Filed Pursuant to Rule 424(b)(4)
Registration No. 333-234020
Registration No. 333-234312

9,563,157 Shares

Phathom™
PHARMACEUTICALS

Common Stock

This is an initial public offering of shares of common stock of Phathom Pharmaceuticals, Inc. We are offering 9,563,157 shares of our common stock.

Prior to this offering, there has been no public market for our common stock. The initial public offering price per share is $19.00.

Our common stock has been approved for listing on the Nasdaq Global Select Market under the symbol "PHAT."

We are an "emerging growth company" as defined under the federal securities laws and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and may elect to do so in future filings.

See "Risk Factors" beginning on page 13 to read about factors you should consider before buying shares of our common stock.

Neither the Securities and Exchange Commission nor any other state securities commission has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share	Total
Initial public offering price	$ 19.00	$ 181,699,983
Underwriting discount(1)	$ 1.33	$ 12,718,999
Proceeds, before expenses, to Phathom Pharmaceuticals, Inc.	$ 17.67	$ 168,980,984

(1) See the section titled "Underwriting" for additional information regarding compensation payable to the underwriters.

To the extent that the underwriters sell more than 9,563,157 shares of common stock, the underwriters have the option to purchase up to an additional 1,434,473 shares from us at the initial price to the public less the underwriting discount.

The underwriters expect to deliver the shares against payment in New York, New York on October 29, 2019.

Goldman Sachs & Co. LLC **Jefferies** **Evercore ISI**

Needham & Company

Prospectus dated October 24, 2019.

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Neither we nor the underwriters have authorized anyone to provide you with information other than that contained in this prospectus or any free writing prospectus prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are offering to sell, and seeking offers to buy, common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus or any free writing prospectus is accurate only as of its date, regardless of its time of delivery or of any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside of the United States: We have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

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PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, especially the section titled "Risk Factors" and our combined financial statements and related notes included elsewhere in this prospectus, before making an investment decision. As used in this prospectus, unless the context otherwise requires, references to "we," "us," "our," "the Company," "Phathom Pharmaceuticals" and "Phathom" refer to Phathom Pharmaceuticals, Inc.

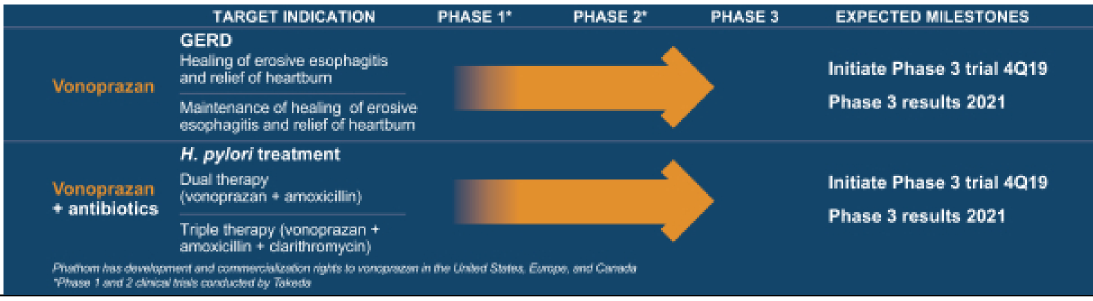
Overview

We are a late clinical-stage biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal, or GI, diseases. Our initial product candidate, vonoprazan, is an oral small molecule potassium competitive acid blocker, or P-CAB. P-CABs are a novel class of medicines that block acid secretion in the stomach. Vonoprazan has shown rapid, potent, and durable anti-secretory effects and has demonstrated clinical benefits over standard of care treatments as a single agent in the treatment of gastroesophageal reflux disease, or GERD, and in combination with antibiotics for the treatment of *Helicobacter pylori,* or *H. pylori,* infection. Takeda Pharmaceutical Company Limited, or Takeda, developed vonoprazan and has received marketing approval in nine countries in Asia and Latin America. Vonoprazan generated over $500 million in net sales in its fourth full year on the market since its approval in Japan in late 2014. In May 2019, we in-licensed the U.S., European, and Canadian rights to vonoprazan from Takeda.

We believe we can leverage Takeda's extensive clinical data, including results from 17 Phase 3 clinical trials, to advance vonoprazan through pivotal trials in the United States and Europe. We plan to initiate two pivotal Phase 3 clinical trials in the fourth quarter of 2019 for vonoprazan: one for the treatment of erosive GERD, also known as erosive esophagitis, and a second for the treatment of *H. pylori* infection. We expect to report top-line data from both trials in 2021. We believe that the successful completion of our Phase 3 clinical trials, together with the existing clinical data, will support regulatory submissions in 2021 and 2022 for marketing approval for the treatment of *H. pylori* infection and erosive esophagitis, respectively. In August 2019, we received qualified infectious disease product, or QIDP, designation from the U.S. Food and Drug Administration, or FDA, for vonoprazan in combination with certain antibiotics for the treatment of *H. pylori* infection which provides, among other benefits, extension of any regulatory exclusivity and potential eligibility for priority review. Vonoprazan has the potential to be the first gastric anti-secretory agent from a novel class approved in the United States, Europe, or Canada in over 30 years.

Our Pipeline

The following chart summarizes our current development programs.



Overview of Acid-Related GI Diseases

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

GERD and *H. pylori* infection are two of the most common acid-related GI diseases and impact millions of people. The prevalence of GERD is estimated to be 20% of the U.S. population and 15% of the population in the five major countries in the European Union (France, Germany, Italy, Spain, and the United Kingdom, or the EU5). We estimate that there are approximately 65 million individuals in the United States and 50 million individuals in the EU5 with GERD. Approximately 30% of GERD patients have erosive esophagitis. *H. pylori* is a bacterial pathogen that infects approximately 35% of the U.S. population and 45% of the EU5 population. We estimate that there are approximately 115 million individuals in the United States and 145 million individuals in the EU5 infected with *H. pylori*.

Current Standard of Care for GERD and *H. pylori*

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

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

Gastric acid is secreted by proton pumps that are expressed on the channeled surfaces of parietal cells in the stomach. Proton pumps are continuously synthesized and switch between active and inactive states in response to various stimuli, such as food. When activated, proton pumps increase acid secretion. PPIs reduce gastric acid secretion by irreversibly binding to and inhibiting active proton pumps expressed on the parietal cells. PPIs require activation by gastric acid, but they are unstable in the presence of acid. This instability, combined with the short circulating half-life of PPIs, limits their efficacy. Additionally, because proton pumps continuously switch between active and inactive states, multiple doses of PPIs are required to inhibit enough proton pumps to achieve a clinical benefit. As a result, PPIs have a relatively slow onset of action and limited potency and duration of effect, which may result in patients experiencing only partial relief, increasing PPI dosage, and/or cycling through multiple PPIs seeking relief.

Our Solution: Vonoprazan

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

- does not require activation by gastric acid;
- is stable in the presence of acid;
- binds with a slow dissociation rate to both active and inactive proton pumps; and
- has a long plasma half-life that replenishes the drug at the site of action over the course of the day.

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

We believe that vonoprazan's anti-secretory profile may demonstrate clinically meaningful advantages over PPIs, such as:

- faster, more complete, and more durable healing of erosive esophagitis;
- faster, more complete, and more durable control of GERD symptoms;
- higher *H. pylori* eradication rates in combination with antibiotics compared to standard of care triple therapy and the potential for antibiotic-sparing dual therapy; and
- more flexible dosing, including dosing independent of food and time of day, and the potential for rapid symptom relief through on-demand dosing.

Vonoprazan generated over $500 million in net sales in its fourth full year on the market in Japan, a 20% increase over the previous year.

Vonoprazan Clinical Data

Vonoprazan has demonstrated clinical advantages over PPIs in the treatment of erosive esophagitis and *H. pylori* infection in completed Phase 3 clinical trials conducted in Japan and other Asian countries.

Erosive esophagitis. In two Phase 3 clinical trials conducted in Japan assessing vonoprazan versus the PPI lansoprazole in the healing and maintenance of healing of erosive esophagitis, vonoprazan met its primary endpoint in demonstrating non-inferiority to lansoprazole. In a post hoc analysis of the healing trial, vonoprazan demonstrated faster healing and a superior overall healing rate compared to lansoprazole in patients with more severe erosive esophagitis. After two weeks of treatment, 88% of erosive esophagitis patients with more severe disease were healed after treatment with vonoprazan versus 64% with lansoprazole ($p=0.0008$). In the maintenance of healing trial, vonoprazan demonstrated lower recurrence rates of erosive esophagitis six months after treatment versus lansoprazole across all grades of severity of erosive esophagitis. Vonoprazan demonstrated a 2% recurrence rate compared to 17% for lansoprazole ($p<0.0001$).

