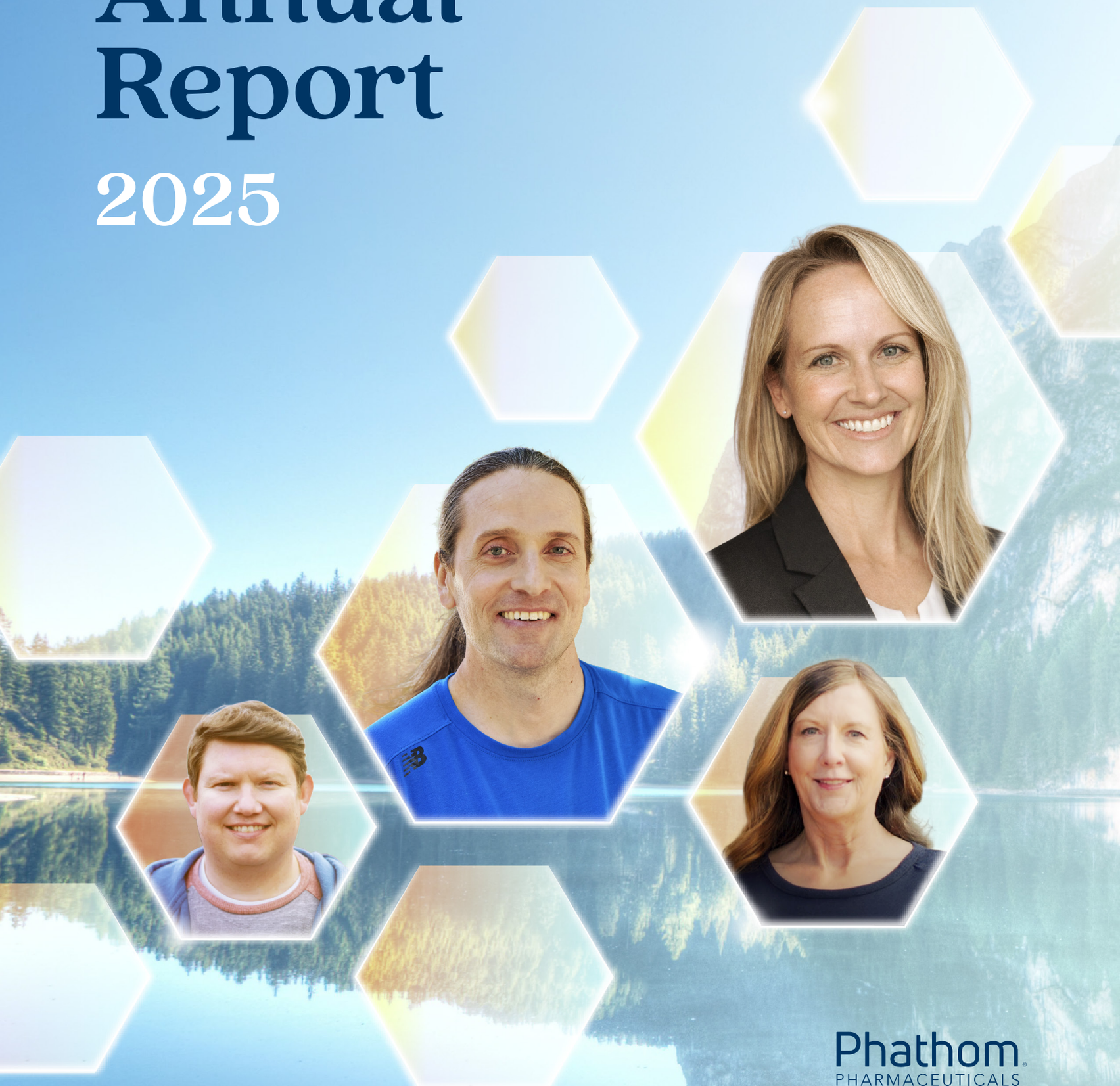
CHANGING THE LANDSCAPE IN GI

Annual Report 2025



Phathom PHARMACEUTICALS

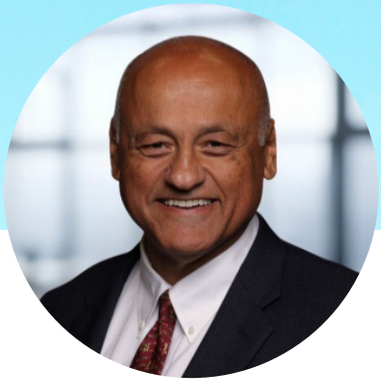
OUR MISSION IS TO ADVANCE GI CARE AND IMPROVE PATIENTS' LIVES

We are committed to developing and delivering innovative therapies that address unmet needs in gastrointestinal (GI) diseases.

Our team is working to usher in a new era of treatment to reshape the GI landscape, guided by a vision to improve care and help patients live healthier lives.

Cover:
Erin, *treated for Erosive Gastroesophageal Reflux Disease (GERD)*
Carson, *treated for Non-Erosive GERD*
Kevin, *treated for Erosive GERD*
LaDawn, *treated for H. pylori infection*

Inside Cover:
Carson, *treated for Non-Erosive GERD*
Judy, *treated for Non-Erosive GERD*
Erin, *treated for Erosive GERD, and her partner*



A Note from Phathom's President & CEO

To Our Stockholders,

2025 was a pivotal year for Phathom Pharmaceuticals as we sharpened our focus on becoming a leader in gastroenterology (GI) and repositioned the company with what we believe is a clear path to profitability.

I joined Phathom in April 2025 because it was clear the company had an extraordinary opportunity. VOQUEZNA® (vonoprazan) expands the range of treatment options for patients with GERD, a condition that remains challenging for many. We are energized by the potential to address ongoing unmet needs in this large patient population. To fully capture this opportunity, we needed to better align our spending and refocus our commercial strategy.

We took deliberate steps to focus our efforts on gastroenterologists who typically treat patients with more persistent GERD symptoms, while also reducing expenses and working to stabilize our financial position. To support this shift, we realigned Phathom's sales team to enable them to spend significantly more time with gastroenterologists and associated physician assistants and nurse practitioners. This targeted focus on GI providers, who have a high concentration of patients who may benefit from VOQUEZNA, contributed to strong sales growth in 2025 while reducing quarterly cash operating expenses by nearly 50%.

In 2025, Phathom generated $175.1 million in net revenue, representing 217% year-over-year growth, and surpassed one million total VOQUEZNA prescriptions filled since launch. We believe we have set the company on a path to continue growing revenue and reach operating profitability.

Building on the strengthened operating performance of our business, we also recently improved the capital structure and financial stability of Phathom. In January 2026, we raised additional capital through a successful equity offering, and in February we modified our term debt to lower our interest costs, reduce the remaining principal and extend the maturity date.

Our GI-focused commercial strategy has been a key driver of performance this past year. Gastroenterologists and their care teams represented the core engine of our commercial growth in 2025, and we believe, will continue to do so for several years. These healthcare providers collectively write approximately 20 million prescriptions each year for proton pump inhibitors (PPIs) and accounted for more than 70% of VOQUEZNA prescriptions in 2025. As positive physician and patient experience with VOQUEZNA continues to expand, we believe we will capture a growing share of the GERD market.

Over time, we believe we have the opportunity to reach $1 billion in annual net revenue from prescriptions through gastroenterologists and associated providers, which would represent conversion of a meaningful portion of PPI prescriptions within this segment. Some high-volume prescribers have already demonstrated meaningful utilization in their clinical practice, and we are working to broaden and deepen adoption of VOQUEZNA for GERD across the gastroenterology community.

As we increase adoption among gastroenterologists, we believe this may also support growth in prescriptions from primary care physicians (PCPs). Patients with persistent or worsening GERD symptoms are often referred to gastroenterologists after initial management by their primary care physician. As experience with VOQUEZNA in GERD expands in GI care, PCPs may become increasingly familiar with its use through the ongoing management of these patients, supporting the potential for broader adoption among PCPs over time.

Importantly, in 2025, the FDA updated the Orange Book for VOQUEZNA tablets to reflect regulatory exclusivity through May 2032, supporting our confidence in a multi-year opportunity to grow VOQUEZNA revenue.

We may also have the potential to extend exclusivity by an additional six months, subject to the outcome of our pHalcon-EoE-201 clinical trial, a Phase 2 study evaluating VOQUEZNA in eosinophilic esophagitis (EoE). Any such extension would depend on the results of the Phase 2 study, our decision to advance development, including initiating and completing a subsequent Phase 3 trial, and receipt of a written request from the FDA to include pediatric patients in the Phase 3 trial.

Looking ahead, our ambition extends beyond VOQUEZNA. Our vision is to build Phathom into a leading GI-focused company that develops and commercializes innovative therapies that address meaningful unmet needs in gastroenterology. As we deepen relationships within the GI community, we believe we are well positioned to pursue opportunities that complement our GI-focused capabilities.

Our success in 2025 is due to the exceptional focus, resilience, and commitment of our entire Phathom team, and to their dedication to help patients and physicians. We are grateful to the physicians who prescribe VOQUEZNA as part of their care for patients and to the patients whose experiences inspire our work.

Finally, I want to thank our shareholders for your continued confidence and support. Phathom enters 2026 with strong commercial momentum, a solid financial position, and a clear strategy to drive towards long term value creation. We believe we are still in the early stages of realizing the full potential of VOQUEZNA and the broader opportunity ahead for our company.

We look forward to continuing this journey together.

Steven Basta
President & Chief Executive Officer

Forward-Looking Statements: This letter contains forward-looking statements. Actual results may differ materially from those described. For more information, see the “Risk Factors” section in our 2025 Form 10-K.

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2025

OR

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

For the transition period from _____ to

Commission file number: 001-39094

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, 2025, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $555.5 million, based on the closing price of the registrant's common stock on the Nasdaq Global Select Market of $9.59 per share.

As of February 23, 2026, the registrant had 78,798,712 shares of common stock ($0.0001 par value) outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain sections of the registrant's definitive proxy statement for the 2026 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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For the Year Ended December 31, 2025

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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 commercial-stage biopharmaceutical company focused on commercializing and developing novel treatments for gastrointestinal, or GI, diseases. Our approved products, VOQUEZNA®, VOQUEZNA® DUAL PAK® and VOQUEZNA® TRIPLE PAK®, contain vonoprazan, an oral small molecule potassium-competitive acid blocker, or PCAB. PCABs are a novel class of molecules that block acid secretion in the stomach. VOQUEZNA is the only PCAB currently approved for marketing and sale in the United States.

We began U.S. commercialization of VOQUEZNA for the treatment of erosive gastroesophageal reflux disease, or Erosive GERD, and Helicobacter pylori, or *H. pylori*, infection, and VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK for the treatment of *H. pylori* infection, in November 2023. The U.S. Food and Drug Administration, or FDA, approved VOQUEZNA for the relief of heartburn associated with Non-Erosive GERD, the largest category of GERD, in July 2024.

Vonoprazan was originally developed by Takeda Pharmaceutical Company Limited, or Takeda, and is marketed in multiple countries outside the United States. We licensed U.S., European and Canadian rights to vonoprazan from Takeda in 2019. We are independently commercializing VOQUEZNA, VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK in the United States.

During the year ended December 31, 2025, we generated increased revenues from sales of our VOQUEZNA products compared to the prior year, reflecting continued execution of our U.S. commercial strategy. The majority of our 2025 revenue was derived from sales of VOQUEZNA. During this period, we also experienced growth in prescription volume and prescriber adoption, with most prescriptions written for GERD indications. As of February 13, 2026, over 1.1 million prescriptions for VOQUEZNA, VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK have been filled since launch. We continue to have broad commercial coverage for VOQUEZNA, with access for over 120 million, or over 80%, of U.S. commercial lives. Our commercial efforts are supported by a targeted sales force and continued focus on prescriber engagement and payer access.

In May 2021, the FDA granted qualified infectious disease product, or QIDP, designation to VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK, resulting in an extension of the five-year new chemical entity, or NCE, exclusivity by an additional five years. In December 2024, we submitted a citizen petition requesting that the FDA update the Orange Book listing for VOQUEZNA to reflect the same ten-year period of NCE exclusivity applicable to VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK. In June 2025, the FDA granted the petition and updated the Orange Book listing for VOQUEZNA to reflect the ten-year period of NCE exclusivity for vonoprazan. As a result, all three VOQUEZNA products now have NCE exclusivity extending through May 3, 2032.

In the fourth quarter of 2025, we initiated a Phase 2 clinical trial evaluating vonoprazan in the treatment of adults with eosinophilic esophagitis, or EoE. While our current focus is on continued U.S. commercialization of VOQUEZNA products for GERD and *H. pylori*, we are also evaluating other potential life-cycle management opportunities for vonoprazan. We may also explore the potential for vonoprazan in Europe and Canada, as well as opportunities to in-license or acquire additional clinical or commercial-stage product candidates for GI diseases.

Our Products and Commercialization

All of our revenue is derived from the sale of three products in the United States: VOQUEZNA (vonoprazan) tablets which are approved for the healing and maintenance of healing of all grades of Erosive GERD and relief of heartburn associated with Erosive GERD in adults, and for the relief of heartburn associated with Non-Erosive GERD in adults, as well as, in combination with amoxicillin with or without clarithromycin, for the treatment of *H. pylori* infection, and VOQUEZNA DUAL PAK, comprised of vonoprazan co-packaged with amoxicillin, and VOQUEZNA TRIPLE PAK, comprised of vonoprazan co-packaged with amoxicillin and clarithromycin, which are both approved for the treatment of *H. pylori* infection. We began U.S. commercialization of VOQUEZNA for the treatment of Erosive GERD and *H. pylori* infection, and of VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK for the treatment of *H. pylori* infection, in the fourth quarter of 2023. In July 2024, the FDA also approved VOQUEZNA for the relief of heartburn associated with Non-Erosive GERD.

The sections below describe the diseases our approved products target, the clinical data supporting their use, and our commercialization efforts.

Our Strategy

Our strategy is focused on building a sustainable, commercial-stage GI company centered on the commercialization of VOQUEZNA and, in the future, the disciplined expansion of our product portfolio.

Our key strategic priorities include:

- Maximizing the U.S. commercial opportunity for VOQUEZNA in its approved indications in the treatment of GERD through a targeted sales force initially focused on gastroenterologists and other high-prescribing healthcare providers, and in the future, potentially expanding marketing and sales efforts to target more broadly those primary care physicians who treat GERD;

- Selectively pursuing life-cycle management opportunities for vonoprazan, including potential additional indications and formulations;

- Exploring the potential for vonoprazan in Europe, Canada, U.S. over-the counter, or OTC, use, and other potential market expansions, including evaluating the feasibility and practicality of potential collaboration or licensing arrangements;

- Maintaining a disciplined and selective approach to business development, including evaluating opportunities to in-license or acquire additional clinical- or commercial-stage product candidates for GI diseases; and

- Operating with financial discipline, prioritizing efficient capital allocation and effective management of manufacturing and supply arrangements.

We continually assess our strategic priorities in light of evolving market conditions, regulatory developments, clinical feasibility, commercial potential, competitive dynamics and our available resources. Our ability to execute on this strategy is subject to significant risks and uncertainties, including those described elsewhere in this Annual Report on Form 10-K.

Disease Background

Gastroesophageal Reflux Disease (GERD)

Gastroesophageal reflux disease, or GERD, is a chronic digestive disorder characterized by the reflux of gastric contents into the esophagus, which can result in symptoms such as heartburn, regurgitation and chest discomfort, as well as potential esophageal injury. GERD is one of the most common GI conditions in the U.S, affecting an estimated 65 million adults in the U.S. Exposure of the esophagus to gastric acid is a primary contributor to GERD symptoms and, in patients with erosive disease, damage to the esophageal lining. Accordingly, pharmacologic therapies designed to suppress gastric acid secretion are a cornerstone of treatment for both Erosive and Non-Erosive GERD and are commonly used for long-term symptom management.

GERD is generally classified into two categories: Erosive GERD, also referred to as erosive esophagitis, and Non-Erosive GERD. Erosive GERD is characterized by visible injury to the esophageal lining and is believed to affect an estimated 20 million adults in the U.S. If left untreated, Erosive GERD may progress to complications such as peptic stricture, Barrett's esophagus or, in some cases, esophageal cancer. Non-Erosive GERD, which is believed to affect an estimated 45 million adults in the U.S, is characterized by persistent symptoms and abnormal gastric acid exposure in the absence of visible esophageal injury. Non-Erosive GERD represents the largest segment of diagnosed GERD patients and accounts for a substantial proportion of individuals seeking medical treatment for chronic heartburn.

GERD is typically a chronic condition. Patients with GERD often initially manage symptoms with over-the-counter antacids or acid-reducing agents for intermittent or mild symptoms. Patients with more frequent, persistent or severe symptoms, or with evidence of esophageal injury, are typically treated with prescription acid-suppressive therapies to try to manage symptoms and reduce the risk of disease progression. We estimate that approximately 22 million adults are prescribed treatments for GERD in the U.S. each year, of which 7 million are treated for Erosive GERD and 15 million are treated for Non-Erosive GERD. Proton pump inhibitors, or PPIs, have historically been the standard of care for GERD among prescribed treatments and are widely prescribed for both erosive and non-erosive disease. We estimate there are approximately 110 million PPI prescriptions written and filled annually across all indications. The PPI class includes drugs such as Prilosec (omeprazole), Nexium (esomeprazole), and Prevacid (lansoprazole). Prior to the introduction 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. PPIs reduce gastric acid secretion by irreversibly inhibiting active proton pumps in gastric parietal cells and are typically dosed prior to meals, as their activity depends on acid-mediated activation and the presence of meal-stimulated proton pumps. An estimated 40% of patients with GERD experience inadequate symptom relief from PPI therapy, including persistent symptoms, delayed symptom relief or incomplete healing. In addition, variability in patient response and strict dosing requirements may limit the effectiveness of PPIs for certain patients. Patients with GERD who continue to experience heartburn symptoms are often referred to gastroenterologists for evaluation and then return to their primary care physicians for ongoing management.

We believe GERD represents an attractive commercial opportunity due to its high prevalence, chronic nature and the ongoing need for effective treatment options for patients with suboptimal outcomes on existing PPI therapies.

H Pylori

H. pylori is a bacterial infection of the stomach that is a leading cause of peptic ulcer disease and is associated with an increased risk of gastric cancer. Infection is typically acquired in childhood and can persist for decades if left untreated. Many infected individuals are asymptomatic; however, chronic infection can result in clinically significant gastrointestinal disease. The primary goal of treatment for *H. pylori* infection is eradication of the bacterium. Eradication typically requires combination therapy consisting of acid suppression and multiple antibiotics administered over a defined treatment course. Acid suppression plays an important role in the treatment of *H. pylori* by enhancing antibiotic stability and activity within the gastric environment. PPIs, in combination with antibiotics, have historically been the standard of care for the treatment of *H. pylori* infection.

Treatment of *H. pylori* infection can be complicated by a number of factors, including increasing rates of antibiotic resistance, regimen complexity, and challenges with patient adherence. As a result, eradication rates can vary, and some patients may require retreatment. These factors contribute to the continued need for effective and well-tolerated treatment regimens for *H. pylori* infection.

Clinical Overview of Vonoprazan

Mechanism of Action

Vonoprazan is an oral, small-molecule PCAB that suppresses gastric acid secretion by inhibiting the gastric H^+/K^+ - ATPase enzyme system at the secretory surface of the gastric parietal cell. This enzyme, commonly referred to as the gastric proton pump, is responsible for the final step of stomach acid production. By blocking the final step of acid production in a potassium-competitive manner, vonoprazan suppresses both basal and stimulated gastric acid secretion.

Unlike PPIs, which require activation in an acidic environment, vonoprazan does not require acid-mediated activation. Vonoprazan binds to the proton pump in a noncovalent and reversible manner and may selectively concentrate in parietal cells in both resting and stimulated states. In practical terms, vonoprazan blocks the final step of stomach acid production directly, which allows it to reduce acid secretion without requiring activation in an acidic environment. In a pharmacokinetic/ pharmacodynamic study conducted in healthy volunteers, vonoprazan demonstrated rapid onset (increased PH in two-three hours), potent suppression (Day 1 mean pH of 4.6), and durable 24-hour acid control of gastric acid secretion compared to a PPI, as measured by intragastric pH.

Clinical Data Supporting VOQUEZNA for GERD

Erosive GERD. FDA approval of VOQUEZNA for the healing and maintenance of healing of all grades of erosive esophagitis and for the relief of heartburn associated with Erosive GERD was based on results from PHALCON-EE, a randomized, controlled Phase 3 clinical trial conducted in the United States and Europe. PHALCON-EE evaluated vonoprazan compared to lansoprazole for both the healing and maintenance of healing of erosive esophagitis in adult patients with Erosive GERD. In PHALCON-EE, vonoprazan met the primary healing endpoint of the trial by demonstrating non-inferiority to lansoprazole in the number of patients who showed complete healing of erosive esophagitis after eight weeks of treatment. In addition, in a pre-specified secondary endpoint, vonoprazan demonstrated superior healing rates after two weeks of treatment in patients with moderate-to-severe Erosive GERD compared to lansoprazole, based on a pre-specified secondary analysis. Following the healing phase, healed patients entered a maintenance phase in which vonoprazan 10 mg and 20 mg were compared to lansoprazole in the maintenance of healing. 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. 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. 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. Based on the totality of clinical data, in November 2023, the FDA approved VOQUEZNA for healing and maintenance of healing of erosive esophagitis and for the relief of heartburn associated with Erosive GERD in adults.

Non-Erosive GERD. FDA approval of VOQUEZNA 10 mg tablets for the relief of heartburn associated with Non-Erosive GERD was based on results from PHALCON-NERD-301, a randomized, double-blind, placebo-controlled Phase 3 clinical trial conducted in adult patients with symptomatic GERD without visible esophageal erosions on endoscopy. The trial enrolled adult patients who experienced frequent heartburn symptoms and evaluated the efficacy of vonoprazan compared to placebo over the treatment period. In the study, 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. The primary endpoint assessed relief of heartburn symptoms using patient-reported outcome measures. Secondary endpoints evaluated additional measures of symptom control and consistency of response over time. Patients who completed the double-blind treatment period were eligible to enter an extension period, during which continued treatment with vonoprazan was evaluated to assess the durability of symptom relief and longer-term safety. Based on the totality of clinical data, in July 2024 the FDA approved VOQUEZNA 10 mg tablets for the relief of heartburn associated with non-Erosive GERD in adults. Non-Erosive GERD represents the largest segment of patients with diagnosed GERD and includes individuals who experience persistent symptoms in the absence of visible esophageal injury. The approval of VOQUEZNA for the relief of heartburn in Non-Erosive GERD expanded the approved indications for VOQUEZNA to address a broader population of patients with chronic GERD-related symptoms.

Clinical Data Supporting VOQUEZNA products for Helicobacter pylori Infection

FDA approval of VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK for the treatment of *H. pylori* infection in adults was based on 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. PHALCON-HP evaluated 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. Vonoprazan triple therapy and vonoprazan dual therapy also met all secondary endpoints in the study, demonstrating superior eradication rates versus lansoprazole triple therapy in all patients and in the subgroup of patients with clarithromycin resistant strains of *H. pylori*. Based on the totality of clinical data, in May 2022, the FDA approved VOQUEZNA DUAL PAK, which combines vonoprazan with amoxicillin, and VOQUEZNA TRIPLE PAK, which combines vonoprazan with amoxicillin and clarithromycin, for the treatment of *H. pylori* infection in adults. The co-packaged formulations are designed to simplify prescribing and administration of combination therapy.

