journal) plus 2.25% to 9.85% (floating rate based on the greater of (a) 9.85% or (b) US WSJ Prime + 1.35%), provided that the cash interest rate shall be capped at 10.35% and upon us achieving the certain milestones, the cash interest shall be decreased by 0.35%, and (v) decreases the payment-in-kind interest rate from 3.35% per annum to 2.15% per annum. In connection with the Fourth Loan Amendment, an amendment fee of $250,000 was paid to the Agent and was recorded as a debt discount and being amortized to interest expense using the effective interest method over the remaining term of the Term Loan.

The Term Loan will mature on December 1, 2027, or the Maturity Date. The Term Loan bears (i) cash interest at a variable annual rate equal to the greater of (a) 9.85% and (b) the Prime Rate (as reported in the Wall Street Journal) plus 1.35%, or the Interest Rate, and (ii) payment-in-kind interest at a per annum rate of interest equal to 2.15%. We may make payments of interest only through the Maturity Date. After the interest-only period, the principal balance and related interest will be required to be repaid in full on the Maturity Date.

In addition, we are obligated to pay a final payment fee of 7.50% of the original principal amount of amounts actually advanced under the Term Loan, or each a Term Loan Advance and together, the Term Loan Advances. In connection with the Fourth Loan Amendment, the final payment fee was amended to be $1 million plus 3.00% of any future tranche drawdowns under the agreement, due upon final maturity. Additionally, the initial final payment fee for the first term Loan advance was amended to become payable on October 1, 2026. As of December 31, 2023, the aggregate final payment fee for the first Term Loan Advance of $7.5 million and $2.2 million for the second Term Loan Advance, and have both been recorded within other long-term liabilities.

Under the Fourth Loan Amendment, we may elect to prepay all or a portion of the Term Loan Advances prior to maturity, subject to a prepayment fee of up to 1.25% of the then outstanding principal balance of the Term Loan Advances being prepaid when such prepayment occurs prior to October 1, 2026, or 0.50% if such prepayment occurs on or after October 1, 2026. After repayment, no Term Loan amounts may be borrowed again.

The Loan Agreement contains customary closing fees, prepayment fees and provisions, events of default, and representations, warranties and covenants, including financial covenants. The financial covenants under the Fourth Loan Amendment include (i) a minimum cash covenant and (ii) a performance covenant as follows:

(i) Minimum cash covenant - We must maintain a minimum cash balance of 20% of the outstanding principal balance at all times. The minimum cash balance may be increased to 35% or 50% under performance covenant (b) below if the performance covenants (a) or (c) are not met beginning September 30, 2024 and all times thereafter.

(ii) Performance covenant- Beginning September 30, 2024 and all times there after we must satisfy any one of the following:

a. Market capitalization exceeding $900 million;

b. Minimum cash balance exceeding (x) outstanding principal amount of term loans, multiplied by (y) (A) 50%, prior to achieving trailing three months net product revenue of greater than $35 million, and (B) 35% thereafter;

c. Trailing three months net product revenue of at least (x) 30% of agreed upon projected net revenues for periods in the calendar year 2024 and 25% for all periods thereafter or (y) $120 million.

Upon the occurrence of an event of default, subject to any specified cure periods, all amounts owed by us may be declared immediately due and payable by Hercules, as collateral agent. As of December 31, 2023, we were in compliance with all applicable covenants under the Loan Agreement.

As collateral for the obligations, we granted Hercules a senior security interest in all of our right, title, and interest in, to and under substantially all of our property, inclusive of intellectual property.

In connection with the entry into the Loan Agreement, we issued to Hercules a warrant, or the Warrant, to purchase a number of shares of our common stock equal to 2.5% of the aggregate amount of the Term Loan advances funded, and will issue to Hercules additional warrants when future Term Loan advances are funded. On the Closing Date, we issued a Warrant for 74,782 shares of common stock. The Warrant is exercisable for a period of seven years from the date of issuance at a per-share exercise price equal to $33.43, which was the closing price of our common stock on September 16, 2021. In connection with the entry into the Third Loan Amendment, we amended the form of warrants to be issued upon drawdowns of future tranches such that the exercise price of such warrants shall be equal to the lesser (i) of $11.6783, which was the trailing ten-day VWAP prior to entering into the Third Loan Amendment and (ii) the trailing ten-day VWAP preceding the date on which we drawdown future tranches. In connection with the entry into the Fourth Amendment, we eliminated the warrant agreement for all future tranches. The Warrant issued with the initial tranche was not modified as part of this amendment. The exercise price and terms of the outstanding Warrant remain unchanged.

The initial $1.3 million fair value of the Warrant, the $9.7 million final interest payment fees and $3.5 million of debt issuance costs have been recorded as debt discount and are being amortized to interest expense using the effective interest method over the term of the Term Loan.

Revenue Interest Financing Agreement

On May 3, 2022, we entered into a Revenue Interest Financing Agreement, or the Revenue Interest Financing Agreement, with entities managed or advised by NovaQuest Capital Management, or NQ, Sagard Holdings Manager LP, or Sagard, and Hercules Capital, Inc., or Hercules, together with NQ and Sagard, or the Initial Investors, pursuant to which we could receive up to $260 million in funding from the Initial Investors. Under the terms of the Revenue Interest Financing Agreement, we received $100 million at the initial closing and received an additional $160 million upon FDA approval of vonoprazan for treatment of Erosive GERD in the fourth quarter of 2023. Additionally, on October 31, 2022, we entered into a Joinder and Waiver Agreement with the Initial Investors and CO Finance LVS XXXVII LLC, or the Additional Investor, and Hercules Capital, Inc. in its capacity as administrative agent and collateral agent for itself and the lenders under that certain Loan Agreement, or the Joinder Agreement, in respect of the Revenue Interest Financing Agreement. Under the terms of the Joinder Agreement, we received $15 million in additional funding upon FDA approval of vonoprazan for Erosive GERD, or Approval Additional Funding, in the fourth quarter of 2023 and provides for $25 million in additional funding for achievement of a sales milestone, or Milestone Additional Funding, and, together with the Approval Additional Funding, or the Additional Investor Funding. The Initial Investors waived their right of first offer for any Additional Investor Funding. The total amount funded by the Initial Investors and any subsequent investors is referred to herein as the Investment Amount.

Under the Revenue Interest Financing Agreement, the Initial Investors and the Additional Investor, are entitled to receive a 10% royalty on net sales of products containing vonoprazan. The royalty rate is subject to a step-down on net sales exceeding certain annual thresholds and if we receive FDA approval for vonoprazan for an indication relating to the treatment of heartburn associated with Non-Erosive GERD. The investors' right to receive royalties on net sales will terminate when the investors have aggregate payments equal to 200% of the Investment Amount. In addition, at any time after the earlier of (i) April 30, 2024 and (ii) the date that the payment for Erosive GERD regulatory approval is made, we have the right to make a cap payment equal to 200% of the Investment Amount less any royalties already paid, at which time the agreement will terminate.

If the investors have not received aggregate payments of at least 100% of the Investment Amount by December 31, 2028, and at least 200% of the Investment Amount by December 31, 2037, each a Minimum Amount, then we will be obligated to make a cash payment to the investors in an amount sufficient to gross the investors up to the applicable Minimum Amount.

Upon the occurrence of an event of default taking place prior to April 1, 2025, between April 1, 2025 and April 1, 2028, and after April 1, 2028, we are obligated to pay 1.30 times Investment Amount, 1.65 times Investment Amount, and 2.0 times investment amount, respectively, less any amounts we previously paid pursuant to the agreement.

At-the-Market-Offerings

On November 10, 2020, we entered into an Open Market Sale Agreement℠, or the Sales Agreement, with Jefferies LLC, or the Sales Agent, under which we may, from time to time, sell shares of our common stock having an aggregate offering price of up to $125 million through the Sales Agent, or the 2020 ATM Offering. Sales of our common stock made pursuant to the Sales Agreement, if any, will be made under our shelf registration statement on Form S-3 which was filed on November 10, 2020 and declared effective by the SEC on November 16, 2020. We are not obligated to, and we cannot provide any assurances that we will, make any sales of the shares under the Sales Agreement. The Sales Agreement may be terminated by the Sales Agent or us at any time. The sales agreement expired on November 9, 2023 For the year ended December 31, 2022, we sold 2,414,897 shares of our common stock under the ATM Offering for net proceeds of approximately $24.6 million after deducting $0.8 million of issuance costs. For the year ended December 31, 2023, we sold 1,514,219 shares of our common stock under the ATM Offering for net proceeds of approximately $14.1 million after deducting $0.4 million of issuance costs. As of December 31, 2023, we utilized $39.9 million of the available $125 million under the 2020 ATM Offering.

On November 9, 2023, we entered into an Open Market Sale Agreement℠, or the Sales Agreement, with Jefferies LLC, or the Sales Agent, under which we may, from time to time, sell shares of our common stock having an aggregate offering price of up to $150 million through the Sales Agent, or the ATM Offering. Sales of our common stock made pursuant to the Sales Agreement, if any, will be made under our shelf registration statement on Form S-3 which was filed on November 9, 2023 and declared effective by the SEC on November 17, 2023. We are not obligated to, and we cannot provide any assurances that we will, make any sales of the shares under the Sales Agreement. As of December 31, 2023, we utilized none of the available $150 million under the ATM Offering.

Underwritten Public Offering

On May 23, 2023, we completed an underwritten public offering, in which we sold 12,793,750 shares of our common stock, which included the exercise in full by the underwriters of their option to purchase 1,668,750 shares, at a price of $11.75 per share for total gross proceeds of $150.3 million. The net purchase price after deducting underwriting discounts and commissions was $11.08 per share, which generated net proceeds of $141.8 million. We incurred an additional $0.4 million of offering expenses in connection with this public offering.

Funding Requirements

Based on our current operating plan, we believe that our existing cash and cash equivalents together with the drawdown of the remaining $160 million under our Loan Agreement with Hercules together with anticipated product revenues, are sufficient to fund operations for at least the next twelve months and will be sufficient to fund our operations through the end of 2026. We expect such amounts will allow us to complete our ongoing Phase 3 clinical trial studying vonoprazan for Non-Erosive GERD (daily dosing), and commercial activities for VOQUEZNA for *H. pylori* and Erosive GERD. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. Additionally, the process of testing product candidates in clinical trials is costly, and the timing of progress and expenses in these trials is uncertain.

Our future capital requirements will depend on many factors, including:

- the initiation, type, number, scope, results, costs and timing of our clinical trials of vonoprazan, and preclinical studies or clinical trials of other potential product candidates we may choose to pursue in the future, including feedback received from regulatory authorities;
- the costs and timing of manufacturing for vonoprazan or any future product candidates, including commercial scale manufacturing if any product candidate is approved;

- the costs, timing and outcome of regulatory review of vonoprazan or any future product candidates;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;
- the costs associated with hiring additional personnel and consultants as our business grows, including additional executive officers and clinical development personnel;
- the timing and amount of the milestone or other payments we must make to Takeda and any future licensors;
- the costs and timing of establishing or securing sales and marketing capabilities for vonoprazan or any future product candidate;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payers and adequate market share and revenue for any approved products;
- patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payers;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements; and
- costs associated with any products or technologies that we may in-license or acquire.

Until such time, if ever, as we can generate substantial product revenues to support our cost structure, we expect to finance our cash needs through equity offerings, the Loan Agreement, the Revenue Interest Financing Agreement, debt financings, or other capital sources, including potential collaborations, licenses and other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, or other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

Including our existing cash and cash equivalents, we believe that we have sufficient working capital on hand to fund operations such that there is no substantial doubt as to our ability to continue as a going concern at the date the financial statements were issued. There can be no assurance that we will be successful in acquiring additional funding, that our projections of future working capital needs will prove accurate, or that any additional funding would be sufficient to continue operations in future years. Based on our current operating plan, we believe that our existing cash and cash equivalents together with the drawdown of the remaining $160 million under our Loan Agreement with Hercules together with anticipated product revenues, are sufficient to fund operations for at least the next twelve months and will be sufficient to fund our operations through the end of 2026.

Cash Flows

The following table sets forth a summary of the net cash flow activity for each of the periods indicated (in thousands):

	Years Ended December 31,		
	2023	**2022**	**$ Change**
Net cash provided by (used in):			
Operating activities	$ (137,580)	$ (146,530)	$ 8,950
Investing activities	(1,634)	(1,041)	(593)
Financing activities	367,580	120,042	247,538
Net increase (decrease) in cash	$ 228,366	$ (27,529)	$ 255,895

Operating Activities

Net cash used in operating activities was approximately $137.6 million and $146.5 million for the years ended December 31, 2023 and 2022, respectively. The net cash used in operating activities for the year ended December 31, 2023 was due to approximately $123.9 million spent on ongoing research and development and selling, general and administrative activities and a $13.6 million net change in operating assets and liabilities. The net change in operating assets and liabilities primarily related to a $6.9 million increase in accounts payable and accrued expenses (including interest, operating lease assets and liabilities, and clinical trial expenses), and a $20.5 million increase in prepaid assets and other current assets, accounts receivable, inventory, and other long-term assets, in support of our growth and commercial operations. The net cash used in operating activities for the year ended December 31, 2022 was due to approximately $152.0 million spent on ongoing research and development and general and administrative activities offset by a $5.5 million change in operating assets and liabilities. The net change in operating assets and liabilities primarily related to a $7.7 million increase in accounts payable and accrued expenses in support of the growth in our operating activities, partially offset by a $2.2 million increase in prepaid assets and other assets.

Investing Activities

Net cash used in investing activities for the years ended December 31, 2023 and 2022 was primarily due to the cash we paid for acquiring property, plant and equipment.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2023 was $367.6 million, due to $172.7 million of net proceeds from the Revenue Interest Financing Agreement, $155.6 million due to the proceeds from the sale of common stock, and $39.3 million from the issuance of debt under our Loan Agreement, as amended, with Hercules. Net cash provided by financing activities for the year ended December 31, 2022 was $120.0 million, due to $95.4 million of net proceeds from the Revenue Interest Financing Agreement and $24.6 million of net proceeds from the issuance of common stock under the 2020 ATM Offering.

Contractual Obligations and Commitments

On May 5, 2020, we entered into a Commercial Supply Agreement with Takeda, pursuant to which Takeda will supply commercial quantities of vonoprazan bulk drug product. We incurred $0.7 million of expenses related to the Commercial Supply Agreement during the year ended December 31, 2022. We have no remaining minimum purchase obligation related to this agreement.

On December 30, 2020, we entered into a Supply and Packaging Services Agreement with Sandoz, pursuant to which Sandoz has agreed to supply commercial quantities of amoxicillin capsules and clarithromycin tablets, to package these antibiotics with vonoprazan, in finished convenience packs, and to supply us with these convenience packs. The supply agreement commits us to a minimum purchase obligation of approximately $3.2 million during the first 24-month period following the launch of the final product. We have incurred $0.3 million of expenses under the agreement during the year ended December 31, 2023.

Additionally, on May 3, 2022, we entered into a Revenue Interest Financing Agreement, or the Revenue Interest Financing Agreement, with entities managed or advised by NovaQuest Capital Management, or NQ, Sagard Holdings Manager LP, or Sagard, and Hercules Capital, Inc. , or Hercules, together with NQ and Sagard, the Initial Investors, and on October 31, 2022, we entered into a Joinder and Waiver Agreement with the Initial Investors and CO Finance LVS XXXVII LLC, or the Additional Investor, and Hercules Capital, Inc. in its capacity as administrative agent and collateral agent for itself and the lenders under that certain Loan Agreement, or the Joinder Agreement, in respect of the Revenue Interest Financing Agreement. We received $100 million at the initial closing and an additional $175 million in fourth quarter 2023 following FDA approval of vonoprazan for treatment of Erosive GERD, or the Investment Amount. In addition, we were eligible for $25 million in additional funding for achievement of a sales milestone. Under the Revenue Interest Financing Agreement, the Initial Investors and Additional Investor are entitled to receive a 10% royalty on net sales of products containing vonoprazan. The investors' right to receive royalties on net sales will terminate when the investors have aggregate payments equal to 200% of the Investment Amount. We have not made any payments under the Revenue Interest Financing Agreement during the years ended December 31, 2023 and 2022.

We enter into contracts in the normal course of business for our contract research services, contract manufacturing services, professional services and other services and products for operating purposes. These contracts generally provide for termination after a notice period, and, therefore, are cancelable contracts.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our financial statements and accompanying notes. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 1 to our financial statements, we believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

Revenue Recognition

Revenues from product sales are recorded at the net sales price, or transaction price, which includes estimates of variable consideration that result from (a) invoice discounts for prompt payment and distribution service fees, (b) government and private payor rebates, chargebacks, discounts and fees, (c) product returns and (d) costs of co-pay assistance programs for patients, as well as other incentives for certain indirect customers. Reserves are established for the estimates of variable consideration based on the amounts earned or to be claimed on the related sales. The reserves are classified as reductions to trade receivable, net if payable to a customer or accrued expenses if payable to a third-party. Where appropriate, we utilize the expected value method to determine the appropriate amount for estimates of variable consideration based on factors such as current contractual and statutory

requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. The amount of variable consideration that is included in the transaction price may be constrained and is included in net product revenues only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from our estimates. If actual results vary from our estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

We make significant estimates and judgments that materially affect our recognition of net product revenue. Claims by third-party payors for rebates, chargebacks and discounts frequently are submitted to us significantly after the related sales, potentially resulting in adjustments in the period in which the new information becomes known. We will adjust our estimates based on new information, including information regarding actual rebates, chargebacks and discounts for our products, as it becomes available.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. We make estimates of our accrued expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments, if necessary. The significant estimates in our accrued research and development expenses include the costs incurred for services performed by our vendors in connection with research and development activities for which we have not yet been invoiced.

Our research and development activities include estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid expense accordingly. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

Revenue Interest Financing Liability

We have accounted for the Revenue Interest Financing Agreement as a debt instrument. Accordingly, we recognized the transaction as a debt obligation with interest expense based on an imputed effective rate derived from the initial carrying value of the obligation and the expected future payments. We recalculate the effective interest rate each period based on the current carrying value and the revised estimated future payments. Changes in future payments from previous estimates are included in the current and future financing expense. See Note 7 "Revenue Interest Financing Liability" for additional details.