***H. pylori*.** A Phase 3 clinical trial was conducted in Japan assessing vonoprazan in combination with the antibiotics amoxicillin and clarithromycin versus lansoprazole in combination with these same antibiotics in first line treatment of *H. pylori* infection. In this trial, the vonoprazan-based regimen met its primary endpoint in demonstrating a non-inferior eradication rate of 93% compared to 76% for lansoprazole-based regimen ($p<0.0001$) and was also superior in a post hoc analysis of this trial ($p<0.0001$). In patients who failed first line therapy, vonoprazan in combination with the antibiotics metronidazole and amoxicillin demonstrated a 98% eradication rate as second line therapy. A p-value is the probability that the reported result was achieved purely by chance, such that a p-value of less than or equal to 0.05 or 0.01 means that there is a 5.0% or 1.0% or less probability, respectively, that the difference between the control group and the treatment group is purely due to chance. A p-value of 0.05 or less typically represents a statistically significant result.

Safety. As of December 2018, 6,683 subjects have been exposed to vonoprazan in completed and ongoing Phase 1 to 3 clinical trials. The doses studied have ranged from 1 to 120 mg with durations up to one year. The most commonly reported adverse events, or AEs, in the clinical development program for vonoprazan, as reflected in the Japanese prescribing information published by Japan's Pharmaceuticals and Medical Devices Agency, were diarrhea, constipation, nausea, elevated liver enzymes, rash, and eosinophilia. All such events had an incidence rate of less than 5.0%, other than diarrhea in the treatment of *H. pylori* which had an incidence rate of 10.6% in combination with antibiotics. No dose-related increase in treatment-emergent AEs, or TEAEs, or serious AEs, or SAEs, was observed. The safety profile of vonoprazan and incidence of TEAEs, drug-related TEAEs, and TEAEs leading to drug discontinuation were similar between vonoprazan and lansoprazole across studies.

The most recent post-marketing safety report from December 2018 includes an estimated 23 million patients who have received vonoprazan in Japan since its launch. Based on the post-marketing experience, the clinically significant adverse reactions section of the Japanese prescribing information for vonoprazan was updated to include skin reactions such as toxic epidermal necrolysis, Steven-Johnson syndrome, and erythema multiforme. The incidence of these skin reactions was considered extremely rare (less than 1 in 100,000 patients) and a causal relationship to vonoprazan could not be ruled out. We believe the overall post-marketing safety and tolerability profile of vonoprazan has been consistent with that observed in clinical trials.

Our Strategy

Our goal is to be a leader in the development and commercialization of novel treatments for GI diseases. Our strategy is initially focused on developing and commercializing vonoprazan as a potential first-in-class P-CAB in the United States, Europe, and Canada for the treatment of acid-related GI diseases. Key elements of this strategy include:

- ***Advance the clinical development of vonoprazan in erosive esophagitis and H. pylori infection and seek marketing approval.*** We believe we can leverage the existing clinical data and post-marketing experience, as well as our management team's experience with vonoprazan, to advance vonoprazan through a single pivotal Phase 3 clinical trial in each of erosive esophagitis and *H. pylori* infection beginning in the fourth quarter of 2019, and we expect to report top-line data from both trials in 2021.
- ***Commercialize vonoprazan in the United States.*** We plan to independently commercialize vonoprazan, if approved, in the United States by building a leading specialty gastroenterology commercial infrastructure to support the adoption of vonoprazan.

- ***Seek commercial partnerships to maximize the vonoprazan opportunity outside of the United States***. We believe there is a significant commercial opportunity for vonoprazan in Europe and Canada. To address these markets, we plan to seek one or more partners with existing commercial infrastructure and expertise in these markets.
- ***Expand the development of vonoprazan across indications, dosing regimens, and alternative formulations and packaging***. We plan to pursue vonoprazan lifecycle extension strategies in areas with clear unmet need, clinical rationale, and commercial justification. These strategies may include additional indications, flexible dosing regimens, and alternative formulations and packaging.
- ***In-license or acquire additional clinical or commercial stage product candidates for the treatment of GI diseases in a capital efficient manner***. We intend to take advantage of our management team's GI expertise to opportunistically in-license or acquire additional innovative therapies for diseases treated by gastroenterologists.

Our Team

Our founders and management team have deep expertise in developing GI therapeutics, including anti-secretory agents, and direct experience developing vonoprazan at Takeda. Our Chairman, Tadataka (Tachi) Yamada, M.D., is the former Chief Medical Officer and Chief Scientific Officer at Takeda. He is the former President of the American Gastroenterological Association and former Chief of Gastroenterology and Internal Medicine at the University of Michigan. Our Chief Executive Officer, David Socks, is the former Chief Executive Officer of Outpost Medicine, LLC, a GI and urology focused company. Mr. Socks was also President and Chief Operating Officer of Incline Therapeutics Inc. through its sale to The Medicines Company in 2013, and Senior Vice President, Corporate Development and Strategy of Cadence Pharmaceuticals, Inc. Azmi Nabulsi, M.D., M.P.H., our Chief Operating Officer, is the former Deputy Chief Medical and Scientific Officer at Takeda. Our Head of Regulatory, Tom Harris, is the former Senior Vice President and Head of Global Regulatory at Takeda. Dr. Yamada, Dr. Nabulsi, and Mr. Harris were extensively involved with the development of vonoprazan at Takeda. Our investors include Frazier Healthcare Partners, Medicxi, RA Capital Management, Abingworth, certain accounts managed by Janus Henderson Investors and BVF Partners LP.

As part of a planned transition, we expect that Terrie Curran, a member of our board of directors, will succeed Mr. Socks as Chief Executive Officer effective upon the closing of the acquisition of her current employer, Celgene Corporation, by Bristol-Myers Squibb Company. Ms. Curran has served as President, Global Inflammation and Immunology (I&I) Franchise and as a member of the Executive Committee at Celgene since 2017. Ms. Curran joined Celgene in 2013 as the U.S. Commercial Head of the I&I Franchise and built the capabilities and recruited the teams that executed the launch of OTEZLA. Following Ms. Curran's appointment as CEO, Mr. Socks will serve as interim Chief Financial Officer and continue to serve as a member of our board of directors.

Financial Update

We estimate that our cash and cash equivalents were approximately $74.5 million as of September 30, 2019. This amount is unaudited and preliminary and is subject to completion of financial closing procedures. As a result, this amount may differ from the amount that will be reflected in our financial statements as of and for the quarter ended September 30, 2019. Our financial statements for the quarter ended September 30, 2019 will not be available until after this offering is completed, and consequently will not be available to you prior to investing in this offering.

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Risks Related to Our Business

Our ability to execute our business strategy is subject to numerous risks, as more fully described in the section titled "Risk Factors" immediately following this Prospectus Summary. These risks include, among others:

- We have a limited operating history, have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.
- We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations.
- We currently depend entirely on the success of vonoprazan, which is our only product candidate. Our assumptions about vonoprazan's development and commercial potential are based in large part on the development, including data from clinical trials conducted by Takeda and independent investigators, and commercial experience of vonoprazan in Japan and other Asian countries, which data the FDA or comparable foreign regulatory authorities may not accept to support approval. If we are unable to advance vonoprazan in clinical development, obtain regulatory approval and ultimately commercialize vonoprazan, or experience significant delays in doing so, our business will be materially harmed.
- We rely on our license agreement with Takeda 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.
- Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and the results of prior clinical trials and other investigator-initiated clinical trials of vonoprazan are not necessarily predictive of our future results. Vonoprazan may not have favorable results in our clinical trials, or receive regulatory approval on a timely basis, if at all.
- Any difficulties or delays in the commencement or completion, or termination or suspension, of our planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.
- We intend to enroll patients in Europe in both of our planned Phase 3 clinical trials. However, the FDA and other comparable foreign regulatory authorities may not accept data from such trials, in which case our clinical development plans will be delayed, which could materially harm our business.
- We rely on third parties to conduct some or all aspects of our product manufacturing, research and preclinical and clinical testing, and these third parties may not perform satisfactorily.
- We face significant competition, and if our competitors develop technologies or product candidates more rapidly than we do or their technologies are more effective, our ability to develop and successfully commercialize products may be adversely affected.
- Our success depends on our ability to protect our intellectual property and our proprietary technologies.
- After this offering, our executive officers, directors, and principal stockholders, if they choose to act together, will continue to 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.

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, with and into our company, with Phathom Pharmaceuticals, Inc. as the surviving entity, or the Merger. References throughout this registration statement to Phathom Pharmaceuticals, Inc. include North Bridge IV, Inc. prior to the Merger. Our principal executive offices are located at 2150 E. Lake Cook Road, Suite 800, Buffalo Grove, Illinois 60089, and our telephone number is 650-325-5156. Our website address is www.phathompharma.com. The information contained in, or accessible through, our website does not constitute part of this prospectus. We have included our website address as an inactive textual reference only.