Safety Experience

The most common side effects of VOQUEZNA for treatment of Non-Erosive Esophagitis or relief of heartburn related to gastroesophageal reflux disease include: stomach inflammation, diarrhea, stomach bloating, stomach pain, nausea, indigestion, constipation, high blood pressure, and urinary tract infection. The most common side effects associated with VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK include: diarrhea, temporary changes in sense of taste, vaginal yeast infection, stomach pain, headache, high blood pressure and cold-like symptoms. Across our clinical development programs, vonoprazan was generally well tolerated. In the PHALCON-EE Phase 3 trial in Erosive GERD, the most commonly reported adverse events were gastrointestinal in nature and occurred at generally similar frequencies across vonoprazan and lansoprazole treatment groups. Rates of discontinuation due to adverse events were low during both the healing and maintenance phases. The frequency of serious adverse events was similar between treatment groups during the healing phase and remained low during the maintenance phase. The PHALCON-EE trial was conducted during the COVID-19 global pandemic. Coronavirus infection was reported in a subset of patients across treatment groups, including during the maintenance phase. Two deaths due to coronavirus infection occurred in patients treated with vonoprazan 20 mg during the PHALCON-EE study; none of the coronavirus infection events were considered related to study drug by the investigators. In Phase 3 clinical trials evaluating vonoprazan for Non-Erosive GERD, including placebo-controlled and extension phases, vonoprazan was generally well tolerated, with overall adverse event rates comparable to placebo during the double-blind

treatment periods. Adverse events observed during extension periods were consistent with those reported in prior vonoprazan studies. Serious adverse events were infrequent across studies, and the overall safety experience was consistent with the established clinical profile of vonoprazan. In the PHALCON-HP Phase 3 trial evaluating vonoprazan-based dual and triple therapy regimens for *H. pylori* infection, the overall incidence and types of adverse events observed with vonoprazan-based regimens were generally comparable to those observed with lansoprazole-based triple therapy. Discontinuation rates due to adverse events in the study were low across treatment arms.

Exclusivity

In May 2021, the FDA granted QIDP designation to VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK, resulting in an extension of the five-year NCE exclusivity by an additional five years. In December 2024, we submitted a citizen petition requesting that the FDA update the Orange Book listing for VOQUEZNA to reflect the same ten-year period of NCE exclusivity applicable to VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK. In June 2025, the FDA granted the petition and updated the Orange Book listing for VOQUEZNA to reflect the ten-year period of NCE exclusivity for vonaprazan. As a result, all three VOQUEZNA products now have NCE exclusivity extending through May 3, 2032.

Sales and Marketing

During the year ended December 31, 2025, we generated increased revenues from sales of our VOQUEZNA products compared to the prior year, reflecting continued execution of our U.S. commercial strategy following launch. The majority of our 2025 revenue was derived from sales of VOQUEZNA. During this period, we also experienced growth in prescription volume and prescriber adoption, with most prescriptions written for GERD indications. As of February 13, 2026, over 1.1 million prescriptions for VOQUEZNA tablets, VOQUEZNA DUAL PAK, and VOQUEZNA TRIPLE PAK have been filled since launch. We continue to have broad commercial payer coverage for VOQUEZNA, with access for over 120 million covered lives, representing over 80% of U.S. commercial lives. Our commercial efforts are supported by a targeted sales force and continued focus on prescriber engagement and payer access.

U.S. Commercial Organization and Sales Strategy

We have established marketing, sales, and distribution capabilities to support the commercialization of our approved products in the United States. We are independently commercializing VOQUEZNA tablets, VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK, through a targeted national sales force primarily focused on gastroenterologists and other high-prescribing healthcare providers, including select primary care physicians. We currently employ a sales force that we expect, at full strength, to consist of approximately 300 sales representatives, although the size of our sales force may vary from time. We also work with third-party pharmacy support service providers to facilitate patient access to our VOQUEZNA products. Through these arrangements, eligible patients may access programs that help identify lower out-of-pocket costs, support prior authorization submissions, and offer home delivery from licensed pharmacies. Our commercial and development activities are supported by an experienced management team with expertise in gastroenterology, product commercialization, and pharmaceutical operations.

Our commercial strategy is focused on driving awareness and adoption among healthcare providers who routinely treat patients with GERD and *H. pylori* infection. We prioritize engagement with high-volume prescribers of acid-suppressive therapies and focus our promotional efforts on communicating the clinical profile and approved indications of our products.

Market Access and Distribution

We actively engage with payers to maintain and expand formulary access for VOQUEZNA products. As of December 31, 2025, we had achieved broad commercial coverage for VOQUEZNA across national and regional health plans. Utilization management for access to VOQUEZNA in the treatment of GERD typically requires a generic PPI step edit via a prior authorization. We continue to evaluate opportunities to improve patient access through formulary positioning and patient support programs.

In the United States, we sell our products primarily to pharmaceutical wholesale distributors and select pharmacies, which in turn distribute our products to their customers. These may include retail pharmacies, institutions, clinics and patients. This distribution model allows us to efficiently reach healthcare providers and patients nationwide. We also work with third-party pharmacy support service providers to facilitate patient access to our VOQUEZNA products. Through these arrangements, eligible patients may access programs that help identify lower out-of-pocket costs, support prior authorization submissions, and offer home

delivery from licensed pharmacies. These relationships are intended to improve patient access and adherence to therapy for prescribers and patients.

Marketing and Promotional Activities

Our marketing strategy includes a combination of healthcare provider–focused and patient-facing initiatives. We utilize a range of promotional channels, including in-person sales interactions, digital engagement, and educational programs directed at healthcare providers.

We also engage in select direct-to-consumer marketing activities, including digital and streaming media platforms and other consumer-facing channels, designed to increase disease awareness and encourage appropriate patient-provider discussions.

Geographic Scope

We currently commercialize our products exclusively in the United States and do not have approved products marketed outside the United States. We continue to evaluate opportunities for vonoprazan in Europe and Canada.

Additional Vonoprazan Development Opportunities

Eosinophilic Esophagitis (EoE)

While our current focus is on the continued U.S. commercialization of VOQUEZNA products for GERD and *H. pylori* infection, we are also pursuing or evaluating potential lifecycle expansion opportunities for vonoprazan. In the fourth quarter of 2025, we initiated a Phase 2 clinical trial evaluating vonoprazan in the treatment of adults with EoE. The PHALCON-EOE-201 study is a randomized, double-blind, placebo-controlled Phase 2 trial in adults with EoE, designed to evaluate the efficacy and safety of vonoprazan 20 mg once daily. Approximately 80 subjects will be randomized 1:1 to vonoprazan or placebo for a 12-week treatment period, with the primary endpoint assessed at Week 12 and followed by a safety follow-up and an optional open-label extension. We anticipate topline data from this trial in 2027. 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. In an investigator-sponsored clinical trial in Japan, vonoprazan demonstrated similar efficacy results when compared to PPIs in the treatment of patients with EoE. Given the data from this trial and the limited choices of therapies for EoE, we believe EoE is an important indication for clinical evaluation.

Other Potential Opportunities

We may explore potential research opportunities for vonoprazan in other indications or specific patient populations related to acid secretion such as Barrett's esophagus where PPIs are the current standard of care as well as other potential formulations and packaging of vonoprazan such as an orally disintegrating tablet, or ODT, formulation. We believe that vonoprazan has a profile that would support its development in the future as an OTC product, including the potential for as-needed symptom relief and a well-tolerated safety profile. We plan to explore the economics and potential development pathway for an OTC product in this market to determine possible future strategies. We also continue to evaluate opportunities to in-license or acquire additional clinical- or commercial-stage product candidates for gastrointestinal diseases.

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 technologies or products that compete 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 United States, 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, if we seek approval in those territories, 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.

For the treatment of Erosive GERD and Non-Erosive GERD, VOQUEZNA primarily competes with generic PPIs marketed by multiple pharmaceutical companies in both the prescription and OTC markets. Generic PPIs are widely available, inexpensive and well established in clinical practice. In addition, we are aware of other PPIs in development in the United States and in our licensed territories outside the United States that, if successfully developed and approved, may compete with vonoprazan.

We are also aware of several PCABs in development in the United States and in our licensed territories outside the United States, that, if approved or introduced, may compete with vonoprazan. For example, Sebela Pharmaceuticals, Inc. has publicly announced the submission of an NDA in the United States seeking approval of tegoprazan for the treatment of Erosive GERD and Non-Erosive GERD based on Phase 3 clinical trials. Outside the United States, tegoprazan is marketed in several countries, including South Korea, where it was originally developed. Daewoong Pharmaceutical Co., Ltd also markets a PCAB, fexuprazan, in certain countries outside the United States, and has indicated that it is seeking a partner to advance development of the compound in the United States. In addition, in 2025, Cinclus Pharma Holding AB initiated a Phase 3 clinical trial in Europe of another PCAB, linaprazan glurate, in patients with severe Erosive GERD and has publicly indicated its intention to initiate a second Phase 3 clinical trial in the United States to support a potential future NDA submission. Additional PCABs have been approved or are in development outside the United States and could compete with vonoprazan if introduced in our licensed territories.

For the treatment of *H. pylori* infection, VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK compete primarily with generic PPI-based triple and quadruple therapies, as well as with branded therapies such as Talicia, a co-formulated capsule containing omeprazole, amoxicillin and rifabutin, marketed by RedHill Biopharma Ltd.

Intellectual Property

Intellectual property, including patents, trade secrets, trademarks and copyrights, is important to our business. Our commercial success depends in significant part on our ability to obtain, maintain and enforce proprietary intellectual property protection for vonoprazan, as well as for any future product candidates, formulations, manufacturing processes and related know-how. Our commercial success also depends on our ability to operate without infringing the proprietary rights of third parties and to prevent others from infringing our proprietary rights.

Our intellectual property strategy is focused on protecting the compound vonoprazan and related technologies through a combination of licensed patent rights, regulatory exclusivities, trade secrets and trademarks.

Our patent portfolio covering vonoprazan consists predominantly of patents and patent applications that are exclusively licensed to us from Takeda pursuant to the license agreement we entered into on May 7, 2019, or the Takeda License. Under the Takeda License, we have exclusive rights in the United States, Europe and Canada to patents and patent applications covering the composition of matter, formulation, use and manufacture of vonoprazan, subject to the terms and conditions of the agreement. This patent portfolio comprises eleven distinct patent families protecting technology relating to vonoprazan and its synthetic intermediates, methods of synthesizing vonoprazan and related compounds, pharmaceutical formulations, and methods of treating diseases using vonoprazan and related compounds. As of December 31, 2025, our portfolio included approximately 26 issued U.S. patents and one pending U.S. patent application, 16 issued European patents validated in individual European countries and two pending European patent applications, and seven issued Canadian patents and two pending Canadian patent applications. The issued patents and pending applications in our portfolio have nominal expiration dates ranging from 2024 to 2038, without accounting for any patent term adjustments or extensions that may be available. We have received a patent term extension, or PTE,

of 607 days for the U.S. composition-of-matter patent covering the vonoprazan molecule based on the FDA approval of the New Drug Application, or NDA, for VOQUEZNA DUAL PAK. Patent term extensions under the Hatch-Waxman Act are granted on a product-specific basis and are limited to claims covering the approved product, a method of using such product, or a method of manufacturing such product. As a result, there can be no assurance that the scope of this PTE will be enforceable with respect to other approved products containing vonoprazan, including VOQUEZNA or VOQUEZNA TRIPLE PAK, or any future product candidates containing the vonoprazan molecule. Absent any such patent term extension, the issued U.S. patent covering the composition of matter of vonoprazan is expected to expire in August 2028, and the issued U.S. patent covering certain formulations of our vonoprazan products is expected to expire in August 2030. However, in May 2022, following FDA approval of VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK, products containing the active moiety vonoprazan received five years of NCE exclusivity, which was extended by an additional five years under the Generating Antibiotic Incentives Now Act, or GAIN Act, resulting in a total of ten years of regulatory exclusivity through May 3, 2032. In June 2025, following our Citizen Petition, the FDA updated the Orange Book to reflect that VOQUEZNA tablets, approved in November 2023 and containing the same active moiety, benefit from the same extended ten-year NCE exclusivity period through May 3, 2032.

Patent terms generally expire 20 years from the earliest effective filing date, subject to statutory adjustments or extensions. While we may seek additional patent term extensions where available, there can be no assurance that any such extensions will be granted or that their scope will provide meaningful additional protection. Similar extension mechanisms are available in certain foreign jurisdictions.

The patent positions of pharmaceutical companies are inherently uncertain and subject to challenge. Our licensed patents or other future patents may be challenged, narrowed, invalidated or circumvented, and third parties may assert blocking patents against us. In addition, because pharmaceutical development and regulatory review require significant time, certain patents may expire or have limited remaining term by the time a product is commercialized. If our patent or regulatory exclusivity protection is reduced or expires, our competitive position could be adversely affected.

Trade Secrets and Trademarks

In addition to patents, we rely on trade secrets, proprietary know-how and confidentiality agreements to protect aspects of our technology and business that are not patentable or that we elect not to patent. We require our employees, consultants and other collaborators to enter into confidentiality and, where applicable, invention assignment agreements. These agreements are intended to protect our proprietary information and assign to us rights in inventions developed during the course of such relationships. However, there can be no assurance that these agreements will provide adequate protection in all circumstances or prevent unauthorized disclosure or use of our trade secrets.

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 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 to a total maximum milestone amount of $250 million. We also agreed to make tiered royalty payments averaging in the low double digits royalty rate on aggregate 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. We rely on third-party contract manufacturers to manufacture commercial and clinical quantities of our products, and expect to do so for any future product candidates. Although we rely on contract manufacturers, we have personnel with manufacturing experience to oversee our relationships with our suppliers, Evonik, Catalent and Sandoz.

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 was extended by two years from 2027 to 2029 upon Evonik's successful qualification of a second manufacturing facility to produce API in December of 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.

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 our 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.

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.

We had previously been informed by Sandoz that there could be a disruption in the supply of clarithromycin tablets, a component of the VOQUEZNA TRIPLE PAK, which could lead to a disruption in supply of VOQUEZNA TRIPLE PAKs. Given more recent communications, however, we do not currently anticipate any near-term disruptions. We plan to continue to actively monitor the situation to determine if a supply disruption may arise in the future. The VOQUEZNA TRIPLE PAK represented approximately 1% of our total revenue for 2025. While we have not experienced any commercial disruption to date, any disruption for such supply would result in our inability to continue to commercialize the VOQUEZNA TRIPLE PAK. The VOQUEZNA bottles and the VOQUEZNA DUAL PAKs are not impacted, as they do not include clarithromycin.

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 certain 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;
- satisfactory completion of potential FDA inspection 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, which is a request for allowance from the FDA to administer an investigational drug product to humans. 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 full or partial clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin, or with respect to a partial hold, begin as intended.

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. 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. There are also requirements governing the reporting of certain ongoing or completed clinical trial to clinicaltrials.gov.

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.

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.

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. 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. 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 additional clinical studies 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.

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. 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.

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, 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 labeling.

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 non-patent regulatory exclusivity or patent term 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 statute or specific intent to violate it in order to have committed a violation.

The federal civil monetary penalties laws, impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies.

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, 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. Coverage and 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; 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 eliminated the statutory cap on manufacturers' Medicaid drug rebate liability, 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.

On August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, 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 replaced the Part D coverage gap discount program with a new discounting program (which began 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. CMS has published the negotiated prices for the initial ten drugs, which went into effect in 2026, and the subsequent 15 drugs, which will first be effective in 2027, as well as the next set of 15 drugs that will be subject to negotiation, although the 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 One Big Beautiful Bill Act, which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect our sales of VOQUEZNA, VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK or any other product candidate that we commercialize.

The Trump administration is pursuing a two-fold strategy to reduce drug costs in the U.S. President Trump has threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers have reportedly entered into confidential pricing agreements with the federal government. The Trump administration is also pursuing traditional regulatory pathways to impose drug pricing policies, and published two proposed regulations in December 2025, referred to as Globe and Guard. If finalized, these regulations would implement mandatory payment models under which manufacturers of eligible drugs would be required to pay rebates to the federal government on a portion of the units of their drugs that are reimbursed by Medicare, with the rebate amount based on most favored nation pricing. While the impact of the Globe and Guard proposed regulations, if finalized, cannot yet be determined, it could be significant. Even regulatory proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business. In addition, pharmaceutical pricing and marketing has long been the subject of considerable discussion in Congress and among policymakers, and it is possible that Congress could enact additional laws that negatively affect the pharmaceutical industry.

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, drug price reporting and other transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states. 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.

Data Privacy and Security Laws

As a pharmaceutical company, we are subject to numerous 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. These laws could apply now or in the future to our operations or the operations of our partners. In the U.S., numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations (such as the California Consumer Privacy Act, or the CCPA) and similar state comprehensive data privacy laws in other states) govern the privacy and security of personal information, including health-related information. In addition, certain foreign laws such as the European Union General Data Protection Regulation, or the EU GDPR, and 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) govern the privacy and security of personal data, including health-related data. 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 December 31, 2025, we had 371 full-time employees, some 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 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 principal 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 may never become profitable or, if we achieve profitability, we may not be able to sustain it;
- We currently depend entirely on the success of our approved VOQUEZNA products, and in particular on the success of VOQUEZNA for the treatment of GERD. If we are unable to successfully commercialize VOQUEZNA at the levels we expect, our business, results of operations, and prospects will be materially harmed;
- We may require additional financing to achieve our goals, finance our operations and meet our financial obligations, 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;
- In the future we will need to successfully acquire, develop and gain approval of one or more product candidates other than VOQUEZNA with significant market potential. If we are not successful in these efforts, our business prospects may be materially and adversely affected;
- We may not achieve favorable results in our ongoing clinical trial of vonoprazan in the treatment of EoE or in future clinical trials of vonoprazan or of any other product candidate we may develop, or receive additional regulatory approvals on a timely basis, if at all;
- We may not decide to develop vonoprazan for additional indications and formulations beyond the ongoing EoE trial, or even if we proceed with such development, our efforts may not be successful or, if successful, may not result in increased revenues. 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 VOQUEZNA or any future product candidates that may receive regulatory approval;
- We currently engage third-party manufacturers for all of our commercial and clinical supplies. The loss of any of these suppliers, or any future single source suppliers, could harm our business;
- We rely on third parties to conduct our 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 complete ongoing development activities on the timelines we expect and the delays may 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 which would materially adversely affect our business, results of operations, and prospects;

- 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 or failure to maintain any of our patent protection or non-patent regulatory exclusivity, our ability to prevent our competitors from commercializing similar or identical products would be adversely affected which could materially and adversely affect our business, results of operations, and prospects;

- The successful commercialization of VOQUEZNA, VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK will depend in part on the extent to which private health insurers and governmental authorities establish and maintain 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 at the levels we expect which could materially and adversely affect our business, results of operations, and prospects;

- If we fail to comply with reporting and payment obligations for VOQUEZNA, VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE 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 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 could 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 commercialization and product development both involve a substantial degree of risk.

We launched VOQUEZNA, VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK in the fourth quarter of 2023. Prior to such launch, we had not conducted sales and marketing activities necessary for successful commercialization of a product or manufactured products on a commercial scale, or arranged for a third party to do so on our behalf. 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 may encounter unforeseen expenses, difficulties, complications and delays, and may not be successful in our commercialization or development efforts.

We have incurred significant operating losses since inception and may never achieve or maintain profitability.

Since our inception, we have incurred significant operating losses. Our net loss was $221.2 million and $334.3 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $1.5 billion. Given our limited history as a commercial-stage company, we face numerous risks associated with our ability to achieve operating profitability and cash flow positivity based on expected revenue and expense levels, and there is no certainty that we will achieve operating profitability or cash flow positivity on the timeline we expect or at all, or that, even if we achieve profitability, that 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 significant expenses for the foreseeable future as we:

- continue commercialization of VOQUEZNA, VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK, and in the future, potentially expand marketing and sales efforts to target more broadly those primary care physicians who treat GERD;

- conduct clinical trials for new potential indications or formulations of vonoprazan or develop any future product candidates, including related support activities;

- 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., or Loan Agreement, entered into in September 2021, as amended;

- build a portfolio of product candidates through the acquisition or in-license of additional product candidates or technologies;

- pursue regulatory approvals for new indications or formulations of vonoprazan or future product candidates, if we conduct and successfully complete clinical trials, seek approvals, and engage in commercialization activities related to such indications, formulations or future product candidates, if approved; and

- incur additional legal, accounting and other expenses in connection with operating as a public company.

To become profitable, we must successfully commercialize VOQUEZNA in the treatment of GERD. To build for long-term success, we must acquire, develop and gain approval of one or more product candidates with significant market potential. We may not be successful in these efforts.

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 commercialization and 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 may require substantial additional financing to achieve our goals, finance our operations or meet our financial obligations, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could materially adversely affect our business.

The development and commercialization of biopharmaceutical products are capital-intensive. We expect to continue to incur significant expenses in connection with our ongoing activities, particularly as we commercialize VOQUEZNA, VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK in the United States, and advance our current, planned or future development programs. In the future, we may decide to expand our commercialization efforts, including increasing our marketing activities or the size of our field force, or to expand our development efforts, including pursuing additional indications or formulations of vonoprazan or acquiring, in-licensing and developing additional product candidates. Any such activities could significantly increase our operating expenses. We cannot reliably estimate the amounts required to generate revenues from VOQUEZNA at the levels we expect, to complete development of additional indications or formulations of vonoprazan or future product candidates, or to successfully commercialize any future products that may be approved. 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, and we have ongoing financial obligations under our Loan Agreement and RIFA. If we pursue additional product acquisitions or in-licenses, we may also be required to make significant upfront, milestone or royalty payments. We may require additional financing to achieve our goals, finance our operations and meet our financial obligations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, limit, reduce or terminate our commercialization activities, product development programs, or other operations.

We believe that our existing cash and cash equivalents are sufficient to fund operations for at least the next 12 months and along with anticipated product revenues and the $122.2 million of net proceeds from our January 2026 offering, will be sufficient to enable us to reach operating profitability, beginning in the third quarter of 2026, excluding stock-based compensation. 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 commercialize VOQUEZNA, develop vonoprazan for additional indications or formulations or develop or any future product candidates.

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

- our ability to achieve and maintain market acceptance, market share, coverage, reimbursement and revenues from sales of VOQUEZNA in its approved GERD indications, and patients' willingness to pay out-of-pocket in the absence of coverage and/or adequate reimbursement from third-party payers;
- the costs of sales and marketing activities in support of the continued commercial launch of VOQUEZNA, VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK, or any future product candidates we may choose to pursue, if successfully developed and approved;
- the costs, timing and availability of manufacturing for vonoprazan as well as the costs of manufacturing for any potential product candidates we may pursue in the future;
- 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, timing and outcome of regulatory review of future vonoprazan applications or such applications for any future product candidates;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights, and the success of our enforcement efforts;
- the timing of market introduction, profile and impact of competitive products;
- the costs associated with hiring additional personnel and consultants as our business grows and enhancing our operational systems;
- the timing and amount of the milestone or other payments we must make to Takeda and any future licensors;
- the timing and impact of our obligations under our Loan and Security Agreement with Hercules Capital, Inc., and our Revenue Interest Financing Agreement; and
- the costs associated with building a portfolio of product candidates through the acquisition or in-license of additional product candidates or technologies, including the terms and timing of establishing and maintaining future collaborations, licenses and other similar arrangement and the costs associated with development of any products or technologies that we may in-license or acquire.