Stock-Based Compensation Expense

Stock-based compensation expense represents the cost of the grant date fair value of equity awards recognized over the requisite service period of the awards (generally the vesting period) on a straight-line basis with forfeitures recognized as they occur. We use the Black-Scholes valuation model to determine the fair value of our stock awards. Through December 31, 2023, our stock-based compensation expense consisted of recognized fair value related to our issuance of restricted stock awards, for which the fair value is determined based on the fair value of the underlying common stock, performance-based awards, stock options, and ESPP awards.

Other Company Information

JOBS Act

As an emerging growth company under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, we can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. We intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of Sarbanes-Oxley.

We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of the consummation of our IPO, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion, (iii) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700 million as of the last business day of the second fiscal quarter of such year, or (iv) the date on which we have issued more than $1 billion in non-convertible debt securities during the prior three-year period.

Recent Accounting Pronouncements

The information required by this item is included in Note 1, Organization, Basis of Presentation and Summary of Significant Accounting Policies included in Item 15 of this annual report.

Off-Balance Sheet Arrangements

During the periods presented we did not have, nor do we currently have, any off-balance sheet arrangements as defined under SEC rules.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

Our cash and cash equivalents consist of cash in readily available checking accounts and money market funds. As a result, the fair value of our investment portfolio is relatively insensitive to interest rate changes. Additionally, our long-term debt bears interest at a variable rate. A 10% increase or decrease in the interest rate on our long-term debt would not have a material effect on our financial position, results of operations or cash flows.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and research and development contract costs. We do not believe inflation has had a material effect on our results of operations during the periods presented.

Item 8. Financial Statements and Supplementary Data

The financial statements required pursuant to this item are incorporated by reference herein from the applicable information included in Item 15 of this annual report and are presented beginning on page F-1.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information 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. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this annual report. Based on such evaluation, our principal executive officer and principal financial officer have concluded that as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act). Internal control over financial reporting is a process designed under the supervision and with the participation of our management to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. Management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control—Integrated Framework (2013 Framework). Based on this assessment, our management concluded that, as of December 31, 2023, our internal control over financial reporting was effective.

Attestation Report of the Registered Public Accounting Firm

This annual report does not include an attestation report of our registered public accounting firm due to an exemption provided by the JOBS Act for "emerging growth companies."

Changes in Internal Control Over Financial Reporting

During the quarter ended December 31, 2023, we implemented processes and internal controls to record product revenue, cost of product revenues, accounts receivable, and inventory as a result of the FDA approval and the U.S commercial launch of VOQUEZNA, VOQUEZNA TRIPLE PAK, and VOQUEZNA DUAL PAK. The implementation of these processes resulted in material changes to our internal controls over financial reporting. There were no other changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act), identified in connection with the evaluation of such internal control that occurred during the fourth quarter ended December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdiction that Prevent Inspection

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item will be contained in our Definitive Proxy Statement to be filed with the SEC in connection with our 2024 Annual Meeting of Stockholders, or the Definitive Proxy Statement, which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2023, under the headings “Election of Directors,” “Executive Officers,” and “Corporate Governance,” and is incorporated herein by reference.

Code of Conduct and Ethics

We have adopted a Code of Conduct and Ethics that applies to our officers, directors and employees, which is available on our website at www.phathompharma.com. The Code of Conduct and Ethics contains general guidelines for conducting the business of our company consistent with the highest standards of business ethics and is intended to qualify as a “code of ethics” within the meaning of Section 406 of the Sarbanes-Oxley Act of 2002 and Item 406 of Regulation S-K. In addition, we intend to promptly disclose (1) the nature of any amendment to our Code of Business Conduct and Ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions and (2) the nature of any waiver, including an implicit waiver, from a provision of our code of ethics that is granted to one of these specified officers, the name of such person who is granted the waiver and the date of the waiver on our website in the future.

Item 11. Executive Compensation

The information required by this item will be set forth in the section headed “Executive Compensation and Other Information” in our Definitive Proxy Statement and is incorporated herein by reference.

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

The information required by this item will be set forth in the section headed “Security Ownership of Certain Beneficial Owners and Management” in our Definitive Proxy Statement and is incorporated herein by reference.

The information required by Item 201(d) of Regulation S-K will be set forth in the section headed “Executive Compensation and Other Information” in our Definitive Proxy Statement and is incorporated herein by reference.

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

The information required by this item will be set forth in the section headed “Certain Relationships and Related Person Transactions,” “Director Independence” and “Board Committees and Independence” in our Definitive Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information required by this item will be set forth in the section headed “Independent Registered Public Accounting Firm's Fees” in our Definitive Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

1. All financial statements.

The financial statements of Phathom Pharmaceuticals, Inc., together with the report thereon of Ernst & Young LLP, an independent registered public accounting firm, are included in this annual report on Form 10-K beginning on page F-1.

2. Financial statement schedules.

All schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

3. Exhibits

A list of exhibits is set forth on the Exhibit Index immediately preceding the signature page of this annual report on Form 10-K and is incorporated herein by reference.

Item 16. Form 10-K Summary

None.

Phathom Pharmaceuticals, Inc.

Index to Financial Statements

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Phathom Pharmaceuticals, Inc. (the Company) as of December 31, 2023 and 2022, the related statements of operations and comprehensive loss, stockholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, 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 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 audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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 since 2019.

Iselin, New Jersey
March 7, 2024

PHATHOM PHARMACEUTICALS, INC.
Balance Sheets
(in thousands, except share and par value amounts)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 381,393	$ 155,385
Prepaid expenses and other current assets	13,194	5,127
Accounts receivable, net	1,637	—
Inventory	1,208	—
Total current assets	397,432	160,512
Property, plant and equipment, net	2,146	1,207
Operating lease right-of-use assets	1,475	2,287
Restricted cash	2,863	505
Inventory, noncurrent	8,234	—
Other long-term assets	1,692	299
Total assets	$ 413,842	$ 164,810
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable (including related party amounts of $25 and $35, respectively)	$ 12,601	$ 9,997
Accrued expenses (including related party amounts of $2,694 and $2,499, respectively)	17,197	14,678
Accrued interest	1,146	854
Operating lease liabilities, current	726	708
Current portion of revenue interest financing liability	7,111	—
Total current liabilities	38,781	26,237
Long-term debt, net of discount	137,842	95,264
Revenue interest financing liability	299,816	109,525
Operating lease liabilities	462	1,098
Other long-term liabilities	9,700	7,500
Total liabilities	486,601	239,624
Commitments and contingencies (Note 4)		
Stockholders' deficit:		
Preferred stock, $0.0001 par value; authorized shares — 40,000,000 at December 31, 2023 and December 31, 2022; no shares issued and outstanding at December 31, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value; authorized shares — 400,000,000 at December 31, 2023 and December 31, 2022; issued shares — 57,970,044 and 41,723,308 at December 31, 2023 and December 31, 2022, respectively; outstanding shares — 57,970,044 and 41,468,871 at December 31, 2023 and December 31, 2022, respectively	5	3
Treasury stock — 19 shares at December 31, 2023 and December 31, 2022	—	—
Additional paid-in capital	855,921	652,276
Accumulated deficit	(928,685)	(727,093)
Total stockholders' deficit	(72,759)	(74,814)
Total liabilities and stockholders' deficit	$ 413,842	$ 164,810

See accompanying notes.

PHATHOM PHARMACEUTICALS, INC.
Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Years Ended December 31,	
	2023	**2022**
Product revenue, net	$ 682	$ —
Cost of revenue	167	—
Gross profit	515	—
Operating expenses:		
Research and development (includes related party amounts of $760 and $2,123, respectively)	49,899	71,441
Selling, general and administrative (includes related party amounts of $55 and $0, respectively)	117,928	100,999
Total operating expenses	167,827	172,440
Loss from operations	(167,312)	(172,440)
Other income (expense):		
Interest income	7,876	2,132
Interest expense	(41,968)	(27,305)
Other (expense), net	(188)	(110)
Total other expense	(34,280)	(25,283)
Net loss and comprehensive loss	$ (201,592)	$ (197,723)
Net loss per share, basic and diluted	$ (3.93)	$ (5.05)
Weighted-average shares of common stock outstanding, basic and diluted	51,289,092	39,118,215

See accompanying notes

PHATHOM PHARMACEUTICALS, INC.
Statements of Stockholders' Equity (Deficit)
(in thousands, except share amounts)

	Common Stock		Treasury Stock	Additional Paid-in	Accumulated	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Capital	Deficit	
Balance at December 31, 2022	41,468,871	$ 3	19	$ 652,276	$ (727,093)	$ (74,814)
401(k) matching contribution	135,956	—	—	1,612	—	1,612
Vesting of restricted shares, performance stock units, and restricted stock units	1,843,954	—	—	6	—	6
Stock-based compensation	—	—	—	45,025	—	45,025
ESPP shares issued	196,873	—	—	1,417	—	1,417
Issuance of common stock under ATM facility	1,514,219	1	—	14,072	—	14,073
Issuance of common stock from exercise of stock options	16,421	—	—	124	—	124
Issuance of common stock in connection with underwritten public offering, net	12,793,750	1	—	141,389	—	141,390
Net loss	—	—	—	—	(201,592)	(201,592)
Balance at December 31, 2023	57,970,044	$ 5	19	$ 855,921	$ (928,685)	$ (72,759)

	Common Stock		Treasury Stock	Additional Paid-in	Accumulated	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Capital	Deficit	
Balance at December 31, 2021	30,511,226	$ 3	1	$ 601,523	$ (529,370)	$ 72,156
Cashless exercise of common stock warrants	7,359,285	—	18	—	—	—
401(k) matching contribution	101,540	—	—	1,116	—	1,116
Vesting of restricted shares and restricted stock units	992,825	—	—	—	—	—
Issuance of common stock under ATM facility	2,414,897	—	—	24,595	—	24,595
Stock-based compensation	—	—	—	24,133	—	24,133
ESPP shares issued	89,098	—	—	909	—	909
Net loss	—	—	—	—	(197,723)	(197,723)
Balance at December 31, 2022	41,468,871	$ 3	19	$ 652,276	$ (727,093)	$ (74,814)

See accompanying notes

PHATHOM PHARMACEUTICALS, INC.
Statements of Cash Flows
(in thousands)

	Years Ended December 31,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (201,592)	$ (197,723)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	575	620
Stock-based compensation	45,025	24,133
Issuance of PIK interest debt	3,583	3,484
Accrued interest on revenue interest financing liability	24,727	14,079
Amortization of debt discount	1,877	2,110
Other	1,869	1,329
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(8,067)	(1,860)
Accounts receivable, net	(1,637)	—
Accounts payable and accrued expenses (includes changes in related party amounts of $184 and $1,139, respectively)	6,410	8,679
Accrued clinical trial expenses	—	(1,402)
Accrued interest	292	377
Operating right-of-use assets and lease liabilities	194	(238)
Inventory	(9,442)	—
Other long-term assets	(1,394)	(118)
Net cash used in operating activities	(137,580)	(146,530)
Cash flows from investing activities		
Cash paid for property, plant and equipment	(1,634)	(1,041)
Net cash used in investing activities	(1,634)	(1,041)
Cash flows from financing activities		
Proceeds from issuance of common stock from exercise of stock options	124	—
Net proceeds from issuance of debt	39,318	—
Net proceeds from underwritten public offering	141,390	—
Net proceeds from revenue interest financing transaction	172,675	95,446
Net proceeds from issuance of common stock under ATM facility	14,073	24,596
Net cash provided by financing activities	367,580	120,042
Net increase (decrease) in cash and cash equivalents and restricted cash	228,366	(27,529)
Cash and cash equivalents and restricted cash – beginning of period	155,890	183,419
Cash and cash equivalents and restricted cash – end of period	$ 384,256	$ 155,890
Supplemental disclosure of cash flow information		
Interest paid	$ 11,133	$ 7,033
Supplemental disclosure of noncash investing and financing activities:		
Property and equipment purchases included in accounts payable and accrued expenses	$ 18	$ 138
Final interest payment fee	$ 2,200	$ —
Settlement of ESPP liability in common stock	$ 1,417	$ 909
Settlement of 401(k) liability in common stock	$ 1,612	$ 1,116
Operating lease liabilities arising from obtaining right-of-use assets	$ —	$ 554

See accompanying notes.

PHATHOM PHARMACEUTICALS, INC.

Notes to Financial Statements

1. Organization, Basis of Presentation and Summary of Significant Accounting Policies

Organization and Basis of Presentation

Phathom Pharmaceuticals, Inc., or the Company or Phathom, was incorporated in the state of Delaware in January 2018. The Company is a biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal diseases. The Company's financial statements are prepared in accordance with U.S. generally accepted accounting principles, or GAAP.

On October 27, 2023, the U.S. Food and Drug Administration, or FDA, approved the prior approval supplements to our new drug applications, or NDAs, for VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK. Additionally, on November 1, 2023, the FDA approved our NDA for VOQUEZNA tablets. As a result, the Company initiated commercial launch for VOQUEZNA for both the Erosive GERD and *H. pylori* indications, and VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK for treatment of *H. pylori* infection in the fourth quarter of 2023.

Liquidity and Capital Resources

From inception to December 31, 2023, the Company has devoted substantially all of its efforts to organizing and staffing the Company, business planning, raising capital, in-licensing its initial and approved product candidate, vonoprazan, meeting with regulatory authorities, managing the clinical trials of vonoprazan, preparing for commercialization of its initial products containing vonoprazan, commercial launch of approved products, and providing other selling, general and administrative support for these operations. The Company has a limited operating history, generated limited revenue to date, and the sales and income potential of its business is unproven. The Company has incurred net losses and negative cash flows from operating activities since its inception and expects to continue to incur additional net losses in the future. From inception to December 31, 2023, the Company has funded its operations through the issuance of convertible promissory notes, commercial bank debt, revenue interest financing debt, the sale of 10,997,630 shares of common stock for net proceeds of approximately $191.5 million in its 2019 IPO, the sale of 2,250,000 shares of common stock for net proceeds of approximately $88.6 million in its December 2020 follow-on public offering, the sale of 3,929,116 shares of common stock for net proceeds of approximately $38.7 million in its issuances of common stock pursuant to the Open Market Sale Agreement℠, or the Sales Agreement, with Jefferies LLC, or the Sales Agent, under which the Company may, from time to time, sell shares of its common stock having an aggregate offering price of up to $150 million, or the ATM Offering, and the sale of 12,793,750 shares of common stock for net proceeds of approximately $141.4 million in its May 2023 public offering.

The accompanying financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or amounts and classification of liabilities. Management is required to perform a two-step analysis over the Company's ability to continue as a going concern. Management must first evaluate whether there are conditions and events that raise substantial doubt about the Company's ability to continue as a going concern (Step 1). If management concludes that substantial doubt is raised, management is also required to consider whether its plans alleviate that doubt (Step 2).

Management believes that it has sufficient working capital on hand to fund operations through at least the next twelve months from the date these financial statements were available to be issued. There can be no assurance that the Company will be successful in acquiring additional funding, if needed, that the Company's projections of its future working capital needs will prove accurate, or that any additional funding would be sufficient to continue operations in future years.

Use of Estimates

The preparation of the Company's financial statements requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues and expenses, and the disclosure of contingent assets and liabilities in the Company's financial statements and accompanying notes. The most significant estimates in the Company's financial statements relate to accruals for net product revenues and research and development expenses, the valuation for the revenue interest financing liability, and various other equity instruments. In addition, management's assessment of the Company's ability to continue as a going concern involves the estimation of the amount and timing of future cash inflows and outflows. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results could differ materially from those estimates and assumptions.

Fair Value Measurements

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or non-recurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets.

Level 2: Inputs, other than the quoted prices in active markets that are observable either directly or indirectly.

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

The carrying amounts of the Company's financial instruments, including cash and cash equivalents, are classified within the Level 1 designation discussed above, while accounts receivable, prepaid and other current assets, accounts payable, and accrued liabilities, approximate fair value due to their short-term maturities.

The Company has no financial assets measured at fair value on a recurring basis. None of the Company's non-financial assets or liabilities are recorded at fair value on a non-recurring basis. No transfers between levels have occurred during the periods presented.

As of December 31, 2023 and 2022, the estimated fair value of the Company's long-term debt approximated the carrying amount given its floating interest rate basis. The fair value of the Company's long-term debt was estimated for disclosure purposes only and was determined based on quoted market data for valuation, and thus categorized as Level 2 in the fair value hierarchy.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less when purchased to be cash equivalents. Cash and cash equivalents include cash in readily available checking accounts and money market funds. Restricted cash primarily consists of cash deposited by the Company to secure corporate leased vehicles.

Accounts Receivable, Net

Accounts receivable consists of amounts due from customers, primarily wholesale distributors, net of customer allowances for prompt pay discounts, distribution service fees, and other adjustments. Our contracts with customers have standard payment terms. The Company assesses the need for an allowance for doubtful accounts primarily based on creditworthiness, historical payment experience and general economic conditions. The Company has not experienced any credit losses to date given our limited commercial operations with any of its customers, and has not currently recognized any allowance for doubtful accounts.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

The Company is also subject to credit risk from our accounts receivable related to our product sales. The Company monitors exposure within accounts receivable and records a reserve against uncollectible accounts receivable as necessary. The Company extends credit primarily to pharmaceutical wholesale distributors. Customer creditworthiness is monitored and collateral is not required. The amount of the allowance for credit losses is determined primarily on the basis of collection experience and known financial factors regarding specific customers.

As of December 31, 2023, three customers accounted for 87% of the accounts receivable balance, with each of these individual customers ranging from 28% to 30% of the accounts receivable balance. For the year ended December 31, 2023, three customers accounted for 86% of our product sales, with each of these individual customers ranging from 27% to 30% of our product sales.

Inventory

The Company capitalizes inventory costs related to products to be sold in the ordinary course of business. The Company makes a determination of capitalizing inventory costs for a product based on, among other factors, status of regulatory approval, information regarding safety, efficacy and expectations relating to commercial sales and recoverability of costs. Inventory currently consists of bulk active pharmaceutical ingredients that will be used to manufacture vonoprazan tablets. Inventory related to indications prior to regulatory approval has been included in research and development expense in the period of purchase.

The Company values its inventory at the lower of cost or net realizable value. The Company measures inventory using actual cost under a first-in, first-out basis. The Company assesses recoverability of inventory each reporting period to determine any write down to net realizable value resulting from excess or obsolete inventories.