We use our pending trademark Phathom Pharmaceuticals in this prospectus. This prospectus also includes trademarks, tradenames, and service marks that are the property of other organizations. Solely for convenience, trademarks and tradenames referred to in this prospectus 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.

Presentation of Japanese Sales Numbers

All Japanese sales numbers presented in this prospectus are shown in U.S. dollars based on the June 30, 2019 conversion ratio of 0.009 yen to one dollar.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

As a company with less than $1.07 billion in revenue during our last fiscal year, we qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or Sarbanes-Oxley Act;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements, unless the SEC determines the new rules are necessary for protecting the public;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the date of the first sale of our common equity securities pursuant to an effective registration statement under the Securities Act of 1933, as amended, or the Securities Act, which such fifth anniversary will occur in 2024. However, if certain events occur prior to the end of such five-year period, including if we become a “large accelerated filer” as defined in Rule 12b-2 under the Securities Exchange Act of 1934, or the Exchange Act, our annual gross revenues exceed $1.07 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We have elected to take advantage of certain of the reduced disclosure obligations in this prospectus and in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information in this prospectus and that we provide to our stockholders in the future may be different than what you might receive from other public reporting companies in which you hold equity interests.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

The Offering

Common stock offered by us	9,563,157 shares.
Underwriters' option to purchase additional shares from us	The underwriters have a 30-day option to purchase up to a total of 1,434,473 additional shares of our common stock.
Common stock to be outstanding immediately after this offering	27,547,593 shares (28,982,066 shares if the underwriters exercise their option to purchase additional shares of common stock in full).
Use of proceeds	We intend to use the net proceeds of this offering to fund the clinical development of vonoprazan and for working capital and general corporate purposes, including pre-commercial activities. See "Use of Proceeds."
Risk factors	See "Risk Factors" and other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our common stock.
Directed share program	At our request, the underwriters have reserved up to 3.0% of the shares of common stock to be offered by this prospectus for sale, at the initial public offering price, to certain of our directors, officers, employees, and their friends and family members through a directed share program. If these persons purchase reserved shares, this will reduce the number of shares available for sale to the general public. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same terms as the other shares offered by this prospectus.
Nasdaq Global Select Market symbol	"PHAT"

The number of shares of our common stock to be outstanding after this offering set forth above is based on 17,984,436 shares of our common stock outstanding as of June 30, 2019, including 4,657,250 shares subject to forfeiture or our right of repurchase, and gives effect to the automatic conversion of $90.3 million of aggregate principal amount, plus accrued interest thereon, of convertible promissory notes we issued in May 2019, or the May 2019 Notes, into an aggregate of 6,107,918 shares of our common stock immediately prior to the closing of this offering (based on the initial public offering price of $19.00 per share and assuming the conversion occurs on October 29, 2019), and excludes:

- 7,588,000 shares of common stock issuable to Takeda upon the exercise of an outstanding warrant, or the Takeda Warrant, as of June 30, 2019, at an exercise price of $0.00004613 per share;

- 1,400,528 shares of common stock issuable upon exercise of stock options granted after June 30, 2019, at a weighted-average exercise price of $9.10 per share;
- 2,700,000 shares of common stock reserved for future issuance under our 2019 Equity Incentive Plan, or the 2019 Plan, which became effective in connection with this offering (which number does not include any potential evergreen increases pursuant to the terms of the 2019 Plan);
- 270,000 shares of common stock reserved for future issuance under our 2019 Employee Stock Purchase Plan, or ESPP, which became effective in connection with this offering (which number does not include any potential evergreen increases pursuant to the terms of the ESPP); and
- 16,446 shares of common stock which may become issuable to the lenders under our loan and security agreement, or the Loan Agreement, upon the exercise of warrants outstanding as of June 30, 2019, or the Lender Warrants, at an exercise price of $15.20 per share (based on the initial public offering price of $19.00 per share), which warrants will only become exercisable if and when we borrow an additional $25.0 million under our Loan Agreement.

Unless otherwise indicated, all information contained in this prospectus assumes or gives effect to:

- the filing and effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws, each of which will occur immediately prior to the closing of this offering;
- the issuance of 6,107,918 shares of common stock upon the automatic conversion of the May 2019 Notes immediately prior to the closing of this offering (based on the initial public offering price of $19.00 per share and assuming the conversion occurs on October 29, 2019);
- the expiration of the right granted to Takeda to receive an additional common stock warrant, or the Takeda Warrant Right, upon the closing of this offering (based on the initial public offering price of $19.00 per share, as further described below in the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Overview—License Agreement with Takeda”);
- a 1,559.1183-for-1 forward stock split of our common stock effected on March 13, 2019;
- a subsequent 2.168-for-1 forward stock split of our common stock, which we effected on October 11, 2019;
- no exercise of the outstanding options or warrants described above; and
- no exercise by the underwriters of their option to purchase 1,434,473 additional shares of our common stock.

Summary Combined Financial Data

The following tables set forth a summary of our historical combined financial data as of, and for the periods ended on, the dates indicated. The combined financial statements include the accounts of our company and YamadaCo IIA, Inc., both of which were entities under common control prior to the Merger. We have derived the summary combined statements of operations data for the year ended December 31, 2018 from our audited combined financial statements included elsewhere in this prospectus. We have derived the summary combined statements of operations data for the six months ended June 30, 2018 and 2019 and the summary combined balance sheet data as of June 30, 2019 from our unaudited combined financial statements included elsewhere in this prospectus. The unaudited combined financial statements have been prepared on a basis consistent with our audited combined financial statements included in this prospectus and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, necessary to fairly state our results of operations for the six months ended June 30, 2018 and 2019 and financial position as of June 30, 2019. You should read these data together with our combined financial statements and related notes included elsewhere in this prospectus and the sections titled “Selected Combined Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Our historical results for any prior period are not necessarily indicative of our future results.

(in thousands, except share and per share data)	Year Ended December 31, 2018	Six Months Ended June 30, 2018	2019
		(unaudited)	
Combined Statements of Operations Data:			
Operating expenses:			
Research and development	$ 20	$ –	$ 3,201
In-process research and development	–	–	78,897
General and administrative (includes related party amounts of $321, $124 and $18, respectively)	1,205	506	2,142
Total operating expenses	1,225	506	84,240
Loss from operations	(1,225)	(506)	(84,240)
Other income (expense):			
Interest income	–	–	101
Interest expense (includes related party amounts of $(13), $(4) and $(82), respectively)	(13)	(4)	(1,148)
Change in fair value of warrant liabilities (includes related party amounts of $0, $0 and $(1,277), respectively)	–	–	(1,284)
Change in fair value of convertible promissory notes (includes related party amounts of $(50), $(4) and $(502), respectively)	(50)	(4)	(2,442)
Total other income (expense)	(63)	(8)	(4,773)
Net loss	$ (1,288)	$ (514)	$ (89,013)
Net loss per share, basic and diluted(1)	$ (0.21)	$ (0.10)	$ (13.40)
Weighted-average shares of common stock outstanding, basic and diluted(1)	6,051,675	5,331,270	6,640,394
Pro forma net loss per share, basic and diluted (unaudited)(1)	$ (0.20)		$ (9.85)
Pro forma weighted-average shares of common stock outstanding, basic and diluted (unaudited)(1)	6,098,429		8,578,296

(1) See Note 1 to our combined financial statements included elsewhere in this prospectus for an explanation of the method used to calculate the historical and pro forma net loss per share, basic and diluted, and the number of shares used in the computation of the per share amounts.

(in thousands)	As of June 30, 2019 Actual (unaudited)	Pro Forma[1] (unaudited)	Pro Forma As Adjusted[2] (unaudited)
Combined Balance Sheet Data:			
Cash and cash equivalents	$ 82,917	$ 82,917	$249,098
Working capital (deficit)[3]	(60,210)	82,520	249,038
Total assets	84,879	84,879	250,723
Convertible promissory notes payable at fair value (including accrued interest)	93,559	–	–
Warrant liabilities	49,597	426	426
Long-term debt, including final payment fee and net of debt discount	24,512	24,512	24,512
Accumulated deficit	(90,301)	(90,301)	(90,301)
Total stockholders' equity (deficit)	(84,385)	58,345	224,526

(1) Gives effect to the (i) automatic conversion of the May 2019 Notes into an aggregate of 6,107,918 shares of our common stock immediately prior to the closing of this offering (based on the initial public offering price of $19.00 per share and assuming the conversion occurs on October 29, 2019), and (ii) the reclassification of the Takeda Warrant to stockholders' equity (deficit).