We expect that, for the foreseeable future, our revenues will be derived exclusively from sales of products containing vonoprazan in the U.S., particularly arising from the use of VOQUEZNA in its current indications in the treatment of GERD. Until we can generate a sufficient amount of product revenue and cash flow from operations to achieve profitability and to fund our future growth opportunities, we may 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.

We expect to continue to finance our cash needs through revenue from product sales and equity offerings, 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 cash covenants and 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 and performance financial covenants and our Revenue Interest Financing Agreement also contains minimum cash 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 currently rely entirely on the commercial success of our VOQUEZNA products, which depends upon the degree of market acceptance of such products by physicians, patients, healthcare payers and others in the medical community.

We currently depend entirely on the success of our approved VOQUEZNA products, and we may not be able to successfully commercialize such products or achieve revenues at the level and timing we expect. The commercial success of our approved products will depend significantly on the broad adoption and use of such products by physicians and patients for the approved indications. The degree of market acceptance of our current products or any product candidates, if approved, will depend on a number of factors, including:

- acceptance of our products 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 private health insurers, government healthcare programs, including, Medicare and Medicaid, 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;
- demonstration of clinical efficacy and safety compared to other more-established products;
- the timing of market introduction, profile and impact of competitive drugs;
- the effectiveness of our or any of our potential future collaborators' sales and marketing strategies;
- the indications for which our current product or any 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;
- any restrictions on the use of our products, and the prevalence and severity of any adverse effects;
- potential product liability claims; and
- unfavorable publicity relating to the product.

If VOQUEZNA, or any product candidate, if approved, does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payers or patients, we may not generate revenue at the levels or on the timing we expect which could have a material adverse effect on our business, financial condition, results of operations and prospects. 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 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, 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.

We may lack the necessary expertise, personnel and resources to successfully commercialize VOQUEZNA, VOQUEZNA DUAL PAK, and VOQUEZNA TRIPLE 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 then planned commercialization of VOQUEZNA, VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK, due to approval and launch delays, we did not hire our field force until late 2023. The success of commercialization of our approved products in the United States and any of our future product candidates that may be successfully developed and approved by the FDA will depend on such marketing, sales and distribution capabilities or any additional capabilities we may build. Factors that may affect our ability to commercialize successfully our approved products and future product candidates, if any, on our own include obtaining access to or persuading adequate numbers of physicians to prescribe our products for the approved indications. 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 and strategy 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 adopt a successful strategy, or to find suitable partners for such commercialization, we may have difficulties generating revenue at the levels and on the timing we expect, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

As a commercial-stage company with FDA-approved products, we are subject to ongoing regulatory obligations and failure to comply with these requirements or changes in regulatory rules could materially adversely affect our business or result in significant additional expense.

In connection with approval of a pharmaceutical product, regulatory authorities may 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. For example, with respect to VOQUEZNA our post-marketing requirements include pregnancy registries and pediatric studies. The FDA and comparable regulatory authorities may also require a risk evaluation and mitigation strategy, or 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, the manufacture, labeling, packaging, distribution, adverse-event reporting, storage, advertising, promotion, import, export and recordkeeping for our approved products, as well as for any future product candidates that may receive regulatory approval, are subject to extensive and ongoing regulatory requirements. These requirements include periodic safety reporting, facility registration, inspections, and continued compliance with current good manufacturing practices, or cGMPs, as well as good clinical practice, or GCP requirements for any clinical trials we conduct.

The 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 or any future product candidates and impair our ability to generate revenue and could require us to expend significant time and resources in response or generate negative publicity. In addition, regulatory requirements and policies are subject to change. New laws,

regulations or guidance, or changes in interpretation or enforcement of existing requirements, could increase the cost or complexity of maintaining compliance or pursuing additional indications, formulations or product candidates. If we are slow or unable to adapt to regulatory changes or maintain compliance, we could be subject to enforcement actions. Any of the consequences of these events could have a material adverse effect on our business, financial condition, results of operations and prospects.

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 successfully developed and 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, for the relief of heartburn associated with Non-Erosive GERD 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 may successfully develop in the future, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Successful commercialization of our current products or any future product candidate, will depend in part on the extent to which private health insurers or governmental authorities provide and maintain coverage with adequate reimbursement levels and without onerous utilization management requirements. Failure to obtain or maintain favorable pricing and adequate coverage and reimbursement policies for our products could limit our ability to market those products and decrease our ability to generate revenue at the levels and on the timelines we expect.

The availability of coverage and the adequacy of reimbursement for VOQUEZNA, VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK by private health insurers, governmental healthcare programs, such as Medicare and Medicaid, and other third-party payers are essential for most patients to be able to afford these medications, and will be essential with respect to any future product candidates that may be successfully developed and approved. Even when coverage is available, third-party payers may impose utilization management requirements, such as prior authorization, step therapy, quantity limits or other restrictions, which may delay or limit patient access, reduce prescribing, or increase administrative burden on healthcare providers. These access requirements may negatively affect adoption and persistence of our products in clinical practice. Our ability to achieve and maintain coverage and acceptable levels of reimbursement for our approved 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 without onerous management utilization requirements, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Coverage and reimbursement policies for our approved products may be changed, reduced or eliminated over time, and we cannot be certain that coverage and reimbursement in the United States, the European Union, or elsewhere will be available for any product that we may develop 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 or with onerous restrictions. For example, utilization management with respect to VOQUEZNA in the treatment of GERD is largely defined by a generic PPI step edit via a prior authorization. Even if we are successful in demonstrating improved efficacy or improved convenience of administration with our future product candidates, if any, 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 may 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, pharmaceutical products are often subject to extensive governmental price controls and other market regulations. In many countries, including those in Europe, pricing and reimbursement are subject to national health system controls or profit limitations, which may reduce the prices we are able to charge and the revenues we are able to generate. If we pursue commercialization outside the United States, reimbursement levels in those markets may be lower than in the United States and may be insufficient to generate commercially reasonable revenues or profitability.

Moreover, ongoing efforts by governmental authorities and third-party payers to contain healthcare costs, including through pricing controls, utilization management, and reimbursement reductions, may further limit coverage or reimbursement for our products. These factors could materially and adversely affect our ability to commercialize our products, generate revenue, and grow our business.

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, results of operations and prospects.

We participate in various governmental pricing and reimbursement programs, including the Medicaid Drug Rebate Program, or MDRP, that impose extensive drug price reporting and payment obligations on pharmaceutical manufacturers. Medicaid is a joint federal and state program administered by the states for low-income and disabled beneficiaries, and Medicare is a federal program administered by the federal government for individuals age 65 and older and certain disabled individuals.

Under the 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 a rebate agreement with the Secretary of Health and Human Services and pay rebates 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. Manufacturers are required to submit pricing data on a monthly and quarterly basis and to correct and resubmit data for prior periods if inaccuracies are identified. 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.

Participation in the MDRP also requires participation in the Public Health Service's 340B drug pricing program, or the 340B program, which is administered by the Health Resources and Services Administration, or HRSA. The 340B program requires participating manufacturers to agree to sell covered outpatient drugs to covered entities at or below a statutorily defined "ceiling price" which is calculated using MDRP pricing data. Manufacturers must report 340B ceiling prices to HRSA on a quarterly basis, and HRSA publishes them to 340B covered entities. Failure to comply with 340B requirements may subject manufacturers to civil

monetary penalties, repayment obligations, and administrative dispute resolution proceedings. Legislative or regulatory changes could further expand the scope or obligations of the 340B program.

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.

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. Compliance with these requirements, including any necessary recalculations or restatements, may increase administrative burden and costs and could result in additional rebate liabilities or penalties for prior periods. We cannot assure you that our pricing submissions will not be found to be incomplete or incorrect, and any failure to comply with these requirements could materially adversely affect our business, results of operations and prospects

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.

Competition in the markets for our approved products is expected to increase, and we may also face competition with respect to any product candidates we may develop, in each case which could materially adversely affect our business, results of operations and prospects.

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.

For the treatment of Erosive GERD and Non-Erosive GERD, VOQUEZNA primarily competes with generic PPIs marketed by multiple pharmaceutical companies in both the prescription and OTC markets. Generic PPIs are widely available, inexpensive and well established in clinical practice. In addition, we are aware of other PPIs in development in the United States and in our licensed territories outside the United States that, if successfully developed and approved, may compete with vonoprazan.

We are also aware of several PCABs in development in the United States and in our licensed territories outside the United States, that, if approved or introduced, may compete with vonoprazan. For example, Sebela Pharmaceuticals, Inc. has publicly

announced the submission of an NDA in the United States seeking approval of tegoprazan for the treatment of Erosive GERD and Non-Erosive GERD based on Phase 3 clinical trials. Outside the United States, tegoprazan is marketed in several countries, including South Korea, where it was originally developed. Daewoong Pharmaceutical Co., Ltd also markets a PCAB, fexuprazan, in certain countries outside the United States, and has indicated that it is seeking a partner to advance development of the compound in the United States. In addition, in 2025, Cinclus Pharma Holding AB initiated a Phase 3 clinical trial in Europe of another PCAB, linaprazan glurate, in patients with severe Erosive GERD and has publicly indicated its intention to initiate a second Phase 3 clinical trial in the United States to support a potential future NDA submission. Additional PCABs have been approved or are in development outside the United States and could compete with vonoprazan if introduced in our licensed territories.

For the treatment of H. pylori infection, VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK compete primarily with generic PPI-based triple and quadruple therapies, as well as with branded therapies such as Talicia, a co-formulated capsule containing omeprazole, amoxicillin and rifabutin, marketed by RedHill Biopharma Ltd.

In July 2012, the Food and Drug Administration Safety and Innovation Act was passed, which included the 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 our approved products, including VOQUEZNA, or for any future product candidates we may develop, are smaller than we expect, our business, results of operations and prospects could be adversely affected.

The precise incidence and prevalence for all the conditions we aim to address with our approved products as well as any future product candidates we may successfully develop are not known with certainty. Our projections of the number of people who have these diseases we target, and the subset of people with these diseases who have the potential to benefit from treatment of our approved products or any future product candidates, are based on our beliefs and estimates and assumptions derived from a variety of sources, including scientific literature, market research and surveys, and claims analysis, and may prove to be incorrect. In addition, future clinical studies or changes in medical practice may alter estimates of disease prevalence or treatment patterns.

The total addressable market across indications for our approved products and any future product candidates will ultimately depend upon a number of factors, including the scope of the approved indications and labeling; the availability and acceptance of competing treatment; the safety, efficacy, convenience and cost of our approved products and any future product candidates relative competing treatments; physician prescribing practices; patient awareness, acceptance and access; and drug pricing and reimbursement. If patients are less willing or able to use our products than we expect, or if access to appropriate patients is more limited than anticipated, or if for other reasons, the market opportunity for our products turns out to be significantly lower than expected, our ability to generate revenues and grow our business could be materially adversely affected.

If our efforts to develop, maintain and effectively deploy sales, marketing and distribution capabilities are unsuccessful, we may not be able to successfully commercialize our approved products or any product candidates we may develop and generate revenues at the levels and on the timing we expect.

We currently market, sell and distribute VOQUEZNA, VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK through our own sales and marketing organization, and our ability to successfully commercialize these products depends on the effectiveness of these capabilities. Our sales force may not be sufficient in size, reach or expertise to effectively address the markets we intend to

target. Our commercial strategy for our approved products currently relies on a targeted national sales force focused primarily on gastroenterologists and other high-prescribing healthcare providers, including select primary care physicians. This strategy is designed to concentrate our resources on prescribers most likely to treat patients with GERD and *H. pylori* infection. However, this targeted approach may not result in sufficient adoption or utilization of our products. In addition, we may in the future seek to expand our sales and marketing efforts to reach a broader group of primary care physicians who treat GERD. Such an expansion could require significant additional investment, increase operational complexity, and may not result in increased prescribing or revenues. If we are unable to successfully execute, or derive sufficient benefit from, any expansion of our commercial strategy, our business, results of operations and prospects could be materially adversely affected. Any deficiencies in our sales, marketing or distribution capabilities or strategies or delays in optimizing or expanding these capabilities and strategies, could adversely impact the commercialization of our products.

To the extent that we enter into collaboration or other arrangements in the future for the marketing, sales or distribution of our products, including in Europe and Canada, our product revenues may be lower than if we were to commercialize such products directly. Any revenues we may generate in these markets would depend, in whole or in part, on the efforts of third parties that are not fully within our control and may not be successful. If we are unable to enter into such arrangements on acceptable terms, or if third parties do not perform as expected, we may not be able to successfully commercialize our products in those markets.

If we are not successful in commercializing our approved products, either through our own commercial organization or through third-party arrangements, our revenues could be materially reduced and our business, results of operations and prospects could be materially adversely affected.

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 seek or 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

Our future growth depends on our ability to develop vonoprazan for additional indications or formulations and to successfully develop or acquire additional product candidates.

We expect that a substantial portion of our efforts and expenses over the next few years will be devoted to the commercialization of VOQUEZNA and the potential development and regulatory approval of vonoprazan for additional indications for formulations in the U.S. We cannot be certain that we will pursue, successfully develop, or obtain regulatory approval of vonoprazan for additional indications or formulations on the timeframes we expect, or at all. Our future growth also depends on our ability to successfully develop or acquire additional product candidates and obtain regulatory approval for such candidates on timelines sufficient to contribute meaningfully to the growth of our business. We may not be successful in these efforts and, even if we are successful, the commercialization of such additional indications, formulations or products may not contribute meaningfully to future growth of our business.

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. As a result, we may not achieve favorable results in our ongoing clinical trial of vonoprazan in the treatment of EoE or in future clinical trials of vonoprazan or of any other product candidate we may develop, or receive additional regulatory approvals on a timely basis, if at all. Failure to obtain regulatory approval for additional indications or formulations for vonoprazan that we may pursue or future product candidates in the United States will prevent us from commercializing in such new indications or as to such additional products.

The success of vonoprazan for additional indications or formulations we may pursue and of any future 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 manufacturing capabilities;
- achieving market acceptance by patients, the medical community and third-party payers, including adequate coverage and reimbursement;
- maintaining successful commercial sales, marketing and distribution operations;
- maintaining a continued acceptable safety profile following approval;
- competing effectively with other therapies; and
- obtaining and maintaining robust intellectual property protection or regulatory exclusivities.

Many of these factors are beyond our control, including the time needed to adequately complete clinical testing, the outcome of such trials, the regulatory review process, potential challenges to our intellectual property rights and changes in the competitive landscape. It is possible that no new indications or formulations for vonoprazan and no future product candidates will ever be successfully developed and obtain regulatory approval even if we expend substantial time and resources conducting development programs and seeking such approval. If we are unable to achieve these objectives in a timely manner or at all, our ability to grow our business could be materially adversely affected.

Clinical development is lengthy, expensive and uncertain, and delays or failures in our clinical trials could limit our ability to obtain additional regulatory approvals and adversely affect our business.

Clinical drug development is expensive, time-consuming and inherently uncertain, and the results of preclinical studies and early clinical trials are not necessarily predictive of results in later-stage trials. Even if we believe that interim or early clinical results are positive, such results may not be indicative of final outcomes, and product candidates may fail to demonstrate sufficient safety or efficacy despite progressing through earlier stages of development. Many companies in the pharmaceutical and biotechnology industries have experienced significant setbacks in clinical development after achieving promising early results.

Before obtaining regulatory approval to commercialize vonoprazan for additional indications or formulations or to commercialize any future product candidates, we must demonstrate through clinical trials that such products are safe and effective for use in the target indication. We may not achieve favorable results in our ongoing or future clinical trials, including our current trial of vonoprazan in eosinophilic esophagitis, or obtain regulatory approvals on a timely basis, or at all. Failure to obtain such approvals would prevent us from commercializing additional indications or formulations for vonoprazan or future product candidates.

The conduct of clinical trials is subject to extensive regulation in the United States and other territories, and regulatory requirements and policies may change. New processes and requirements for the authorization and oversight of clinical trials may affect the planning, conduct, timing and cost of trials.

The commencement, timing and completion of our clinical trials depend on many factors, including regulatory approvals to commence or continue trials, clinical trial design, manufacturing and supply of study drug, performance of third-party contractors and clinical sites, our ability to enroll and retain a sufficient number of eligible patients and the impact of interim results, if any. Patient enrollment may be delayed or limited by factors such as the size and characteristics of the patient population, eligibility criteria, proximity to trial sites, competing clinical trials, availability of approved therapies, and patient and physician perceptions of risks and benefits. If we are unable to enroll or retain sufficient patients, our trials may be delayed, suspended or terminated.

Delays, suspensions or failures in our clinical trials could increase our development costs, delay or prevent regulatory approval, prevent us from commercializing such products and generating revenues, or reduce the period during which we may have exclusive rights to commercialize our products, and allow competitors to bring competing products to market sooner. We do not know whether any of our ongoing or future studies will be completed on schedule and successfully, if at all. Any delays or adverse outcomes in our clinical trials could materially adversely affect our business, results of operations and prospects.

Use of VOQUEZNA, VOQUEZNA Dual Pak or VOQUEZNA Triple Pak, any new vonoprazan formulation we may develop, or any future product candidates could be associated with side effects, adverse events or other safety risks, which could cause us to have to withdraw the product or could materially impair market acceptance, in the case of approved products, or cause us to suspend or discontinue clinical trials, abandon development, or narrow the target indications or patient population, in the case of product candidates, 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, there are known side effects and adverse events associated with VOQUEZNA, VOQUEZNA Dual Pak and VOQUEZNA Triple Pak. As use of these approved products increases, or as we conduct further clinical trials in additional indications or formulations, we could see an unacceptable severity or prevalence of these known side effects or our products may be associated with other undesirable side effects, adverse events or product characteristics. Further, serious safety issues may be identified in connection with commercialization or development of vonoprazan by third parties outside the U.S. Our future product candidates may also be associated with undesirable side effects, adverse events and product characteristics.

If any of our product candidates is associated with undesirable side effects, adverse events or product characteristics in preclinical studies or clinical development, including development of vonoprazan in new indications or formulations, we may elect to abandon development of such product candidate, alter or delay our study plans, or limit 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. Any drug-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Even if we continue with development of such product candidates, the undesirable side effects, adverse events or product characteristics may cause us to have to conduct additional safety studies, limit our ability to gain regulatory approval or cause a regulatory authority to require warnings on the label, such as a “black box” warning or contraindications, or to impose other significant restrictions on our approval, any of which may limit the commercial expectations for the product candidate, if approved.

If any of our approved products is associated with undesirable side effects or adverse events or to have other negative product characteristics, 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;
- requirements by regulatory authorities of additional warnings on the label, such as a "black box" warning or contraindications;
- requirements that we implement a REMS or create a medication guide outlining the risks of such side effects for distribution to patients;
- requirements to conduct expensive additional post-approval safety studies;
- failure to achieve or maintain market acceptance among patients, healthcare providers and patients;
- 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 significantly harm our business, financial condition, results of operations and prospects.

Obtaining regulatory approval for product candidates, including additional indications or formulations of approved products, is subject to extensive regulation and is costly, time-consuming and uncertain.

We are not permitted to market a new product candidate or an approved product for a new indication or formulation until we receive the necessary regulatory approval from the relevant regulatory authority. Gaining regulatory approval of a product candidate is subject to extensive regulation by the FDA in the United States and by comparable foreign regulatory authorities in other foreign markets. 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.

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 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 arise;

- 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 the product candidate is safe and effective for its proposed indication and that its 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 are acceptable or sufficient to support the submission of an NDA, sNDA 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 proposed formulation, labeling and/or the specifications;
- 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 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, new indications or new formulations based on safety, efficacy, or other regulatory considerations and may result in significant delays in obtaining regulatory approvals.

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.

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 and regulatory decisions may result in our failing to obtain additional regulatory approvals to market vonoprazan in additional indications, or formulations or any future product candidates we may pursue. Any delay in obtaining, or inability to obtain, additional regulatory approvals, and any limitations on such approvals would delay or prevent commercialization of that indication or product candidate and would materially adversely impact our business and prospects, which would significantly harm our business, financial condition, results of operations and prospects.

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

Given our limited financial and managerial resources, our current focus is primarily on the commercialization of our approved products, and we may decide not to pursue or continue development of additional indications or formulations for vonoprazan. Even if we elect to pursue such opportunities, we may allocate our limited resources to particular indications or formulations that ultimately prove unsuccessful or less commercially viable than other potential opportunities. In addition, we may fail to generate the

clinical data needed for approval or encounter other issues such as unexpected side effects or formulation-related technical hurdles, and we may decide to pause or such development efforts.

We may never apply for or receive regulatory approval for vonoprazan in any additional indication or formulation. Even if we do obtain approval, we may not have accurately assessed the commercial potential or target market for such new indication or new formulation or we may enter into collaborations, licenses and other similar arrangements under which we relinquish valuable rights that, in hindsight, would have been more advantageous to retain.

In addition, we may seek to expand our pipeline through in-licenses or acquisitions of development-stage assets or programs, which entails additional risk to us. Identifying, evaluating and acquiring promising product candidates requires substantial technical, financial and human resources. Efforts to do so may not result in the actual acquisition or license of a particular product candidate, potentially diverting management's attention and our resources without corresponding benefit.

We enrolled patients in Europe in our Erosive GERD and H. pylori trials with VOQUEZNA, and the FDA accepted data from those sites as part of the basis for approval of VOQUEZNA, VOQUEZNA Dual Pak and VOQUEZNA Triple Pak. However, the FDA and other comparable foreign regulatory authorities may not accept data from future trials conducted outside the United States.

We enrolled patients in Europe in our Erosive GERD and H. pylori trials with VOQUEZNA, and the FDA accepted data from those sites as part of the basis for approval of VOQUEZNA, VOQUEZNA Dual Pak and VOQUEZNA Triple Pak. We are not currently seeking regulatory approval for our VOQUEZNA products in Europe or any other foreign jurisdiction.

We may conduct future clinical trials outside the United States for vonoprazan or any future product candidates. Although the FDA may accept data from clinical trials conducted outside the United States and not subject to an investigational new drug application, or IND, acceptance of such data is subject to certain conditions imposed by the FDA. For example, regardless of whether the applicable clinical trials were conducted under an IND, 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 trials conducted outside the United States and not under an IND, the FDA generally does not provide advance input on trial design or protocols, which increases the risk that the FDA may later determine that such trials were inadequate and require additional clinical studies. In addition, foreign trials are subject to local laws and regulatory requirements, and there can be no assurance that the FDA or other regulatory authorities will accept data from such trials.

If regulatory authorities do not accept data from our foreign clinical trials for future regulatory submissions, we may be required to conduct additional clinical trials, which would be costly and time consuming and could delay or prevent our development efforts.

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. Even if final data from a clinical trial are positive, such results may not be replicated or confirmed in subsequent clinical trials.

From time to time, we or others, may publicly disclose preliminary or top-line data from clinical trials that are based on a preliminary analysis of then-available data and may be subject to change following more careful review and finalization of the results. Interim data are subject to the risk that the results and related findings and conclusions may change materially as patient enrollment continues, additional data are collected, longer follow-up periods are completed, or assumptions and conclusions change following a more comprehensive review of the 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. Adverse differences between interim, preliminary or top-line data and final results could significantly harm our business prospects.