Property, Plant, and Equipment, Net

Property, plant and equipment are recorded at cost, less accumulated depreciation. Depreciation expense is recognized using the straight-line method over the useful life of the asset. Computer equipment and related software are depreciated over two to three years. Equipment is depreciated over five years. Furniture and fixtures are depreciated over three years. Leasehold improvements are amortized over the lesser of the lease term or the estimated useful lives of the related assets. Expenditures for repairs and maintenance of assets are charged to expense as incurred. Upon retirement or sale, the cost and related accumulated depreciation of assets disposed of are removed from the accounts and any resulting gain or loss is included in loss from operations.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property, plant and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than the carrying amount. The impairment loss, if recognized, would be based on the excess of the carrying value of the impaired asset over its respective fair value. No impairment losses have been recorded through December 31, 2023 and 2022.

Other Long-Term Assets

Other long-term assets consist of deposits relating to our copay and patient support programs and security deposits on our leased properties.

Leases

At the inception of a contractual arrangement, the Company determines whether the contract contains a lease by assessing whether there is an identified asset and whether the contract conveys the right to control the use of the identified asset in exchange for consideration over a period of time. If both criteria are met, the Company records the associated lease liability and corresponding right-of-use asset upon commencement of the lease using the implicit rate or a discount rate based on a credit-adjusted secured borrowing rate commensurate with the term of the lease. The Company additionally evaluates leases at their inception to determine if they are to be accounted for as an operating lease or a finance lease. A lease is accounted for as a finance lease if it meets one of the following five criteria: the lease has a purchase option that is reasonably certain of being exercised, the present value of the future cash flows is substantially all of the fair market value of the underlying asset, the lease term is for a significant portion of the remaining economic life of the underlying asset, the title to the underlying asset transfers at the end of the lease term, or if the underlying asset is of such a specialized nature that it is expected to have no alternative uses to the lessor at the end of the term. Leases that do not meet the finance lease criteria are accounted for as an operating lease. Operating lease assets represent a right to use an underlying asset for the lease term and operating lease liabilities represent an obligation to make lease payments arising from the lease. Operating lease liabilities with a term greater than one year and their corresponding right-of-use assets are recognized on the balance sheet at the commencement date of the lease based on the present value of lease payments over the expected lease term. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received. As the Company's leases do not typically provide an implicit rate, the Company utilizes the appropriate incremental borrowing rate, determined as the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term and in a similar economic environment. Lease cost is recognized on a straight-line basis over the lease term and variable lease payments are recognized 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. The Company has elected the practical expedient to not separate between lease and non-lease components.

Revenue Interest Financing Liability

The Company entered into a revenue interest financing agreement, or the Revenue Interest Financing Agreement, with entities managed or advised by NovaQuest Capital Management, or NQ, Sagard Holdings Manager LP, or Sagard, and Hercules Capital, Inc., or Hercules, together with NQ and Sagard, the Initial Investors, in which the Company received funds in return for royalties on net sales of products containing vonoprazan, in May 2022. Subsequently, in October 2022, the Company entered into a Joinder Agreement with the Initial Investors and CO Finance LVS XXXVII LLC or the Additional Investor, together as the Investors. The net proceeds received under the transactions are recognized as short-term and long-term liabilities with interest expense based on an imputed effective rate derived from the expected future payments to the Investors. The Company recalculates the effective interest rate each period based on the current carrying value and the revised estimated future payments to the Investors. Changes in future payments to the Investors from previous estimates are included in current and future financing expense.

Revenue Recognition

Pursuant to Accounting Standards Codification 606, Revenue from Contracts with Customers or ASC 606, the Company recognizes revenue when a customer obtains control of promised goods or services. The Company records the amount of revenue that reflects the consideration that it expects to receive in exchange for those goods or services. The Company applies the following five-step model in order to determine this amount: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that it will collect the consideration to which it is entitled in exchange for the goods or services that it transfers to the customer. Once a contract is determined to be within the scope of ASC 606 at contract inception, the Company reviews the contract to determine which performance obligations it must deliver and

which of these performance obligations are distinct. The Company recognizes as revenue the amount of the transaction price that is allocated to each performance obligation when that performance obligation is satisfied or as it is satisfied. Generally, the Company's performance obligations are transferred to customers at a point in time, typically upon delivery.

Product Revenue, Net

The Company sells its product to its customers in the United States. The Company's customers subsequently resell the products to pharmacies and health care providers. In accordance with ASC 606, the Company recognizes net product revenues from sales when the customers obtain control of the Company's products, which typically occurs upon delivery to the Customer.

Revenues from product sales are recorded at the net sales price, or transaction price, which includes estimates of variable consideration that result from (a) invoice discounts for prompt payment and distribution service fees, (b) government and private payor rebates, chargebacks, discounts and fees, (c) product returns and (d) costs of co-pay assistance programs for patients, as well as other incentives for certain indirect customers. Reserves are established for the estimates of variable consideration based on the amounts earned or to be claimed on the related sales. The reserves are classified as reductions to accounts receivable, net if payable to a customer or accrued expenses if payable to a third-party. Where appropriate, the Company utilizes the expected value method to determine the appropriate amount for estimates of variable consideration based on factors such as current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. The amount of variable consideration that is included in the transaction price may be constrained and is included in net product revenues only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results vary from the Company's estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Distribution Service Fees: The Company engages with wholesalers to distribute its products to end customers. The Company pays the wholesalers a fee for services such as: Data Reporting, Inventory Management, Chargeback Administration and Service Level Commitment. The Company estimates the amount of distribution services fees to be paid to the customers and adjusts the transaction price with the amount of such estimate at the time of sale to the customer.

Prompt Pay Discounts: The Company provides its customers with a percentage discount on their invoice if the customers pay within the agreed upon timeframe. The Company estimates the probability of customers paying promptly and the percentage of discount outlined in the agreement, and deducts the full amount of these discounts from its gross product revenues and accounts receivable at the time such revenues are recognized.

Product Returns: The Company provides customers a return credit in the amount of the purchase price paid by customers for all products returned in accordance with the Company's returned goods policy. In the initial sales period, the Company estimates its provision for sales returns based on industry data and adjusts the transaction price with such estimate at the time of sale to the customer. Once sufficient history has been collected for product returns, the Company will utilize that history to inform its estimate assumption. Once the product is returned, it is destroyed. The Company does not record a right-of-return asset.

Chargebacks: A chargeback is the difference between the manufacturer's invoice price to the wholesaler and the contract price the wholesaler's customer has negotiated directly with the manufacturer. The wholesaler tracks these sales and "charges back" the manufacturer for the difference between the negotiated prices paid between the wholesaler's customers and wholesaler's acquisition cost. The Company estimates the percentage of goods sold that are eligible for chargeback and adjusts the transaction price for such discount at the time of sale to the customer.

Administration Fees: The Company engages with Pharmacy Benefit Managers, or PBMs, to administer prescription-drug plans for people with third-party insurance through a self-insured employer, health insurance plan, labor union or government plan. The Company pays PBMs "administrative fees" for their role in providing utilization data, administering rebates, and administering claims payments. The Company estimates the amount of administration fees to be paid to PBMs and adjusts the transaction price with the amount of such estimate at the time of sale to the customer.

Rebates: Rebates apply to:

- Medicaid, managed care, and supplemental rebates to all applicable states as defined by the statutory government pricing calculation requirements under the Medicaid Drug Rebate Program, and;
- Medicare Part D and Commercial Managed Care rebates are paid based on the contracts with PBMs and Managed Care Organizations. Rebates are paid to these entities upon receipt of an invoice from the contracted entity which is based on the utilization of the product by the members of the contracted entity. The Company estimates the percentage of goods sold that are eligible for rebates and adjusts the transaction price for such discounts at the time of sale to the customers.

Coverage Gap: The Medicare Part D coverage gap, also called the donut hole, is a period of consumer payment for prescription medication costs which lies between the initial coverage limit and the catastrophic-coverage threshold, when the patient is a member of a Medicare Part D prescription-drug program administered by the Centers for Medicare & Medicaid Services. The Company estimates the percentage of goods sold under Coverage Gap and adjusts the transaction price for such discount at the time of sale to the Customer. The Company makes significant estimates and judgments that materially affect its recognition of net product revenue. Claims by third-party payors for rebates, chargebacks and discounts frequently are submitted to the Company significantly after the related sales, potentially resulting in adjustments in the period in which the new information becomes known. The Company will adjust its estimates based on new information, including information regarding actual rebates, chargebacks and discounts for its products, as it becomes available.

Cost of Revenue

Cost of revenue includes the cost of producing and distributing inventories that are related to product sales. This also includes royalties payable to Takeda Pharmaceutical Company Limited, or Takeda, pursuant to the Takeda License Agreement (Refer to Note 4 for further details). In addition, shipping and handling costs for product sales are recorded as incurred. Finally, cost of revenue may also include costs related to excess or obsolete inventory adjustment charges.

In connection with the FDA approvals of VOQUEZNA, VOQUEZNA TRIPLE PAK, and VOQUEZNA DUAL PAK , the Company began capitalizing inventory manufactured or purchased. As a result, certain manufacturing costs associated with product shipments were expensed prior to FDA approval and, therefore, are not included in cost of goods sold during the current period. These previously expensed costs were not material for the year ended December 31, 2023.

Research and Development Expenses and Accruals

All research and development costs are expensed in the period incurred and consist primarily of salaries, payroll taxes, employee benefits, stock-based compensation charges for those individuals involved in research and development efforts, external research and development costs incurred under agreements with contract research organizations, or CROs, and consultants to conduct and support the Company's ongoing clinical trials of vonoprazan, and costs related to manufacturing vonoprazan for clinical trials.

The Company has entered into various research and development contracts with clinical research organizations, clinical manufacturing organizations and other companies. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and payments made in advance of or after performance are reflected in the accompanying balance sheets as prepaid expenses or accrued liabilities, respectively. The Company records accruals for estimated costs incurred for ongoing research and development activities. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the services, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates may be made in determining the prepaid or accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist of salaries, stock-based compensation, facilities and third-party expenses. Selling, general and administrative expenses are associated with the activities of the commercial, executive, finance, accounting, information technology, legal, medical affairs and human resource functions.

Advertising and Marketing Costs

Advertising and marketing costs are expensed as incurred. Advertising and marketing costs are included in selling, general and administrative expenses and were not material for the years ended December 31, 2023 and 2022.

Stock-Based Compensation

Stock-based compensation expense represents the cost of the grant date fair value of equity awards recognized over the requisite service period of the awards (generally the vesting period) on a straight-line basis with forfeitures recognized as they occur.

The Company also maintains an employee stock purchase program, or ESPP, under which it may issue shares. The Company estimates the fair value of shares that will be issued under the ESPP, and of stock options using the Black-Scholes valuation model, which requires the use of estimates. The Company recognizes stock-based compensation cost for shares that it will issue under the ESPP on a straight-line basis over the requisite service period of the award.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in the statements of operations in the period that includes the enactment date.

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby (i) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (ii) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability.

Beginning in 2022, the Tax Cuts and Jobs Act eliminates the option to deduct research and development expenditures currently and requires taxpayers to amortize domestic and foreign research and development expenditures over 5 years and 15 years, respectively. The requirement did not impact cash from operations in the periods presented.

Comprehensive Loss

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. The Company's comprehensive loss was the same as its reported net loss for all periods presented.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker in making decisions on how to allocate resources and assess performance. The Company views its operations and manages its business as one operating segment.

Net Loss Per Share

Basic net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding for the period, without consideration for potentially dilutive securities. For the years ended December 31, 2023 and 2022, the Company has excluded weighted-average unvested shares of 34,503 and 686,703, respectively, from the weighted-average number of common shares outstanding. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares and dilutive common stock equivalents outstanding for the period determined using the treasury-stock and if-converted methods. Dilutive common stock equivalents are comprised of unvested common stock, options and warrants. For the periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding as inclusion of the potentially dilutive securities (warrants, stock options, and common shares subject to repurchase) would be antidilutive.

Recently Adopted Accounting Standards

In June 2016, the FASB issued ASU 2016-13, Financial Instruments — Credit Losses, or ASU 2016-13, which changes the accounting for recognizing impairments of financial assets. Under the new guidance, credit losses for certain types of financial instruments will be estimated based on expected losses. ASU 2016-13 also modifies the impairment models for available-for-sale debt securities and for purchased financial assets with credit deterioration since their origination. ASU 2016-13 is effective for annual periods beginning after December 15, 2022 (fiscal year 2023 for the Company), and interim periods within those periods, with early adoption permitted. The Company adopted ASU 2016-13 effective January 1, 2023. The standard did not have a material impact on the financial statements.

Recently Issued Accounting Pronouncements

The Company assesses the adoption impacts of recently issued accounting standards by the Financial Accounting Standards Board or other standard setting bodies on the Company's financial statements as well as material updates to previous assessments. There were no new accounting standards issued or adopted in year of 2023 that materially impacted or are expected to materially impact the Company's financial statements.

2. Balance Sheet Details

Property, Plant and Equipment, net

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

	December 31,	
	2023	**2022**
Computer equipment and software	$ 1,477	$ 1,078
Furniture and fixtures	1,089	1,086
Leasehold improvements	139	115
Equipment	1,487	—
Construction in process	—	399
Total property, plant and equipment, gross	4,192	2,678
Less: accumulated depreciation and amortization	(2,046)	(1,471)
Total property, plant and equipment, net	$ 2,146	$ 1,207

Depreciation and amortization expense for both the years ended December 31, 2023 and 2022 was approximately $0.6 million. No property, plant or equipment was disposed of during the years ended December 31, 2023 and 2022.

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31,	
	2023	2022
Accrued research and development expenses	$ 1,009	$ 3,080
Accrued compensation expenses	13,318	8,447
Accrued professional & consulting expenses	1,771	3,000
Accrued sales discounts and allowances	982	—
Accrued other	117	151
Total accrued expenses	$ 17,197	$ 14,678

Inventory

Inventory consist of the following (in thousands):

	December 31, 2023
Finished goods	$ 647
Raw materials	561
Total inventory, current	1,208
Raw materials, noncurrent	8,234
Total inventory	$ 9,442

Raw materials consist of materials, including active pharmaceutical ingredients, to be consumed in the production of inventory related to FDA approved products. Prior to FDA approvals, all costs related to manufacturing were charged to research and development expense in the period incurred, therefore, inventory is not included as of December 31, 2022. Inventory that is used for clinical development purposes is expensed to research and development expense when consumed. Inventory, noncurrent includes inventory expected to remain on-hand beyond one year from the balance sheet date presented.

3. Related Party Transactions

Frazier is a principal stockholder of the Company with representation on the Board of Directors. Frazier is compensated for their participation on the Board of Directors and as of December 31, 2023 and December 31, 2022, the Company had $28,000 and $15,000, respectively, outstanding accounts payable and accrued expenses related to these services. For the years ended December 31, 2023 and 2022, the Company incurred $55,000 and $15,000, respectively, of expenses related to participation on the Board of Directors. Frazier is also a principal stockholder in PCI Pharma Services, or PCI. Starting in the third quarter of 2019, the Company engaged PCI for clinical manufacturing services. As of December 31, 2023 and 2022, the Company had $1.2 million and $1.1 million, respectively, in outstanding accounts payable and accrued expenses related to these manufacturing services. For the years ended December 31, 2023 and 2022, the Company incurred $0.6 million and $0.7 million, respectively, of expenses related to services performed by PCI.

Takeda became a common stockholder of the Company in connection with the May 2019 license agreement (see Note 4). In connection with the Takeda License, the Company entered into a temporary services agreement, or the Temporary Services Agreement, with Takeda on November 24, 2020. Pursuant to the Temporary Services Agreement, Takeda agreed to provide or procure the provision of services related to the ongoing clinical development of vonoprazan. The Temporary Services Agreement will terminate immediately upon termination of the Takeda License in accordance with its terms. As of December 31, 2023 and December 31, 2022, the Company had $1.5 million and $1.4 million, respectively, in outstanding accounts payable and accrued expenses related to these agreements. For the years ended December 31, 2023 and 2022, the Company incurred $0.1 million and $1.4 million, respectively, of expenses related to these agreements. The Company has no remaining minimum purchase obligation related to these agreements.

4. Commitments and Contingencies

License Agreement

On May 7, 2019, the Company entered into a license agreement with Takeda pursuant to which it was granted an exclusive license to commercialize vonoprazan fumarate in the United States, Canada and Europe, or the Takeda License. The Company also has the right to sublicense its rights under the agreement, subject to certain conditions. The agreement will remain in effect, on a country-by-country and product-by-product basis, until the later of (i) the expiration of the last to expire valid patent claim covering vonoprazan fumarate alone or in combination with at least one other therapeutically active ingredient, (ii) the expiration of the applicable regulatory exclusivity and (iii) 15 years from the date of first commercial sale, unless earlier terminated. The Company may terminate the Takeda License upon six months' written notice. The Company and Takeda may terminate the Takeda License in the case of the other party's insolvency or material uncured breach. Takeda may terminate the Takeda License if the Company challenges, or assists in challenging, licensed patents.

In consideration of the Takeda License, the Company (i) paid Takeda $25 million in cash, (ii) issued Takeda 1,084,000 shares of its common stock at a fair value of $5.9 million, (iii) issued the Takeda Warrant to purchase 7,588,000 shares of its common stock at an exercise price of $0.00004613 per share at an initial fair value of $47.9 million, and (iv) issued a right to receive an additional common stock warrant, or, the Takeda Warrant Right, should Takeda's fully-diluted ownership of the Company represent less than a certain specified percentage of the fully-diluted capitalization, including shares issuable upon conversion of then outstanding convertible promissory notes, calculated immediately before the closing of the Company's IPO, with a nominal initial fair value due to the low probability of issuance. The Takeda Warrant Right expired without effect since no fair value had been allocated to it upon completion of the IPO, and no additional warrant was issued. In addition, the Company is obligated to pay Takeda up to an aggregate of $250 million in sales milestones upon the achievement of specified levels of product sales, and a low double-digit royalty rate on aggregate net sales of licensed products, subject to certain adjustments. The Takeda Warrant had an exercise price of $0.00004613 per share, and was to expire on May 7, 2029 and became exercisable upon the consummation of the IPO. All Takeda Warrants were exercised in 2022.