(2) Gives effect to (i) the pro forma adjustments set forth in footnote (1) above, and (ii) the issuance and sale of 9,563,157 shares of our common stock in this offering at the initial public offering price of $19.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

(3) We define working capital (deficit) as current assets less current liabilities. See our combined financial statements included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this prospectus, including our combined financial statements and related notes included elsewhere in this prospectus and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" before making an investment decision. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that event, the trading price of our common stock could decline and you could lose part or all of your investment.

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

We have a limited operating history, have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a late clinical-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We commenced operations in 2018, and to date, we have focused primarily on organizing and staffing our company, business planning, raising capital, in-licensing our initial product candidate, vonoprazan, meeting with regulatory authorities, and preparing for our planned Phase 3 clinical trials of vonoprazan. As a company, we have not yet demonstrated an ability to successfully complete any clinical trials, obtain regulatory approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biopharmaceutical products.

We have incurred significant operating losses since our inception. If vonoprazan is not successfully developed and approved in the United States, Europe and/or Canada, we may never generate any revenue. Our net losses were $1.3 million and $89.0 million for the year ended December 31, 2018 and the six months ended June 30, 2019, respectively. As of June 30, 2019, we had an accumulated deficit of $90.3 million. Substantially all of our losses have resulted from expenses incurred in connection with in-licensing and developing vonoprazan and from general and administrative costs associated with our operations. Vonoprazan and any future product candidates will require substantial additional development time and resources before we will be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially as we continue our development of, seek regulatory approval for, and potentially commercialize vonoprazan and seek to identify, assess, acquire, in-license, or develop additional product candidates.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing clinical trials and preclinical studies of vonoprazan and any future product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling any products. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. In addition, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical industry. Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, continue our product development efforts, diversify our product candidate pipeline or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

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

The development of biopharmaceutical product candidates is capital-intensive. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our planned Phase 3 clinical trials of vonoprazan and seek regulatory approval for vonoprazan. In addition, if vonoprazan receives approval and is commercialized, we will be 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 license agreement, dated May 7, 2019, between us and Takeda, or the Takeda License. Furthermore, if and to the extent we seek to acquire or in-license additional product candidates in the future, we may be required to make significant upfront payments, milestone payments, and/or licensing payments. If we obtain regulatory approval for vonoprazan or any future product candidate, we also expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Because the outcome of any clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of vonoprazan or any future product candidate. Furthermore, following the completion of this offering, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operations for at least the next 24 months. In particular, we expect that the net proceeds from this offering will allow us to complete our planned Phase 3 clinical trials of vonoprazan in the treatment of erosive esophagitis and *H. pylori* infection. We have based these estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop vonoprazan or any future product candidates.

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

- the initiation, type, number, scope, results, costs and timing of, our clinical trials of vonoprazan, and preclinical studies or clinical trials of other potential product candidates we may choose to pursue in the future, including feedback received from regulatory authorities;

- the costs and timing of manufacturing for vonoprazan or any future product candidates, including commercial scale manufacturing if any product candidate is approved;
- the costs, timing and outcome of regulatory review of vonoprazan or any future product candidates;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;
- the costs associated with hiring additional personnel and consultants as our business grows, including additional executive officers, clinical development personnel and commercial personnel;
- the timing and amount of the milestone or other payments we must make to Takeda and any future licensors;
- the costs and timing of establishing or securing sales and marketing capabilities if vonoprazan or any future product candidate is approved;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements; and
- the costs associated with any products or technologies that we may in-license or acquire.

Conducting clinical trials and preclinical studies is a time consuming, expensive, and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, vonoprazan and other potential product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, would initially be derived from sales of vonoprazan, which we do not expect to be commercially available in our licensed territories for many years, if at all.

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

Raising additional capital may cause dilution to our stockholders, including purchasers of common stock in this offering, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through equity offerings, our loan and security agreement, or the Loan Agreement, with Silicon Valley Bank, or SVB, as administrative and collateral agent, and lenders SVB and WestRiver Innovation Lending Fund VIII, L.P., or WestRiver, 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 includes, and any future debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

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.

Our management, as of December 31, 2018, and our independent registered public accounting firm, in their report on our combined financial statements as of and for the fiscal year ended December 31, 2018, have concluded that there is substantial doubt as to our ability to continue as a going concern.

Our audited combined financial statements for the fiscal year ended December 31, 2018 were prepared assuming that we will continue as a going concern. The going concern basis of presentation assumes that we will continue in operation for the foreseeable future and will be able to realize our assets and satisfy our 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 that may result from our inability to continue as a going concern. As of December 31, 2018, our management concluded that, based on our expected operating losses, negative cash flows and maturities of outstanding convertible promissory notes, there is substantial doubt about our ability to continue as a going concern for the twelve months after the date the combined financial statements were issued. Our ability to continue as a going concern is subject to our ability to obtain sufficient financing. If we cannot continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our combined financial statements, and it is likely that our stockholders may lose some or all of their investment in us. After this offering, we may not raise the funding we require such that substantial doubt about our ability to continue as a going concern continues. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all.

Risks Related to the Development and Regulatory Approval of Product Candidates

We currently depend entirely on the success of vonoprazan, which is our only product candidate. If we are unable to advance vonoprazan in clinical development, obtain regulatory approval and ultimately commercialize vonoprazan, or experience significant delays in doing so, our business will be materially harmed.

We currently only have one product candidate, vonoprazan, which we in-licensed from Takeda. Our business presently depends entirely on our ability to successfully develop, obtain regulatory approval for, and commercialize vonoprazan in a timely manner. This may make an investment in our company riskier than similar companies that have multiple product candidates in active development that may be able to better sustain failure of a lead product candidate. We plan to initiate two pivotal Phase 3 clinical trials in the fourth quarter of 2019 for vonoprazan: one for the treatment of erosive esophagitis, and a second for the treatment of *H. pylori* infection. Our assumptions about vonoprazan's development and commercial potential are based in large part on the development and commercial experience of vonoprazan in Japan and other Asian countries. However, our assumptions may prove to be wrong, and we may encounter a materially and adversely different development and commercial experience. The success of vonoprazan will depend on several factors, including the following:

- acceptance by the FDA or by comparable foreign regulatory authorities of our proposed design of the planned Phase 3 clinical trials of vonoprazan and any future clinical trials;
- successful enrollment in clinical trials and completion of clinical trials with favorable results;
- the willingness of the FDA, the European Medicines Agency, or EMA, and other comparable foreign regulatory authorities to accept the data from our planned Phase 3 clinical trials conducted in Europe and preclinical studies and clinical trials conducted outside of our licensed territories by Takeda and independent investigators as part of the basis for review and approval of vonoprazan;
- demonstrating safety and efficacy to the satisfaction of applicable regulatory authorities;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, EMA, and other comparable foreign regulatory authorities;
- receipt of marketing approvals from applicable regulatory authorities, including one or more new drug applications, or NDAs, from the FDA and maintaining such approvals;
- making arrangements with Takeda or any future third-party manufacturers for, or establishing, commercial manufacturing capabilities and receiving/importing commercial supplies approved by FDA and other regulators from Takeda or any future third-party manufacturer;
- establishing sales, marketing and distribution capabilities and commercializing vonoprazan, if approved, whether alone or in collaboration with others;
- establishment and maintenance of patent and trade secret protection or regulatory exclusivity for vonoprazan;
- maintaining an acceptable safety profile of vonoprazan following approval; and
- maintaining and growing an organization of people who can develop and, if approved, commercialize, market, and sell vonoprazan to physicians, patients, healthcare payors, and others in the medical community.

The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of vonoprazan, which may never occur. We have not yet succeeded and may not succeed in demonstrating efficacy and safety for vonoprazan in clinical trials or in obtaining marketing approval thereafter. It may be several years, if at all, before we have demonstrated the safety and efficacy of a treatment sufficient to warrant approval for commercialization. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize vonoprazan, we may not be able to generate sufficient revenue to continue our business.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and the results of prior clinical trials and other investigator-initiated clinical trials of vonoprazan are not necessarily predictive of our future results. Vonoprazan may not have favorable results in our clinical trials, or receive regulatory approval on a timely basis, if at all.

Clinical drug development is expensive and can take many years to complete, and its outcome is inherently uncertain. Our clinical trials may not be conducted as planned or completed on schedule, if at all, and failure can occur at any time during the preclinical study or clinical trial process. Despite promising preclinical or clinical results, any product candidate can unexpectedly fail at any stage of preclinical or clinical development. The historical failure rate for product candidates in our industry is high.