Even if final data from a clinical trial are positive, such results may not be replicated or confirmed in subsequent clinical trials, including larger trials, trials in different patient populations, or trials designed to support additional indications or regulatory approvals. Failure to replicate clinical results could limit, delay or prevent regulatory approval, restrict labeling, reduce commercial potential, or otherwise adversely affect the value of a product or development program.

Further, regulatory agencies and other third parties 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 affect further development, approvability, labeling, or commercialization of a particular product candidate or product. In addition, the information we publicly disclose regarding a clinical trial necessarily reflects our judgment regarding what is material or appropriate, and other parties may disagree with those judgments or later view omitted information as significant.

If the preliminary, interim or top-line data we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, are not replicated in subsequent studies, or are interpreted differently by regulatory authorities or other third parties, our ability to obtain regulatory approval for, or successfully commercialize, our current products or any future product candidates could be materially adversely affected, which could harm our business, financial condition, results of operations and prospects.

Disruptions at the FDA and other government agencies caused by funding shortages, staffing limitations, government shutdowns or policy changes could delay regulatory review and approval processes and adversely affect our business.

The ability of the FDA and other government agencies to review and approve new or supplemental drug applications, modifications to approved products, or clinical development of new product candidates can be affected by a variety of factors, including government budget and funding levels, government shutdowns, statutory, regulatory and policy changes, a government agency's ability to hire and retain key personnel, their ability to accept the payment of user fees, and other events that may otherwise impair the government agency's ability to perform routine functions. As a result, average review times at the FDA and other government agencies have fluctuated in recent years. In addition, government funding for 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, may also slow the time necessary for review or approval of new drugs, supplements or modifications to approved drugs or review of clinical trials, which could adversely affect our business. For example, in recent 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. In addition, the current U.S. Presidential administration has issued certain policies and Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, which have led to substantial personnel changes, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities. If a prolonged government shutdown occurs, or if funding shortages, staffing limitations or similar factors hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, such events could significantly impact the ability of the FDA or other such 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 studies 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 any ongoing or future 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 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, sNDA or similar marketing application we submit by the FDA or by comparable regulatory authority. Any such delay or rejection could prevent us from obtaining approval to commercialize vonoprazan for any additional indications or formulations we may decide to study and any future product candidates we may develop.

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 commercial sale and any clinical development, 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 have a material adverse impact on our business, results from operation and prospects.

We do not own or operate manufacturing facilities and have no plans to build our own commercial or clinical 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 commercial sale and any clinical development. 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 commercialization of vonoprazan, and any ongoing or future development plans, could be significantly adversely affected. We have previously been informed by Sandoz of the potential for a disruption in the supply of clarithromycin tablets, a component of VOQUEZNA TRIPLE PAK. Based on more recent communications, we do not currently anticipate any near-term supply disruption; however, there can be no assurance that a disruption will not occur in the future, and we continue to actively monitor this situation. Our VOQUEZNA tablets and VOQUEZNA DUAL PAK are not affected, as they do not include clarithromycin.

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, have been approved by the FDA for the manufacture of our current products in the United States and are subject to ongoing and periodic inspection by the FDA to ensure continued compliance with applicable cGMP and other regulatory requirements. Regulatory authorities may inspect these facilities at any time, and continued approval is not assured. We do not control the manufacturing processes of, and are completely dependent on, Catalent, Evonik and Sandoz for compliance with applicable cGMP and similar requirements. If the FDA identifies deficiencies during an inspection, issues a warning letter, or otherwise determines that a facility is not in compliance, use of that facility for our approved products could be withdrawn or approval of that facility for use in connection with any of our product candidates could be delayed, limited, suspended or withdrawn, which could disrupt the manufacture or supply of our products. In addition, if we seek regulatory approval for our products outside the United States, the facilities used to manufacture vonoprazan and related components would be subject to inspection and approval by foreign regulatory authorities, and we may be required to satisfy additional or different regulatory requirements. There can be no assurance that such facilities would be approved for ex-U.S. commercial supply on a timely basis or at all. If the FDA withdraws approval of facilities of any third-party manufacturer for the manufacture of our approved products or the FDA or a comparable foreign regulatory authority does not approve any other third party manufacturer we seek to use in the future with respect to vonoprazan or other products we may develop, we may need to find alternative manufacturing facilities which would significantly adversely impact our ability to continue to market our approved products and to continue our development programs and obtain additional regulatory approvals.

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, suspension or withdrawal of approvals, seizures or recalls of products or product candidates, clinical holds, fines, injunctions, civil penalties, delays, 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 to comply with cGMP or similar foreign requirements, could adversely affect our business in a number of ways, including:

- inability to meet commercial demands for our approved products;
- recall of batches of our approved products or product candidates;
- inability to initiate and continue clinical trials of vonoprazan or any future product candidates;

- delays in submitting regulatory applications, or receiving marketing approvals for new indications or formulations of vonoprazan or future product candidates that we might successfully develop; and
- third-party manufacturing facilities or our facilities being subjected to additional inspections by regulatory authorities;

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 products and product candidates for access to manufacturing capacity, and there are a limited number of third-party manufacturers that operate under cGMP and similar regulations and are capable of manufacturing our products. 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 or any third-party manufacturer we rely on cannot perform as agreed, materially breaches its obligations or terminates or elects not to renew its agreement with us, or otherwise becomes unable or unwilling to continue manufacturing our products or product candidates, we may be required to identify and qualify alternative manufacturing facilities. The process of transferring manufacturing operations, validating processes, qualifying new suppliers and obtaining required regulatory approvals could be time-consuming, costly and subject to significant technical and regulatory risks, and may not be successful on a timely basis or at all. In addition, Catalent, Evonik, Sandoz and any other third-party manufacturers we may use in the future may experience manufacturing or shipping disruptions due to resource constraints or as a result of natural disasters, labor disputes, geopolitical instability, or public health emergencies or ongoing hostilities in the Ukraine, Middle East or elsewhere. Any such disruption could jeopardize our ability to meet demand for our approved products or the supply of product candidates for clinical trials.

In addition, our inventory of drug substance, drug product or finished goods, whether held by us or by third parties, could be lost, damaged, destroyed or rendered unusable as a result of natural disasters, power outages, equipment failures, contamination, transportation incidents or other unforeseen events, which could further disrupt our supply and adversely affect our ability to meet commercial demand and clinical trial needs.

Our current and anticipated future dependence upon others for the manufacture of our approved products or any future product candidates could result in supply interruptions, increased manufacturing costs, reduced profit margins, an inability to meet patient or market demand on a timely and competitive basis and a decrease in market acceptance, any of which could materially adversely affect our business, financial condition, results of operations and prospects.

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 current and future 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

may impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations and prospects.

The loss of, or significant reduction in business from, one or more of our major customers could significantly reduce our revenue, earnings or other operating results.

We sell our products primarily to established wholesale distributors and retailers in the pharmaceutical industry. A significant portion of our revenue is derived from a relatively small number of these customers. Three of our customers combined provided approximately 69% of our product sales during the year ended December 31, 2025, with each of these individual customers ranging from 22% to 23% of our product sales. The loss of any of these customers, or any of our other large customers, or reductions in business from them, could have a material adverse effect on our business, financial condition, results of operations, and cash flow. There can be no assurance that revenue from any customer will continue at their historical levels.

In addition, we work with third-party pharmacy support service providers to facilitate patient access to our VOQUEZNA products. Through these arrangements, eligible patients may access programs designed to help identify lower out-of-pocket costs, support prior authorization submissions and offer home delivery from licensed pharmacies, including for certain cash-pay patients. If any of these third-party service providers were to discontinue or materially limit their services, experience operational disruptions, or otherwise be unable to support patient access on acceptable terms, patient utilization of our products could be adversely affected, which could in turn negatively impact demand for our products and our revenue.

Further, as of December 31, 2025, three customers accounted for 78% of our accounts receivable balance, with each of these individual customers ranging from 19% to 30% of the accounts receivable balance. As a result, we are exposed to credit risk from these customers and if any of these customers were to fail to pay us in a timely manner, our cash flows could be materially harmed.

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 continue to evaluate the potential for vonoprazan in Europe and Canada. In the future we will also need to successfully acquire, develop and gain approval of one or more product candidates other than our vonoprazan products. We may seek to enter into collaborations, joint ventures, licenses and other similar arrangements for the development or commercialization of vonoprazan in Europe or Canada or to acquire future product candidates. We may not be successful in our efforts to establish such arrangements because, among other reasons, third parties may not view our current products or future product candidates as having sufficient commercial potential, acceptable pricing or reimbursement prospects, or an appropriate risk-return profile or because potential licensors or sellers of product candidates may prefer to retain rights, partner with larger or better-capitalized companies, pursue alternative transactions, or may not agree with us on valuation, deal structure, development plans, intellectual property terms or other key transaction terms. In addition, we face significant competition in seeking appropriate strategic partners and attractive product candidates, and the negotiation process can be time consuming and complex. Further, any future arrangements 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 arrangements, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such arrangements 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 in Europe or Canada or any future product candidates and may not conduct those activities in the same manner as we do. Any termination of arrangements we enter into in the future, or any delay in entering into such arrangements, could delay or impair the development and commercialization of vonoprazan in Europe and Canada 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 performance. As a commercial-stage company with a limited product portfolio, a substantial portion of our revenue is derived from sales of our VOQUEZNA products, and our operating results are highly sensitive to factors affecting these products, and even modest changes in market acceptance, payer access, pricing, demand or supply could have a disproportionate impact on our operating results, particularly changes related to VOQUEZNA as a treatment for GERD. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- variability in the level of demand VOQUEZNA for the treatment of GERD, including market acceptance, prescribing trends among gastroenterologists and primary care physicians, use of cash-pay or access programs, and seasonality;
- the timing, cost and level of investment in our commercialization activities, including sales force deployment, marketing initiatives and payer access efforts;
- pricing, coverage and reimbursement decisions and prior authorization requirements for our approved products, and potential changes in payer policies;
- competitive dynamics affecting our approved products, including competition from generic therapies, new branded products, or alternative treatment approaches, and the impact of the introduction of competitive products on demand, market share, pricing, payor coverage, reimbursement and policies and other market dynamics;
- the timing, cost of, and level of investment in, research, development and regulatory activities for any future indications or formulations of vonoprazan or new product candidates, which may change from time to time, and the results of such efforts;
- 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;
- the timing and amount of the milestone or other payments we will be required to pay to Takeda pursuant to the Takeda License;
- our obligations under our Loan Agreement with Hercules Capital and under our Revenue Interest Financing Arrangement, or RIFA, including required interest, royalty or other payments, compliance with financial and other covenants, and limitations on our operating flexibility, which may affect the timing and availability of capital and our ability to manage expenses and investments;
- expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies; and
- future accounting pronouncements or changes in our accounting policies.

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 our expectations or 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 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 licensed 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, $10 million in March 2024, $25 million in June 2024, and $25 million in December 2024. In February 2026, we entered into an amendment to the Loan Agreement which provided for a new term loan tranche of $175 million with a new maturity date of February 1, 2029. We used the proceeds from the new loan tranche, along with cash on our balance sheet, to repay in full the existing secured obligations outstanding under the Loan Agreement among other changes. All obligations under the Loan Agreement are secured by a first priority lien on substantially all of our assets, excluding our licensed 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.

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 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.

In order to service our current indebtedness and any additional indebtedness we may incur in the future, including meeting cash covenants, 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, meet our cash covenant obligations 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 or meet our cash covenant obligation 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.

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 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 in its Erosive GERD indication. In addition, we were eligible for $25 million in additional funding for achievement of a sales milestone. On December 23, 2024, CO Finance LVS XXXVII LLC agreed to assign and transfer to OC III LVS LX LP all of its rights, title and interest as an Additional Investor and in connection therewith, OC III LVS LX LP executed a Joinder Agreement. As of December 31, 2025, no additional funding is available under the Revenue Interest Financing Agreement.

Under the Revenue Interest Financing Agreement, the Initial Investors and the Additional 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 upon FDA approval for vonoprazan for an indication relating to the treatment of heartburn associated with Non-Erosive GERD, which occurred on July 17, 2024. 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, 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.

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 Revenue Interest Financing Agreement from net sales of VOQUEZNA and other products containing vonoprazan.

To meet our obligations under the Revenue Interest Financing Agreement, including meeting future cash covenants and Minimum Amounts, we need to generate cash from our operating activities. Our ability to generate cash from our operating activities 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 meet our obligations under the Revenue Interest Financing Agreement and fund our other liquidity needs. A failure to meet our obligations under the Revenue Interest Financing Agreement could have a material adverse effect on our business, financial condition and results of operations.

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. For example, effective April 1, 2025, Steven Basta was appointed as our President and Chief Executive Officer, replacing Terrie Curran. In addition, effective April 30, 2025, Azmi Nabulsi, M.D., our Chief Operating Officer, Molly Henderson, our Chief Financial Officer, Martin Gilligan, our Chief Commercial Officer, and Tom Harris, our Chief Development Sciences Officer resigned as officers and we announced that Jonathan Bentley will join us as our Senior Vice President, Head of Sales. On October 6, 2025, Sanjeev Narula joined us as Chief Financial and Business Officer. Executive leadership transitions can be inherently difficult to manage and, as a result, if we have further resignations or terminations, we may experience disruption or have difficulty in managing our operations and achieving our business objectives. 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 commercialization and development 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 are subject to various foreign, federal, and state healthcare laws and regulations, and our failure to comply with these laws and regulations could result in significant fines, damages and penalties and 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 civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- 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, 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, cost and uncertainty for us of commercializing vonoprazan and any future product candidates and may adversely affect pricing, reimbursement and patient access.

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;
- 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.

While the Affordable Care Act remains in effect, more recent federal and state initiatives, including drug pricing reform, reimbursement constraints and coverage management tools, may have a more direct impact on the commercialization of branded pharmaceutical products such as vonoprazan. 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 remains 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 eliminated the statutory cap on manufacturers' Medicaid drug rebate liability, 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.

On August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, 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 replaced the Part D coverage gap discount program with a new discounting program (which began 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. CMS has published the negotiated prices for the initial ten drugs, which went into effect in 2026, and the subsequent 15 drugs, which will first be effective in 2027, as well as the next set of 15 drugs that will be subject to negotiation, although 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. Even if our products are not selected for negotiation, the IRA may indirectly affect our business by influencing payer formulary decisions, coverage restrictions, utilization management practices and pricing expectations for branded drugs. 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.

The One Big Beautiful Bill Act, which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect our sales of VOQUEZNA, VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK or any other product candidate that we commercialize.

The Trump administration is pursuing a two-fold strategy to reduce drug costs in the U.S. President Trump has threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers have reportedly entered into confidential pricing agreements with the federal government. The Trump administration is also pursuing traditional regulatory pathways to impose drug pricing policies, and published two proposed regulations in December 2025, referred to as Globe and Guard. If finalized, these regulations would implement mandatory payment models under which manufacturers of eligible drugs would be required to pay rebates to the federal government on a portion of the units of their drugs that are reimbursed by Medicare, with the rebate amount based on most favored nation pricing. While the impact of the Globe and Guard proposed regulations, if finalized, cannot yet be determined, it is likely to be significant. Even regulatory proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business. In addition, pharmaceutical pricing and marketing has long been the subject of considerable discussion in Congress and among policymakers, and it is possible that Congress could enact additional laws that negatively affect the pharmaceutical industry.

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, drug price reporting and other transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states or impose additional administrative burdens that could delay access or complicate commercialization. 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. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers, limit patient access, reduce prescribing or require additional discounts, any of which could materially adversely affect our ability to generate revenue, achieve or maintain profitability and successfully commercialize vonoprazan and any future products.

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 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, and 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.

U.S. legislation, sanctions, trade restrictions and other foreign regulatory requirements could adversely impact the supply of material from foreign CROs and CMOs to us or our ability to secure government commitments to purchase potential therapies.

We currently and may in the future rely on foreign CROs and CMOs, such as Evonik based in Germany and Sandoz based in Austria. Such foreign CROs and CMOs may be subject to U.S. legislation, sanctions, trade restrictions and other foreign regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material or have an adverse effect on our ability to secure significant commitments from governments to purchase potential therapies. For example, members of the U.S. Congress have introduced bills aimed at commercial supply of pharmaceutical products and the Trump Administration has announced tariffs on certain industries, such as steel and aluminum imports, and the intent to impose additional tariffs for other industries or countries. If these bills become law, or similar laws are passed, or if sanctions applicable to our commercial supply chain are imposed, they would have the potential to severely increase our costs or we may be required to shift manufacturing to other third parties which could be costly and cause supply disruptions which could adversely impact our operations. In addition, the U.S. BIOSECURE Act, which was enacted in December 2025, prohibits federal agencies from procuring or using any biotechnology equipment or services from "biotechnology companies of concern", or entering into, extending, or renewing any contracts with entities that use such biotechnology equipment or services from "biotechnology companies of concern". Congress has interpreted a "biotechnology company of concern" as an entity that is under the control of a foreign adversary and that poses a risk to national security based on its research or multiomic data collection (e.g., collection of genomic information). While the U.S. BIOSECURE Act has a grandfathering period of five years for existing contracts, and has

carveouts for manufacture of drugs for supply under Medicaid and Medicare Part B, subject to the Secretary of Veteran Affairs' discretion, the impact of the U.S. BIOSECURE Act on the biotechnology industry is uncertain. If the foreign CROs and CMOs we rely on become subject to trade restrictions, sanctions, increased tariffs or other regulatory requirements by the U.S. government (including designation as a "biotechnology company of concern" under the U.S. BIOSECURE Act), or if the U.S. or Chinese or other foreign governments take retaliatory actions due to recent or increased tensions between the U.S. and China or other countries, it may have the potential to severely restrict the ability of U.S. biopharmaceutical companies like us to purchase services or products from, or otherwise collaborate with, certain "biotechnology companies of concern" without losing the ability to contract with, or otherwise receive funding from, the U.S. government.

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 sale and use of VOQUEZNA, VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK, and any other approved products in the future, and the use of product candidates by us in clinical trials, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, distributors, 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 and commercialization of our products, and, if approved, our future product candidates, and could negatively impair our results of operations and prospects.

Although the clinical trial process and post-marketing surveillance are designed to identify and characterize potential side effects, it is possible that a drug, including an approved product, may be associated with adverse events that were not observed during clinical development or that occur at a greater frequency or severity in broader patient populations or with longer-term use. While VOQUEZNA, VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK have been approved and have been evaluated in clinical trials, additional adverse events or safety signals may be identified through continued clinical experience, post-marketing surveillance or real-world use. If our products or any future product candidates are associated with serious or unexpected adverse events, we could be subject to product liability claims, regulatory actions, labeling changes, additional post-marketing study requirements, restrictions on use, or other actions that could limit or delay commercialization. In addition, physicians and patients may not comply with prescribing information, contraindications or warnings, including limitations on patient populations for whom use may be appropriate, which could increase the risk of adverse events and potential liability.

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 are subject to ongoing adverse event reporting obligations for our approved products and any failure to comply with these requirements could result in regulatory action that would materially harm our business.

The FDA and comparable foreign regulatory authorities require us, Takeda (with respect to products containing vonoprazan) and any of our potential future collaborators, to collect, monitor and report certain information about adverse medical events associated with our approved products. These reporting obligations are subject to detailed regulatory requirements, including strict timelines that are generally triggered by when we or such third parties become aware of an adverse event and the nature and seriousness of the event. We plan to rely, in part, on third parties, including Takeda and any future collaborators, vendors or contract research organizations, to comply with these adverse event reporting requirements. Any failure by us or such third parties to accurately or timely report adverse events, or to maintain adequate pharmacovigilance systems and processes, could result in regulatory actions by the FDA or other regulatory authorities. Such actions may include warning letters, civil monetary penalties, seizure of products, requirements to modify labeling or conduct additional post-marketing studies, restrictions on commercialization, delays in approval of product candidates or, in severe cases, criminal prosecution. Any such actions could materially harm our business, financial condition, results of operations and prospects.

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 and sales 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.

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. For instance, we may obtain health information from third parties, such as research institutions with which we collaborate, that are subject to privacy and security requirements under HIPAA. Although we do not believe that we are directly subject to HIPAA, other than potentially with respect to providing certain employee benefits, we could be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA.. 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 are subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and future potential strategic partners. For example, the CCPA requires covered businesses that process the personal information of California residents to, among other things: (i) provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; (ii) receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information; and (iii) enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. Similar laws have passed in other states, 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. As such compliance with applicable laws may be challenging and may involve significant

expenditure and resources. 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 companies for online collection, use, dissemination and security practices that appear to be unfair or deceptive. 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 and the possibility of future activities, we are also subject to 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 scrutiny of transfers of personal data from the EEA and the UK to the United States and other jurisdictions that the European Commission or UK government respectively, does not recognize as providing an "adequate" level of data protection. Case law from the Court of Justice of the European Union has raised questions regarding the sufficiency of certain transfer mechanisms, including standard contractual clauses, in particular circumstances and requires case-by-case assessments of cross-border transfers. The European Commission has adopted an adequacy decision for the EU-U.S. Data Privacy Framework, or DPF, and the United Kingdom has adopted a corresponding extension; however, the legal landscape governing international data transfers remains complex and subject to ongoing regulatory scrutiny and potential legal challenge. As a result, we expect uncertainty regarding international personal data transfers to continue. If applicable transfer mechanisms are invalidated, restricted or otherwise limited, or if we are unable to comply with evolving regulatory requirements, we could incur additional costs, face complaints, investigations or fines, be required to change vendors or operational practices, or be required to modify how and where we process personal data, any of which could adversely affect our business, financial condition and results of operations.

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.

We rely on computer systems, hardware, software, technology infrastructure and online sites and networks for both internal and external operations that are critical to our business. We own and manage some of these IT Systems but also rely on third parties for a range of IT Systems and related products and services, including but not limited to cloud computing services. We and certain of our third-party providers collect, maintain and process data about customers, employees, business partners and others, including personally identifiable information, as well as proprietary information belonging to our business such as trade secrets. 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. We and certain of our third-party providers regularly experience cyberattacks and other incidents, and we expect such attacks and incidents to continue in varying degrees. 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, 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 for a period of time. As a result, we were forced to make alternative arrangements in order to facilitate processing of patient co-pay assistance card program transactions. While the Change Healthcare-related disruption was limited in time, a similar incident in the future with Change Healthcare or other service providers 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. Additionally, any integration of artificial intelligence in our or any third party's operations, products or services is expected to pose new or unknown cybersecurity risks and challenges. 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 commercial operations, 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 will rely on third parties to manufacture any future product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. 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 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, legal claims or proceedings (including class actions), regulatory investigations, enforcement actions, and other penalties or liabilities for any noncompliance to certain privacy and cybersecurity laws. Further, our insurance coverage may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems.

Our business may be affected by the evolving regulatory framework for AI Technologies

We use artificial intelligence, machine learning and automated decision-making technologies, or collectively, AI Technologies, in certain aspects of our business and may increase our investment in these capabilities over time. The development, implementation and oversight of AI Technologies involve significant risks, including the possibility that AI-generated analyses or recommendations may be inaccurate, incomplete, biased, based on data to which we do not have sufficient rights, or otherwise deficient. AI models may degrade in performance over time, be adversely affected by technical failures or cybersecurity threats, or require substantial resources to maintain and monitor. Our use of AI Technologies may also increase regulatory, data protection, cybersecurity, intellectual property and contractual risks, and may expose us to liability if such technologies are used improperly or in violation of applicable laws.