During the year ended December 31, 2023, the Company recorded $0.1 million of royalty expense under the Takeda License, which is included within accrued expenses as of December 31, 2023.

Purchase Commitments

In December 2020, the Company entered into a supply agreement with Sandoz pursuant to which Sandoz will supply commercial quantities of amoxicillin capsules and clarithromycin tablets, package these antibiotics with vonoprazan, and provide in finished convenience packs. The supply agreement commits the Company to a minimum purchase obligation of €2.9 million, or approximately $3.2 million, in the first 24-month period following the launch of the final product. The Company has incurred $0.3 million and no expenses under the agreement during the years ended December 31, 2023 and 2022, respectively.

Contingencies

In the event the Company becomes subject to claims or suits arising in the ordinary course of business, the Company would accrue a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated.

5. Lease Commitments

As of December 31, 2023, the Company had operating leases for office space in both Buffalo Grove, Illinois and Florham Park, New Jersey, with weighted average remaining lease terms of 1.3 years and 1.7 years, respectively. All operating leases contain an option to extend the term for one additional five-year period, which was not considered in the determination of the right-of-use asset or lease liability as the Company did not consider it reasonably certain that it would exercise such options.

The total rent expense for the years ended December 31, 2023 and 2022 was approximately $1.1 million and $1.0 million, respectively.

The following table summarizes supplemental balance sheet information related to the operating leases (in thousands):

	December 31,	
	2023	2022
Assets:		
Operating lease right-of-use assets	$ 1,475	$ 2,287
Total right-of-use assets	1,475	2,287
Liabilities:		
Operating lease liabilities, current	726	708
Operating lease liabilities, non-current	462	1,098
Total operating lease liabilities	$ 1,188	$ 1,806

As of December 31, 2023, the future minimum annual lease payments under the operating leases were as follows (in thousands):

2024	$ 752
2025	513
Total minimum lease payments	1,265
Less: amount representing interest	(77)
Present value of operating lease liabilities	1,188
Less: operating lease liabilities, current	(726)
Operating lease liabilities	$ 462
Weighted-average remaining lease term (in years)	1.6
Weighted-average incremental borrowing rate	8.21%

Operating cash flows for both the years ended December 31, 2023 and 2022 included cash payments for operating leases of $1.1 million, of which $0.1 million as of December 31, 2023 were prepaid lease payments.

6. Debt

Total debt consists of the following (in thousands):

	December 31,	
	2023	2022
Long-term debt, current portion	$ —	$ —
Long-term debt, non-current portion	148,057	104,474
Unamortized debt discount	(10,215)	(9,210)
Total debt, net of debt discount	$ 137,842	$ 95,264

On September 17, 2021, or the Closing Date, the Company entered into a Loan and Security Agreement, or, the Loan Agreement, with Hercules Capital, Inc., in its capacity as administrative agent and collateral agent and as a lender, or, in such capacity, the Agent or Hercules, and the other financial institutions that from time to time become parties to the Loan Agreement as lenders, or, collectively, the Lenders.

The Loan Agreement provides for term loans in an aggregate principal amount of up to $200 million, or the Term Loan, under multiple tranches. The tranches consist of (i) a first tranche consisting of term loans in an aggregate principal amount of $100 million, all of which was funded on the Closing Date, or the First Advance, (ii) a second tranche consisting of up to an additional $50 million, (iii) a third and fourth tranches consisting of an additional total $50 million, which became available to us in May 2022.

On September 27, 2022, the Company entered into an amendment to the Loan Agreement, or the Second Loan Amendment, pursuant to which the date the second tranche of funding of $50 million will remain available to the Company has been moved until May 15, 2023, rather than December 15, 2022.

On May 9, 2023, the Company entered into the Third Amendment to Loan and Security Agreement, or the Third Loan Amendment, with the lenders, pursuant to which, among other things, (i) the second tranche availability was extended from through May 15, 2023, to through December 15, 2023, and became available on October 1, 2023, (ii) the third tranche availability was extended from through September 30, 2023, to through December 15, 2023, and became available on October 1, 2023, (iii) the effective date of the Performance Covenants was amended to provide an option to extend the covenant trigger date to May 15, 2024, subject to the achievement of the FDA approval of vonoprazan for Erosive GERD or the EE Milestone, prior to February 15, 2024, and (iv) the warrant agreement with Hercules was amended as described below. On November 1, 2023 the EE Milestone was achieved and the covenant trigger date was extended to May 15, 2024. In connection with the Third Loan Amendment, a tranche extension amendment fee of $150,000 and a covenant extension amendment fee of $100,000 was paid to the Agent. These fees have been recorded as debt discount and are being amortized to interest expense using the effective interest method over the remaining term of the Term Loan.

On December 14, 2023, the Company entered into a Fourth Amendment to Loan and Security Agreement, or the Fourth Loan Amendment, with the lenders, pursuant to which, among other things, (i) increases the aggregate principal amount of the term loans from $200 million to $300 million; (ii) provides for the possibility of accessing the remaining $200 million commitment through five tranches referred to as the second through sixth tranches, which are available subject to certain milestones and conditions: (a) Second Tranche: $50 million, $40 million of which was funded on December 14, 2023, available through March 15, 2024, (b) Third Tranche: $25 million available through June 15, 2024, (c) Fourth Tranche: $25 million available through December 15, 2024, (d) Fifth Tranche: $50 million available, subject to the achievement of trailing three month net revenues greater than $60 million, or the Fifth Tranche milestone, through June 30, 2025, and (e) Sixth Tranche: $50 million available, subject to the achievement of trailing three month net revenues greater than $80 million, or the Sixth Tranche milestone, through December 31, 2025; (iii) extends the interest only period and the maturity date from October 2026 to December 2027, (iv) reduces the cash interest rate from 10.75% (floating annual rate equal to the greater of (a) 5.50% and (b) the Prime Rate (as reported in the Wall Street Journal) plus 2.25% to 9.85% (floating rate based on the greater of (a) 9.85% or (b) US WSJ Prime + 1.35%), provided that the cash interest rate shall be capped at 10.35% and upon the Company achieving the Sixth Tranche milestone, the cash interest floating rated shall be decreased by 0.35% to 9.50%, and (v) decreases the payment-in-kind interest rate from 3.35% per annum to 2.15% per annum. In connection with the Fourth Loan Amendment, an amendment fee of $250,000 was paid to the Agent and was recorded as a debt discount and being amortized to interest expense using the effective interest method over the remaining term of the Term Loan.

The Term Loan will mature on December 1, 2027, or the Maturity Date. The Term Loan bears (i) cash interest at a variable annual rate equal to the greater of (a) 9.85% and (b) the Prime Rate (as reported in the Wall Street Journal) plus 1.35%, or the Interest Rate, and (ii) payment-in-kind interest at a per annum rate of interest equal to 2.15%. The Company may make payments of interest only through the Maturity Date. After the interest-only period, the principal balance and related interest will be required to be repaid in full on the Maturity Date.

In addition, the Company is obligated to pay a final payment fee of 7.50% of the original principal amount of amounts actually advanced under the Term Loan, or each a Term Loan Advance and together, the Term Loan Advances. In connection with the Fourth Loan Amendment, the final payment fee was amended to be $1 million plus 3.00% of any future tranche drawdowns under the agreement, due upon final maturity. Additionally, the initial final payment fee for the first term Loan advance was amended to become payable on October 1, 2026. As of December 31, 2023, the aggregate final payment fee for the first Term Loan Advance of $7.5 million and $2.2 million for the second Term Loan Advance, have both been recorded within other long-term liabilities.

Under the Fourth Loan Amendment the Company may elect to prepay all or a portion of the Term Loan Advances prior to maturity, subject to a prepayment fee of up to 1.25% of the then outstanding principal balance of the Term Loan Advances being prepaid when such prepayment occurs prior to October 1, 2026, or 0.50% if such prepayment occurs on or after October 1, 2026. After repayment, no Term Loan amounts may be borrowed again.

As collateral for the obligations, the Company has granted to Hercules a senior security interest in all of Company's right, title, and interest in, to and under substantially all of Company's property, inclusive of intellectual property.

The Loan Agreement contains customary closing fees, prepayment fees and provisions, events of default, and representations, warranties and covenants, including financial covenants. The financial covenants under the Fourth Loan Amendment include (i) a minimum cash covenant and (ii) a performance covenant as follows:

(i) Minimum cash covenant - The Company must maintain a minimum cash balance of 20% of the outstanding principal balance at all times. The minimum cash balance may be increased to 35% or 50% under performance covenant (b) below if the performance covenants (a) or (c) are not met beginning September 30, 2024 and all times thereafter.

(ii) Performance covenant- Beginning September 30, 2024 and all times thereafter the Company must satisfy any one of the following:

a. Market capitalization exceeding $900 million;

b. Minimum cash balance exceeding (x) outstanding principal amount of term loans, multiplied by (y) (A) 50%, prior to achieving trailing three months net product revenue of greater than $35 million, and (B) 35% thereafter;

c. Trailing three months net product revenue of at least (x) 30% of agreed upon projected net revenues for periods in the calendar year 2024 and 25% for all periods thereafter or (y) $120 million.

Upon the occurrence of an event of default, subject to any specified cure periods, all amounts owed by the Company may be declared immediately due and payable by Hercules, as collateral agent. As of December 31, 2023, the Company was in compliance with all applicable covenants under the Loan Agreement.

In connection with the entry into the Loan Agreement, the Company issued to Hercules a warrant, or, the Warrant, to purchase a number of shares of the Company's common stock equal to 2.5% of the aggregate amount of the Term Loan advances funded, and will issue to Hercules additional warrants when future Term Loan advances are funded. On the Closing Date, the Company issued a Warrant for 74,782 shares of common stock. The Warrant will be exercisable for a period of seven years from the date of issuance at a per-share exercise price equal to $33.43, which was the closing price of the Company's common stock on September 16, 2021. In connection with the entry into the Third Loan Amendment, we amended the form of warrants to be issued upon drawdowns of future tranches such that the exercise price of such warrants shall be equal to the lesser (i) of $11.6783, which was the trailing ten-day VWAP prior to entering into the Third Loan Amendment and (ii) the trailing ten-day VWAP preceding the date on which we drawdown future tranches. In connection with the entry into the Fourth Loan Amendment, we eliminated the warrant agreement for all future tranches. The Warrant issued with the initial tranche was not modified as part of this amendment. The exercise price and terms of the outstanding Warrant remain unchanged.

The initial $1.3 million fair value of the Warrant, the $9.7 million final interest payment fees and $3.5 million of debt issuance costs have been recorded as debt discount and are being amortized to interest expense using the effective interest method over the term of the Term Loan.

Future minimum principal payments under the Term Loan, including the final payment fees, as of December 31, 2023 are as follows (in thousands):

Year ending December 31:		
2024	$	—
2025		—
2026		7,500
2027		163,444
2028		—
Total principal and interest payments		170,944
Less: payment-in-kind and final payment fee		(30,944)
Total term loan borrowings	$	140,000

During the years ended December 31, 2023 and 2022, the Company recognized $17.1 million and $13.0 million, respectively, of interest expense, including amortization of the debt discount, in connection with the Hercules Loan Agreement. As of December 31, 2023 and 2022, the Company had outstanding loan balance of $148.1 million and $104.5 million, respectively, and accrued interest of $1.1 and $0.9 million, respectively.

7. Revenue Interest Financing Liability

On May 3, 2022, the Company entered into a Revenue Interest Financing Agreement with Initial Investors NQ, Sagard, and Hercules pursuant to which the Company will receive up to $260 million in funding from the Initial Investors. Under the terms of the Revenue Interest Financing Agreement, the Company received $100 million at the initial closing and received an additional $160 million upon FDA approval of VOQUEZNA for treatment of Erosive GERD during the fourth quarter of 2023.

Additionally, on October 31, 2022, the Company entered into a Joinder Agreement with the Initial Investors and CO Finance LVS XXXVII LLC, or the Additional Investor, and Hercules, together as the investors. Under the terms of the Joinder Agreement, we received $15 million in additional funding upon FDA approval of vonoprazan for Erosive GERD, or Approval Additional Funding, during the fourth quarter of 2023, and provides for $25 million in additional funding for achievement of a sales milestone, or Milestone Additional Funding, and, together with the Approval Additional Funding, or the Additional Investor Funding. The Initial Investors waived their rights of first offer regarding the Additional Investor Funding and the Additional Investor and joined the Revenue Interest Financing Agreement to extend commitments for the Additional Investor Funding. The total amount funded by the Initial Investors and any subsequent investors is referred to herein as the Investment Amount.

Under the Revenue Interest Financing Agreement, the investors are entitled to receive a 10% royalty on net sales of products containing vonoprazan. The royalty rate is subject to a step-down on net sales exceeding certain annual thresholds and if the Company receives FDA approval for vonoprazan for an indication relating to the treatment of heartburn associated with Non-Erosive GERD. The investors' right to receive royalties on net sales will terminate when the investors have aggregate payments equal to 200% of the Investment Amount. In addition, at any time after the earlier of (i) April 30, 2024 and (ii) the date that the payment for Erosive GERD regulatory approval is made, the Company has the right to make a cap payment equal to 200% of the Investment Amount less any royalties already paid, at which time the agreement will terminate.

If the investors have not received aggregate payments of at least 100% of the Investment Amount by December 31, 2028, and at least 200% of the Investment Amount by December 31, 2037, each a Minimum Amount, then the Company will be obligated to make a cash payment to the investors in an amount sufficient to gross the investors up to the applicable Minimum Amount.

Upon the occurrence of an event of default taking place prior to April 1, 2025, between April 1, 2025 and April 1, 2028, and after April 1, 2028, the Company is obligated to pay 1.30 times Investment Amount, 1.65 times Investment Amount, and 2.0 times investment amount, respectively, less any amounts the Company previously paid pursuant to the agreement.

During the year ended December 31, 2023, the Company received gross proceeds of $175.0 million before deducting transaction costs of $2.3 million, resulting in net proceeds of $172.7 million. During the year ended December 31, 2022, the Company received gross proceeds of $100.0 million before deducting transaction costs of $4.6 million, which resulted in net proceeds of $95.4 million.

The Company has evaluated the terms of the Revenue Interest Financing Agreement and concluded that the features of the Investment Amount are similar to those of a debt instrument. Accordingly, the Company has accounted for the transaction as a debt obligation with interest expense based on an imputed effective rate derived from the initial carrying value of the obligation and the expected future payments. The Company recalculates the effective interest rate each period based on the current carrying value and the revised estimated future payments. Changes in future payments from previous estimates are included in the current and future financing expense. The carrying value of the revenue interest financing liability was $306.9 million and $109.5 million as of December 31, 2023 and 2022, respectively.

Total revenue interest financing liability consists of the following (in thousands):

Liability balance as of January 1, 2022	$	-
Proceeds from the Revenue Interest Financing Agreement		100,000
Less: transaction costs		(4,554)
Less: royalty payments and payables		—
Plus: interest expense		14,079
Ending liability balance as of December 31, 2022	$	109,525

Liability balance as of January 1, 2023	$	109,525
Proceeds from the Revenue Interest Financing Agreement		175,000
Less: transaction costs		(2,325)
Less: royalty payments and payables		—
Plus: interest expense		24,727
Ending liability balance as of December 31, 2023		306,927
Less: current portion		(7,111)
Long-term liability balance as of December 31, 2023	$	299,816

During the years ended December 31, 2023 and 2022, the Company recognized $24.7 million and $14.1 million, respectively, of interest expense in connection with the revenue interest financing liability.

The Company will record liabilities associated with achievement of the sales milestone when such contingent event occurs. To determine the accretion of the liability related to the Revenue Interest Financing Agreement, the Company is required to estimate the total amount of future royalty payments and estimated timing of such payments based on the Company's revenue projections. As royalty payments are made, the balance of the debt obligation will be effectively repaid. Based on the Company's periodic review, the exact timing of repayment is likely to be different in each reporting period as compared to those estimated in the Company's initial revenue projections. A significant increase or decrease in actual net sales of vonoprazan compared to the Company's revenue projections could impact the interest expense associated with the revenue interest financing liability. Also, the Company's total obligation can vary depending on default events and achievement of the sales milestone.

8. Stockholders' Equity

Common Stock

In March 2019, the founders granted the Company a repurchase right for the 3,373,408 shares of common stock originally purchased in 2018. The Company has the right, but not the obligation, to repurchase unvested shares in the event the founder's relationship with the Company is terminated, subject to certain limitations, at the original purchase price of the stock. The repurchase right lapsed for 843,352 shares in March 2019 and the repurchase right for the remaining 2,530,056 shares lapses in equal monthly amounts over the following 48-month period ending March 2023. The fair value of the founder shares at the date the repurchase right was granted was recognized as stock-based compensation expense on a straight-line basis over the vesting period. As of December 31, 2023 and 2022, no shares and 79,064 shares, respectively, of common stock were subject to repurchase by the Company. The amount of recognized and unrecognized stock-based compensation related to the founder stock was immaterial for all periods presented.

From inception through December 31, 2023, the Company sold 26,041,380 shares of common stock, generating net proceeds of approximately $421.5 million, after deducting underwriting discounts, commissions and offering costs. This includes the May 2023 underwritten public offering, in which the Company sold 12,793,750 shares of its common stock, which included the exercise in full by the underwriters of their option to purchase 1,668,750 shares, at a price of $11.75 per share for total gross proceeds of $150.3 million. The net purchase price after deducting underwriting discounts and commissions was $11.08 per share, which generated net proceeds of $141.8 million. The Company incurred an additional $0.4 million of offering expenses in connection with this public offering.

ATM Agreements

In November 2020, the Company entered into the Sales Agreement, pursuant to which, the Company will pay the Sales Agent a commission for its services in acting as an agent in the sale of common stock in an amount equal to 3% of the gross sales price per share sold. In September 2022, the Company sold 2,414,897 shares for net proceeds of approximately $24.6 million under the 2020 ATM Offering after deducting $0.8 million of issuance costs. In February 2023, the Company sold 1,514,219 shares for net proceeds of approximately $14.1 million under the ATM Offering after deducting $0.4 million of issuance costs. The Company utilized $39.9 million of the available $125 million under the ATM Offering prior to expiration in November 2023.