The results from clinical trials or preclinical studies of a product candidate may not predict the results of later clinical trials of the product candidate, and interim results of a clinical trial are not necessarily indicative of final results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials. In particular, while vonoprazan has been studied in an extensive clinical program by Takeda, including 17 Phase 3 clinical trials, we do not know how vonoprazan will perform in future clinical trials, including as a result of differences between the clinical trials conducted to date by Takeda or other third parties and our planned Phase 3 clinical trial designs. These differences include, among other things: including higher doses of antibiotics and longer duration of treatment and inclusion of a dual therapy arm in our planned Phase 3 clinical trial for the treatment of *H. pylori* infection, and conducting a single Phase 3 clinical trial for both the healing and maintenance of erosive esophagitis, rather than two separate trials. Further, the large majority of the clinical development of vonoprazan was conducted in Asian subjects, who naturally have differences in height, weight, drug metabolism, and potentially, acid-secretory capacity from Western populations. Although there are data across two Phase 1 clinical trials in healthy volunteers showing that the vonoprazan pharmacokinetic and pharmacodynamic profile is similar in Japanese and non-Japanese subjects, our clinical trials of vonoprazan in a broader population comprised of patients in the United States and Europe may not yield the same results as prior clinical trials. Additionally, Western patients may be more likely to deviate from clinical trial protocols or drop out of clinical trials than Japanese patients, which may negatively impact the results of our clinical trials. Further, in our planned Phase 3 clinical trial for the treatment of *H. pylori* infection, the vonoprazan dual therapy arm will not be double-blinded because patients in this arm will be administered amoxicillin three times daily, versus twice daily for the triple therapy regimens. Both triple therapy regimens will be double-blinded. The inability to double-blind the dual therapy arm may impact the results of this trial and how regulatory agencies or healthcare payors interpret such results. For example, the EMA has noted that it expects additional analyses of treatment compliance and drop-out rates in the dual therapy arm because it will not be double-blinded.

A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after the product candidate achieved promising results in earlier clinical trials. The results of our planned trials may not be comparable to those achieved previously, whether as a result of differences in trial design, patient population or otherwise.

Further, the FDA, the EMA, or other comparable foreign regulatory authorities may not view the data from clinical trials conducted by Takeda and other third parties discussed above, together with our single planned Phase 3 clinical trial in each of erosive esophagitis and *H. pylori* infection, as sufficient to support the regulatory approval of vonoprazan for the treatment of erosive esophagitis or *H. pylori* infection. The FDA, EMA, or other comparable foreign regulatory authorities may also disagree with the adequacy of our trial designs, including as a result of the differences between our designs and those of Takeda's Phase 3 clinical trials discussed above. As a result, we could be required to conduct additional clinical trials prior to seeking and obtaining regulatory approval and our planned development timeline could materially change. In addition, in July 2019, we received scientific advice from the EMA on our planned Phase 3 clinical trial of vonoprazan in the healing and maintenance of healing of erosive esophagitis. For the healing phase of the study, the EMA recommended that we include an endoscopy to assess healing at Week 4 in addition to the planned endoscopies at Week 2 and Week 8 because the summary of product characteristics for lansoprazole suggests four weeks of treatment to assess healing in erosive esophagitis. We have decided not to incorporate this change into the study design given the additional burden on study subjects to return for a third endoscopy in an eight-week period. This decision may impact the future summary of product characteristics for vonoprazan or may cause the EMA to require us to conduct additional clinical trials for vonoprazan to support marketing approval.

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

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

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

Before obtaining marketing approval from regulatory authorities for the sale of vonoprazan or any future product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of vonoprazan or any future product candidates in humans. In August 2019, we submitted three separate INDs to the FDA for vonoprazan: one for erosive esophagitis; a second for dual therapy treatment of *H. pylori* infection; and a third for triple therapy treatment of *H. pylori* infection. These three INDs were accepted by the FDA in September 2019. We plan to initiate two pivotal Phase 3 clinical trials in the fourth quarter of 2019 for vonoprazan: one for the treatment of erosive esophagitis and a second for the treatment of *H. pylori* infection.

We will have to submit the results of preclinical studies to the FDA along with other information, including information about product candidate chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND for any future product candidates that we advance to clinical development, and we may also be required to submit regulatory filings to foreign regulatory authorities to the extent we initiate clinical trials outside of the United States.

We do not know whether our planned trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- the FDA, EMA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials and reaching consensus among the FDA and EMA over the design of the same clinical trial;
- any failure or delay in obtaining regulatory authorizations to commence a trial;
- any failure or delay in reaching an agreement with contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- institutional review boards, or IRBs, refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes to clinical trial protocols;
- clinical sites deviating from trial protocols or dropping out of a trial;
- manufacturing or obtaining sufficient quantities of vonoprazan and any future product candidates and obtaining sufficient quantities of lansoprazole, which will be used in both of our planned Phase 3 clinical trials, and/or antibiotics for use in clinical trials, including amoxicillin and clarithromycin, which will be used in our planned Phase 3 clinical trial of vonoprazan for the treatment of *H. pylori* infection;
- subjects failing to enroll or remain in our trials at the rate we expect, or failing to return for post- treatment follow-up;
- subjects choosing an alternative treatment for the indication for which we are developing vonoprazan and any future product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected drug-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies;
- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;
- a facility manufacturing vonoprazan or any future product candidates or any of their components being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of current good manufacturing, or cGMP, regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices, or GCP, or other regulatory requirements;
- third-party contractors not performing data collection or analysis in a timely or accurate manner; or

- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

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

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

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

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

In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. We may make formulation or manufacturing changes to vonoprazan or any future product candidates, in which case we may need to conduct additional preclinical studies to bridge our modified product candidates to earlier versions. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize vonoprazan or any future product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of vonoprazan and any future product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition, and prospects significantly.

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

We may not be able to initiate or continue clinical trials for vonoprazan or any future product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Subject enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, the risk that enrolled patients will not complete a clinical trial, our ability to recruit clinical trial investigators with the appropriate competencies and experience, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating as well as any drugs under development. We will be required to identify and enroll a sufficient number of patients for each of our clinical trials. Potential patients for any planned clinical trials may not be adequately diagnosed or identified with the diseases which we are targeting or may not meet the entry criteria for such trials. For example, a key secondary analysis in our planned Phase 3 clinical trial for the treatment of *H. pylori* infection is the eradication rate in clarithromycin-resistant patients. However, because the process of assessing antibiotic resistance to *H. pylori* takes several weeks, we believe it is not practical to use resistance as an enrollment criteria in our clinical trial. Therefore, the percentage of clarithromycin-resistant patients enrolled in this clinical trial is unpredictable and may affect the results of the trial. We also may encounter difficulties in identifying and enrolling patients with a stage of disease appropriate for our planned clinical trials and monitoring such patients adequately during and after treatment. For example, in our Phase 3 clinical trial of vonoprazan in erosive esophagitis, we intend for 30% of the patients to have Los Angeles Class C or D erosive esophagitis, which are the most severe forms of erosive esophagitis and are estimated to only represent approximately 10 to 20% of erosive esophagitis patients. We may not be able to initiate or continue clinical trials if we are unable to locate a sufficient number of eligible patients to participate in the clinical trials required by the FDA or comparable foreign regulatory authorities. In addition, the process of finding and diagnosing patients may prove costly as these patients are required to undergo an endoscopy before being diagnosed as having Los Angeles Class C or D erosive esophagitis.

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

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

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

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

Moreover, if vonoprazan or any other future product candidates are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for the product candidate, if approved. We may also be required to modify our study plans based on findings in our clinical trials.

As of December 2018, 6,683 subjects have been exposed to vonoprazan in completed and ongoing Phase 1 to 3 clinical trials. The doses studied have ranged from 1 to 120 mg with durations up to one year. The most commonly reported AEs in the clinical development program for vonoprazan, as reflected in the Japanese prescribing information published by Japan's Pharmaceutical and Medical Devices Agency, or PMDA, were diarrhea, constipation, nausea, elevated liver enzymes, rash, and eosinophilia. All such events had an incidence rate of less than 5.0% other than diarrhea in the treatment of *H. pylori* which had an incidence rate of 10.6% in combination with antibiotics. No dose-related increase in TEAEs or SAEs was observed. The safety profile of vonoprazan and incidence of TEAEs, drug-related TEAEs, and TEAEs leading to drug discontinuation were similar between vonoprazan and lansoprazole across studies.

Certain earlier generation P-CABs previously under development by other companies may have been discontinued in part due to their hepatic safety profile. These hepatic safety concerns may be compound-specific and not generalizable to the P-CAB class. Vonoprazan has had a similar hepatic safety profile to lansoprazole across all clinical studies conducted by Takeda, in which 1.0% of subjects treated with vonoprazan 10 mg or 20 mg and 0.8% of subjects treated with lansoprazole 15 mg or 30 mg had ALT or AST elevations greater than three times the upper limit of normal or bilirubin elevations greater than two times the upper limit of normal.