The legal and regulatory landscape governing AI Technologies is rapidly evolving at the federal, state and international levels, and existing laws may be interpreted in ways that affect our use of these technologies. Compliance with new or changing requirements may require us to modify our practices, incur significant costs, or limit our use of AI Technologies in certain

jurisdictions. If we fail to appropriately manage the risks associated with AI Technologies or comply with applicable laws and regulations, our business, reputation, financial condition and results of operations could be adversely affected.

Our employees and independent contractors, including consultants, vendor, principal investigators and CROs, 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 consultants, vendors, principal investigators or CROs, may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or other unauthorized activities that violate applicable laws or regulations, including: (i) the laws and regulations of the FDA and other similar regulatory bodies, (ii) manufacturing standards, including cGMP and similar requirements, (iii) federal and state healthcare, security, fraud and abuse laws, data privacy and cybersecurity laws, and (iv) laws and regulations requiring the true, complete and accurate reporting of financial information, pricing data or other required disclosures. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of commercial activities, patient access programs, reimbursement support, sales and marketing activities, or 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 develop and, if approved, sell our products in the territories outside the United States to which we have rights, 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. 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 approved products 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 approved products 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 to the extent we believe such patent protection will be important to our business. We do not own any issued patents at this time. We currently own one pending patent application. 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 any products and product candidates incorporating the relevant intellectual property.

We may need to obtain further licenses from third parties to advance our research or continue 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 products and 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, processes, formulations 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 regulatory exclusivity. In May 2021, the FDA granted qualified infectious disease product, or QIDP, designations to vonoprazan 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 products contained the active moiety vonoprazan, which had not previously been approved, the approvals triggered the standard five-year period of NCE exclusivity. In addition, because the products were designated as QIDPs, that five-year NCE exclusivity period was extended by an additional five years pursuant to the GAIN Act, resulting in a total of ten years of NCE exclusivity through May 3, 2032. In November 2023, we received approval for VOQUEZNA tablets, which also contain vonoprazan. The FDA has interpreted NCE exclusivity to preclude FDA from accepting abbreviated new drug applications, or ANDAs, or certain new drug applications submitted under Section 505(b)(2) of the FDCA containing the same active moiety as the applicable approved active moiety. On June 16, 2025, we announced that, following our Citizen Petition, FDA updated the Orange Book listing for VOQUEZNA tablets, which contain the same active moiety as VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL to reflect the same total ten-year period of NCE exclusivity, consisting of the standard five-year NCE exclusivity period plus the five-year GAIN Act extension, through May 3, 2032. Patent protections listed in the Orange Book are distinct from regulatory exclusivities and generally do not prevent the FDA from accepting ANDAs or 505(b)(2) NDAs, but may delay approval or result in litigation depending on the certifications made by the applicant.

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 our approved products 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 our VOQUEZNA products 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 our VOQUEZNA products and any future product candidates.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our VOQUEZNA products 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 our VOQUEZNA products 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 our VOQUEZNA products 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 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 our VOQUEZNA products and any future product candidates from being marketed.

Any patent-related legal action against us claiming damages and seeking to enjoin activities relating to our VOQUEZNA products 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 market such products 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 our VOQUEZNA products 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 commercializing our VOQUEZNA products 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 approved products 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 our VOQUEZNA products 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 product candidates, 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 "Unitary Patent" and Unified Patent Court, or UPC, framework was adopted to create a new court system for litigation involving European patents. The UPC began operating on June 1, 2023 and has become a common forum for challenging patents in the pharmaceutical space. The UPC provides a forum in which competitors may seek centralized revocation of our European patents and may seek injunctions with effect across multiple participating jurisdictions, which could adversely affect our business and our ability to commercialize our products. During a transitional period, actions concerning traditional European patents may be brought either before the UPC or national courts. Proprietors (or applicants) of certain European patents and applications may also elect to opt out of the UPC's jurisdiction for the life of the patent, unless an action has already been brought before the UPC, but doing so could limit our ability to take advantage of the UPC system. If we do not meet the applicable procedural requirements for an effective opt-out, our European patents could remain subject to UPC jurisdiction.

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. Although certain extensions or adjustments may be available, they are not guaranteed and may not be sufficient to meaningfully extend the commercial life of a patent. 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 any future product candidates, our business may be materially harmed.

Based on the first marketing approval by the FDA for a product, the product 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. 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, or the government may disagree that the patent term extension should apply to a particular product. 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. *For more information regarding our patent term extensions for our patents, see the section entitled "Business—Intellectual Property."*

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 our approved products 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 our activities. 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. 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 any product candidates 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 product or product candidate;
- 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:

- achievement of expected product sales, market acceptance and profitability for VOQUEZNA and any future products;
- changes in coverage, reimbursement, utilization management or pricing policies affecting VOQUEZNA and any future products, including changes in the structure of healthcare payment systems;
- manufacturing, supply or distribution delays or shortages;
- any changes to our relationships with manufacturers, suppliers, licensors, future collaborators or other strategic partners;
- innovations, new products or generic alternatives introduced by our competitors;
- market conditions in the biopharmaceutical sector and the issuance of securities analysts' reports or recommendations;
- establishment of short positions by holders or non-holders of our common stock;
- 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;
- sales of our common stock by insiders or other stockholders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- an inability to obtain additional funding on acceptable terms or at all;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- additional regulatory approvals of vonoprazan or any future product candidates, limitations on approved labeling or patient populations, or changes or delays in regulatory review processes that affect commercialization;
- regulatory developments in the United States and foreign countries;
- our ability to enroll patients in our ongoing and any future clinical trials and to generate data to support additional indications or formulations;
- results of our clinical trials or other clinical studies, including studies supporting additional indications or formulations, as well as clinical results reported by Takeda, our competitors or other companies in our market sector;
- the success or failure of our efforts to acquire, license or develop additional product candidates;
- any termination or loss of rights under the Takeda License;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- additions or departures of key personnel;

- intellectual property, product liability or other litigation against us;
- general economic, industry and market conditions, public health emergencies or other events or factors, many of which are beyond our control; 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.

We have ceased to qualify as a smaller reporting company in 2026, and as a result we are subject to increased reporting, compliance and internal control requirements, which may increase our costs and strain management resources.

As of January 1, 2026, we no longer qualify as a smaller reporting company under the U.S. securities laws. As a result, we will be subject to expanded disclosure requirements, accelerated filing deadlines, and increased compliance obligations under the Securities Exchange Act of 1934, including, over time, the requirement that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act.

These requirements will increase our legal, accounting, compliance and internal control costs and require significant management time and attention. We may need to implement additional systems, procedures and controls to maintain compliance, and we may need to hire additional personnel or engage additional third-party advisors. If we are unable to effectively manage these increased requirements, or if we experience material weaknesses in our internal controls, our ability to timely file required reports, our financial reporting reliability and investor confidence in our company could be adversely affected, which could negatively impact our stock price.

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, or NOL, carryforwards and other tax attributes may be limited.

We have incurred substantial losses during our history. Our ability to use our federal and state NOL carryforwards to offset potential future taxable income is dependent upon our generation of future taxable income before any applicable expiration dates of the NOL carryforwards, and we cannot predict with certainty when or whether we will generate sufficient taxable income to use all of our NOL carryforwards. 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 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 other 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.

Changes in tax laws may materially adversely affect our financial condition, results of operations and cash flows.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, or interpreted, changed, modified or applied adversely to us, any of which could adversely affect our business operations and financial performance. The likelihood of these changes being enacted or implemented is unclear. We are currently unable to predict whether such changes will occur and, if so, the ultimate impact on our business. To the extent that such changes have a negative impact on us, our customers or our suppliers, including as a result of related uncertainty, these changes may materially and adversely impact our business, financial condition, results of operations and cash flows. We urge our investors to consult with their legal and tax advisors with respect to any new tax 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 DUAL PAK and VOQUEZNA TRIPLE PAK and any future product candidates. Our ability to obtain commercial and 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 business may be adversely affected by epidemics, pandemics or other public health emergencies.

Epidemics, pandemics or other public health emergencies could adversely affect our business, financial condition and results of operations. Such events may disrupt economic activity globally and could materially impact our operations, including by limiting access to healthcare providers and patients, reducing in-person promotional activities, disrupting manufacturing or supply chains for

our products, delaying regulatory reviews or inspections, constraining our workforce or that of our third-party manufacturers, CROs, suppliers or service providers, and impairing our ability to raise capital or access the financial markets on acceptable terms.

Public health emergencies may also result in governmental actions, travel restrictions, workplace closures or other mitigation measures that could adversely affect our commercial execution, distribution of our products or demand for our products. While the impact of any future public health emergency is difficult to predict, such events could materially impair our ability to successfully commercialize our approved products, pursue development activities or otherwise operate our business, and could have a material adverse effect on our business, financial condition and results of operations.

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 apply to us. 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 the Sarbanes-Oxley Act of 2002, our management is required to assess and report on the effectiveness of our internal control over financial reporting. Beginning with fiscal year 2026, as a result of our filer status, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing internal control over financial reporting are complex and require significant documentation, testing, oversight and ongoing evaluation. Compliance with these requirements places significant demands on management, finance, accounting and internal audit resources and may increase our costs. As we continue to scale our operations and commercial activities, the risk of deficiencies in our internal control environment may increase. There can be no assurance that we will be able to maintain effective internal control over financial reporting on a timely basis or at all. In the future, we may identify material weaknesses or significant deficiencies in our internal control over financial reporting, including as a result of changes in business processes, personnel, systems or increased transaction volume. Any failure to maintain effective internal control over financial reporting could impair our ability to accurately report our financial condition, results of operations or cash flows. If we or our independent registered public accounting firm are unable to conclude that our internal control over financial reporting is effective, or if we are required to remediate material weaknesses, 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 become subject to increased regulatory scrutiny, enforcement actions or limitations on our ability to access 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.

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. This does not mean, however, that we meet any technical standards, specifications, or requirements.

Our cybersecurity risk management program is part of our overall risk management program and shares similar governance processes and reporting channels that apply across the risk management program to financial, legal, compliance, and other operational risk areas.

Key elements of our cybersecurity risk management program include but are not limited to the following:

- risk assessments designed to help identify material risks from cybersecurity threats to our critical systems and information;
- 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 processes;
- cybersecurity awareness training of our employees, including incident response personnel and senior management;
- artificial intelligence based managed detection and response system that provides 24×7 monitoring of our networks, endpoints, and cloud environments; alerts from this system are handled by an external 24x7 staff that reviews the alerts and acts where necessary;
- a cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents; and
- a third-party risk management evaluation process for key service providers, based on our assessment of their criticality to our operations and respective risk profile.

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

Cybersecurity Governance

Our Board of Directors considers cybersecurity risk as part of its risk oversight function and has delegated to the Audit Committee, or Committee, oversight of cybersecurity risks, including oversight of 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 where it deems appropriate, regarding any cybersecurity incidents it considers to be significant or potentially significant.

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

Our management team, led by our Vice President of Information Technology, is responsible for managing and directing day-to-day assessment and management of materials risks from cybersecurity threats, including oversight of our cybersecurity tools, controls and strategies to protect organization assets, networks and data. The Vice President of Information Technology has primary responsibility for our overall cybersecurity risk management program and supervises both our internal IT personnel and our retained external cybersecurity consultants. The Vice President of Information Technology has over 25 years of experience in information technology.

Our information technology team takes steps to stay informed about and monitor efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include briefings from internal 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 leased offices 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 4, 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 February 23, 2026, there were 78,798,712 shares of our common stock outstanding held by approximately 56 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 commercial-stage biopharmaceutical company focused on commercializing and developing novel treatments for gastrointestinal, or GI, diseases. Our approved products, VOQUEZNA®, VOQUEZNA® DUAL PAK® and VOQUEZNA® TRIPLE PAK®, contain vonoprazan, an oral small molecule potassium-competitive acid blocker, or PCAB. PCABs are a novel class of molecules that block acid secretion in the stomach. VOQUEZNA is the only PCAB currently approved for marketing and sale in the United States.

We began U.S. commercialization of VOQUEZNA for the treatment of erosive gastroesophageal reflux disease, or Erosive GERD, and Helicobacter pylori, or *H. pylori*, infection, and VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK for the treatment of *H. pylori* infection, in November 2023. The U.S. Food and Drug Administration, or FDA, approved VOQUEZNA for the relief of heartburn associated with Non-Erosive GERD, the largest category of GERD, in July 2024.

Vonoprazan was originally developed by Takeda Pharmaceutical Company Limited, or Takeda, and is marketed in multiple countries outside the United States. We licensed U.S., European and Canadian rights to vonoprazan from Takeda in 2019. We are independently commercializing VOQUEZNA, VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK in the United States.

During the year ended December 31, 2025, we generated increased revenues from sales of our VOQUEZNA products compared to the prior year, reflecting continued execution of our U.S. commercial strategy. The majority of our 2025 revenue was derived from sales of VOQUEZNA. During this period, we also experienced growth in prescription volume and prescriber adoption, with most prescriptions written for GERD indications. As of February 13, 2026, over 1.1 million prescriptions for VOQUEZNA, VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK have been filled since launch. We continue to have broad commercial coverage for VOQUEZNA, with access for over 120 million, or over 80%, of U.S. commercial lives. Our commercial efforts are supported by a targeted sales force and continued focus on prescriber engagement and payer access.

In May 2021, the FDA granted qualified infectious disease product, or QIDP, designation to VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK, resulting in an extension of the five-year new chemical entity, or NCE, exclusivity by an additional five years. In December 2024, we submitted a citizen petition requesting that the FDA update the Orange Book listing for VOQUEZNA to reflect the same ten-year period of NCE exclusivity applicable to VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK. In June 2025, the FDA granted the petition and updated the Orange Book listing for VOQUEZNA to reflect the ten-year period of NCE exclusivity for vonoprazan. As a result, all three VOQUEZNA products now have NCE exclusivity extending through May 3, 2032.

In the fourth quarter of 2025, we initiated a Phase 2 clinical trial evaluating vonoprazan in the treatment of adults with eosinophilic esophagitis, or EoE. While our current focus is on continued U.S. commercialization of VOQUEZNA products for GERD and *H. pylori*, we are also selectively pursuing life-cycle management opportunities for vonoprazan. We may also explore the potential for vonoprazan in Europe and Canada, as well as opportunities to in-license or acquire additional clinical or commercial-stage product candidates for GI diseases.

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 vonoprazan, meeting with regulatory authorities, managing our clinical trials of vonoprazan, preparing for commercialization of our products containing vonoprazan, commercially launching our approved products in the U.S., and providing other selling, general and administrative support for our operations. Our operations to date have been funded primarily through commercial bank debt, our revenue interest financing debt and various equity offerings, including our at-the-market offerings. From our inception through December 31, 2025, we sold 34,737,032 shares of our common stock and 2,608,922 pre-funded warrants, generating net proceeds of approximately $543.3 million, after deducting underwriting discounts, commissions and offering costs. In January 2026, we sold 6,875,000 shares of our common stock, or our January 2026 Offering, at a price of $16.00 per share and pre-funded warrants to purchase 1,250,078 shares of our common stock at a price of $15.999 per pre-funded warrant for total gross proceeds of $130.0 million or $122.2 million of net proceeds after deducting underwriting discounts, commissions and offering costs.

As of December 31, 2025, we had cash and cash equivalents of $130.0 million. Based on our current operating plan, we believe that our existing cash and cash equivalents together with anticipated product revenues and the $122.2 million of net proceeds from our January 2026 offering, are sufficient to fund operations for at least the next twelve months and will be sufficient to enable us to reach operating profitability beginning in the third quarter of 2026, excluding stock-based compensation. 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 commercialize VOQUEZNA, develop vonoprazan for additional indications or formulations or develop or any future product candidates.

Since inception, we have incurred significant operating losses. Our net loss was $221.2 million and $334.3 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $1.5 billion. Despite our plans and expectations, we could continue to incur operating losses for the foreseeable future. If we do not achieve our goals, it could be several years, if ever, before our current products or potential future product candidates, if successfully developed and approved, generate significant revenues to offset these operating losses. As a result, we are uncertain if we will achieve profitability on our current expected timeline, if at all, 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.

While we have generated revenue to date, until such time as we can generate significant revenue from sales of our approved products containing vonoprazan, we also expect to finance our cash needs through equity offerings, 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 and if 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.

Restructuring

In May 2025, we implemented a cost reduction and organizational restructuring plan to reduce cash burn and focus resources on commercial execution. In connection with the restructuring, our workforce was reduced by 26 employees, or approximately 6%, including certain leadership changes all designed to right-size the organization. During the year ended December 31, 2025, total restructuring charges incurred were $9.2 million consisting of one-time termination benefits to affected employees for severance, non-cash stock-based compensation costs, healthcare benefits and outplacement assistance. As of December 31, 2025, approximately $0.5 million of restructuring related accruals remain on our balance sheet.

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 are 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 averaging 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. We currently pay royalties to Takeda on sales of VOQUEZNA tablets, VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK in the U.S. During the years ended December 31, 2025 and 2024, we recorded $17.5 million and $5.5 million, respectively, of royalty expense under the Takeda License, of which $5.8 million is included within accrued expenses as of December 31, 2025.

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 3 Commitments and Contingencies for further details). In addition, shipping and handling costs for product sales are recorded as incurred. Cost of revenue also includes 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. We do not track total research and development expenses by indication.

Research and development expenses include:

- *Clinical development expenses:* external research and development expenses incurred under agreements with CROs, regulatory costs, and consultants to conduct and support our clinical trials of vonoprazan;
- *Personnel related expenses*: salaries, payroll taxes, employee benefits, and restructuring expenses in 2025;
- *Chemistry manufacturing and controls, or CMC, expenses:* costs related to the manufacturing of vonoprazan for our clinical trials;
- *Consulting, professional and other costs:* external costs related to consulting and professional services and other research costs incurred; and
- *Stock-based compensation expenses*: stock-based compensation expense recognized for those individuals involved in research and development efforts including for any restructuring expenses in 2025.

The following table summarizes our research and development expenses for the years ended December 31, 2025 and 2024 (in thousands):

	Years Ended December 31,	
	2025	2024
Clinical development and regulatory	$ 10,491	$ 10,877
Personnel related	11,166	11,909
Chemistry manufacturing and controls	3,179	4,090
Consulting, professional and other costs	1,080	1,639
Stock-based compensation	6,864	5,567
Total research and development expenses	$ 32,780	$ 34,082

We plan to invest in our research and development expenses for the foreseeable future as we continue the development of vonoprazan and potentially in the future also develop additional product candidates. 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, actual results and development costs can differ materially from expectations. In addition, we cannot forecast which product candidates, if any, 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.

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, restructuring expenses in 2025, legal fees relating to intellectual property and corporate matters, and professional fees for accounting and consulting services.

Interest Income

Interest income consists of interest on our money market funds.

Interest Expense

Revenue Interest Financing Agreement

Interest expense under the Revenue Interest Financing Agreement is based on the imputed effective interest 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 interest expense.

Loan Agreement with Hercules

Interest expense under the Loan Agreement 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 us 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 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, 2025 and 2024

The following table summarizes our results of operations for the years ended December 31, 2025 and 2024 (in thousands):

	Years Ended December 31,		
	2025	2024	Change
Product revenue, net	$ 175,110	$ 55,252	$ 119,858
Cost of revenue	22,599	7,973	14,626
Gross profit	152,511	47,279	105,232
Operating expenses:			
Research and development	32,780	34,082	(1,302)
Selling, general and administrative	279,717	290,664	(10,947)
Total operating expenses	312,497	324,746	(12,249)
Loss from operations	(159,986)	(277,467)	117,481
Other (expense) income:			
Interest income	7,044	15,158	(8,114)
Interest expense	(68,115)	(72,009)	3,894
Other expense, net	(190)	(8)	(182)
Total other expense	(61,261)	(56,859)	(4,402)
Net loss	$ (221,247)	$ (334,326)	$ 113,079

Revenue. Product revenues were $175.1 million and $55.3 million for the years ended December 31, 2025 and 2024, respectively, related to sales of VOQUEZNA, VOQUEZNA TRIPLE PAK, and VOQUEZNA DUAL PAK which was launched during the fourth quarter of 2023.

Cost of Revenue. Cost of revenue was $22.6 million and $8.0 million for the years ended December 31, 2025 and 2024, respectively. The increase of $14.6 million was due to the increase in revenues for the year ended December 31, 2025 as well as an increase in Takeda royalty payments.

Research and Development Expenses. Research and development expenses were $32.8 million and $34.1 million for the years ended December 31, 2025 and 2024, respectively. The decrease of $1.3 million consists of $2.6 million of lower CMC costs, clinical and regulatory costs, and lower project and consulting costs, partially offset by $1.3 million related to higher stock-based compensation expense due to restructuring charges.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $279.7 million and $290.7 million for the years ended December 31, 2025 and 2024, respectively. The decrease of $11.0 million was due to decreases of $19.1 million of commercial related promotional expenses in support of launching VOQUEZNA and a decrease of $0.2 million in consulting expenses, partially offset by an increase of $8.3 million in personnel-related expenses primarily due to $7.3 million of restructuring charges.

Other Income (Expense). Other expense of $61.3 million for the year ended December 31, 2025 consisted of $68.1 million of interest expense under the Loan Agreement and Revenue Interest Financing Agreement, partially offset by $7.0 million of interest income related to cash held in money market funds. Other expense of $56.9 million for the year ended December 31, 2024 consisted of $72.0 million of interest expense under the Loan Agreement and Revenue Interest Financing Agreement, partially offset by $15.1 million of interest income related to cash held in money market funds.

Liquidity and Capital Resources

We have incurred net losses and negative cash flows from operations since our inception and while we expect to continue to incur a net loss in the near term, we anticipate achieving operating profitability beginning in the third quarter of 2026, excluding stock-based compensation. As of December 31, 2025, we had cash and cash equivalents of $130.0 million and received $122.2 million of net proceeds from our January 2026 offering.

Loan Agreement with Hercules

On September 17, 2021, or the Closing Date, we entered into the Loan Agreement with Hercules (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). We've entered into several amendments to the Loan Agreement which are described below, most recently in February 2026.

The Loan Agreement originally provided for term loans in an aggregate principal amount of up to $200 million, or the Term Loan, under multiple tranches. The tranches consisted 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 us 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, which, among other things, (i) increased the aggregate principal amount of the term loans from $200 million to $300 million; (ii) provided 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 which we did not draw down, and (e) Tranche 6: $50 million available, subject to the achievement of a specified revenue milestone, through December 31, 2025 and which we did not draw down; (iii) extended the interest only period and the maturity date from October 2026 to December 2027, (iv) reduced 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) decreased 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.

As amended through the Fourth Amendment, the Term Loan had a maturity date of December 1, 2027. As of December 31, 2025, the Term Loan bore (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 of the Term Loan. 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, under the Fourth Amendment, we were 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 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 of $7.5 million for the first Term Loan Advance was amended to become payable on October 1, 2026, and has been recorded within other current liabilities as of December 31, 2025. The remaining aggregate $4.0 million of final payment fees includes $2.5 million for the second Term Loan Advance, $0.8 million for the third Term Loan Advance, and $0.7 million for the fourth Term Loan Advance and have been recorded within other long-term liabilities as of December 31, 2025.