On November 9, 2023, the Company entered into an Open Market Sale Agreement℠, or the 2023 Sales Agreement, with Jefferies LLC, or the Sales Agent, under which the Company may, from time to time, sell shares of the Company's common stock having an aggregate offering price of up to $150 million through the Sales Agent, or the ATM Offering. Sales of the Company's common stock made pursuant to the 2023 Sales Agreement, if any, will be made under the Company's shelf registration statement on Form S-3 which was filed on November 9, 2023 and declared effective by the SEC on November 17, 2023. As of December 31, 2023, the Company utilized none of the available $150 million under the ATM Offering.

A summary of the Company's unvested shares is as follows:

Balance at December 31, 2022	254,437
Share vesting	(254,437)
Balance at December 31, 2023	—

For accounting purposes, unvested awards are considered issued, but not outstanding until they vest.

Common stock reserved for future issuance consists of the following:

	December 31, 2023
Common stock warrants	91,228
Stock options, restricted stock units, and performance-based awards outstanding	7,203,973
Shares available for issuance under the 2019 Incentive Plan	1,110,376
Shares available for issuance under the ESPP Plan	973,298
Balance at December 31, 2023	9,378,875

Preferred Stock

The Company is authorized to issue up to 40 million shares of preferred stock. As of December 31, 2023, and December 31, 2022, there were no shares of preferred stock issued or outstanding.

Equity Incentive Plan

The Company's 2019 Equity Incentive Plan, or the Existing Incentive Plan, provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, and other stock awards to eligible recipients, including employees, directors or consultants of the Company. The Company had 2,231,739 shares of common stock authorized for issuance under the Existing Incentive Plan, of which, 1,400,528 stock options and 16,260 restricted stock awards were granted in 2019. As a result of the adoption of the 2019 Incentive Award Plan, or the 2019 Plan, in October 2019, no further shares are available for issuance under the Existing Incentive Plan.

2019 Incentive Award Plan

In October 2019, the Board of Directors adopted, and the Company's stockholders approved, the 2019 Plan, which became effective in connection with the IPO. Under the 2019 Plan, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units and other awards to individuals who are then employees, officers, non-employee directors or consultants of the Company or its subsidiaries. The number of shares initially available for issuance will be increased by (i) the number of shares subject to stock options or similar awards granted under the Existing Incentive Plan that expire or otherwise terminate without having been exercised in full after the effective date of the 2019 Plan and unvested shares issued pursuant to awards granted under the Existing Incentive Plan that are forfeited to or repurchased by the Company after the effective date of the 2019 Plan, with the maximum number of shares to be added to the 2019 Plan pursuant to clause (i) above or equal to 1,416,788 shares, and (ii) an annual increase on January 1 of each calendar year beginning in 2020 and ending in 2029, equal to the lesser of (a) 5% of the shares of common stock outstanding on the final day of the immediately preceding calendar year and (b) such smaller number of shares as determined by the Board of Directors.

On July 14, 2023, the Company completed a voluntary, one-time stock option exchange program, or the Option Exchange, pursuant to which eligible employees were able to exchange certain outstanding stock options granted under the 2019 Plan for a lesser amount of new RSUs issued under the 2019 Plan. Participants in the Option Exchange received one RSU for every two shares of Phathom common stock underlying the eligible options surrendered. This exchange ratio was applied on a grant by grant basis. The Option Exchange resulted in 2,406,622 options being exchanged for 1,203,341 RSUs. The Company is recognizing an additional $2.2 million of incremental expense related to the Option Exchange to be recognized over a three-year vesting period.

As of December 31, 2023, 1,110,376 shares remain available for issuance, which reflects 4,492,336 stock options, performance-based units, and restricted stock units, or RSUs, awards granted, and 2,558,662 of awards cancelled or forfeited, during the year ended December 31, 2023 as well as an annual increase of 2,086,165 shares authorized on January 1, 2023.

Performance-Based Units

During 2020, the Company granted the initial performance-based units, or PSUs, whereby vesting depends upon the approval by the FDA of vonoprazan for *H. pylori* and then, or concurrent with, Erosive GERD. As of December 31, 2023, the PSU milestones have been achieved upon FDA approval of vonoprazan for *H. pylori* and Erosive GERD during the fourth quarter of 2023. As a result, stock-based compensation cost of $19.3 million was recognized within the statements of operations and comprehensive loss during the year ended December 31, 2023.

The following table summarizes PSU activity under the 2019 Incentive Award Plan during the years ended December 31, 2023 and 2022:

	Number of Stock Units	Weighted-Average Grant Date Fair Value Per Share
Unvested balance at January 1, 2022	394,300	$ 32.23
Granted	37,500	20.06
Vested	—	—
Forfeited	(19,500)	35.39
Unvested balance at December 31, 2022	412,300	$ 30.97
Granted	597,650	10.89
Vested	(1,009,950)	19.09
Forfeited	—	—
Unvested balance at December 31, 2023	—	$ —

Restricted Stock Units

The following table summarizes RSU activity under the 2019 Incentive Award Plan during the years ended December 31, 2023 and 2022:

	Number of Stock Units	Weighted-Average Grant Date Fair Value Per Share
Unvested balance at January 1, 2022	—	$ —
Granted	1,010,437	10.79
Vested	(102,453)	8.51
Forfeited	(30,517)	12.14
Unvested balance at December 31, 2022	877,467	$ 11.03
Granted[(1)]	2,419,776	11.77
Vested	(579,567)	9.85
Forfeited	(63,784)	13.07
Unvested balance at December 31, 2023	2,653,892	$ 11.91

(1) The number of RSUs granted includes those exchanged in the Option Exchange (as defined above).

As of December 31, 2023, the Company had $26.6 million of unrecognized stock-based compensation expense, which is expected to be recognized over a weighted-average period of 2.4 years. The total fair value of RSUs vested during the years ended December 31, 2023 and 2022, was approximately $5.7 million and $0.9 million, respectively.

Employee Stock Purchase Plan

In October 2019, the Board of Directors adopted, and the Company's stockholders approved, the Employee Stock Purchase Plan, or the ESPP, which became effective in connection with the IPO. The ESPP permits participants to purchase common stock through payroll deductions of up to 20% of their eligible compensation, which includes a participant's gross base compensation for services to the Company, including overtime payments and excluding sales commissions, incentive compensation, bonuses, expense reimbursements, fringe benefits and other special payments. A total of 270,000 shares of common stock was initially reserved for issuance under the ESPP. In addition, the number of shares available for issuance under the ESPP will be annually increased on January 1 of each calendar year beginning in 2020 and ending in 2029, by an amount equal to the lesser of: (i) 1% of the shares outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares as is determined by the Board of Directors. As of December 31, 2023, 973,298 shares of common stock remain available for issuance, which includes the 196,873 shares sold to employees during the year ended December 31, 2023 as well as an annual increase of 417,233 shares authorized on January 1, 2023.

The ESPP is considered a compensatory plan, and the Company recorded related stock-based compensation of $0.6 million and $0.5 million for the years ended December 31, 2023 and 2022, respectively. The weighted-average assumptions used to estimate the fair value of ESPP awards using the Black-Scholes option valuation model were as follows:

	Years Ended December 31,	
	2023	**2022**
Assumptions:		
Expected term (in years)	0.49	0.50
Expected volatility	69.73 %	68.59 %
Risk free interest rate	5.03 %	2.04 %
Dividend yield	—	—

The estimated weighted-average fair value of ESPP awards during 2023 and 2022 was $3.64 and $3.98, respectively. As of December 31, 2023, the total unrecognized compensation expense related to the ESPP was less than $0.1 million, which is expected to be recognized over a weighted-average period of approximately 0.5 months.

401(k) Plan

The Company established a 401(k) savings plan during the year ended December 31, 2020. The Company's contributions to the plan are discretionary. During the years ended December 31, 2023 and 2022, the Company incurred $1.9 million and $1.3 million, respectively, of expense related to estimated employer contribution liabilities, which was based on a 75% match of employees' contributions during the periods. During the years ended December 31, 2023 and 2022, the Board of Directors approved employer matching contributions settled by contributing 135,956 and 101,540, respectively, shares of Company stock.

Stock Options

The fair value of each employee and non-employee stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company, prior to the IPO on October 29, 2019, was a private company and lacked company-specific historical and implied volatility information. Therefore, it estimated its expected volatility based on the historical volatility of a publicly traded set of peer companies. Due to the lack of historical exercise history, the expected term of the Company's stock options for employees was determined utilizing the "simplified" method for awards. The expected term of stock options granted to non-employees was equal to the contractual term of the option award. The risk-free interest rate was determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield was zero based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

A summary of the Company's stock option activity and related information is as follows during the years ended December 31, 2023 and 2022:

	Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value (in thousands)
Balance at January 1, 2022	4,186,729	$ 27.53	7.91	$ 13,973
Options granted	1,741,931	14.62		
Options exercised	—	—		
Options cancelled	(342,190)	29.32		
Balance at December 31, 2022	5,586,470	$ 23.40	7.90	$ 4,476
Options granted	1,474,910	8.54		
Options exercised	(16,421)	7.54		
Options cancelled[(1)]	(2,494,878)	35.96		
Balance at December 31, 2023	4,550,081	$ 11.75	7.50	$ 3,379
Options exercisable as of December 31, 2023	2,272,248	$ 12.65	6.14	$ 2,088
Vested and expected to vest as of December 31, 2023	4,550,081	$ 11.75	7.50	$ 3,379

(1) The number of stock options cancelled includes those exchanged in the Option Exchange (as defined above).

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock at December 31, 2023. The total intrinsic value of stock options exercised for the year ended December 31, 2023 was approximately $0.1 million.

The estimated weighted-average fair value of employee and nonemployee director stock options granted during 2023 was $5.34 and during 2022 was $8.40 per option. As of December 31, 2023, the Company had $13.2 million of unrecognized stock-based compensation expense, which is expected to be recognized over a weighted-average period of 2.4 years.

The weighted-average assumptions used to estimate the fair value of stock options using the Black-Scholes option valuation model were as follows:

	Years Ended December 31,	
	2023	2022
Assumptions:		
Expected term (in years)	6.04	5.88
Expected volatility	66.05%	66.00%
Risk free interest rate	3.65%	2.06%
Dividend yield	—	—

Stock-Based Compensation Expense

Stock-based compensation expense recognized for all equity awards, including founder stock, has been reported in the statements of operations and comprehensive loss as follows (in thousands):

	Years Ended December 31,	
	2023	2022
Research and development expense	$ 12,302	$ 5,534
Selling, general and administrative expense	32,723	18,599
Total	$ 45,025	$ 24,133

9. Revenue Recognition

To date, our only source of revenue has been from the U.S. sales of VOQUEZNA products, which the Company began selling in November 2023. The Company records its best estimate of chargebacks, sales discounts and other reserves to which customers are likely to be entitled as contra accounts receivable charges on the balance sheet as of December 31, 2023. During the year ended December 31, 2023, we recognized $0.7 million of net product revenues related to sales of VOQUEZNA. Sales allowances and accruals mostly consisted of distribution fees and rebates.

10. Income Taxes

For the years ended December 31, 2023 and 2022, the Company did not record a provision for income taxes due to a full valuation against its deferred taxes. A reconciliation between the provision for income taxes and income taxes computed using the U.S. federal statutory corporate tax rate is as follows (in thousands):

	Years Ended December 31,	
	2023	2022
Income taxes computed at the statutory rate	$ (42,334)	$ (41,522)
State income taxes, net of federal benefit	(4,310)	—
Permanent items	1,310	1,605
Officers' compensation	2,534	1,109
Research and development credit	(2,971)	(2,453)
Change in state rate	(3,762)	—
Change in valuation allowance	49,745	41,137
Other	(212)	124
Provision (benefit) for income taxes	$ —	$ —

Significant components of the Company's net deferred tax assets are as follows (in thousands):

	Years Ended December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 120,092	$ 85,918
Research credits	11,815	8,897
Intangible assets	33,095	25,319
Other	11,256	6,517
Gross deferred tax assets	176,258	126,651
Less valuation allowance	(175,915)	(126,170)
Deferred tax assets, net of valuation allowance	343	481
Deferred tax liabilities:		
Other	(343)	(481)
Net deferred tax assets	$ —	$ —

Based upon the Company's history of operating losses, the Company is unable to conclude that it is more likely than not that the benefit of its deferred tax assets will be realized. Accordingly, the Company has provided a full valuation allowance for its deferred tax assets as of December 31, 2023 and 2022.

As of December 31, 2023 and 2022, the Company had federal net operating loss carryforwards of approximately $554.7 million and $408.7 million, respectively, which are carried over indefinitely.

As of December 31, 2023, the Company had approximately $62.3 million of state net operating loss carryforwards that begins to expire in 2036.

As of December 31, 2023, the Company has available federal research and development credits of $13.7 million which begin to expire in 2038. The Company has $1.3 million of state research and development credits, some of which, begin to expire in 2025.

The Company has not completed a formal analysis of the potential impact of Section 382 on its deferred tax assets as of December 31, 2023. Until this analysis has been completed, the Company has not adjusted any of its deferred tax assets, including net operating losses or research and development credits. The Company will reassess the amount of net operating losses and credits subject to limitation under Section 382 when a study is complete. Due to the existence of the valuation allowance, future changes in the deferred tax assets related to these tax attributes will not impact the Company's effective tax rate.

The Company recognizes liabilities for uncertain tax positions based on a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement. While the Company believes that it has appropriate support for the positions taken on its tax returns, the Company regularly assesses the potential outcome of examinations by tax authorities in determining the adequacy of its provision for income taxes.

The following table summarizes the activity related to the Company's gross unrecognized tax benefits (in thousands):

	Years Ended December 31,	
	2023	2022
Beginning balance	$ 2,327	$ 1,704
Increases related to prior year tax positions	51	—
Increases related to current year tax positions	632	623
Ending balance	$ 3,010	$ 2,327

As of December 31, 2023 and 2022, the Company has gross unrecognized tax benefits of $3,010 and $2,327, respectively, none of which would affect the effective tax rate due to a full valuation allowance. The Company does not anticipate any significant changes in its unrecognized tax benefits over the next 12 months. The Company's policy is to recognize the interest expense and/or penalties related to income tax matters as a component of income tax expense. The Company has no accrual for interest or penalties on its balance sheet as of December 31, 2023 and 2022, and has not recognized interest and/or penalties in its statement of operations for the years ended December 31, 2023 and 2022.

The Company is subject to taxation in the United States and various states. The Company is not currently under examination by any taxing authorities. Due to the carryover of tax attributes, the statute of limitations is currently open for tax years since inception.

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation	8-K	10-29-2019	3.1	
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation, as filed with the Secretary of the State of Delaware on May 26, 2023	8-K	5-30-2023	3.1	
3.3	Amended and Restated Bylaws, effective as of December 13, 2023	8-K	12-15-2023	3.1	
4.1	Form of Common Stock Certificate	S-1/A	10-15-2019	4.1	
4.2	Warrant to purchase stock issued to Silicon Valley Bank, dated May 14, 2019	S-1	9-30-2019	4.3	
4.3	Warrant to purchase stock issued to WestRiver Innovation Lending Fund VIII, L.P., dated May 14, 2019	S-1	9-30-2019	4.4	
4.4	Note Purchase Agreement, dated May 7, 2019, by and among the Registrant and the other parties party thereto, as amended	S-1/A	10-15-2019	4.5	
4.5	Warrant to purchase stock issued to Hercules Capital, dated September 17, 2021	10-Q	11-8-2021	10.2	
4.6	Form of Warrant to purchase stock issuable pursuant to the Loan and Security Agreement, as amended, by and between the Registrant and Hercules Capital, Inc.	10-Q	5-10-2023	4.6	
4.7	First Amendment to Warrant to purchase stock issued to Hercules Capital, dated May 9, 2023	10-Q	5-10-2023	4.5	
4.8	Description of Registered Securities				X
10.1#	Phathom Pharmaceuticals, Inc. 2019 Equity Incentive Plan	S-1	9-30-2019	10.1	
10.2#	Form of Stock Option Grant Notice and Stock Option Agreement under the Phathom Pharmaceuticals, Inc. 2019 Equity Incentive Plan	S-1	9-30-2019	10.2	
10.3#	Form of Restricted Stock Grant Notice and Restricted Stock Agreement under Phathom Pharmaceuticals, Inc. 2019 Equity Incentive Plan	S-1	9-30-2019	10.3	
10.4#	Phathom Pharmaceuticals, Inc. 2019 Incentive Award Plan	S-1/A	10-15-2019	10.4	
10.5#	Form of Stock Option Grant Notice and Stock Option Agreement under the Phathom Pharmaceuticals, Inc. 2019 Incentive Award Plan	10-Q	8-6-2020	10.3	
10.6#	Phathom Pharmaceuticals, Inc. 2019 Employee Stock Purchase Plan	S-1/A	10-15-2019	10.5	
10.7#	Amended and Restated Non-Employee Director Compensation Policy	10-Q	8-10-2023	10.2	

10.8#	Amended and Restated Employment Letter Agreement, dated September 25, 2019, by and between Azmi Nabulsi, M.D., M.P.H. and the Registrant	S-1	9-30-2019	10.9	
10.9#	Form of Indemnification Agreement for Directors and Officers	S-1	9-30-2019	10.11	
10.10†	License Agreement, dated May 7, 2019, by and between Takeda Pharmaceuticals Company Limited and the Registrant	S-1	9-30-2019	10.12	
10.11#	Employment Letter Agreement, dated August 29, 2019, by and between Terrie Curran and the Registrant	S-1	9-30-2019	10.14	
10.12†	Amendment No. 1 to Takeda License Agreement, dated September 21, 2020	10-K	3-30-2021	10.20	
10.13†	Supply and Packaging Services Agreement, by and between Sandoz GmbH and the Registrant, dated December 30, 2020	10-K	3-30-2021	10.21	
10.14†	Commercial Supply Agreement with Catalent Pharma Solutions, LLC entered into on July 2, 2021	10-Q	8-10-2021	10.4	
10.15	Loan and Security Agreement, dated September 17, 2021, by and among Hercules Capital and the Registrant	10-Q	11-8-2021	10.1	
10.16†	First Amendment to the Supply and Packaging Services Agreement, by and between Sandoz GmbH and the Registrant, dated December 4, 2021	10-K	3-1-2022	10.30	
10.17#	Employment Letter Agreement, dated March 22, 2022, by and between Molly Henderson and the Company	10-Q	5-10-2022	10.1	
10.18#	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under Phathom Pharmaceuticals, Inc. 2019 Equity Incentive Plan	10-Q	8-1-2022	10.2	
10.19†	Revenue Interest Financing Agreement, dated May 3, 2022, by and among NovaQuest Capital Management, Sagard Holding Manager, Hercules Capital and the Registrant	10-Q	8-1-2022	10.3	
10.20	First Amendment to the Loan and Security Agreement, dated September 17, 2021, by and among Hercules Capital and the Registrant	10-Q	8-1-2022	10.4	
10.21†	Commercial Supply Agreement with Evonik Operations GmbH entered into on August 1, 2022	10-Q	11-9-2022	10.1	
10.22	Second Amendment to the Loan and Security Agreement, dated September 17, 2021, by and among Hercules Capital and the Registrant	10-Q	11-9-2022	10.2	
10.23†	Joinder and Waiver agreement dated October 31, 2022 by and among Hercules Capital, CO Finance LVS XXXVII LLC and the Registrant	10-K	2-28-2023	10.37	
10.24^	Third Amendment to the Loan and Security Agreement, dated May 9, 2023, by and among Hercules Capital and the Registrant	10-Q	5-10-2023	10.1	
10.25^	First Amendment to Vonoprazan Commercial Supply Agreement, dated August 1, 2022, by and among Evonik Operations GmbH and the Registrant	10-Q	8-10-2023	10.1	
10.26†	First Amendment to the Commercial Supply Agreement, dated as of December 6, 2023, by and among Catalent Pharma Solutions, LLC and the Registrant				X
10.27^	Fourth Amendment to the Loan and Security Agreement, dated December 14, 2023, by and among Hercules Capital and the Registrant				X
10.28#	Phathom Pharmaceuticals Inc. 2024 Bonus Plan				X
23.1	Consent of Independent Registered Public Accounting Firm				X

24.1	Power of Attorney	X
31.1	Certification of Chief Executive Officer of Phathom Pharmaceuticals, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended	X
31.2	Certification of Principal Financial Officer of Phathom Pharmaceuticals, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended	X
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X
32.2*	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X
97	Policy for Recovery of Erroneously Awarded Compensation	X
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document	X
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents	X
104	Cover Page formatted as Inline XBRL and contained in Exhibit 101	X

# Indicates management contract or compensatory plan.

† Portions of this exhibit have been omitted for confidentiality purposes.