The most recent post-marketing safety report from December 2018 includes an estimated 23 million patients who have received vonoprazan in Japan since launch. Based on the post-marketing experience, the clinically significant adverse reactions section of the Japanese prescribing information for vonoprazan was updated to include skin reactions such as toxic epidermal necrolysis, Steven-Johnson syndrome, and erythema multiforme. The incidence of these skin reactions was considered extremely rare (less than 1 in 100,000 patients) and a causal relationship to vonoprazan could not be ruled out.

Serious hepatic adverse events have also been observed among patients exposed to vonoprazan in Japan in the post-marketing setting. These cases were typically confounded by comorbidities or other concomitant medications and are believed to be idiosyncratic reactions. The incidence of these events was considered extremely rare (less than 1 in 100,000 patients). The post-marketing safety data, including the December 2018 post-marketing safety report and the reported hepatic safety events, have been submitted to the PMDA. To date, there have been no changes to the Japan prescribing information related to hepatic safety. We may also observe hepatic-related events in our clinical trials.

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

In addition, if vonoprazan or any future product candidate receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw, suspend or limit approvals of such product, or seek an injunction against its manufacturer;
- we may be required to recall a product or change the way such product is administered to patients;
- regulatory authorities may require additional warnings on the label, such as a “black box” warning or a contraindication;
- we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way a product is distributed or administered, conduct additional clinical trials or change the labeling of a product or be required to conduct additional post-marketing studies or surveillance;
- we could be sued and held liable for harm caused to patients;
- sales of the product may decrease significantly or the product could become less competitive; and
- our reputation may suffer.

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

As a company, we have never conducted a clinical trial or submitted an NDA or comparable foreign regulatory filing, and may be unable to do so for vonoprazan or any future product candidates.

We are early in our development efforts for vonoprazan, and we will need to successfully complete pivotal clinical trials in order to obtain FDA, EMA or comparable foreign regulatory approval to market vonoprazan or any future product candidates. Carrying out late-stage clinical trials and the submission of a successful new drug application, or NDA, is a complicated process. As an organization, we plan to commence pivotal Phase 3 clinical trials of vonoprazan in erosive esophagitis and *H. pylori* infection in the fourth quarter of 2019. We have not yet conducted any clinical trials for vonoprazan or any other product candidates and have limited experience as a company in preparing, submitting and prosecuting regulatory filings. As a company, we have not previously submitted an NDA, whether for one or multiple indications, or other comparable foreign regulatory submission for any product candidate. In addition, we have had limited interactions with the FDA and cannot be certain how many clinical trials of vonoprazan or any other product candidates will be required or how such trials should be designed. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to regulatory submission and approval of vonoprazan or any future product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in submitting NDAs for and commercializing vonoprazan or any future product candidates.

Vonoprazan and any future product candidates are subject to extensive regulation and compliance obligations, which is costly and time consuming, and such regulation may cause unanticipated delays or prevent the receipt of the required approvals to commercialize vonoprazan and any future product candidates.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of vonoprazan and any future product candidates are subject to extensive regulation by the FDA in the United States, the EMA in the European Union and by comparable foreign regulatory authorities in other foreign markets. In the United States, we are not permitted to market vonoprazan and any future product candidates until we receive regulatory approval from the FDA and in Europe, we are not permitted to market vonoprazan and any future product candidates until we receive regulatory approval from the EMA. 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 EMA 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 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 vonoprazan and any future product candidates are promising, such data may not be sufficient to support approval by the FDA and comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities, as the case may be, may also require us to conduct additional preclinical studies or clinical trials for vonoprazan and any future product candidates either prior to or post-approval, or may object to elements of our clinical development program.

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

- such authorities may disagree with the design or implementation of our clinical trials;

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

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

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

Even if we eventually complete clinical trials and receive approval of an NDA or foreign marketing application for vonoprazan and any future product candidates, the FDA, EMA or other comparable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials, including confirmatory Phase 3 clinical trials, Phase 4 clinical trials, and/or the implementation of a REMS, which may be required to ensure safe use of the drug after approval. The FDA, EMA 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, EMA or other comparable foreign regulatory authority may not approve the labeling that we believe is necessary or desirable for the successful commercialization of a product. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

Designation of vonoprazan as a QIDP, and the potential to receive priority review or fast track designations, may not actually lead to a faster development or regulatory review, and would not assure FDA approval of vonoprazan or any future product candidates which may receive such designations.

Vonoprazan has been designated as a QIDP by the FDA for the treatment of *H. pylori* infection in combination with both amoxicillin and clarithromycin, and with amoxicillin alone, respectively, and we may seek QIDP designation for future product candidates. A QIDP is 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 to be established and maintained by the FDA under the Generating Antibiotic Incentives Now, or GAIN Act. 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 exclusivity period awarded for a new chemical entity. This extension is in addition to any pediatric exclusivity extension that may be awarded. Receipt of QIDP status also does not assure ultimate approval by the FDA or related GAIN Act exclusivity benefits.

While QIDP designation makes vonoprazan potentially eligible for priority review and fast track designation, the FDA has broad discretion, so even if we believe vonoprazan or any future product candidate is eligible for fast track designation or priority review status, the FDA could decide not to grant it. The fast track program is intended to expedite or facilitate the process for reviewing new drug candidates that meet certain criteria. Specifically, new drugs are eligible for fast track designation if they are intended, alone or in combination with one or more drugs, to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the drug candidate and the specific indication for which it is being studied. With a fast track drug candidate, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA. Priority review means the FDA’s goal is to take action on an application within 6 months (compared to 10 months under standard review). The FDA automatically grants priority review to the first application or efficacy supplement submitted for a specific drug and indication that has received the QIDP designation.

Obtaining a QIDP designation, priority review, or fast track designation does not change the standards for product approval, but may expedite the development or approval process. Even though the FDA has granted QIDP designation for vonoprazan, and even if vonoprazan receives priority review or fast track designations, it may not actually result in faster clinical development or regulatory review or approval. Furthermore, QIDP designation, priority review, and fast track designation do not increase the likelihood that vonoprazan will receive marketing approval in the United States.

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

Because we have limited financial and managerial resources, we focus on specific indications and formulations for vonoprazan. As a result, we may fail to generate additional clinical development opportunities for vonoprazan for a number of reasons, including, vonoprazan may in certain indications, on further study, be shown to have harmful side effects, limited to no efficacy, or other characteristics that suggest it is unlikely to receive marketing approval and achieve market acceptance in such additional indications. For example, we believe the rapid onset of action of vonoprazan may enable on-demand, or as needed, use for the management of non-erosive reflux disease, or NERD. However, two Phase 3 clinical trials of vonoprazan in Japanese patients with endoscopically confirmed NERD conducted by Takeda did not demonstrate a statistically significant difference in symptom scores between vonoprazan and placebo. We believe that this result may be due to the selection of patients with mild to moderate symptoms rather than more frequent and severe symptoms. In addition, Takeda conducted a Phase 2 clinical trial in Europe in 256 patients with NERD who were partial responders to high dose PPIs. Patients were randomized to receive vonoprazan 20 mg, vonoprazan 40 mg, or esomeprazole 40 mg for four weeks. Neither vonoprazan dose demonstrated a benefit versus esomeprazole on the primary endpoint of the percentage of heartburn free days over the treatment period. We believe this result may be due to patient selection. Specifically, the trial may not have adequately selected for patients with NERD and may have included patients with functional GI disorders that are unrelated to acid, such as functional dyspepsia or functional heartburn. We may be incorrect in our beliefs regarding the results of such trials and any future clinical trials we conduct in NERD patients may not succeed for similar or other reasons, including as a result of our design and enrollment criteria.

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

Additionally, we may pursue additional in-licenses or acquisitions of development-stage assets or programs, which entails additional risk to us. Identifying, selecting and acquiring promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit.

We intend to enroll patients in Europe in both of our planned Phase 3 clinical trials. Additionally, we may conduct future clinical trials outside of the United States. However, the FDA and other comparable foreign regulatory authorities may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

We plan to enroll patients in Europe in both of our planned Phase 3 clinical trials, and we may conduct one or more of our future clinical trials outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. For example, the FDA requires the clinical trial to have been conducted in accordance with GCPs, and the FDA must be able to validate the data from the clinical trial through an onsite inspection if it deems such inspection necessary. In addition, when clinical trials are conducted only at sites outside of the United States, the FDA generally does not provide advance comment on the clinical protocols for the trials, and therefore there is an additional potential risk that the FDA could determine that the study design or protocol for a non-U.S. clinical trial was inadequate, which would likely require us to conduct additional clinical trials. The FDA may not accept data from clinical trials conducted outside of the United States. If the FDA does not accept data from our clinical trials of vonoprazan and any future product candidates, it would likely result in the need for additional clinical trials, which would be costly and time consuming and delay or permanently halt our development of vonoprazan and any future product candidates.