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 included (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; or

  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.

As of December 31, 2025, we were in compliance with all applicable covenants under the Loan Agreement.

On February 25, 2026, or the Fifth Amendment Closing Date, we entered into the Fifth Amendment to the Loan and Security Agreement, or the Fifth Loan Amendment, with the lenders, which, among other things, (i) provides for a new term loan tranche of $175 million, the proceeds of which, along with cash on our balance sheet, were used to repay in full the existing secured obligations outstanding under the Loan Agreement, including principal, capitalized payment-in-kind interest, existing final fee payments, and any applicable prepayment fees, (ii) provides for an additional loan tranche of up to $25 million which shall be available to us at the lenders' discretion, (iii) extends the maturity date from December 1, 2027 to February 1, 2029, subject to further extension to December 1, 2030 upon the achievement of a specified revenue milestone and subject to a certain pro forma liquidity test; (iv) extends the interest only period from October 2026 to December 2027, thereafter, monthly payment of interest and 2.5% of the original principal amount advanced through the maturity date, with any remaining payments to be repaid in full on the maturity date, (v) changes the cash interest rate to 9.85% (floating rate based on the greater of (a) US WSJ Prime + 3.10% or (b) 9.85%, (vi) eliminates the payment-in-kind interest rate of 2.15% per annum, (vii) amends the prepayment charge, which is a percentage of the principal amount actually advanced under the Term Loans under the Fifth Loan Amendment, or each a Term Loan Advance and together, the Term Loan Advances, as follows: (a) if the Term Loan Advances are prepaid after the Fifth Amendment Closing Date but prior to the twelfth month anniversary of the Fifth Amendment Closing Date, 2.50%; (b) if the Term Loan Advances are prepaid on or after the twelfth month anniversary of the Fifth Amendment Closing Date but prior to the twenty-fourth month anniversary of the Fifth Amendment Closing Date, 2.00%; (c) if the Term Loan Advances are prepaid on or after the twenty-fourth month anniversary of the Fifth Amendment Closing Date but prior to the thirty-sixth month anniversary of the Fifth Amendment Closing Date, 1.50%; (d) thereafter, 1.00%; and (viii) provides for a new final payment fee which is as a percentage of the Term Loan Advances so prepaid, as follows: (a) if the Term Loan Advances are repaid prior to September 2027, 1.25%; (b) if the Term Loan Advances are repaid after September 1, 2027 but on or prior to February 1, 2029, 2.00%; (c) if the Term Loan Advances are repaid

after February 1, 2029 but on or prior to January 1, 2030, 3.00%, and (d) if the Term Loan Advances are repaid after January 1, 2030, 3.50%.

In addition, the financial covenants under the Fifth 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, which will decrease to 15% of the outstanding principal amount upon us reporting and maintaining $75 million of trailing three months net product revenue.

ii. Performance covenant - Beginning on the Fifth Amendment Closing Date and all times there after we must satisfy any one of the following:

   a. Market capitalization exceeding $900 million;

   b. Minimum cash balance of 50% of the outstanding principal amount of term loans, which will decrease to 40% upon achieving $65 million of trailing three months nets product revenue, and to 30% upon achieving $85 million, of trailing three months net product revenue; or

   c. Trailing three months net product revenue equal to 75% of projected revenue in 2026 and 70% of projected revenue in 2027 and beyond, tested on a quarterly basis.

In connection with the Fifth Loan Amendment, the existing final fee payments under the Loan and Security Agreement in the aggregate amount of $11.5 million were fully paid to Agent and a facility fee of $1.8 million was also paid to the Agent.

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 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 these amendments. The exercise price and terms of the outstanding Warrant remain unchanged.

The initial $1.3 million fair value of the Warrant, the $11.5 million final interest payment fees and $4.6 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, together with NQ and Sagard, or the Initial Investors, pursuant to which we had the right to 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 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 provided 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. On December 23, 2024, CO Finance LVS XXXVII LLC agreed to assign and transfer to OC III LVS LX LP all of its rights, title and interest as an Additional Investor and in connection therewith, OC III LVS LX LP executed a Joinder Agreement. The total amount funded by the Initial Investors and any subsequent investors is referred to herein as the Investment Amount. As of December 31, 2025, no additional funding is available under the Revenue Interest Financing Agreement.

Under the Revenue Interest Financing Agreement, the Initial Investors and the Additional 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 upon FDA approval for vonoprazan for an indication relating to the treatment of heartburn associated with Non-Erosive GERD, which occurred on July 17, 2024. 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 April 30, 2024, 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 between April 1, 2025 and April 1, 2028, or 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.

Additionally, under the terms of Revenue Interest Financing Agreement, we are subject to a minimum cash covenant of at least (a) beginning on the date that the Hercules Loan Agreement is terminated and each day thereafter until September 30, 2026, $30 million, and (b) beginning on October 1, 2026 and on each day thereafter until September 30, 2029, a certain percentage of the minimum cash reference amount defined as the difference between the Investment Amount and the amount of all royalty payments received by the Investors as of each such date as follows: (i) 50% from October 1, 2026 to September 30, 2027 (ii) 75% from October 1, 2027 to September 30, 2028, and (iii) 100% from October 1, 2028 to September 30, 2029. As of December 31, 2025, we are in compliance with all applicable covenants under the Revenue Interest Financing Agreement.

At-the-Market-Offerings

In November 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 an amount registered under an effective registration statement through the Sales Agent.

In November 2023, we filed a shelf registration statement on Form S-3 which was declared effective by the SEC on November 17, 2023, which included an at-the-market prospectus pursuant to which we may, from time to time, sell up to an aggregate of $150 million of our common stock through the Sales Agent, or the 2023 ATM Offering. 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. No shares were sold under the Sales Agreement during the years ended December 31, 2025 and 2024. As of December 31, 2025, all of the available $150 million under the 2023 ATM Offering remains available.

Underwritten Public Offerings

On January 9, 2026, we sold 6,875,000 shares of common stock at a price of $16.00 per share and pre-funded warrants to purchase 1,250,078 shares of common stock at a price of $15.999 per pre-funded warrant for total gross proceeds of $130.0 million, before deducting underwriting discounts, commissions and offering costs. The net purchase price after deducting the underwriting discounts and commissions and other offering expenses, was $15.04 per share or net proceeds of $122.2 million.

On August 20, 2024, we completed an underwritten public offering, in which we sold 8,695,652 shares of our common stock at a price of $11.50 per share and pre-funded warrants to purchase 2,608,922 shares of our common stock at a price of $11.499 per pre-funded warrant for total gross proceeds of $130.0 million. The net purchase price after deducting the underwriting discounts and commissions and other offering expenses, was $10.77 per share or net proceeds of $121.8 million.

Funding Requirements

Based on our current operating plan, we believe that our existing cash and cash equivalents together with anticipated product revenues and the $122.2 million of net proceeds from our January 2026 offering, are sufficient to fund operations for at least the next twelve months. However, our forecast of the period of time through which our financial resources may 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 inaccurate, and we could deplete our capital resources sooner than we expect based on the amount and timing of product sales and operating expenses, among other factors. Additionally, the process of testing product candidates in clinical trials is costly, and the timing of progress and expenses in ongoing and future trials is uncertain.

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

- our ability to achieve and maintain market acceptance, market share, coverage, reimbursement and revenues from sales of VOQUEZNA in its approved GERD indications, and patients' willingness to pay out-of-pocket in the absence of coverage and/or adequate reimbursement from third-party payers;
- the costs of sales and marketing activities in support of the continued commercial launch of VOQUEZNA, VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK, or any future product candidates we may choose to pursue, if successfully developed and approved;
- the costs, timing and availability of manufacturing for vonoprazan as well as the costs of manufacturing for any potential product candidates we may pursue in the future;
- 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, timing and outcome of regulatory review of future vonoprazan applications or such applications for any future product candidates;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights, and the success of our enforcement efforts;
- the timing of market introduction, profile and impact of competitive products;
- the costs associated with hiring additional personnel and consultants as our business grows and enhancing our operational systems;
- the timing and amount of the milestone or other payments we must make to Takeda and any future licensors;
- the timing and impact of our obligations under our Loan and Security Agreement with Hercules Capital, Inc., and our Revenue Interest Financing Agreement; and
- the costs associated with building a portfolio of product candidates through the acquisition or in-license of additional product candidates or technologies, including the terms and timing of establishing and maintaining future collaborations, licenses and other similar arrangement and the costs associated with development of 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 also finance our cash needs through equity offerings, 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 and if 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 audited financial statements were issued. There can be no assurance that we will be successful in acquiring additional funding, that our projections of future revenues or working capital needs will prove accurate, or that any additional funding would be sufficient to continue operations in future years.

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,		
	2025	**2024**	**Change**
Net cash provided by (used in):			
Operating activities	$ (166,775)	$ (266,770)	$ 99,995
Investing activities	(229)	(135)	(94)
Financing activities	(288)	182,774	(183,062)
Net decrease in cash	$ (167,292)	$ (84,131)	$ (83,161)

Operating Activities

Net cash used in operating activities was approximately $166.8 million and $266.8 million for the years ended December 31, 2025 and 2024, respectively. The net cash used in operating activities for the year ended December 31, 2025 was due to approximately $154.4 million spent on ongoing research and development and selling, general and administrative activities and a $12.4 million net change in operating assets and liabilities. The net change in operating assets and liabilities is related to a $34.4 million increase in accounts payable and accrued expenses (including interest, operating lease assets and liabilities), a $5.5 million decrease in prepaid assets and other current assets, and a $52.3 million increase in accounts receivable, inventory, and other long-term assets. The net cash used in operating activities for the year ended December 31, 2024 was due to approximately $251.5 million spent on ongoing research and development and selling, general and administrative activities and a $15.3 million net change in operating assets and liabilities. The net change in operating assets and liabilities primarily related to a $35.7 million increase in accounts payable and accrued expenses (including interest, operating lease assets and liabilities), and a $51.0 million increase in accounts receivable, inventory, and prepaid assets and other current assets in support of our growth and continued launch of our commercial products.

Investing Activities

Net cash used in investing activities for the years ended December 31, 2025 and 2024 was related to payments for acquiring property and equipment.

Financing Activities

Net cash used in financing activities for the year ended December 31, 2025 was $0.3 million primarily related to $1.9 million payments of employee tax obligations related to vesting of PSUs and RSUs offset by $1.6 million of proceeds from the issuance of common stock from exercise of stock options. Net cash provided by financing activities for the year ended December 31, 2024 was $182.8 million, primarily related to $59.4 million of net proceeds from the issuance of debt under our Loan Agreement, $121.8 million of net proceeds from issuance of common stock and pre-funded warrants in connection with the underwritten public offering completed in August 2024, and $1.6 million of proceeds from the exercise of stock options.

Contractual Obligations and Commitments

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 $1.7 million and $0.3 million of expenses under the agreement during each of the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, €1.2 million, or approximately $1.4 million, remains of the minimum purchase obligation and for which we have recorded within accrued expenses on the balance sheet and within our statement of operations and comprehensive loss during the year ended December 31, 2025.

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. 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. On December 23, 2024, CO Finance LVS XXXVII LLC agreed to assign and transfer to OC III LVS LX LP all of its rights, title and interest as an Additional Investor and in connection therewith, OC III LVS LX LP executed a Joinder Agreement. As of December 31, 2025, no additional funding is available under the Revenue Interest Financing Agreement. Under the Revenue Interest Financing Agreement, the Initial Investors and Additional Investors 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 less any royalties already paid. During the years ended December 31, 2025 and 2024 we incurred $14.8 million and $2.6 million, respectively, of royalty payments under the Revenue Interest Financing Agreement.

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 may vary due to rebates, chargebacks, discounts and fees provided under government and other programs, product returns and other sales-related deductions. 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 or related to product returns. 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, co-pay assistance and discounts for our products, as it becomes available.

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 6 Revenue Interest Financing Liability for additional details.

Other Company Information

Smaller Reporting Company Status

We are currently a smaller reporting company as defined in Rule 12b-2 of the Exchange Act. 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 (i) 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 (ii) 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.

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, 2025, 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 independent registered public accounting firm due to an exclusion for non-accelerated filers.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the fourth quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

On February 25, 2026, or the Fifth Amendment Closing Date, the Company entered into the Fifth Amendment to the Loan and Security Agreement, or the Fifth Loan Amendment, with the lenders, which, among other things, (i) provides for a new term loan tranche of $175 million, the proceeds of which, along with cash on our balance sheet, were used to repay in full the existing secured obligations outstanding under the Loan Agreement, including principal, capitalized payment-in-kind interest, existing final fee payments, and any applicable prepayment fees, (ii) provides for an additional loan tranche of up to $25 million which shall be

available to the Company at the lenders' discretion, (iii) extends the maturity date from December 1, 2027 to February 1, 2029, subject to further extension to December 1, 2030 upon the achievement of a specified revenue milestone and subject to a certain pro forma liquidity test; (iv) extends the interest only period from October 2026 to December 2027, thereafter, monthly payment of interest and 2.5% of the original principal amount advanced through the maturity date, with any remaining payments to be repaid in full on the maturity date, (v) changes the cash interest rate to 9.85% (floating rate based on the greater of (a) US WSJ Prime + 3.10% or (b) 9.85%, (vi) eliminates the payment-in-kind interest rate of 2.15% per annum, (vii) amends the prepayment charge, which is a percentage of the principal amount actually advanced under the Term Loans under the Fifth Loan Amendment, or each a Term Loan Advance and together, the Term Loan Advances, as follows: (a) if the Term Loan Advances are prepaid after the Fifth Amendment Closing Date but prior to the twelfth month anniversary of the Fifth Amendment Closing Date, 2.50%; (b) if the Term Loan Advances are prepaid on or after the twelfth month anniversary of the Fifth Amendment Closing Date but prior to the twenty-fourth month anniversary of the Fifth Amendment Closing Date, 2.00%; (c) if the Term Loan Advances are prepaid on or after the twenty-fourth month anniversary of the Fifth Amendment Closing Date but prior to the thirty-sixth month anniversary of the Fifth Amendment Closing Date, 1.50%; (d) thereafter, 1.00%; and (viii) provides for a new final payment fee which is as a percentage of the Term Loan Advances so prepaid, as follows: (a) if the Term Loan Advances are repaid prior to September 2027, 1.25%; (b) if the Term Loan Advances are repaid after September 1, 2027 but on or prior to February 1, 2029, 2.00%; (c) if the Term Loan Advances are repaid after February 1, 2029 but on or prior to January 1, 2030, 3.00%, and (d) if the Term Loan Advances are repaid after January 1, 2030, 3.50%.

In addition, the financial covenants under the Fifth 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, which will decrease to 15% of the outstanding principal amount upon the Company reporting and maintaining $75 million of trailing three months net product revenue.

ii. Performance covenant - Beginning on the Fifth Amendment Closing Date and all times there after we must satisfy any one of the following:

   a. Market capitalization exceeding $900 million;

   b. Minimum cash balance of 50% of the outstanding principal amount of term loans, which will decrease to 40% upon achieving $65 million of trailing three months nets product revenue, and to 30% upon achieving $85 million, of trailing three months net product revenue; or

   c. Trailing three months net product revenue equal to 75% of projected revenue in 2026 and 70% of projected revenue in 2027 and beyond, tested on a quarterly basis.

In connection with the Fifth Loan Amendment, the existing final fee payments under the Loan and Security Agreement in the aggregate amount of $11.5 million were fully paid to Agent and a facility fee of $1.8 million was also paid to the Agent.

Director and Officer Trading Arrangements:

Rule 10b5-1 Trading Plans

From time to time, our officers (as defined in Rule 16a-1(f) of the Exchange Act) and directors may enter into Rule 10b5-1 or non-Rule 10b5-1 trading arrangements (as each such term is defined in Item 408 of Regulation S-K). During the three months ended December 31, 2025, none of our officers or directors adopted, modified or terminated any such trading arrangements.

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 2026 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, 2025, under the headings “Election of Directors,” “Executive Officers,” “Corporate Governance,” and is incorporated herein by reference.

Insider Trading Policies and Procedures

We have adopted a formal policy against insider trading which provides guidelines to all of our directors, officers, employees, and consultants with respect to trading in our securities, as well as the securities of publicly traded companies with whom we have a business relationship. This policy has been designed to prevent insider trading or even allegations of insider trading.

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 and 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, 2025 and 2024, the related statements of operations and comprehensive loss, stockholders' deficit and cash flows for each of the two years in the period ended December 31, 2025, 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, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, 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.

Critical Audit Matter

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

Reserve for Product Returns

Description of the Matter	During the year ended December 31, 2025, the Company's net product revenues were $175.1 million. As explained in Note 1 of the financial statements, net product revenue includes estimates of variable consideration for which reserves are established, including the reserve for 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. The Company estimates its provision for sales returns based on available industry data,

including visibility into the inventory remaining in the distribution channel, and adjusts the transaction price with such estimate at the time of sale to the customer.

Auditing the Company's measurement of the reserve for product returns was challenging due to (1) the significant judgment required in determining the estimated returns rate and inventory in the distribution channel that will not ultimately be sold to the end user and returned, and (2) the limited returns history on which the estimated returns rate is based. The reserve for product returns is sensitive to the level of inventory in the distribution channel, which could exceed future market demand and be subject to return.

How We Addressed the Matter in Our Audit

To test the reserve for product returns, we performed audit procedures that included, among others, testing the accuracy and completeness of the underlying data used in the calculations and evaluating the assumptions used by management to estimate the Company's reserves. We tested the industry data used in the calculation of the estimated returns rate by inspecting industry publications. We compared actual returns received to date with the Company's estimated return rate. In addition, we tested the Company's analysis of inventory held at various stages in the distribution channel. We obtained third-party confirmation of prescription data and tested inventory in the distribution channel reported by significant customers. We also inspected agreements with significant customers to validate the rights of return and performed inquiries with management, including the Commercial and Legal departments, regarding any changes to the terms and conditions of customer contracts. We also performed a sensitivity analysis over the Company's returns rate to assess the effect of changes in assumptions.

/s/ Ernst & Young LLP
We have served as the Company's auditor since 2019.

Iselin, New Jersey
February 26, 2026

PHATHOM PHARMACEUTICALS, INC.
Balance Sheets
(in thousands, except share and par value amounts)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 129,972	$ 297,263
Prepaid expenses and other current assets	15,353	20,866
Accounts receivable, net	78,129	38,797
Inventory	5,518	3,208
Total current assets	228,972	360,134
Property and equipment, net	1,064	1,476
Operating lease right-of-use assets	2,603	613
Restricted cash	2,861	2,862
Inventory, non-current	20,732	11,540
Other long-term assets	2,917	1,693
Total assets	$ 259,149	$ 378,318
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 4,983	$ 10,507
Accrued expenses	89,831	53,232
Accrued interest	1,833	1,711
Operating lease liabilities, current	648	501
Current portion of revenue interest financing liability	27,249	19,777
Other current liabilities	7,500	—
Total current liabilities	132,044	85,728
Long-term debt, net of discount	209,087	201,409
Revenue interest financing liability	350,122	333,261
Operating lease liabilities	2,065	—
Other long-term liabilities	4,000	11,500
Total liabilities	697,318	631,898
Commitments and contingencies (Note 3)		
Stockholders' deficit:		
Preferred stock, $0.0001 par value; authorized shares — 40,000,000 at December 31, 2025 and December 31, 2024; no shares issued and outstanding at December 31, 2025 and December 31, 2024	—	—
Common stock, $0.0001 par value; authorized shares — 400,000,000 at December 31, 2025 and December 31, 2024; issued and outstanding shares — 71,419,025 and 68,518,238 at December 31, 2025 and December 31, 2024, respectively	6	6
Treasury stock — 19 shares at December 31, 2025 and December 31, 2024	—	—
Additional paid-in capital	1,046,083	1,009,425
Accumulated deficit	(1,484,258)	(1,263,011)
Total stockholders' deficit	(438,169)	(253,580)
Total liabilities and stockholders' deficit	$ 259,149	$ 378,318

See accompanying notes.

PHATHOM PHARMACEUTICALS, INC.
Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Years Ended December 31,	
	2025	**2024**
Product revenue, net	$ 175,110	$ 55,252
Cost of revenue	22,599	7,973
Gross profit	152,511	47,279
Operating expenses:		
Research and development	32,780	34,082
Selling, general and administrative	279,717	290,664
Total operating expenses	312,497	324,746
Loss from operations	(159,986)	(277,467)
Other (expense) income:		
Interest income	7,044	15,158
Interest expense	(68,115)	(72,009)
Other expense, net	(190)	(8)
Total other expense	(61,261)	(56,859)
Net loss and comprehensive loss	$ (221,247)	$ (334,326)
Net loss per share, basic and diluted	$ (3.03)	$ (5.29)
Weighted-average shares of common stock outstanding, basic and diluted	72,918,764	63,176,210

See accompanying notes

PHATHOM PHARMACEUTICALS, INC.
Statements of Stockholders' Deficit
(in thousands, except share amounts)

	Common Stock		Treasury Stock	Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Capital	Deficit	Deficit
Balance at December 31, 2024	68,518,238	$ 6	19	$ 1,009,425	$ (1,263,011)	$ (253,580)
401(k) matching contribution	616,377	—	—	5,258	—	5,258
Vesting of restricted stock units and performance stock units, net of employee tax obligations	1,615,577	—	—	(1,926)	—	(1,926)
Stock-based compensation	—	—	—	28,719	—	28,719
ESPP shares issued	505,293	—	—	2,969	—	2,969
Issuance of common stock from exercises of stock options	163,540	—	—	1,638	—	1,638
Net loss	—	—	—	—	(221,247)	(221,247)
Balance at December 31, 2025	71,419,025	$ 6	19	$ 1,046,083	$ (1,484,258)	$ (438,169)

	Common Stock		Treasury Stock	Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Capital	Deficit	Deficit
Balance at December 31, 2023	57,970,044	$ 5	19	$ 855,921	$ (928,685)	$ (72,759)
401(k) matching contribution	383,589	—	—	3,683	—	3,683
Vesting of restricted stock units	965,681	—	—	—	—	—
Stock-based compensation	—	—	—	24,047	—	24,047
ESPP shares issued	375,381	—	—	2,401	—	2,401
Issuance of common stock from exercise of stock options	127,891	—	—	1,599	—	1,599
Issuance of common stock and pre-funded warrants in connection with the underwritten public offering, net	8,695,652	1	—	121,774	—	121,775
Net loss	—	—	—	—	(334,326)	(334,326)
Balance at December 31, 2024	68,518,238	$ 6	19	$ 1,009,425	$ (1,263,011)	$ (253,580)

See accompanying notes

PHATHOM PHARMACEUTICALS, INC.
Statements of Cash Flows
(in thousands)

	Years Ended December 31,	
	2025	**2024**
Cash flows from operating activities		
Net loss	$ (221,247)	$ (334,326)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	633	795
Stock-based compensation	28,719	24,047
Accrued payment-in-kind interest on debt	4,664	3,775
Accrued interest on revenue interest financing liability, net of payments	24,333	46,111
Amortization of debt discount	3,014	2,192
Inventory reserve	280	836
Other	5,205	5,098
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	5,513	(7,672)
Accounts receivable, net	(39,331)	(37,160)
Accounts payable and accrued expenses	34,104	34,936
Accrued interest	121	565
Operating right-of-use assets and lease liabilities	222	175
Inventory	(11,781)	(6,142)
Other long-term assets	(1,224)	—
Net cash used in operating activities	(166,775)	(266,770)
Cash flows from investing activities		
Cash paid for property and equipment	(229)	(135)
Net cash used in investing activities	(229)	(135)
Cash flows from financing activities		
Proceeds from issuance of common stock from exercise of stock options	1,638	1,599
Net proceeds from issuance of debt	—	59,400
Net proceeds from underwritten public offering	—	121,775
Payment of employee tax obligations related to vesting of PSUs and RSUs	(1,926)	—
Net cash (used in) provided by financing activities	(288)	182,774
Net decrease in cash and cash equivalents and restricted cash	(167,292)	(84,131)
Cash and cash equivalents and restricted cash – beginning of period	300,125	384,256
Cash and cash equivalents and restricted cash – end of period	$ 132,833	$ 300,125
Supplemental disclosure of cash flow information		
Interest paid	$ 21,368	$ 17,293
Supplemental disclosure of noncash investing and financing activities:		
Property and equipment purchases included in accounts payable and accrued expenses	$ —	$ 8
Final interest payment fee	$ —	$ 1,800
Settlement of ESPP liability in common stock	$ 2,969	$ 2,401
Settlement of 401(k) liability in common stock	$ 5,258	$ 3,683

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 commercial-stage biopharmaceutical company focused on commercializing and developing novel treatments for gastrointestinal, or GI, diseases. The Company's financial statements are prepared in accordance with U.S. generally accepted accounting principles, or GAAP.