* These certifications are being furnished solely to accompany this annual report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

^ Certain exhibits and schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant hereby undertakes to furnish supplementally a copy of any omitted exhibit or schedule upon request by the SEC.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this annual report to be signed on its behalf by the undersigned, thereunto duly authorized.

PHATHOM PHARMACEUTICALS, INC.

/s/ Terrie Curran
Terrie Curran
Chief Executive Officer

Date: March 7, 2024

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

Signature	Title	Date
/s/ Terrie Curran **Terrie Curran**	President, Chief Executive Officer and Director (Principal Executive Officer)	March 7, 2024
/s/ Molly Henderson **Molly Henderson**	Chief Financial and Business Officer (Principal Financial and Accounting Officer)	March 7, 2024
* **Michael F. Cola**	Director	March 7, 2024
* **Frank Karbe**	Director	March 7, 2024
* **Heidi Kunz**	Director	March 7, 2024
* **Asit Parikh, M.D., Ph.D.**	Director	March 7, 2024
* **David Socks**	Director	March 7, 2024
* **Mark Stenhouse**	Director	March 7, 2024
* **James Topper, M.D., Ph.D.**	Director	March 7, 2024

*By: /s/ Terrie Curran
Terrie Curran, Attorney-in-fact

Exhibit 4.8

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2023, Phathom Pharmaceuticals, Inc. ("we," "us" and "our") had one class of securities registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended: our common stock.

Description of Common Stock

General

The following description summarizes some of the terms of our common stock. Because it is only a summary, it does not contain all the information that may be important to you and is subject to and qualified in its entirety by reference to our amended and restated certificate of incorporation (the "certificate of incorporation"), and amended and restated Bylaws ("bylaws"), which are filed as exhibits to our most recent Annual Report on Form 10-K and are incorporated by reference herein. We encourage you to read our certificate of incorporation and our bylaws for additional information.

As of December 31, 2023, our authorized capital stock consisted of 400,000,000 shares of common stock, $0.0001 par value per share, and 40,000,000 shares of preferred stock, $0.0001 par value per share.

Voting Rights

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders, including the election of directors, and do not have cumulative voting rights. Accordingly, the holders of a majority of the outstanding shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they so choose, other than any directors that holders of any preferred stock we may issue may be entitled to elect. Subject to the supermajority votes for some matters, other matters shall be decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter. Our amended and restated certificate of incorporation and amended and restated bylaws also provide that our directors may be removed only for cause and only by the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon. In addition, the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon is required to amend or repeal, or to adopt any provision inconsistent with, several of the provisions of our amended and restated certificate of incorporation.

Dividend Rights

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared by the board of directors out of legally available funds.

Liquidation Rights

In the event of our liquidation, dissolution or winding up, the holders of common stock will be entitled to share ratably in the assets legally available for distribution to stockholders after the payment of or provision for all of our debts and other liabilities, subject to the prior rights of any preferred stock then outstanding.

Rights and Preferences

Holders of common stock have no preemptive or conversion rights or other subscription rights and there are no redemption or sinking funds provisions applicable to the common stock.

Fully paid and nonassessable

The outstanding shares of common stock are duly authorized, validly issued, fully paid and nonassessable.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A.

The Nasdaq Global Market Listing

Our common stock is listed and traded on the Nasdaq Global Select Market under the ticker symbol "PHAT."

Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws

Some provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares. These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids.

These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Undesignated Preferred Stock

The ability of our board of directors, without action by the stockholders, to issue up to 40,000,000 shares of undesignated preferred stock with voting or other rights or preferences as designated by our board of directors could impede the success of any attempt to change control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

Stockholder Meetings

Our amended and restated bylaws provide that a special meeting of stockholders may be called only by our chairman of the board of directors, chief executive officer or president, or by a resolution adopted by a majority of our board of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of Stockholder Action by Written Consent

Our amended and restated certificate of incorporation and amended and restated bylaws eliminate the right of stockholders to act by written consent without a meeting.

Staggered Board of Directors

Our board of directors is divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders. This system of electing and removing directors may tend to discourage a third party from attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Removal of Directors

Our amended and restated certificate of incorporation provides that no member of our board of directors may be removed from office except for cause and, in addition to any other vote required by law, upon the approval of not less than two thirds of the total voting power of all of our outstanding voting stock then entitled to vote in the election of directors.

Stockholders Not Entitled to Cumulative Voting

Our amended and restated certificate of incorporation does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits persons deemed to be "interested stockholders" from engaging in a "business combination" with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

Choice of Forum

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative form, the Court of Chancery of the State of Delaware will be the sole and exclusive forum under Delaware statutory or common law for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders, creditors or other constituents; (iii) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our amended and restated certificate of incorporation or amended and restated bylaws; (iv) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; or (v) any action asserting a claim governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934 (the "Exchange Act"), or any other claim for which the federal courts have exclusive jurisdiction.

In addition, our bylaws provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended (the "Securities Act"). Our certificate of incorporation and bylaws each provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to this choice of forum provision.

While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Amendment of Charter Provisions

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock, would require approval by holders of at least two thirds of the total voting power of all of our outstanding voting stock.

The provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board of directors and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED. THE OMISSIONS HAVE BEEN INDICATED BY "[***]."

Exhibit 10.26

FIRST AMENDMENT TO

COMMERCIAL SUPPLY AGREEMENT

This First Amendment to the Commercial Supply Agreement (this "**Amendment"**), is made as of this December 6, 2023 ("**Amendment Effective Date**"), by and between Phathom Pharmaceuticals, Inc., an Illinois company, with a place of business at 2150 E. Lake Cook Road, Suite 800 Buffalo Grove, Illinois 60089, USA ("**Client**" or "**Phathom**"), and Catalent Pharma Solutions, LLC, a Delaware limited liability company with a place of business at 14 Schoolhouse Road, Somerset, New Jersey 08873, USA ("**Catalent**") (each, a "**Party**" and, collectively, the "**Parties**").

RECITALS

A. WHEREAS Catalent and Phathom entered into a Commercial Supply Agreement effective as of June 30, 2021 ("Agreement"), pursuant to which Catalent manufactures and supplies to Phathom the Product;

B. WHEREAS Catalent and Phathom desire to provide for and include language covering the Prices of the Product, and other changes as set forth herein; and

C. WHEREAS Catalent and Phathom desire to amend the Agreement and to record their mutual understanding of certain revised terms and conditions.

THEREFORE, in consideration of the mutual covenants, terms and conditions set forth below, the Parties agree as follows:

1. **Definitions.** Capitalized terms used and not otherwise defined in this Amendment shall have the meanings assigned to them in the Agreement. For clarity, the term "Agreement" as used in the Agreement and herein shall mean the Agreement as amended hereby.

2. **Specific Amendments.** In connection with and/or as a result of the revised terms and conditions agreed by the Parties, the Agreement is hereby amended as follows:

   A. The Definition of "**Facility**" as set forth in Section 1.25 of the Agreement is hereby deleted in its entirety and replaced with the following:

““**Facility”** means Catalent’s facility located in [***] USA, and/or [***] USA or such other facility as agreed by the parties in writing.”

B. The Definition of “**Commencement Date**” as set forth in Section 1.19 of the Agreement is hereby deleted in its entirety and replaced with the following:

““**Commencement Date**” means the first date on which Catalent is scheduled to deliver (pursuant to Section 6.1) to Client Product intended for commercial sale, excluding validation Batches, and the parties agree such Commencement Date to be January 1, 2024.”

C. A new Section 7.1.E is hereby added to the Agreement:

“Annual volume tiers work as follows: Based on the forecasted demand, Client will decide and notify Catalent at least [***] prior to the start of each Contract Year the annual Volume Tier for each strength that Client projects its orders will reflect (the “Forecasted Volume”) for that Contract Year, and Catalent shall notify Client [***] for that Contract Year. [***]. For all future years, pricing letters will be issued pursuant to Section 7 of the Agreement as amended. At the end of the Contract Year, [***]. For clarity the term “delivery” shall have the meaning ascribed to it in Section 6.1 of the Agreement. However, should the [***].

D. Attachment C to the Agreement is hereby deleted in its entirety and is hereby replaced with **Attachment C** attached hereto and made a part hereof, which sets forth the Unit Pricing for Product delivered pursuant to the Agreement.

3. **No Other Variation**. Except as expressly provided in this Amendment, all the terms, conditions and provisions of the Agreement (including the rights, duties, liabilities and obligations of the Parties thereunder) remain in full force and effect and shall apply to the construction of this Amendment.

4. **Entire Agreement.** This Amendment and the Agreement, including their respective Attachments and Exhibits, constitute the entire agreement between the Parties relating to the subject matter hereof and thereof, and may not be varied except in writing signed by a duly authorized representative of each Party.

5. **Counterparts.** This Amendment may be executed in one or more counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the Parties have caused their respective duly authorized representatives to execute this Amendment effective as of the Amendment Effective Date.

CATALENT PHARMA SOLUTIONS, LLC	**PHATHOM PHARMACEUTICALS, INC.**
By: /s/ Louis Weiner	By: /s/ Jay Buchanan
Name: Louis Weiner	Name: Jay Buchanan
Title: VP, Commercial Operations	Title: VP, Manuf. and Supply Chain

ATTACHMENT C

Unit Pricing and Fees

[***]

Exhibit 10.27

FOURTH AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS FOURTH AMENDMENT TO LOAN AND SECURITY AGREEMENT (this "Amendment"), dated as of December 14, 2023, is entered into by and among PHATHOM PHARMACEUTICALS, INC., a Delaware corporation ("Phathom"), each of its Subsidiaries from time to time party to the Loan Agreement (as defined below) as borrower (together with Phathom, individually or collectively, as the context may require, "Borrower"), the several banks and other financial institutions or entities parties to this Amendment (collectively, referred to as the "Lenders"), and HERCULES CAPITAL, INC., a Maryland corporation, in its capacity as administrative agent and collateral agent for itself and the Lenders (as defined in the Loan Agreement) (together with its successors and assigns, in such capacity, the "Agent").

A. Borrower, Lenders and the Agent are parties to that certain Loan and Security Agreement, dated as of September 17, 2021 (as amended by that certain Consent and First Amendment to Loan and Security Agreement dated as of May 3, 2022, as further amended by that certain Second Amendment to Loan and Security Agreement dated as of September 26, 2022, as further amended by that certain Third Amendment to Loan and Security Agreement dated as of May 9, 2023, and as further amended, restated, supplemented or otherwise modified from time to time prior to the date of this Amendment, the "Loan Agreement"). The Lenders have extended credit to Borrower for the purposes permitted in the Loan Agreement.

B. Borrower has requested that Agent and the Lenders amend the Loan Agreement to (i) adjust the availability of Tranche II, Tranche III and Tranche IV and the Term Loan Advances pursuant to Sections 2.1(a)(ii), 2.1(a)(iii) and 2.1(a)(iv) of the Loan Agreement, (ii) incorporate a new Tranche V and Tranche VI pursuant to Sections 2.1(a)(v) and 2.1(a)(vi) of the Loan Agreement, (iii) adjust the parameters of the financial covenants set forth in Section 7.20 of the Loan Agreement, and (iv) make certain other revisions to the Loan Agreement as more fully set forth herein. Agent and Lenders have agreed to so amend certain provisions of the Loan Agreement, but only to the extent, in accordance with the terms, subject to the conditions and in reliance upon the representations and warranties set forth below.

SECTION 1Definitions; Interpretation.

(a) **Terms Defined in Loan Agreement**. All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan Agreement (as amended by this Amendment).

(b) **Rules of Construction**. The rules of construction in Section 1.2 of the Loan Agreement shall be applicable to this Amendment and are incorporated herein by this reference.

SECTION 2Amendments to the Loan Agreement.

(a) Upon the occurrence of the Fourth Amendment Effective Date, the Loan Agreement is hereby amended as follows:

(i) New Definition. The following definitions are added to Section 1.1 of the Loan Agreement in their proper alphabetical order:

""Base Rate" means the greater of (a) (i) the Prime Rate plus (ii) 1.35%, and (b) 9.85%.

"Fourth Amendment" means that certain Fourth Amendment to Loan and Security Agreement, dated as of December 14, 2023, by and among the Borrower, Agent and the Lenders party thereto.

"Fourth Amendment Effective Date" has the meaning given to such term in the Fourth Amendment.

"Modified Rate" means the greater of (a) (i) the Prime Rate plus (ii) 1.00%, and (b) 9.50%.

"Performance Covenant B Milestone Date" means the first date on which Borrower has reported to Agent, subject to verification by Agent (acting reasonably), that T3M Net Product Revenue was no less than $35,000,000 for any three-month period ending on the final day of any month falling from the Fourth Amendment Effective Date until the Term Loan Maturity Date.

"Prime Rate" means the lesser of (a) the "prime rate" as reported in *The Wall Street Journal* or any successor publication thereto, and (b) 9.00%.

"Tranche I" means the advances pursuant to Section 2.1(a)(i).

"Tranche II Facility Charge" means 0.50% of the principal amount of any Advance pursuant to Tranche II, which is payable to Lenders in accordance with Section 4.2(d).

"Tranche III Milestone Date" means the earliest to occur of (a) March 15, 2024, and (b) the date on which Tranche II is drawn in full.

"Tranche IV Milestone Date" means the earliest to occur of (a) June 15, 2024, and (b) the date on which Tranche III is drawn in full.

"Tranche V" means the advances pursuant to Section 2.1(a)(v).

"Tranche V Facility Charge" means 0.50% of the principal amount of any Advance pursuant to Tranche V, which is payable to Lenders in accordance with Section 4.2(g).

"Tranche V Milestone Date" means the first date on which Borrower has reported to Agent, subject to verification by Agent (acting reasonably), that T3M Net Product Revenue was no less than $60,000,000 for any three-month period ending on the final day of any month falling from the Fourth Amendment Effective Date until (and including) June 30, 2025.

"Tranche VI" means the advances pursuant to Section 2.1(a)(vi).

"Tranche VI Facility Charge" means 0.50% of the principal amount of any Advance pursuant to Tranche VI, which is payable to Lenders in accordance with Section 4.2(h).

"Tranche VI Milestone Date" means the first date on which Borrower has reported to Agent, subject to verification by Agent (acting reasonably), that T3M Net Product Revenue was no less than $80,000,000 for any three-month period ending on the final day

of any month falling from the Fourth Amendment Effective Date until (and including) December 31, 2025."

(ii) Amended and Restated Definitions. The following definitions appearing in Section 1.1 of the Loan Agreement are hereby amended in their entirety and replaced with the following:

""Amortization Date" means December 1, 2027.

"Performance Covenant B" means that Borrower at all times maintains Qualified Cash in an amount greater than or equal to (x) the outstanding principal amount of the Term Loan Advances, multiplied by (y) (i) at all times prior to the Performance Covenant B Milestone Date, 50%, and (ii) at all times on and after the Performance Covenant B Milestone Date, 35%.

"Performance Covenant C" means Borrower's achievement of T3M Net Product Revenue equal to or greater than the least of (i) (x) as of any testing date occurring from January 1, 2024 until December 31, 2024, 30% of the amount set forth for the applicable month in the Performance Covenant C Schedule, or (y) thereafter, 25% of the amount set forth for the applicable month in the Performance Covenant C Schedule, and (ii) $120,000,000, tested monthly.

"Performance Covenant C Schedule" means that certain Performance Covenant C Schedule delivered by Borrower to the Agent, and approved by the Agent, after the Third Amendment Effective Date but prior to the Fourth Amendment Effective Date.

"Term Loan Cash Interest Rate" means, for any day, a per annum rate of interest equal to (a) prior to the Fourth Amendment Effective Date, the greater of (i) (x) the prime rate as reported in The Wall Street Journal plus (y) 2.25%, and (ii) 5.50%, and (b) on and from the Fourth Amendment Effective Date, (i) prior to the Tranche VI Milestone Date, the Base Rate, and (ii) on and from the Tranche VI Milestone Date, the Modified Rate.