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

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

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

From time to time, we or others, such as Takeda, may publicly disclose preliminary or top-line data from clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line 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 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 data should be viewed with caution until the final data are available. From time to time, we or others may also disclose interim data from clinical trials. Interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

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

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 regulatory 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 vonoprazan, which in turn would have a material adverse effect on our business, operating results and prospects.

We intend to 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 regulatory approval for or commercialize vonoprazan and any future product candidates.

We will be dependent on third parties to conduct our preclinical and clinical trials, including our planned Phase 3 clinical trials of vonoprazan. Specifically, we intend to use and rely on, medical institutions, clinical investigators, CROs and consultants to conduct our clinical trials in accordance with our clinical protocols and regulatory requirements. These CROs, investigators and other third parties will play a significant role in the conduct and timing of these trials and subsequent collection and analysis of data. While we have agreements governing the activities of our third-party contractors, we have limited influence over their actual performance. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for vonoprazan and any future product candidates that reach clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs or trial sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP 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 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 we submit by the FDA. Any such delay or rejection could prevent us from commercializing vonoprazan and any future product candidates.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties or do so on commercially reasonable terms. Switching or adding additional CROs, investigators and other third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, investigators and other third parties, we may encounter challenges or delays in the future and these delays or challenges may have a material adverse impact on our business, financial condition and prospects.

We currently rely on Takeda for the manufacture of vonoprazan for clinical development and expect to continue to do so for the foreseeable future. This reliance on a third party increases the risk that we will not have sufficient quantities of vonoprazan or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not own or operate manufacturing facilities and have no plans to build our own clinical or commercial scale manufacturing capabilities. Pursuant to the Takeda License, we entered in a clinical manufacturing and supply agreement with Takeda for the supply of vonoprazan for our clinical trials. In addition, we have the option to negotiate in good faith to enter into a commercial supply agreement with Takeda for the commercial supply of vonoprazan, and we are exploring additional options for commercial supply of vonoprazan from other third party contract manufacturers. As a result, we currently rely, and expect to continue to rely, on Takeda for the manufacture of vonoprazan and related raw materials for clinical development, as well as for commercial manufacture if vonoprazan receives marketing approval. However, we may not be able to enter into a commercial supply agreement with Takeda or other third parties on acceptable terms, or at all. The facilities used by Takeda to manufacture vonoprazan must be approved by the FDA for the manufacture of vonoprazan pursuant to inspections that may be conducted after we submit marketing authorizations to the FDA and comparable foreign regulatory authorities. We do not control the manufacturing process of, and are completely dependent on, Takeda for compliance with cGMP requirements for manufacture of drug products. If Takeda, or any other third party manufacturer we contract with in the future, cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, including requirements related to the manufacturing of high potency compounds, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over Takeda’s ability to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve of facilities of the third-party manufacturer for the manufacture of vonoprazan or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market vonoprazan, if approved. Our failure, or Takeda's failure, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. Furthermore, Takeda may choose to prioritize the manufacture of vonoprazan for its markets over the manufacture of vonoprazan for our licensed markets.

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

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

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

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

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

Any performance failure on the part of Takeda or any future manufacturers could delay clinical development or marketing approval, and any related remedial measures may be costly or time consuming to implement. We do not currently have arrangements in place for redundant supply or a second source for all required raw materials used in the manufacture of vonoprazan and any future product candidates. If Takeda cannot perform as agreed, we may be required to replace Takeda and we may be unable to replace them on a timely basis or at all.

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

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

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

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

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

In addition, any potential future collaborations may be terminable by our strategic partners, and we may not be able to adequately protect our rights under these agreements. Furthermore, strategic partners may negotiate for certain rights to control decisions regarding the development and commercialization of vonoprazan and any future product candidates, if approved, and may not conduct those activities in the same manner as we do. Any termination of collaborations we enter into in the future, or any delay in entering into collaborations related to vonoprazan or any future product candidates, could delay the development and commercialization of vonoprazan or 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 Commercialization of Vonoprazan and Any Future Product Candidates

Even if we receive regulatory approval for vonoprazan and any future product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, vonoprazan and any future product candidates, if approved, could be subject to labeling and other restrictions on marketing or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with vonoprazan and any future product candidates, if approved.

Following potential approval of vonoprazan or any future product candidates, the FDA, EMA or other comparable regulatory authority may impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly and time consuming post-approval studies, post-market surveillance or clinical trials to monitor the safety and efficacy of the product. The FDA may also require a REMS as a condition of approval of vonoprazan or 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, if the FDA, EMA or a comparable foreign regulatory authority approves vonoprazan or any future product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCP requirements for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our products, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

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

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

In addition, if vonoprazan or any future product candidate is approved, our product labeling, advertising and promotion will be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. If we receive marketing approval for vonoprazan or any future product candidate, 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 FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. 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.

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

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or internationally. The policies of the FDA and of other regulatory authorities may change and additional governmental regulations may be enacted that could prevent, limit or delay regulatory approval of vonoprazan or any future product candidates. For example, certain policies of the current U.S. administration may impact our business and industry. Namely, the current U.S. administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions, including the Executive Orders, will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations. Non-compliance by us or any future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population can also result in significant financial penalties.

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

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

- demonstration of clinical efficacy and safety compared to other more-established products;

- the indications for which vonoprazan or any future product candidates are approved;
- the limitation of our targeted patient population and other limitations or warnings contained in any FDA-approved labeling;
- acceptance of a new drug for the relevant indication by healthcare providers and their patients;
- the pricing and cost-effectiveness of our products, as well as the cost of treatment with our products in relation to alternative treatments and therapies;
- our ability to obtain and maintain sufficient third-party coverage and adequate reimbursement from government healthcare programs, including Medicare and Medicaid, private health insurers and other third-party payors;
- the willingness of patients to pay all, or a portion of, out-of-pocket costs associated with our products in the absence of sufficient third-party coverage or adequate reimbursement;
- any restrictions on the use of our products, and the prevalence and severity of any adverse effects;
- potential product liability claims;
- the timing of market introduction of our products as well as competitive drugs;
- the effectiveness of our or any of our potential future collaborators' sales and marketing strategies; and
- unfavorable publicity relating to the product.

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

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

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

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, as vonoprazan and any future product candidates would be, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, 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 vonoprazan or any future product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

The successful commercialization of vonoprazan or any future product candidates, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our products could limit our ability to market those products and decrease our ability to generate revenue.

The availability of coverage and the adequacy of reimbursement by governmental healthcare programs, such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as vonoprazan or any future product candidate, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our products by third-party payors 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 payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the European Union or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors 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 payor may consider our products as substitutable and only offer to reimburse patients for the less expensive product. Even if we are successful in demonstrating improved efficacy or improved convenience of administration with our products, pricing of existing drugs may limit the amount we will be able to charge for our products. These payors 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 payor coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, 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 payors 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 payors 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 payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

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

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with the sale of any of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

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

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

We expect that vonoprazan, if approved for the treatment of erosive esophagitis and treatment of *H. pylori* infection, will primarily compete with generic PPIs marketed by multiple pharmaceutical companies in both the prescription and OTC markets. Additionally, RedHill Biopharma Ltd. is developing Talicia, a co-formulated capsule comprising generic omeprazole, amoxicillin, and rifabutin for the treatment of *H. pylori* infection, and filed an NDA in the United States in May 2019. Ironwood Pharmaceuticals, Inc. is developing IW-3718, a bile acid sequestrant, currently in Phase 3 clinical trials as an adjunct to PPIs for the treatment of patients with persistent GERD.

We are also aware of other P-CABs in territories outside of the United States that, if developed and approved in our territories, may compete with vonoprazan. Revaprazan is marketed by Yuhan Corporation in South Korea. Tegoprazan is marketed by CJ Healthcare Corp. in South Korea and is currently in Phase 3 development in Japan by RaQualia Pharma, Inc. Daewoong Pharmaceutical Co., Ltd.'s DWP14012 has been studied in Phase 2 clinical trials in South Korea, and Cinclus Pharma AG's X842 has completed a Phase 1 clinical trial in Europe.

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

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. If we successfully obtain approval for vonoprazan or any future product candidate, we will face competition 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 timing and 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 vonoprazan 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 vonoprazan or any future products are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer.

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

We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate product revenue.