In May 2022, the U.S. Food and Drug Administration, or FDA, approved the Company's new drug applications, or NDAs for vonoprazan triple therapy, under the brand name VOQUEZNA TRIPLE PAK, and vonoprazan dual therapy, under the brand name VOQUEZNA DUAL PAK. On October 27, 2023, the FDA approved the prior approval supplements to the Company's NDAs, for VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK. Additionally, on November 1, 2023, the FDA approved the Company's NDA for VOQUEZNA tablets. The Company initiated commercial launch for VOQUEZNA in the U.S. 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. Additionally, on July 17, 2024, the FDA approved VOQUEZNA 10 mg tablets for the relief of heartburn associated with Non-Erosive GERD.

Liquidity and Capital Resources

From inception to December 31, 2025, 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, commercially launching its approved products in the U.S., and providing other selling, general and administrative support for these operations. The Company has a limited operating history as a commercial company, has generated limited product revenue to date, and the sales and income potential of its business remains uncertain. The Company has incurred net losses and negative cash flows from operating activities since its inception and despite the Company's plans and expectations, could continue to incur additional net losses in the future. The Company has funded its operations primarily through commercial bank debt, the revenue interest financing debt and various equity offerings, including the Company's at-the-market, or ATM, offerings. From inception through December 31, 2025, the Company sold 34,737,032 shares of common stock and 2,608,922 pre-funded warrants, generating net proceeds of approximately $543.3 million, after deducting underwriting discounts, commissions and offering costs. In January 2026, the Company sold 6,875,000 shares of common stock at a price of $16.00 per share and pre-funded warrants to purchase 1,250,078 shares of common stock at a price of $15.999 per pre-funded warrant for total gross proceeds of $130.0 million or $122.2 million of net proceeds after deducting underwriting discounts, commissions and offering costs.

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 in accordance with GAAP. 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 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 the valuation for the revenue interest financing liability. 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, 2025 and 2024, 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 credit losses 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 a material allowance for credit losses.

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 an allowance for credit losses as necessary. The Company extends credit primarily to wholesale distributors. Customer creditworthiness is monitored and collateral is not required. The allowance for credit losses

reflects the best estimate of expected credit losses of the accounts receivable portfolio determined on the basis of historical experience, current information, and forecasts of future economic conditions. The Company determines its allowance methodology by pooling receivable balances at the customer level. The Company considers various factors, including its previous loss history, individual credit risk associated to each customer, and the current and future conditions of the general economy. These credit risk factors are monitored on a quarterly basis and updated as necessary. To the extent that any individual debtor is identified whose credit quality has deteriorated, the Company establishes allowances based on the individual risk characteristics of such customer. The Company makes concerted efforts to collect all outstanding balances due from customers; however, account balances are charged off against the allowance when management believes it is probable the receivable will not be recovered. The Company does not have any off-balance-sheet credit exposure related to customers.

As of December 31, 2025, three customers accounted for 78% of the accounts receivable balance, with each of these individual customers ranging from 19% to 30% of the accounts receivable balance. As of December 31, 2024, three customers accounted for 81% of the accounts receivable balance, with each of these individual customers ranging from 25% to 31% of the accounts receivable balance. For the year ended December 31, 2025, three customers accounted for 69% of the product sales, with each of these individual customers ranging from 22% to 23% of the product sales. For the year ended December 31, 2024, three customers accounted for 69% of the product sales, with each of these individual customers ranging from 22% to 25% of the 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 consists of bulk active pharmaceutical ingredients that are used to manufacture vonoprazan tablets and finished goods. Inventory related to indications prior to regulatory approval has been included in research and development expense in the period of purchase.

The Company states its inventory at the lower of cost or net realizable value. The Company measures inventory cost 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. During the years ended December 31, 2025 and 2024, the Company recorded approximately $0.3 million and $0.8 million, respectively, of charges for inventory not expected to be sold prior to its expiration date.

Property and Equipment, Net

Property 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 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 for the years ended December 31, 2025 and 2024.

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. On December 23, 2024, CO Finance LVS XXXVII LLC agreed to assign and transfer to OC III LVS LX LP all of its rights, title and interest as an Additional Investor and in connection therewith, OC III LVS LX LP executed a Joinder Agreement. 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 interest 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, primarily wholesale distributors, 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 or related to product returns. 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 and specialty pharmacies 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 based on a contractually fixed percentage of wholesaler acquisition costs and are calculated at the time of sale based on the purchase amount and the transaction price is adjusted with the amount of such estimate at the time of sale to the customer. Estimated distribution service fees are recorded within accounts receivable or accrued expenses, net on the balance sheets.

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. Estimated prompt pay discounts are recorded within accounts receivable, net on the balance sheets.

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 available industry data including visibility into the inventory remaining in the distribution channel, 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 assumptions. Once the product is returned, it is destroyed. The Company does not record a right-of-return asset. Estimated product returns are recorded as accrued expenses on the balance sheets.

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. Estimated chargebacks are recorded within accounts receivable, net on the balance sheets.

Co-pay Assistance: The Company provides for financial assistance to qualified patients, assisting them with prescription drug co-payments required by insurance. The Company uses third-party administers for the co-payment program for pharmacy benefit claims. The calculation of the accrual for copay is based on an estimate of claims and the cost per claim that the Company expects to receive associated with actual sales and inventory that exists in the distribution channel at period end. Estimated co-pay assistance accruals are recorded within accrued expenses on the balance sheets.

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. Estimated administration fees are recorded within accrued expenses on the balance sheets.

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. Estimated rebates are recorded as accrued expenses on the balance sheets.

Manufacturer Discount Program: The Medicare Part D coverage gap, previously referred to as the donut hole, was redesigned and replaced beginning on January 1, 2025 as part of The Inflation Reduction Act, or IRA, of 2022. This included the creation of a new manufacturer discount program, or MDP, in place of the prior coverage gap discount program. Prior to the IRA enactment, the Company estimated the percentage of goods sold under coverage gap and adjusted the transaction price for such discount at the time of sale to the customer. Beginning January 1, 2025, the calculation of the accrual under the MDP program is based on an estimate of prescriptions covered by Medicare and the estimated manufacturer portion of our obligation under the Part D redesign. Estimated accruals are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a liability. Estimated MDP accruals are recorded as accrued expenses on the balance sheets.

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, co-pay assistance 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 3 Commitments and Contingencies for further details). In addition, shipping and handling costs for product sales are recorded as incurred. Cost of revenue also includes costs related to excess or obsolete inventory adjustment charges and other inventory write-offs.

In connection with the FDA approvals of VOQUEZNA, VOQUEZNA TRIPLE PAK, and VOQUEZNA DUAL PAK, the Company began capitalizing inventory manufactured by or purchased from third parties. Prior to receiving FDA approvals, manufacturing costs related to inventory purchased were expensed as research and development expense and therefore are excluded from cost of revenue during the current year. The exclusion of these previously expensed costs did not have a material impact on cost of revenue in the current year.

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.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist of salaries and employee-related costs, including stock-based compensation, for personnel in commercial, executive, finance, accounting, information technology, legal, medical affairs and human resources functions.

Advertising and Marketing Costs

Advertising and marketing costs are expensed as incurred. Advertising and marketing costs for each of the years ended December 31, 2025 and 2024 was approximately $61.3 million and are included in selling, general and administrative expenses.

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 fair value of stock options are determined by using the Black-Scholes option-pricing model. The fair value of performance awards with a market condition is estimated at the date of grant using a Monte Carlo Simulation model. The Black-Scholes and Monte Carlo Simulation valuation models incorporate assumptions as to stock price volatility, the expected life of options or awards, a risk-free interest rate and dividend yield. The fair value of restricted stock, including performance awards, without a market condition is estimated using the current market price of our common stock on the date of grant.

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.

Pre-funded Warrants

The Company issued pre-funded warrants in connection with an underwritten public offering that were accounted for as a freestanding equity-linked financial instrument that met the criteria for equity classification under ASC 480, Distinguishing Liabilities from Equity, and ASC 815, Derivatives and Hedging. Accordingly, the Company classified the pre-funded warrants as a component of shareholders' equity within additional paid-in capital. The Company valued the pre-funded warrants at issuance, concluding that their sales price approximated their fair value, and allocated the net proceeds from the offering proportionately to the common shares and pre-funded warrants. See Note 7 Stockholders' Equity for further discussion related to the offering.

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 and pre-funded warrants for the period, without consideration for other potentially dilutive securities. For the years ended December 31, 2025 and 2024, basic shares outstanding includes the weighted average effect of the Company's outstanding pre-funded warrants, the exercise of which requires little or no consideration for the delivery of shares of common stock. For the years ended December 31, 2025 and 2024, the Company had no weighted-average unvested shares to exclude 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 restricted stock units) would be antidilutive.

Recently Adopted Accounting Standards

In December 2023, the FASB issued ASU 2023-09 – Income Taxes (Topic 740) – Improvements to Income Tax Disclosures, which improves income tax disclosures primarily relating to the rate reconciliation and income taxes paid information. This includes a tabular reconciliation using both percentages and reporting currency amounts, covering various tax and reconciling items, and disaggregated summaries of income taxes paid during the period. For public business entities, the guidance is effective for annual periods beginning after December 15, 2024, with early adoption permitted. The Company prospectively adopted this guidance, which did not have an impact on the Company's financial statements, although it did result in expanded income tax-related disclosures, which are included in Note 9 Income Taxes to the financial statements.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-03 - Disaggregation of Income Statement Expenses, which requires more detailed disclosures about specified categories of expenses (including employee compensation, depreciation, and amortization) included in certain expense captions presented on the face of the income statement. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and for interim periods within fiscal years beginning after December 15, 2027, may be applied prospectively or retrospectively, and allows for early adoption. This standard is not expected to have an impact on any amounts recognized in our financial statements, but will result in more detailed disclosures addressing the categorization of expenses.

2. Balance Sheet Details

Property and Equipment, net

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

	December 31,	
	2025	2024
Computer equipment and software	$ 1,685	$ 1,546
Furniture and fixtures	1,125	1,124
Leasehold improvements	242	160
Equipment	1,487	1,487
Total property and equipment, gross	4,539	4,317
Less: accumulated depreciation and amortization	(3,475)	(2,841)
Total property and equipment, net	$ 1,064	$ 1,476

Depreciation and amortization expense for the years ended December 31, 2025 and 2024 was approximately $0.6 million and $0.8 million, respectively. No property or equipment was disposed of during the years ended December 31, 2025 and 2024.

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31,	
	2025	2024
Accrued compensation expenses	$ 14,841	$ 16,659
Accrued professional & consulting expenses	1,253	1,203
Accrued research and development expenses	1,355	2,339
Accrued revenue allowances	65,462	29,987
Accrued other	6,920	3,044
Total accrued expenses	$ 89,831	$ 53,232

Inventory

Inventory consists of the following (in thousands):

	December 31,	
	2025	2024
Finished goods	$ 1,457	$ 1,479
Raw materials	4,061	1,729
Total inventory, current	5,518	3,208
Raw materials, non-current	20,732	11,540
Total inventory	$ 26,250	$ 14,748

Raw materials consist of materials, including active pharmaceutical ingredients, to be consumed in the production of inventory related to FDA-approved products. 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 dates presented.

3. 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 initial public offering, or 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 by March 2022.

During the years ended December 31, 2025 and 2024, the Company recorded $17.5 million and $5.5 million, respectively, of royalty expense under the Takeda License, of which $5.8 million is included within accrued expenses as of December 31, 2025.

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 incurred $1.7 million and $0.3 million of expenses under the agreement during each of the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, approximately €1.2 million, or approximately $1.4 million, of the minimum purchase obligation remains and for which the Company has recorded within accrued expenses on the balance sheet and within the Company's statement of operations and comprehensive loss during the year ended December 31, 2025.

The Company had previously been informed by Sandoz that there could be a disruption in the supply of clarithromycin tablets, a component of the VOQUEZNA TRIPLE PAK, which could lead to a disruption in supply of the VOQUEZNA TRIPLE PAKs. Given more recent communications, however, the Company does not currently anticipate any near-term disruptions. The Company plans to continue to actively monitor the situation to determine if a supply disruption may arise in the future. The VOQUEZNA TRIPLE PAK represented approximately 1% of our total revenue for 2025. While the Company has not experienced any commercial disruption to date, any disruption for such supply would result in our inability to continue to commercialize the VOQUEZNA TRIPLE PAK. The VOQUEZNA bottles and the VOQUEZNA DUAL PAKs are not impacted, as they do not include clarithromycin.

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.

4. Lease Commitments

As of December 31, 2025, 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 4.5 years and 5.2 years, respectively. In September 2025, the Company entered into amendments to its lease agreements for the New Jersey office space to extend the terms of the leases through February 2031. 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, 2025 and 2024 was approximately $1.0 million and $1.1 million, respectively. Total short-term lease costs relating to leased vehicles was approximately $6.9 million and $8.8 million for the years ended December 31, 2025 and 2024, respectively.

As of December 31, 2025, the future minimum annual lease payments under the operating leases were as follows (in thousands):

Year ending December 31:		
2026	$	686
2027		719
2028		736
2029		753
2030		702
Thereafter		100
Total minimum lease payments		3,696
Less: amount representing interest		(983)
Present value of operating lease liabilities		2,713
Less: operating lease liabilities, current		(648)
Operating lease liabilities, non-current	$	2,065
Weighted-average remaining lease term (in years)		4.99
Weighted-average incremental borrowing rate		13.83%

Operating cash flows for the years ended December 31, 2025 and 2024 included cash payments for operating leases of $0.7 million and $1.0 million, respectively, of which $0.1 million as of December 31, 2024 were prepaid lease payments.

5. Debt

Total debt consists of the following (in thousands):

	December 31,	
	2025	**2024**
Long-term debt, current portion	$ —	$ —
Long-term debt, non-current portion	216,495	211,831
Unamortized debt discount	(7,408)	(10,422)
Total debt, net of debt discount	$ 209,087	$ 201,409

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 Company has entered into several amendments to the Loan Agreement which are described below, and in Note 12 Subsequent Events. Note 12 Subsequent Events describes the Fifth Amendment to the Loan and Security Agreement which the Company entered into on February 25, 2026 and which amends certain of the provisions of the Loan Agreement described below which is as of December 31, 2025.

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 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 was to remain available to the Company, was moved to 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, which, among other things, (i) increased the aggregate principal amount of the term loans from $200 million to $300 million; (ii) provided 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, and the remaining $10 million of which was funded on March 15, 2024, (b) Third Tranche: $25 million which was funded on June 14, 2024, (c) Fourth Tranche: $25 million which was funded on December 15, 2024, (d) Fifth Tranche: $50 million which was available, subject to the achievement of a specified revenue milestone, or the Fifth Tranche milestone, through June 30, 2025 and which the Company did not draw down, and (e) Sixth Tranche: $50 million available, subject to the achievement of a specific revenue milestone, or the Sixth Tranche milestone, through December 31, 2025 and which the Company did not draw down; (iii) extended the interest only period and the maturity date from October 2026 to December 2027, (iv) reduced 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 rate shall be decreased by 0.35% to 9.50%, and (v) decreased 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 is 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 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 of $7.5 million for the first Term Loan Advance was amended to become payable on October 1, 2026, and has been recorded within other current liabilities as of December 31, 2025. The remaining aggregate $4.0 million of final payment fees includes $2.5 million for the second Term Loan Advance, $0.8 million for the third Term Loan Advance, and $0.7 million for the fourth Term Loan Advance and have been recorded within other long-term liabilities as of December 31, 2025.

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; or

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, 2025, 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 if any 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, the Company 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 the Company drawdown future tranches. In connection with the entry into the Fourth Loan Amendment, the Company 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 $11.5 million final interest payment fees and $4.6 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 Loan Agreement.

Future minimum principal payments under the Term Loan, including the final payment fees, as of December 31, 2025 are as follows (in thousands):

Year ending December 31:		
2026 (final payment fee on first term loan advance)	$	7,500
2027		229,706
Total principal and interest payments		237,206
Less: payment-in-kind and remaining final payment fees		(37,206)
Total term loan borrowings	$	200,000

During the years ended December 31, 2025 and 2024, the Company recognized $29.0 million and $23.2 million, respectively, of interest expense, including amortization of the debt discount, in connection with the Loan Agreement. As of December 31, 2025 and 2024, the Company had outstanding loan balance of $216.5 million and $211.8 million, respectively, and accrued interest of $1.8 and $1.7 million, respectively.

6. Revenue Interest Financing Liability

On May 3, 2022, the Company entered into a Revenue Interest Financing Agreement with Initial Investors NovaQuest Capital Management, or NQ, Sagard Holdings Manager LP, or Sagard, and Hercules pursuant to which the Company had the right to 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, the Company 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 provided 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. On December 23, 2024, CO Finance LVS XXXVII LLC agreed to assign and transfer to OC III LVS LX LP all of its rights, title and interest as an Additional Investor and in connection therewith, OC III LVS LX LP executed a Joinder Agreement. The total amount funded by the Initial Investors and any subsequent investors is referred to herein as the Investment Amount. As of December 31, 2025, no additional funding is available under the Revenue Interest Financing Agreement.

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 when the Company received FDA approval for vonoprazan for an indication relating to the treatment of heartburn associated with Non-Erosive GERD, which occurred on July 17, 2024. 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 April 30, 2024, 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 between April 1, 2025 and April 1, 2028, or 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.

Additionally, under the terms of Revenue Interest Financing Agreement, the Company is subject to a minimum cash covenant of at least (a) beginning on the date that the Hercules Loan Agreement is terminated and each day thereafter until September 30, 2026, $30 million, and (b) beginning on October 1, 2026 and on each day thereafter until September 30, 2029, a certain percentage of the minimum cash reference amount defined as the difference between the Investment Amount and the amount of all royalty payments received by the Investors as of each such date as follows: (i) 50% from October 1, 2026 to September 30, 2027 (ii) 75% from October 1, 2027 to September 30, 2028, and (iii) 100% from October 1, 2028 to September 30, 2029. As of December 31, 2025, the Company was in compliance with all applicable covenants under the Revenue Interest Financing Agreement.

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. As of December 31, 2025, the effective interest rate of the revenue interest financing liability was approximately 9.67%. Changes in future payments from previous estimates are included in the current and future interest expense. The carrying value of the revenue interest financing liability was $377.4 million and $353.0 million as of December 31, 2025 and 2024, respectively.

Total revenue interest financing liability consists of the following (in thousands):

Liability balance as of January 1, 2024	$	306,927
Proceeds from the Revenue Interest Financing Agreement		—
Less: transaction costs		—
Less: royalty payments and payables		(2,627)
Plus: interest expense		48,738
Ending liability balance as of December 31, 2024		353,038
Less: current portion		(19,777)
Long-term liability balance as of December 31, 2024	$	333,261

Liability balance as of January 1, 2025	$	353,038
Proceeds from the Revenue Interest Financing Agreement		—
Less: transaction costs		—
Less: royalty payments and payables		(14,719)
Plus: interest expense		39,052
Ending liability balance as of December 31, 2025		377,371
Less: current portion		(27,249)
Long-term liability balance as of December 31, 2025	$	350,122

During the years ended December 31, 2025 and 2024, the Company recognized $39.1 million and $48.7 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.

7. Stockholders' Equity

Common Stock

Underwritten Public Offerings

In August 2024, the Company sold 8,695,652 shares of common stock at a price of $11.50 per share and pre-funded warrants to purchase 2,608,922 shares of common stock at a price of $11.499 per pre-funded warrant for total gross proceeds of $130.0 million. The net purchase price after deducting the underwriting discounts and commissions and other offering expenses, was $10.77 per share, which generated net proceeds of $121.8 million. Certain affiliates of Frazier Life Sciences IX, L.P., or collectively, Frazier, a significant stockholder and Dr. James Topper, who currently serves on the Company's Board of Directors, share voting and investment power of the securities held by Frazier. Frazier participated in the offering by purchasing pre-funded warrants on the same terms as all other investors at a purchase price of $11.499, which represents the per share public offering price for the common stock less the $0.001 per share exercise price for each pre-funded warrant. Each pre-funded warrant became exercisable

upon issuance and will not expire until exercised in full. The pre-funded warrants may not be exercised if the aggregate number of ordinary shares beneficially owned by the holders thereof immediately following such exercise would exceed a specified beneficial ownership limitation.

The pre-funded warrants were classified as a component of equity in the Company's balance sheets as they are freestanding financial instruments that are immediately exercisable, do not embody an obligation for the Company to repurchase its own shares and permit the holders to receive a fixed number of shares of common stock upon exercise. The Company valued the pre-funded warrants at issuance, concluding that their sales price approximated their fair value, and allocated net proceeds from the sale proportionately to the common stock and pre-funded warrants, of which $28.2 million was allocated to the pre-funded warrants and recorded as a component of additional paid-in capital. As of December 31, 2025, none of the pre-funded warrants have been exercised.

ATM Agreements

In November 2020, the Company entered into an 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 common stock having an aggregate offering price of up to an amount registered under an effective registration statement through the Sales Agent.

In November 2023, the Company filed a shelf registration statement on Form S-3 which was declared effective by the SEC on November 17, 2023, which included an at-the-market prospectus pursuant to which the Company may, from time to time, sell up to an aggregate of $150 million of the Company's common stock through the Sales Agent, or the 2023 ATM Offering. The Company is not obligated to, and cannot provide any assurances that the Company will, make any sales of the shares under the Sales Agreement. The Sales Agreement may be terminated by the Sales Agent or the Company at any time. No shares were sold under the Sales Agreement during the years ended December 31, 2025 and 2024. As of December 31, 2025, all of the available $150 million under the 2023 ATM Offering remains available.

Common Stock Reserves

Common stock reserved for future issuance consists of the following:

	December 31, 2025
Common stock warrants including pre-funded warrants	2,700,150
Stock options, performance stock units and restricted stock units outstanding	12,093,331
Shares available for issuance under the 2019 Incentive Plan	1,617,376
Shares available for issuance under the ESPP Plan	1,357,508
Shares available for issuance under the Inducement Plan	417,734
Balance at December 31, 2025	18,186,099

Preferred Stock

The Company is authorized to issue up to 40 million shares of preferred stock. As of December 31, 2025 and 2024, there were no shares of preferred stock issued or outstanding.