"Term Loan Maturity Date" means December 1, 2027; provided that if such day is not a Business Day, the Term Loan Maturity Date shall be the immediately preceding Business Day.

"Term Loan PIK Interest Rate" means, for any day, a per annum rate of interest equal to (a) on any day prior to the Fourth Amendment Effective Date, 3.35%, and (b) thereafter, 2.15%.

"Tranche III Facility Charge" means 0.50% of the principal amount of any Advance pursuant to Tranche II, which is payable to Lenders in accordance with Section 4.2(e).

"Tranche IV Facility Charge" means 0.50% of the principal amount of any Advance pursuant to Tranche II, which is payable to Lenders in accordance with Section 4.2(f)."

(iii) Deleted Definitions. The following defined terms set forth in Section 1.1 of the Loan Agreement hereby are deleted in their entirety: "*Availability Trigger*"; "*First Interest Only Extension Conditions*"; "*Initial Performance Covenant Test Date*"; "*Performance Test Period*"; "*PDUFA Action Date*"; "*Second Interest Only Extension Conditions*".

(iv) Amended and Restated Cross References. The following terms appearing in Section 1.2 of the Loan Agreement are hereby amended in their entirety and replaced with the following:

Defined Term	Section
"Agent"	Preamble
"Assignee"	11.13
"Borrower"	Preamble
"Claims"	11.10
"Collateral"	3.1
"Confidential Information"	11.12
"End of Term Charge"	2.5
"Event of Default"	9
"Financial Statements"	7.1
"Initial End of Term Charge"	2.5
"Lenders"	Preamble
"Maximum Rate"	2.2
"Performance Covenant	7.20
Cure"	Cure"
"Prepayment Charge"	2.4
"Publicity Materials"	11.18
"Register"	11.7
"Rights to Payment"	1.1
"SBA"	7.16
"SBIC"	7.16
"SBIC Act"	7.16
"Subsequent End of Term Charge"	2.5

(v) Tranche II Commitment. Section 2.1(a)(ii) of the Loan Agreement is hereby amended in its entirety and replaced with the following:

"(ii) *Tranche II*. Subject to the terms and conditions of this Agreement, beginning on the Fourth Amendment Effective Date and continuing through and including March 15, 2024, Borrower may request, and Lenders shall severally (and not jointly) make, one or more additional Term Loan Advances in minimum increments of $10,000,000 (or if less than $10,000,000, the remaining amount of Term Loan Advances available to be drawn pursuant to this Section 2.1(a)(ii)) in an aggregate principal amount up to $50,000,000. Borrower shall request no less than $40,000,000 in Term Loan Advances under this Section 2.1(a)(ii) on the Fourth Amendment Effective Date."

(vi) Tranche III Commitment. Section 2.1(a)(iii) of the Loan Agreement is hereby amended in its entirety and replaced with the following:

"(iii) *Tranche III*. Subject to the terms and conditions of this Agreement, beginning on the occurrence of the Tranche III Milestone Date and continuing through and

including June 15, 2024, Borrower may request, and Lenders shall severally (and not jointly) make, a single Term Loan Advance in a principal amount of $25,000,000."

(vii) Tranche IV Commitment. Section 2.1(a)(iv) of the Loan Agreement is hereby amended in its entirety and replaced with the following:

"(iv) *Tranche IV*. Subject to the terms and conditions of this Agreement, beginning on the occurrence of the Tranche IV Milestone Date and continuing through and including December 15, 2024, Borrower may request, and Lenders shall severally (and not jointly) make, a single Term Loan Advance in a principal amount of $25,000,000."

(viii) Tranche V Commitment. The following new Section 2.1(a)(v) of the Loan Agreement is hereby inserted in Section 2.1 of the Loan Agreement immediately following Section 2.1(a)(iv):

"(v) *Tranche V*. Subject to the terms and conditions of this Agreement, beginning on the occurrence of the Tranche V Milestone Date and continuing through and including the earlier of (A) June 30, 2025 and (B) the date which is 90 days after the Tranche V Milestone Date, Borrower may request, and Lenders shall severally (and not jointly) make, one or more additional Term Loan Advances in minimum increments of $25,000,000 (or if less than $25,000,000, the remaining amount of Term Loan Advances available to be drawn pursuant to this Section 2.1(a)(v)) in an aggregate principal amount up to $50,000,000."

(ix) Tranche VI Commitment. The following new Section 2.1(a)(vi) of the Loan Agreement is hereby inserted in Section 2.1 of the Loan Agreement immediately following Section 2.1(a)(v):

"(vi) *Tranche VI*. Subject to the terms and conditions of this Agreement, beginning on the occurrence of the Tranche VI Milestone Date and continuing through and including the earlier of (A) December 31, 2025 and (B) the date which is 90 days after the Tranche VI Milestone Date, Borrower may request, and Lenders shall severally (and not jointly) make, one or more additional Term Loan Advances in minimum increments of $25,000,000 (or if less than $25,000,000, the remaining amount of Term Loan Advances available to be drawn pursuant to this Section 2.1(a)(vi)) in an aggregate principal amount up to $50,000,000."

(x) Advance Request. Section 2.1(b) of the Loan Agreement is hereby amended in its entirety and replaced with the following:

"(b) Advance Request. To obtain a Term Loan Advance, Borrower shall complete, sign and deliver an Advance Request to Agent at least ten (10) Business Days (or such shorter period as the Agent may agree to in its sole discretion) before the Advance Date, other than the Term Loan Advance to be made on the Closing Date or the Fourth Amendment Effective Date, which shall be at least one (1) Business Day before the Advance Date. Lenders shall fund the Term Loan Advance in the manner requested by the Advance Request provided that each of the conditions precedent to such Term Loan Advance is satisfied as of the requested Advance Date. The proceeds of any Term Loan Advance shall be deposited into an account that is subject to an Account Control Agreement.

(xi) Prepayment. Section 2.4 of the Loan Agreement is hereby amended in its entirety and replaced with the following:

"2.4 Prepayment. At its option, Borrower may at any time prepay all or a portion of the outstanding Advances by paying the entire principal balance (or such portion thereof), all accrued and unpaid interest thereon, together with a prepayment charge equal to (a) where such prepayment occurs prior to October 1, 2026, one and one quarter percent (1.25%) of the principal amount of the Advance being prepaid, or (b) where such prepayment occurs on or after October 1, 2026, one-half of one percent (0.50%) of the principal amount of the Advance being prepaid (a "Prepayment Charge"). Borrower agrees that the Prepayment Charge is a reasonable calculation of Lenders' lost profits in view of the difficulties and impracticality of determining actual damages resulting from an early repayment of the Advances. Borrower shall prepay the outstanding amount of all principal and accrued interest through the prepayment date upon the occurrence of a Change in Control. Notwithstanding the foregoing, Agent and Lenders agree to waive the Prepayment Charge if (i) Borrower prepays all the outstanding advances as the result of the occurrence of a Change in Control, or (ii) Agent and Lenders or their respective Affiliates (in their sole and absolute discretion) agree in writing to refinance the Advances prior to the Term Loan Maturity Date. Any amounts paid under this Section shall be applied by Agent to the then unpaid amount of any Secured Obligations (including principal and interest) pro rata to all scheduled amounts owed. For the avoidance of doubt, if a payment hereunder becomes due and payable on a day that is not a Business Day, the due date thereof shall be the immediately preceding Business Day."

(xii) End of Term Charge. Section 2.5 of the Loan Agreement is hereby amended in its entirety and replaced with the following:

"2.5 End of Term Charge. On the earliest to occur of (i) October 1, 2026, (ii) the date that Borrower prepays the outstanding Secured Obligations (other than any inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) in full, or (iii) the date that the Secured Obligations become due and payable in full pursuant to the terms of this Agreement, Borrower shall pay Lenders a charge of Seven Million Five Hundred Thousand Dollars ($7,500,000) (the "Initial End of Term Charge"). On the earliest to occur of (i) the Term Loan Maturity Date, (ii) the date that Borrower prepays the outstanding Secured Obligations (other than any inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) in full, or (iii) the date that the Secured Obligations become due and payable in full pursuant to the terms of this Agreement, Borrower shall pay Lenders a charge of the sum of (A) One Million Dollars ($1,000,000), plus (B) 3.00% of the aggregate original principal amount of the Term Loan Advances made hereunder (but excluding the original principal amount of the Term Loan Advances made under Tranche I) (the "Subsequent End of Term Charge"; together with the Initial End of Term Charge, collectively, the "End of Term Charge"). Notwithstanding the required payment date of such End of Term Charge, the applicable pro rata portion of the End of Term Charge shall be deemed earned by Lenders on the date the applicable Term Loan Advance is made. For the avoidance of doubt, if a payment hereunder becomes due and payable on a day that is not a Business Day, the due date thereof shall be the immediately preceding Business Day."

(xiii) Treatment of Prepayment Charge and End of Term Charge. All references to "the Closing Date" in Section 2.8 of the Loan Agreement shall hereby be amended in their entirety and replaced with "the Closing Date and the Fourth Amendment Effective Date".

(xiv) Further Conditions Precedent. Section 4.2 of the Loan Agreement is hereby amended in its entirety and replaced with the following:

"4.2 All Advances. On each Advance Date:

(a) Agent shall have received (i) an Advance Request for the relevant Advance as required by Section 2.1(b), duly executed by Borrower's Chief Executive Officer, Chief Financial Officer or Chief Accounting Officer, and (ii) any other documents Agent may reasonably request in its good faith business discretion.

(b) The representations and warranties set forth in this Agreement shall be true and correct in all material respects on and as of the applicable Advance Date with the same effect as though made on and as of such date, except to the extent such representations and warranties expressly relate to an earlier date.

(c) Borrower shall be in compliance with all the terms and provisions set forth herein and in each other Loan Document on its part to be observed or performed, and at the time of and immediately after such Advance no Event of Default shall have occurred and be continuing.

(d) With respect to any Advance pursuant to Tranche II, Borrower shall have paid the Tranche II Facility Charge.

(e) With respect to any Advance pursuant to Tranche III, Borrower shall have paid the Tranche III Facility Charge.

(f) With respect to any Advance pursuant to Tranche IV, Borrower shall have paid the Tranche IV Facility Charge.

(g) With respect to any Advance pursuant to Tranche V, Borrower shall have paid the Tranche V Facility Charge.

(h) With respect to any Advance pursuant to Tranche VI, Borrower shall have paid the Tranche VI Facility Charge.

Each Advance Request shall be deemed to constitute a representation and warranty by Borrower on the relevant Advance Date as to the matters specified in subsections (b) and (c) of this Section 4.2 and as to the matters set forth in the Advance Request."

(xv) Minimum Cash. Section 7.20(a)(i) of the Loan Agreement is hereby amended in its entirety and replaced with the following:

"At all times, Borrower shall maintain Qualified Cash in an amount greater than or equal to (x) the outstanding aggregate principal amount of the Term Loan Advances, multiplied by (y) 20%."

(xvi) Performance Covenant. Section 7.20(b) of the Loan Agreement is hereby amended in its entirety and replaced with the following:

"(b) Performance Covenant. Beginning on such date for which financial statements have been (or are required to be delivered) under Section 7.1(a) for the month ending September 30, 2024 and at all times thereafter, Borrower shall satisfy either of (i) Performance Covenant A or Performance Covenant B, tested at all times, or (ii) Performance Covenant C, tested monthly."

(xvii) Exhibit A to the Loan Agreement is hereby replaced with Exhibit A attached hereto.

(xviii) Exhibit E to the Loan Agreement is hereby replaced with Exhibit E attached hereto.

(xix) Exhibit I to the Loan Agreement is hereby deleted in its entirety.

(xx) Schedule 1.1(a) to the Loan Agreement is hereby replaced with Schedule 1.1(a) attached hereto.

(b) **References Within Loan Agreement**. Each reference in the Loan Agreement to "this Agreement" and the words "hereof," "herein," "hereunder", or words of like import, shall mean and be a reference to the Loan Agreement as amended by this Amendment. This Amendment shall be a Loan Document.

SECTION 3Amendment Fee. Borrower will pay to Agent, for the account of the Lenders (in accordance with Section 2.6 of the Loan Agreement), an amendment fee (the "Amendment Fee") equal to Two Hundred Fifty Thousand Dollars ($250,000). The Amendment Fee shall be fully earned, due and payable on the date hereof.

SECTION 4Conditions of Effectiveness. The effectiveness of this Amendment (the "Fourth Amendment Effective Date") shall be subject to Agent's receipt of the following documents, in form and substance satisfactory to Agent, or, as applicable, the following conditions being met:

(a) this Amendment, executed by Agent, each Lender and Borrower;

(b) Borrower shall have paid (i) the Amendment Fee, (ii) the Tranche II Facility Charge payable for the Term Loan Advances requested pursuant to Section 4(c), (iii) all invoiced costs and expenses then due in accordance with Section 7(d), and (iv) all other fees, costs and expenses, if any, due and payable as of the date hereof under the Loan Agreement;

(c) Borrower shall have submitted an Advance Request for Term Loan Advances under Tranche II in an amount that is no less than $40,000,000;

(d) a good standing certificate of Borrower, certified by the Secretary of State of Delaware, dated as of a date no earlier than 30 days prior to the date hereof;

(e) certified copies, dated as of a recent date, of financing statement and other lien searches of Borrower, as Agent may request and which shall be obtained by Agent, accompanied by written evidence (including any UCC termination statements) that the Liens revealed in any such searches either (i) will be terminated prior to or in connection with the execution of this Amendment, or (ii) in the sole discretion of Agent, will constitute Permitted Liens; and

(f) on the Fourth Amendment Effective Date, immediately after giving effect to the amendment of the Loan Agreement contemplated hereby:

(i) the representations and warranties contained in Section 5 shall be true and correct on and as of the Fourth Amendment Effective Date as though made on and as of such date; and

(ii) there exist no Events of Default or events that with the passage of time would result in an Event of Default.

SECTION 5Representations and Warranties. To induce Agent and Lenders to enter into this Amendment, Borrower hereby confirms, as of the date hereof, (a) that the representations and warranties made by it in Section 5 of the Loan Agreement and in the other Loan Documents are true and correct in all material respects; *provided*, *however*, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; *provided, further,* that to the extent such representations and warranties by their terms expressly relate only to a prior date such representations and warranties shall be true and correct as of such prior date, and (a) that no Event of Default has occurred and is continuing; (b) that there has not been and there does not exist a Material Adverse Effect; (c) Lenders have and shall continue to have valid, enforceable and perfected first-priority liens, subject only to Permitted Liens, on and security interests in the Collateral and all other collateral heretofore granted by Borrower to Lenders, pursuant to the Loan Documents or otherwise granted to or held by Lenders; (d) the agreements and obligations of Borrower contained in the Loan Documents and in this Amendment constitute the legal, valid and binding obligations of Borrower, enforceable against Borrower in accordance with their respective terms, except as the enforceability thereof may be limited by bankruptcy, insolvency or other similar laws of general application affecting the enforcement of creditors' rights or by the application of general principles of equity; and (e) the execution, delivery and performance of this Amendment by Borrower will not violate any law, rule, regulation, order, contractual obligation or organizational document of Borrower and will not result in, or require, the creation or imposition of any lien, claim or encumbrance of any kind on any of its properties or revenues. For the purposes of this **Error! Reference source not found.**5, each reference in Section 5 of the Loan Agreement to "this Agreement," and the words "hereof", "herein", "hereunder", or words of like import in such Section, shall mean and be a reference to the Loan Agreement as amended by this Amendment.

SECTION 6Release. In consideration of the agreements of Agent and each Lender contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Borrower, on behalf of itself and its successors, assigns, and other legal representatives, hereby to the extent possible under applicable law fully, absolutely, unconditionally and irrevocably releases, remises and forever discharges Agent and each Lender, and its successors and assigns, and its present and former shareholders, affiliates, subsidiaries, divisions, predecessors, directors, officers, attorneys, employees, agents and other representatives (Agent, Lenders and all such other persons being hereinafter referred to collectively as the "**Releasees**" and individually as a "**Releasee**"), of and from all demands, actions, causes of action, suits, covenants, contracts, controversies, agreements, promises, sums of money, accounts, bills, reckonings, damages and any and all other claims, counterclaims, defenses, rights of set-off, demands and liabilities whatsoever of every name and nature, known or unknown, suspected or unsuspected, both at law and in equity, which Borrower, or any of its successors, assigns, or other legal representatives may now or hereafter own, hold, have or claim to have against the Releasees or any of them for, upon, or by reason of any circumstance, action, cause or thing whatsoever which arises at any time on or prior to the day and date of this Amendment, for or on account of, or in relation to, or in any way in connection with the Loan Agreement, or any of the other Loan Documents or transactions thereunder or related thereto. Borrower understands, acknowledges and agrees that the release set forth above may be pleaded as a full and complete defense and may be used as a basis for an injunction against any action, suit or other proceeding which may be instituted, prosecuted or attempted in breach of the provisions of such

release. Borrower agrees that no fact, event, circumstance, evidence or transaction which could now be asserted or which may hereafter be discovered shall affect in any manner the final, absolute and unconditional nature of the release set forth above.

SECTION 7Miscellaneous.

(a) **Loan Documents Otherwise Not Affected; Reaffirmation; No Novation**.

(i) Except as expressly amended pursuant hereto or referenced herein, the Loan Agreement and the other Loan Documents shall remain unchanged and in full force and effect and are hereby ratified and confirmed in all respects. The Lenders' and Agent's execution and delivery of, or acceptance of, this Amendment shall not be deemed to create a course of dealing or otherwise create any express or implied duty by any of them to provide any other or further amendments, consents or waivers in the future.

(ii) Borrower hereby expressly (1) reaffirms, ratifies and confirms its Secured Obligations under the Loan Agreement and the other Loan Documents, (2) reaffirms, ratifies and confirms the grant of security under Section 3 of the Loan Agreement, (3) reaffirms that such grant of security in the Collateral secures all Secured Obligations under the Loan Agreement, including without limitation any Term Loan Advances funded on or after the Fourth Amendment Effective Date, as of the date hereof, and with effect from (and including) the Fourth Amendment Effective Date, such grant of security in the Collateral: (x) remains in full force and effect notwithstanding the amendments expressly referenced herein; and (y) secures all Secured Obligations under the Loan Agreement, as amended by this Amendment, and the other Loan Documents, (4) agrees that this Amendment shall be a "Loan Document" under the Loan Agreement, and (5) agrees that the Loan Agreement and each other Loan Document shall remain in full force and effect following any action contemplated in connection herewith.

(iii) This Amendment is not a novation and the terms and conditions of this Amendment shall be in addition to and supplemental to all terms and conditions set forth in the Loan Documents. Nothing in this Amendment is intended, or shall be construed, to constitute an accord and satisfaction of Borrower's Secured Obligations under or in connection with the Loan Agreement and any other Loan Document or to modify, affect or impair the perfection or continuity of Agent's security interest in, (on behalf of itself and the Lenders) security titles to or other liens on any Collateral for the Secured Obligations.

(b) **Conditions**. For purposes of determining compliance with the conditions specified in Section 4, each Lender that has signed this Amendment shall be deemed to have consented to, approved or accepted or to be satisfied with, each document or other matter required thereunder to be consented to or approved by or acceptable or satisfactory to the Lenders unless Agent shall have received notice from such Lender prior to the date hereof specifying its objection thereto.

(c) **No Reliance**. Borrower hereby acknowledges and confirms to Agent and Lenders that Borrower is executing this Amendment on the basis of its own investigation and for its own reasons without reliance upon any agreement, representation, understanding or communication by or on behalf of any other Person.

(d) **Costs and Expenses**. Borrower agrees to pay to Agent on the date hereof the out-of-pocket costs and expenses of Agent and each Lender party hereto, and the documented out-of-pocket fees and disbursements of counsel to Agent and each Lender party hereto in connection with the negotiation, preparation, execution and delivery of this Amendment and any other documents to be delivered in connection herewith on the date hereof.

(e) **Binding Effect**. This Amendment binds and is for the benefit of the successors and permitted assigns of each party.

(f) **Governing Law.** THIS AMENDMENT AND THE OTHER LOAN DOCUMENTS SHALL BE GOVERNED BY, AND CONSTRUED AND ENFORCED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF CALIFORNIA, EXCLUDING CONFLICT OF LAWS PRINCIPLES THAT WOULD CAUSE THE APPLICATION OF LAWS OF ANY OTHER JURISDICTION.

(g) **Complete Agreement; Amendments**. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to such subject matter. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Amendment and the Loan Documents merge into this Amendment and the Loan Documents.

(h) **Severability of Provisions.** Each provision of this Amendment is severable from every other provision in determining the enforceability of any provision.

(i) **Counterparts**. This Amendment may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Amendment. Delivery of an executed counterpart of a signature page of this Amendment by facsimile, portable document format (.pdf) or other electronic transmission will be as effective as delivery of a manually executed counterpart hereof.

(j) **Electronic Execution of Certain Other Documents**. The words "execution," "execute", "signed," "signature," and words of like import in or related to any document to be signed in connection with this Amendment and the transactions contemplated hereby (including without limitation assignments, assumptions, amendments, waivers and consents) shall be deemed to include electronic signatures, the electronic matching of assignment terms and contract formations on electronic platforms approved by the Agent, or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the California Uniform Electronic Transactions Act, or any other similar state laws based on the Uniform Electronic Transactions Act.

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IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment, as of the date first above written.

BORROWER:

PHATHOM PHARMACEUTICALS, INC.

Signature: /s/ Molly Henderson

Print Name: Molly Henderson

Title: Chief Financial and Business Officer

[SIGNATURES CONTINUE ON THE NEXT PAGE]

AGENT:
HERCULES CAPITAL, INC.

Signature: /s/ Seth Meyer

Print Name: Seth Meyer

Title: Chief Financial Officer

LENDERS:

HERCULES CAPITAL, INC.

Signature: /s/ Seth Meyer

Print Name: Seth Meyer

Title: Chief Financial Officer

HERCULES VENTURE GROWTH CREDIT OPPORTUNITIES FUND 1 L.P.

By: Hercules Adviser LLC, its Investment Adviser

Signature: /s/ Seth Meyer

Print Name: Seth Meyer

Title: Authorized Signatory

HERCULES PRIVATE CREDIT FUND 1 L.P.

By: Hercules Adviser LLC, its Investment Adviser

By: /s/ Seth Meyer

Print Name: Seth Meyer

Title: Authorized Signatory

HERCULES PRIVATE GLOBAL VENTURE GROWTH FUND I L.P.

By: Hercules Private Global Venture Growth Fund GP I LLC, its general partner

By: Hercules Adviser LLC, its sole member

Signature: /s/ Seth Meyer

Print Name: Seth Meyer

Title: Chief Financial Officer

SAGARD HEALTHCARE PARTNERS (DELAWARE), LP

By: Sagard Healthcare Royalty Partners GP LLC, its general partner

Signature: /s/ Jason Sneah

Print Name: Jason Sneah

Title: Manager

Signature: /s/ Adam Vigna

Print Name: Adam Vigna

Title: Chief Investment Officer

Table of Exhibits and Schedules

Exhibit A: Advance Request

Exhibit E: Compliance Certificate

Schedule 1.1(a): Term Commitments

Exhibit 10.28

PHATHOM PHARMACEUTICALS BONUS PLAN
Effective January 1, 2024

INTRODUCTION AND PURPOSE

The Phathom Pharmaceuticals (“Phathom” or the “Company”) Bonus Plan (the “Plan”) is designed to reward eligible employees for the achievement of corporate objectives, as well as measured individual objectives that are consistent with and support the overall corporate objectives. Since cooperation between departments and employees will be required to achieve corporate objectives that represent a significant portion of the Plan, the Plan should help foster teamwork and build a cohesive management team. For purposes of the Plan, the "Plan year" will mean each calendar year.

The Plan is designed to:

- Encourage high performance by providing an incentive program to achieve overall corporate objectives and to enhance shareholder value.
- Reward those individuals who significantly impact corporate results.
- Encourage increased teamwork among all disciplines within Phathom.
- Incorporate an incentive program in the Phathom overall compensation program to help attract and retain employees.
- Provide an incentive for eligible employees to remain employed by Phathom through and beyond the payout of any earned bonus.

ELIGIBILITY

All regular employees are eligible to participate in the Plan. Employees are not eligible if included in a separate formal incentive plan provided by the Company. In order to be eligible, a participant must remain employed through the date awards are paid for a Plan year. If the participant is not employed on the date awards are paid, the participant will not have earned any bonus. If the participant has been subject to a performance improvement plan or other disciplinary procedure during the Plan year, any award to such individual will be at the discretion of the CEO or Chief Human Resources Officer, with respect to executive officers, the Compensation Committee.

Change in Status During the Plan Period:

a. *Participants hired during the Plan year:*
   - Participants hired during the Plan year are eligible for a prorated award based the number of days employed in an eligible position.

b. *Promotion/change in level:*
   - For promotions that occur after the fourth month of the applicable Plan year, the calculation will be prorated, based on the number

of months at each bonus percentage level.

c. *Transfer to a position that is included in a separate formal Incentive Plan:* Awards will be pro-rated using the same discipline as outlined for promotions above and in the separate formal incentive plan.
d. *Termination of employment:*
   - If a participant's employment is terminated voluntarily prior to the date awards are paid, the participant will not be eligible to receive an award.
   - If a participant's employment is terminated involuntarily prior to the date awards are paid, it will be at the absolute discretion of the Company whether or not an award payment is made.
e. *Leave of Absence:* Employee may be considered for a prorated award in the event of a leave of absence during the Plan year. The proration requirement can be waived at the discretion of the CEO or Chief Human Resources Officer, or for members of Executive Leadership team at the discretion of the Compensation Committee.

AWARD CALCULATION

Awards will be determined by applying a "bonus percentage" to the participant's base salary earned or hourly wages earned during the Plan year. While the Compensation Committee may change the bonus percentage for any Plan year, the following bonus percentages will initially be used for this purpose:

Position Title	Bonus Percentage
CEO	65%
COO	50%
Executive Leadership Team	45%
VP	30%
Senior Director, Director	25%
Associate Director	20%
Senior Manager, Manager	15%
Below Manager	10%

Corporate and Individual Performance Factors

The CEO will present to the Compensation Committee a list of weighted corporate objectives for the applicable Plan year, which are subject to approval by the Compensation Committee. All participants in the Plan will then develop a list of key individual objectives, which must be approved by the responsible Vice President or Senior Vice President and, in the case of executive officers, by the CEO.

The relative weight between corporate and individual performance factors varies based on the individual's assigned level within the organization. The weighting may be reviewed periodically and may be adjusted for any Plan year. The weighting for the performance factors will initially be as follows:

	Corporate	Individual
Executive Leadership Team	100%	—
Vice President and Above	80%	20%
Director Level	70%	30%
Senior Manager and Below	60%	40%

Performance Award Multipliers

Separate award multipliers will be established for both the corporate and, if applicable, the individual components of each award. The award multiplier for the corporate component shall be determined by the Compensation Committee each Plan year, in its sole discretion. The same award multiplier for the corporate component of the award shall be used for all Plan participants. The award multiplier for the individual component shall be determined by the responsible Vice President or Senior Vice President and by the President and / or CEO.

While the Compensation Committee may change the award multipliers for any Plan year, the following scale will be used to determine the actual performance award multiplier based upon the measurement of corporate and, if applicable, individual performance objectives.

Corporate Award Multipliers

Performance Category	Award Multiplier
1. Performance was truly outstanding or exceeded all objectives	125% - 150%
2. Performance met or exceeded all objectives or was excellent in view of prevailing conditions	100% - 125%
3. Performance generally met the year's objectives and was very acceptable in view of prevailing conditions	50% - 100%
4. Performance for the year met some, but not all, objectives	0% - 50%
5. Performance for the year was not acceptable in view of prevailing conditions	0%

Example for Employee (Other than Executive Leadership Team)

The example below shows a sample cash bonus award calculation under the Plan for a non-executive employee, which is determined after the end of the Plan year.

Step #1: A potential target bonus award is calculated by multiplying the employee's base salary by the participant's assigned target bonus percentage.

Step #2: The calculated potential target bonus award is then split between the corporate and individual performance factors by the employee's assigned level (per the weighting above). This calculation establishes specific potential dollar awards for the performance period based on both the individual and corporate performance factor components.

Step #3: After the end of the Plan year, corporate and individual award multipliers will be established using the criteria described above. Awards are determined by multiplying the potential target bonus awards in Step #2 by the actual corporate and individual award multipliers.

Example: Step #1: Determine Target Bonus Award

Position:	Associate Director
Base salary:	$100,000
Target bonus percentage:	20%
Potential target bonus:	$ 20,000

Step #2: Split Target Bonus Award Based on Corporate/Individual Weightings

Potential corporate performance bonus (70%): $ 14,000 Potential individual performance bonus (30%): $ 6,000

Step # 3: Actual Bonus Award Calculation

Assumed payment multipliers based on assessment of corporate and individual performance:

Corporate multiplier 75%-performance generally met objectives
Individual multiplier 125%-performance exceeded objectives

Cash Award:

Corporate component	$ 10,500 ($14,000 x 75%)
Individual component	$ 7,500 ($ 6,000 x 125%)
Total Award	**$ 17,500**

AWARD PAYMENTS

Bonus award payments may be made in cash, through the issuance of stock, stock options or another form of equity award, or by a combination of cash, stock, stock options and/or another form of equity award, at the discretion of the Compensation Committee. All bonus award payments are subject to applicable tax withholdings. In the event that the Compensation Committee elects to pay bonus awards in stock or stock options, the Compensation Committee, in its sole discretion, will make a determination as to the number of shares of stock or stock options to be issued to each Plan participant in satisfaction of such bonus awards. The issuance of stock and stock options may also be subject to the approval of the Company's stockholders, and any stock options issued will be subject to the terms and conditions of the Company's equity plan.

Payment of bonus awards will be made at such times as determined by the Compensation Committee, but not later than four months following the Plan year.

PLAN PROVISIONS

Governance

The Plan will be administered by the Compensation Committee of the Board of Directors (the "Compensation Committee"). The CEO and Chief Human Resources Officer of Phathom will be responsible for the administration of the Plan with respect to non-executive employees. The Compensation Committee will be responsible for approving any compensation or incentive awards to executive officers of the Company. All determinations of the Compensation Committee or the CEO and Chief Human Resources Officer, as applicable, under the Plan, shall be final and binding on all Plan participants.

Compensation Committee's Absolute Right to Alter or Abolish the Plan

The Compensation Committee reserves the right in its absolute discretion to abolish the Plan at any time or to alter the terms and conditions under which incentive compensation will be paid. Such discretion may be exercised any time before, during, and after the Plan year is completed. No participant shall have any vested right to receive any compensation hereunder until actual delivery of such compensation. Participation in the Plan at any given time does not guarantee ongoing participation.

Employment Duration/Employment Relationship

This Plan does not, and Phathom's policies and practices in administering this Plan do not, constitute an express or implied contract or other agreement concerning the duration of any participant's employment with the Company. The employment relationship of each participant is "at will" and may be terminated at any time by Phathom or by the participant, with or without cause.

Plan Unfunded

The Plan shall be unfunded. Amounts payable under the Plan are not and will not be transferred into a trust or otherwise set aside. The Company shall not be required to establish any special or separate fund or to make any other segregation of assets to assure the payment of any award under the Plan. Any accounts under the Plan are for bookkeeping purposes only and do not represent a claim against the specific assets of the Company.

Rights Not Transferable

No rights of any participant to payments of any amounts under the Plan may be sold, transferred, pledged, assigned, or otherwise alienated or hypothecated. All

rights with respect to an award granted to a participant under the Plan shall be available during his or her lifetime only to the participant.

Governing Law
The Plan shall be construed, interpreted and the rights of the parties determined in accordance with the laws of the State of New Jersey (without regard to principles of conflicts of law).

Any questions pertaining to this plan should be directed to the Human Resources Department.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

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

(1) Registration Statement (Form S-8 No. 333-234357) pertaining to the 2019 Equity Incentive Plan, 2019 Incentive Award Plan, and 2019 Employee Stock Purchase Plan of Phathom Pharmaceuticals, Inc.,

(2) Registration Statement (Form S-8 No. 333-263420) pertaining to the 2019 Incentive Award Plan and 2019 Employee Stock Purchase Plan of Phathom Pharmaceuticals, Inc., and

(3) Registration Statement (Form S-3 No. 333-275431) of Phathom Pharmaceuticals, Inc.;

of our report dated March 7, 2024, with respect to the financial statements of Phathom Pharmaceuticals, Inc. included in this Annual Report (Form 10-K) of Phathom Pharmaceuticals, Inc. for the year ended December 31, 2023.

/s/ Ernst & Young

Iselin, New Jersey
March 7, 2024

Exhibit 24.1

LIMITED POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person or entity whose signature appears below constitutes, designates and appoints each of Terrie Curran and Molly Henderson, each of whom are officers of Phathom Pharmaceuticals, Inc. (the "Company"), as its true and lawful attorneys-in-fact and agent, each with power of substitution, with full power to act without the other and on behalf of and as attorney for me, for the purpose of executing and filing with the Securities and Exchange Commission the Company's Annual Report on Form 10-K for the year ended December 31, 2023, and any and all amendments thereto, and to do all such other acts and execute all such other instruments which said attorney may deem necessary or desirable in connection therewith.

Signature	**Title**	**Date**
/s/ Michael Cola Michael Cola	Director	March 7, 2024
/s/ Frank Karbe Frank Karbe	Director	March 7, 2024
/s/ Heidi Kunz Heidi Kunz	Director	March 7, 2024
/s/ Asit Parikh Asit Parikh	Director	March 7, 2024
/s/ David Socks David Socks	Director	March 7, 2024
/s/ Mark Stenhouse Mark Stenhouse	Director	March 7, 2024
/s/ James Topper James Topper	Director	March 7, 2024

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Terrie Curran, certify that:

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

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

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

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

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

   b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

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

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

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

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

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

Date: March 7, 2024

/s/ Terrie Curran

Terrie Curran

Chief Executive Officer and President
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Molly Henderson, certify that:

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

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

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

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

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

   b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

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

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

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

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

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

Date: March 7, 2024

/s/ Molly Henderson

Molly Henderson

Chief Financial and Business Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Phathom Pharmaceuticals, Inc. (the "Company") for the year ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Terrie Curran, as Chief Executive Officer of the company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to my knowledge, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Date: March 7, 2024

/s/ Terrie Curran
Terrie Curran
Chief Executive Officer and President

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.

Exhibit 32.2

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Phathom Pharmaceuticals, Inc. (the "Company") for the year ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Molly Henderson, as Principal Financial Officer of the company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to my knowledge, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Date: March 7, 2024

/s/ Molly Henderson

Molly Henderson
Chief Financial and Business Officer
(Principal Financial Officer)

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.

PHATHOM PHARMACEUTICALS, INC. POLICY FOR RECOVERY OF ERRONEOUSLY AWARDED COMPENSATION

Phathom Pharmaceuticals, Inc. (the "***Company***") has adopted this Policy for Recovery of Erroneously Awarded Compensation (the "***Policy***"), effective as of October 2, 2023 (the "***Effective Date***"). Capitalized terms used in this Policy but not otherwise defined herein are defined in Section 11.

1. Persons Subject to Policy

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

2. Compensation Subject to Policy

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

3. Recovery of Compensation

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

4. Manner of Recovery; Limitation on Duplicative Recovery

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

5. Administration

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

6. Interpretation

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

7. No Indemnification; No Liability

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

8. Application; Enforceability

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

Company.

9. Severability

The provisions in this Policy are intended to be applied to the fullest extent of the law; provided, however, to the extent that any provision of this Policy is found to be unenforceable or invalid under any applicable law, such provision will be applied to the maximum extent permitted and shall automatically be deemed amended in a manner consistent with its objectives to the extent necessary to conform to any limitations required under applicable law.

10. Amendment and Termination

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

11. Definitions

"***Applicable Rules***" means Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder, the listing rules of the national securities exchange or association on which the Company's securities are listed, and any applicable rules, standards or other guidance adopted by the Securities and Exchange Commission or any national securities exchange or association on which the Company's securities are listed.

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

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

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

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

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

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

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

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

of the Company, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and the regulations thereunder.

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

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

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