Equity Incentive Plan

The Company’s 2019 Equity Incentive Plan, or the Prior Incentive Plan, provided 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 Prior 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 awards may be available for issuance under the Prior 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, or RSUs, performance stock units, or PSUs, 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 Prior 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 Prior 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.

As of December 31, 2025, 1,617,376 shares remain available for issuance, which reflects 5,889,882 stock options, PSUs and RSUs awards granted, and 2,502,457 of awards cancelled or forfeited, during the year ended December 31, 2025 as well as an annual increase of 3,425,913 shares authorized on January 1, 2025.

2025 Employment Inducement Incentive Award Plan

On March 30, 2025, the Board of Directors adopted the 2025 Employment Inducement Incentive Award Plan, or the Inducement Plan, and reserved 2,500,000 shares of the Company's common stock for issuance pursuant to equity awards granted under the Inducement Plan to individuals not previously employees or non-employee directors of the Company (or following such individuals' bona fide period of non-employment with the Company) as an inducement to join the Company. The Inducement Plan provides for the grant of equity-based awards, including nonstatutory stock options, RSUs, restricted stock, stock appreciation rights, performance shares and PSUs, and its terms are substantially similar to the Company's 2019 Plan, but with such other terms and conditions intended to comply with the Nasdaq inducement award exception or to comply with the Nasdaq acquisition and merger exception. During the year ended December 31, 2025, the Company granted 2,082,266 stock options, RSUs and PSUs under the Inducement Plan. As of December 31, 2025, 417,734 shares remain available for issuance.

Performance-Based Units

In 2025, the Board of Directors approved the grant of PSUs, whereby vesting depends on certain revenue performance milestones each year and over the next three years and stock price hurdle PSUs granted pursuant to the Inducement Plan. The Company estimates the likelihood of achievement of performance milestones for all PSU awards at the end of each reporting period. To the extent those awards or portions thereof are considered probable of being achieved, such awards or portions thereof are expensed over the performance period. Recognition of stock-based compensation expense relating to the stock price hurdle PSU commenced on the date of grant and the expense is recognized ratably over the requisite service period of the award. The stock price hurdle PSUs are considered a market condition under FASB ASC Topic 718 Compensation – Stock Compensation and is estimated on the grant date using Monte Carlo simulations. The key assumptions used in determining this valuation included an expected volatility of 86.84%, a dividend yield of zero, a risk-free interest rate of 3.67%, and an expected term of 3.75 years.

The following table summarizes all PSU activity during the year ended December 31, 2025:

	Number of Stock Units	Weighted-Average Grant Date Fair Value Per Share
Unvested balance at January 1, 2025	—	$ —
Granted	1,189,893	6.56
Vested	(269,644)	6.32
Forfeited	(425,125)	5.76
Unvested balance at December 31, 2025	495,124	$ 7.39

For performance milestone PSUs, stock-based compensation expense is recorded based on the market price of the Company's common stock on the grant date and is recognized if and when the achievement of such performance milestones are determined to be probable by the Company. During the year ended December 31, 2025, a revenue performance milestone was considered probable, and the Company recognized stock-based compensation expense related to the probable vesting of PSUs. In addition, during 2025 stock price hurdle milestones were achieved. The fair value of the PSUs that vested was $1.7 million at the vesting date. The Company recognized $3.3 million of stock-based compensation expense related to all PSU awards during the year ended December 31, 2025. As of December 31, 2025, there was approximately $2.5 million of related unrecognized stock-based compensation expense related to PSUs, which is expected to be recognized over a weighted-average period of approximately 2.0 years.

Restricted Stock Units

The following table summarizes RSU activity under the 2019 Plan during the year ended December 31, 2025:

	Number of Stock Units	Weighted-Average Grant Date Fair Value Per Share
Unvested balance at January 1, 2025	2,382,660	$ 10.32
Granted	1,958,619	6.32
Vested	(1,482,618)	10.88
Forfeited	(704,077)	9.00
Unvested balance at December 31, 2025	2,154,584	$ 6.73

As of December 31, 2025, the Company had $11.2 million of unrecognized stock-based compensation expense related to RSUs, which is expected to be recognized over a weighted-average period of 1.7 years. The total fair value of RSUs vested during the year ended December 31, 2025, was approximately $16.1 million.

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 were 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, 2025, 1,357,508 shares of common stock remain available for issuance, which includes the 505,293 shares sold to employees during the year ended December 31, 2025 as well as an annual increase of 685,183 shares authorized on January 1, 2025.

The ESPP is considered a compensatory plan, and the Company recorded related stock-based compensation of $1.5 million and $1.8 million for the years ended December 31, 2025 and 2024, 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,	
	2025	2024
Assumptions:		
Expected term (in years)	0.49	0.49
Expected volatility	112.83%	105.23%
Risk free interest rate	4.29%	5.19%
Dividend yield	—	—

The estimated weighted-average fair value of ESPP awards during 2025 and 2024 was $3.62 and $4.03, respectively. As of December 31, 2025, 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

During 2020, the Company established a 401(k) savings plan. The Company's contributions to the plan are discretionary. During the years ended December 31, 2025 and 2024, the Company incurred $5.2 million and $5.1 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, 2025 and 2024, the Board of Directors approved employer matching contributions settled by contributing 616,377 and 383,589, respectively, shares of common 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, the Company 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 year ended December 31, 2025:

	Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value (in thousands)
Balance at January 1, 2025	6,157,532	$ 10.29	7.59	$ 2,133
Options granted	4,823,636	5.53		
Options exercised	(164,290)	9.96		
Options cancelled	(1,373,255)	7.17		
Balance at December 31, 2025	9,443,623	$ 8.32	6.45	$ 80,509
Options exercisable as of December 31, 2025	4,553,458	$ 10.70	3.71	$ 29,213
Vested and expected to vest as of December 31, 2025	9,443,623	$ 8.32	6.45	$ 80,509

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, 2025. The total intrinsic value of stock options exercised for the years ended December 31, 2025 and 2024 was approximately $0.8 million and $0.6 million, respectively.

The estimated weighted-average fair value of employee and nonemployee director stock options granted during 2025 was $4.09 and during 2024 was $5.61 per option. As of December 31, 2025, the Company had $18.2 million of unrecognized stock-based compensation expense related to stock options, which is expected to be recognized over a weighted-average period of 2.9 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,	
	2025	2024
Assumptions:		
Expected term (in years)	6.07	6.04
Expected volatility	84.68%	74.78%
Risk free interest rate	4.06%	4.14%
Dividend yield	—	—

Stock-Based Compensation Expense

Stock-based compensation expense recognized for all equity awards has been reported in the statements of operations and comprehensive loss for the years ended December 31, 2025 and 2024 as follows (in thousands):

	Years Ended December 31,	
	2025	2024
Research and development expense	$ 6,864	$ 5,567
Selling, general and administrative expense	21,855	18,480
Total	$ 28,719	$ 24,047

8. Revenue Recognition

To date, our only source of revenue has been from the U.S. sales of VOQUEZNA products, which the Company began selling during the fourth quarter of 2023. The Company records its best estimate of chargebacks, sales discounts and other reserves to which customers are likely expected to be entitled to as contra accounts receivable charges, and within accrued expenses if payable to a third-party or related to product returns on the balance sheets. During the years ended December 31, 2025 and 2024, the Company recognized $175.1 million and $55.3 million, respectively, of net product revenues related to sales of VOQUEZNA, VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK.

The following table provides a summary of the Company's revenue allowances and related accruals for the year ended December 31, 2025 which have been deducting in arriving at product revenues, net (in thousands):

	Customer Credits, Discounts and Allowances (contra accounts receivable)	Rebates, Returns and Co-Pay Assistance (accrued expenses)	Total
Balance as of January 1, 2025	$ 5,659	$ 29,987	$ 35,646
Accruals	65,653	174,330	239,983
Utilizations	(60,666)	(138,855)	(199,521)
Balance as of December 31, 2025	$ 10,646	$ 65,462	$ 76,108

9. Income Taxes

For the years ended December 31, 2025 and 2024, the pre-tax net loss from operations by jurisdiction is as follows (in thousands):

	Years Ended December 31,	
	2025	2024
U.S.	$ (221,247)	$ (334,326)
Foreign	—	—
Total	$ (221,247)	$ (334,326)

For the years ended December 31, 2025 and 2024, 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 for the year ended December 31, 2025 is as follows (in thousands):

	Year Ended December 31, 2025	
Tax computed at federal statutory rate	$ (46,462)	21.00%
State tax, net of federal income tax effect [(1)]	44	(0.02%)
Non-taxable or nondeductible items:		
Permanent items	3,121	(1.41%)
Stock-based compensation	3,459	(1.56%)
Change in valuation allowance	40,994	(18.53%)
Tax credits		
Federal research and development credit	(1,391)	0.63%
Changes in unrecognized tax benefits	235	(0.11%)
Provision (benefit) for income taxes	$ —	0%

(1) The states that contributed to the majority (greater than 50%) of the tax effect in this category are Arizona, California, Massachusetts, New York, and Tennessee for the year ended December 31, 2025.

A reconciliation between the provision for income taxes and income taxes computed using the U.S. federal statutory corporate tax rate for the year ended December 31, 2024 is as follows (in thousands):

	Year Ended December 31, 2024	
Income taxes computed at the statutory rate	$ (70,209)	21.00%
State income taxes, net of federal benefit	(10,540)	3.15%
Permanent items	3,332	(1.00%)
Officers' compensation	1,637	(0.49%)
Research and development credit	(1,739)	0.52%
Change in state rate	(1,921)	0.57%
Change in valuation allowance	79,427	(23.76%)
Other	13	-
Provision (benefit) for income taxes	$ —	0%

Significant components of the Company's net deferred tax assets are as follows (in thousands):

	Years Ended December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 240,652	$ 195,225
Research credits	14,491	13,554
Intangible assets	33,802	34,749
Other	17,333	11,964
Gross deferred tax assets	306,278	255,492
Less valuation allowance	(305,623)	(255,342)
Deferred tax assets, net of valuation allowance	655	150
Deferred tax liabilities:		
Other	(655)	(150)
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, 2025 and 2024.

On July 4, 2025, the One Big Beautiful Bill Act, or OBBBA, was enacted into law. The new tax law contains several key provisions affecting corporations including but are not limited to expensing of domestic specified research or experimental expenditures and one hundred percent bonus depreciation on eligible property after January 19, 2025. In accordance with Accounting Standards Codification (ASC) 740, Income Taxes, the Company is required to recognize the effect of the tax law changes in the period of enactment, such as remeasuring the estimated U.S. deferred tax assets and liabilities. Because of a full valuation allowance, there is no net impact to deferred tax assets and liabilities for the year ended December 31, 2025. The Company will continue to apply OBBBA tax law changes as required or elected in future years.

As of December 31, 2025 and 2024, the Company had federal net operating loss carryforwards of approximately $1.0 billion and $863.2 million, respectively, which are carried over indefinitely. As of December 31, 2025, the Company had approximately $387.1 million of state net operating loss carryforwards that begins to expire in 2033. As of December 31, 2025, the Company has available federal research and development credits of $17.2 million which begin to expire in 2038. The Company has $1.2 million of state research and development credits, some of which, begin to expire in 2026.

The Company has not completed a formal analysis of the potential impact of Section 382 on its deferred tax assets as of December 31, 2025. 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,	
	2025	2024
Beginning balance	$ 3,452	$ 3,010
Decreases related to prior year tax positions	(64)	—
Increases related to current year tax positions	287	442
Ending balance	$ 3,675	$ 3,452

As of December 31, 2025 and 2024, the Company has gross unrecognized tax benefits of $3.7 million and $3.5 million, respectively, none of which would affect the effective tax rate due to a full valuation allowance. 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, 2025 and 2024, and has not recognized interest and/or penalties in its statement of operations for the years ended December 31, 2025 and 2024.

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.

10. Segment Information

The Company's chief operating decision maker, or CODM, the Chief Executive Officer, manages the Company’s business activities as a single reportable segment. The segment derives its current revenues from the sale of VOQUEZNA products. Accordingly, the CODM uses net loss to measure segment profit or loss, allocate resources and assess performance. Further, the CODM reviews and utilizes functional expenses (research and development, general and administrative, sales and marketing and stock-based compensation) to manage the Company’s operations. Other segment items included in net loss are interest income, interest expense and other expense, which are reflected in the statements of operations and comprehensive loss. The measure of segment assets is reported on the balance sheets as total assets.

The following table presents selected financial information with respect to the Company’s single operating segment for the years ended December 31, 2025 and 2024 (in thousands):

	Years Ended December 31,	
	2025	2024
Product revenue, net	$ 175,110	$ 55,252
Less:		
Cost of revenue	22,599	7,973
Research and development	25,916	28,515
General and administrative	35,329	28,192
Sales and marketing	222,533	243,992
Stock-based compensation	28,719	24,047
Interest income	(7,044)	(15,158)
Interest expense	68,115	72,009
Other expense, net	190	8
Segment net loss	$ (221,247)	$ (334,326)

11. Restructuring

In May 2025, the Company implemented a cost reduction and organizational restructuring plan to reduce cash burn and focus resources on commercial execution. In connection with the restructuring, the Company's workforce was reduced by 26 employees, or approximately 6%, including certain leadership changes all designed to right-size the organization. During the year ended December 31, 2025, total restructuring charges incurred were $9.2 million consisting of one-time termination benefits to affected employees for severance, non-cash stock-based compensation costs, healthcare benefits and outplacement assistance. The costs are included in research and development and selling, general, and administrative expenses on the Company's statements of operations and comprehensive loss for the year ended December 31, 2025.

The following table summarizes activity related to the restructuring accrual during the year ended December 31, 2025 (in thousands):

	Total
Restructuring expenses incurred	$ 9,214
Cash paid	(4,125)
Non-cash expenses	(4,597)
Balance as of December 31, 2025	$ 492

12. Subsequent Events

In January 2026, the Company sold 6,875,000 shares of common stock at a price of $16.00 per share and pre-funded warrants to purchase 1,250,078 shares of common stock at a price of $15.999 per pre-funded warrant, which represents the per share price for the common stock less the $0.001 per share exercise price for each such pre-funded warrant. The Company received gross proceeds of $130 million, before deducting underwriting discounts and commissions. The net purchase price after deducting the underwriting discounts and commissions and other offering expenses, was $15.04 per share or net proceeds of $122.2 million.

On February 25, 2026, or the Fifth Amendment Closing Date, the Company entered into the Fifth Amendment to the Loan and Security Agreement, or the Fifth Loan Amendment, with the lenders, which, among other things, (i) provides for a new term loan tranche of $175 million, the proceeds of which, along with cash on our balance sheet, were used to repay in full the existing secured obligations outstanding under the Loan Agreement, including principal, capitalized payment-in-kind interest, existing final fee payments, and any applicable prepayment fees, (ii) provides for an additional loan tranche of up to $25 million which shall be available to the Company in the lenders' discretion, (iii) extends the maturity date from December 1, 2027 to February 1, 2029, subject to further extension to December 1, 2030 upon the achievement of a specified revenue milestone and subject to a certain pro forma liquidity test; (iv) extends the interest only period from October 2026 to December 2027, thereafter, monthly payment of interest and 2.5% of the original principal amount advanced through the maturity date, with any remaining payments to be repaid in full on the maturity date, (v) changes the cash interest rate to 9.85% (floating rate based on the greater of (a) US WSJ Prime + 3.10% or (b) 9.85%, (vi) eliminates the payment-in-kind interest rate of 2.15% per annum, (vii) amends the prepayment charge, which is a percentage of the principal amount actually advanced under the Term Loans under the Fifth Loan Amendment, or each a Term Loan Advance and together, the Term Loan Advances, as follows: (a) if the Term Loan Advances are prepaid after the Fifth Amendment Closing Date but prior to the twelfth month anniversary of the Fifth Amendment Closing Date, 2.50%; (b) if the Term Loan Advances are prepaid on or after the twelfth month anniversary of the Fifth Amendment Closing Date but prior to the twenty-fourth month anniversary of the Fifth Amendment Closing Date, 2.00%; (c) if the Term Loan Advances are prepaid on or after the twenty-fourth month anniversary of the Fifth Amendment Closing Date but prior to the thirty-sixth month anniversary of the Fifth Amendment Closing Date, 1.50%; (d) thereafter, 1.00%; and (viii) provides for a new final payment fee which is as a percentage of the Term Loan Advances so prepaid, as follows: (a) if the Term Loan Advances are repaid prior to September 2027, 1.25%; (b) if the Term Loan Advances are repaid after September 1, 2027 but on or prior to February 1, 2029, 2.00%; (c) if the Term Loan Advances are repaid after February 1, 2029 but on or prior to January 1, 2030, 3.00%, and (d) if the Term Loan Advances are repaid after January 1, 2030, 3.50%.

In addition, the financial covenants under the Fifth 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, which will decrease to 15% of the outstanding principal amount upon the Company reporting and maintaining $75 million of trailing three months net product revenue.

ii. Performance covenant - Beginning on the Fifth Amendment Closing Date and all times there after the Company must satisfy any one of the following:

   a. Market capitalization exceeding $900 million;

   b. Minimum cash balance of 50% of the outstanding principal amount of term loans, which will decrease to 40% upon achieving $65 million of trailing three months nets product revenue, and to 30% upon achieving $85 million, of trailing three months net product revenue; or

   c. Trailing three months net product revenue equal to 75% of projected revenue in 2026 and 70% of projected revenue in 2027 and beyond, tested on a quarterly basis.

In connection with the Fifth Loan Amendment, the existing final fee payments under the Loan and Security Agreement in the aggregate amount of $11.5 million were fully paid to Agent and a facility fee of $1.8 million was also paid to the Agent.

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	Warrant to purchase stock issued to Hercules Capital, dated September 17, 2021	10-Q	11-8-2021	10.2	
4.5	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	
4.6	First Amendment to Warrant to purchase stock issued to Hercules Capital, dated May 9, 2023	10-Q	5-10-2023	4.5	
4.7	Description of Registered Securities				X
4.8	Form of Pre-Funded Warrant to purchase common stock	8-K	8-19-2024	4.1	
4.9	Form of Pre-Funded Warrant to purchase common stock	8-K	1-8-2026	4.1	
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 Program	10-Q	8-8-2024	10.1	

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				X
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	10-K	3-7-2024	10.26	
10.27^	Fourth Amendment to the Loan and Security Agreement, dated December 14, 2023, by and among Hercules Capital and the Registrant	10-K	3-7-2024	10.27	
10.28#	Phathom Pharmaceuticals Inc. 2024 Bonus Plan	10-K	3-7-2024	10.28	
10.29†	Letter Agreement to Vonoprazan Commercial Supply Agreement, dated September 4, 2024, by and among Evonik Operations GmbH and the Registrant	10-Q	11-7-2024	10.1	

10.30	Joinder Agreement dated December 23, 2024 by and among CO Finance III LVS LX LP and the Registrant	10-K	3-6-2025	10.30	
10.31#	Phathom Pharmaceuticals, Inc. 2025 Employment Inducement Incentive Award Plan and related forms of stock option, restricted stock unit and performance stock unit agreements thereunder	S-8	4-3-2025	10.1	
10.32#	Employment Letter Agreement, dated March 31, 2025, by and between Steven Basta and the Registrant	10-Q	5-1-2025	10.1	
10.33#	Separation Agreement, dated April 2, 2025, by and between Terrie Curran and the Registrant	10-Q	5-1-2025	10.2	
10.34#	Separation Agreement and Release of Claims, dated May 18, 2025, by and between Azmi Nabulsi, M.D., M.P.H. and the Registrant	10-Q	8-7-2025	10.1	
10.35#	Separation Agreement and Release of Claims, dated May 20, 2025, by and between Molly Henderson and the Registrant	10-Q	8-7-2025	10.2	
10.36#	Employment Letter Agreement, dated June 4, 2025, by and between Anne Marie Cook and the Registrant	10-Q	8-7-2025	10.3	
10.37#	Employment Letter Agreement, dated September 29, 2025, by and between Sanjeev Narula and the Registrant	10-Q	10-30-2025	10.1	
10.38^	Fifth Amendment to the Loan and Security Agreement, dated February 25, 2026, by and among Hercules Capital and the Registrant				X
19	Phathom Pharmaceuticals, Inc. Insider Trading Compliance Policy and Procedures	10-K	3-6-2025	19	
23.1	Consent of Independent Registered Public Accounting Firm				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	10-K	3-7-2024	97	
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/ Steven Basta
Steven Basta
Chief Executive Officer

Date: February 26, 2026

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/ Steven Basta **Steven Basta**	President, Chief Executive Officer and Director (Principal Executive Officer)	February 26, 2026
/s/ Sanjeev Narula **Sanjeev Narula**	Chief Financial and Business Officer (Principal Financial Officer)	February 26, 2026
/s/ Michael F. Cola **Michael F. Cola**	Director	February 26, 2026
/s/ Frank Karbe **Frank Karbe**	Director	February 26, 2026
/s/ Heidi Kunz **Heidi Kunz**	Director	February 26, 2026
/s/ Asit Parikh **Asit Parikh, M.D., Ph.D.**	Director	February 26, 2026
/s/ Ted Schroeder **Ted Schroeder**	Director	February 26, 2026
/s/ Mark Stenhouse **Mark Stenhouse**	Director	February 26, 2026
/s/ James Topper **James Topper, M.D., Ph.D.**	Director	February 26, 2026

MANAGEMENT

Steven Basta
Chief Executive Officer & President

Paul Cocja
Chief People Officer

Anne Marie Cook, JD
Chief Legal Officer & Corporate Secretary

Eckhard Leifke, MD
Chief Medical Officer

Sanjeev Narula
Chief Financial & Business Officer

BOARD OF DIRECTORS

Michael Cola
Chairman of the Board
Chief Executive Officer, Helus Pharma

Steven Basta
Chief Executive Officer & President,
Phathom Pharmaceuticals

Frank Karbe
Former Chief Financial Officer,
Cidara Therapeutics

Heidi Kunz
Former Chief Financial Officer,
Blue Shield of California

Asit Parikh, MD, PhD
Chief Executive Officer & President,
MOMA Therapeutics

Ted Schroeder
Former Chief Executive Officer,
Nabriva Therapeutics

Mark Stenhouse
Former Chief Operating Officer,
Prometheus Biosciences

James Topper, MD, PhD
Managing Partner,
Frazier Life Sciences

CORPORATE INFORMATION

Phathom Pharmaceuticals, Inc.
100 Campus Drive, Suite 102
Florham Park, NJ 07932
877-742-8466
www.phathompharma.com

ANNUAL MEETING

May 19, 2026 at 9:00 a.m. EDT

The annual meeting of stockholders will be held via live webcast at:
www.virtualshareholdermeeting.com/PHAT2026

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Ernst & Young, LLP

LEGAL COUNSEL

Latham & Watkins, LLP

STOCK INFORMATION

Our common stock is traded on
The Nasdaq Global Select Market
under the symbol PHAT

TRANSFER AGENT

Address:
Computershare
PO Box 505000
Louisville, Kentucky 40233-5000
United States

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Louisville, Kentucky 40202
United States

Phone:
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Toll: 781.575.3100


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