We have no internal sales, marketing or distribution capabilities, nor have we commercialized a product. If vonoprazan or any future product candidates ultimately receive regulatory approval, we must build a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and time consuming, or collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. We plan to independently commercialize vonoprazan in the United States by building a leading specialty gastroenterology commercial infrastructure to support the adoption of vonoprazan and we plan to seek one or more partners with existing commercial infrastructure and expertise in Europe and Canada. We have no prior experience as a company in the marketing, sale and distribution of biopharmaceutical products and there are significant risks involved in building and managing a marketing and sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing vonoprazan or any future product candidates, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

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

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

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

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

- the timing and cost of, and level of investment in, research, development, regulatory approval and commercialization activities relating to vonoprazan or any future product candidates, which may change from time to time;
- coverage and reimbursement policies with respect to vonoprazan or any future product candidates, if approved, and potential future drugs that compete with such products, if approved;
- the cost of manufacturing vonoprazan or any future product candidates, which may vary depending on the quantity of production and the terms of our agreements with Takeda and any future third-party manufacturers;
- the timing and amount of the milestone or other payments we will be required to pay to Takeda pursuant to the Takeda License;
- expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies;
- the level of demand for any approved products, which may vary significantly;

- future accounting pronouncements or changes in our accounting policies; and
- the timing and success or failure of preclinical studies or clinical trials for vonoprazan or any future product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners.

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

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

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

In May 2019, we entered into the Loan Agreement with SVB and WestRiver. We borrowed $25.0 million, or Term Loan A, at the inception of the Loan Agreement and have the right to borrow an additional $25.0 million, or Term Loan B, and which we collectively refer to as the Term Loans. Term Loan B is available through March 31, 2020, provided that (i) we have received at least $150.0 million of net cash proceeds in connection with the issuance and sale, subsequent to April 1, 2019, of our equity securities and subordinated debt, (ii) we have initiated Phase 3 clinical trials for vonoprazan, and (iii) no event of default has occurred. All obligations under the Term Loans are secured by a first priority lien on substantially all of our assets, excluding intellectual property and certain other assets. We have agreed not to encumber our intellectual property assets without SVB's prior written consent unless a security interest in the underlying intellectual property is necessary to have a security interest in the accounts and proceeds that are part of the assets securing the Term Loans, in which case our intellectual property will automatically be included within the assets securing the Term Loans. As a result, if we default on any of our obligations under the Loan Agreement, SVB could foreclose on its security interest and liquidate some or all of the collateral, which would harm our business, financial condition and results of operations and could require us to reduce or cease operations.

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

The Loan Agreement contains customary affirmative and negative covenants that limit our ability to engage in certain transactions that may be in our long-term best interest. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, 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 Loan 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.

We are dependent on the services of our current management and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our current senior management team, our Chairman and our development personnel. The loss of services of any of these individuals or personnel could delay or prevent the successful development of our product pipeline, initiation or completion of our planned clinical trials or the commercialization of vonoprazan or any other future product candidates. Although we have executed employment agreements or offer letters with each member of our senior management team, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected. We do not currently maintain “key person” life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

In addition, we expect that Terrie Curran, a member of our board of directors, will become our Chief Executive Officer effective upon the closing of the acquisition of her current employer, Celgene Corporation, by Bristol-Myers Squibb Company. In the event Ms. Curran succeeds Mr. Socks as Chief Executive Officer, Mr. Socks will serve as interim Chief Financial Officer and continue to serve on our board of directors. If Ms. Curran decides not to join us as Chief Executive Officer, our board of directors will evaluate additional candidates for the position, during which time David Socks will continue to serve as our Chief Executive Officer. Although this is a planned management transition, we may experience business disruptions and our ability to achieve our development objections could be adversely affected.

We will continue to expand and need to effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be successful in maintaining our unique company culture and continuing to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among pharmaceutical, biotechnology and other businesses. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, integrate, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

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

We have substantially increased our organization from four employees in February 2018 to 16 full-time employees as of September 30, 2019. As we continue development and pursue the potential commercialization of vonoprazan and any future product candidates, as well as function as a public company, we will continue to expand our financial, development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to develop and commercialize vonoprazan and any future product candidates and to compete effectively will depend, in part, on our ability to manage our recent substantial growth and any future growth effectively.

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.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers expose us to broadly applicable foreign, federal and state fraud and abuse and other healthcare and privacy 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. 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 U.S. civil and criminal federal false claims and civil monetary penalties laws, including the civil False Claims Act, which can be enforced through civil whistleblower or qui tam actions, 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;
- 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;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, also impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information of covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;
- 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 the Centers for Medicare & Medicaid Services, or CMS, information related to certain payments and other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) 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 payors, 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; 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; state and local laws that require the registration of pharmaceutical sales representatives; state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA; state and foreign governments that have enacted or proposed requirements regarding the collection, distribution, use, security, and storage of personally identifiable information and other data relating to individuals (including the EU General Data Protection Regulation 2016/679, or GDPR, and the California Consumer Privacy Act, or CCPA), and federal and state consumer protection laws are being applied to enforce regulations related to the online collection, use, and dissemination of data, thus complicating compliance efforts.

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.

In addition, California recently enacted the CCPA, which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling certain personal data of consumers or households. The CCPA will require covered companies to provide new disclosure to consumers about such companies' data collection, use and sharing practices, provide such consumers new ways to opt-out of certain sales or transfers of personal information, and provide consumers with additional causes of action. The CCPA goes into effect on January 1, 2020, and the California Attorney General may bring enforcement actions for violations beginning July 1, 2020. The CCPA was amended on September 23, 2018, and it remains unclear what, if any, further modifications will be made to this legislation or how it will be interpreted. As currently written, the CCPA may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

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

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

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

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively the Affordable Care Act, was enacted in the United States. Among the provisions of the Affordable Care Act of importance to our potential product candidates, the Affordable Care Act includes:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, which is apportioned among these entities according to their market share in certain government healthcare programs;
- a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price 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 Public Health Service pharmaceutical pricing program;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial and political challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. For example, the Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the Affordable Care Act are invalid as well. While the Texas District Court Judge, as well as the Trump Administration and CMS, have stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act and our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018, will remain in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. 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.

At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid and to eliminate cost sharing for generic drugs for low-income patients. While proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. Furthermore, there has been increased interest by third party payors 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.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

We expect that these new laws and other 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 payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize vonoprazan and any future product candidates, if approved.

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

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

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

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

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

We face an inherent risk of product liability as a result of the clinical trials of vonoprazan and any future product candidates and will face an even greater risk if we commercialize vonoprazan and any future product candidates. For example, we may be sued if vonoprazan and any future product candidates allegedly cause injury or are found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product candidate, negligence, strict liability and a breach of warranties. Claims may be brought against us by clinical trial participants, patients or others using, administering or selling products that may be approved in the future. Claims could also be asserted under state consumer protection acts.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit 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 vonoprazan and any future product candidates; and
- a decline in our stock price.

We currently do not have product liability insurance coverage, but will need to obtain such coverage as we begin our clinical trials or if we commence commercialization of vonoprazan and any future product candidates. Insurance coverage is increasingly expensive. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of vonoprazan and any future product candidates. Although we plan to maintain such 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 will also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may 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.

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

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

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

The United States federal and various state and foreign governments have adopted or proposed requirements regarding the collection, distribution, use, security, and storage of personally identifiable information and other data relating to individuals, and federal and state consumer protection laws are being applied to enforce regulations related to the online collection, use, and dissemination of data. Despite the implementation of security measures, our internal computer systems and those of our current and any future CROs and other contractors, consultants and collaborators are vulnerable to damage from computer viruses, cybersecurity threats, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations or result in the unauthorized disclosure of or access to personally identifiable information or individually identifiable health information (violating certain privacy laws such as GDPR), it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions. Some of the federal, state and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular personally identifiable 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 security breach could impact our reputation, cause us to incur significant costs, including legal expenses, harm customer confidence, hurt our expansion into new markets, cause us to incur remediation costs, or cause us to lose existing customers. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We also rely on third parties to manufacture vonoprazan and any future product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, the further development and commercialization of vonoprazan and any future product candidates could be delayed, and we could be subject to significant fines, penalties or liabilities for any noncompliance to certain privacy and security laws.

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 on third-party manufacturers to produce vonoprazan and any future product candidates. Our ability to obtain clinical supplies of vonoprazan and any future product candidates could be disrupted if the operations of these suppliers were affected by a man-made 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 employees and independent contractors, including principal investigators, CROs, consultants and vendors, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

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

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

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department’s Office of Foreign Assets Controls, and anti-corruption and anti-money laundering laws and regulations, including the U.S. Foreign Corrupt

Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, clinical research organizations, contractors and other collaborators and partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, clinical research organizations, contractors and other collaborators and partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

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

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

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

The patent prosecution process is also expensive and time consuming, and we and our licensor may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we and our licensor will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances such as under the Takeda License, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, directed to technology that we license from third parties. We may also require the cooperation of our licensors in order to enforce the licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. We cannot be certain that patent prosecution and maintenance activities by our licensors have been or will be conducted in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. If they fail to do so, this could cause us to lose rights in any applicable intellectual property that we in-license, and as a result our ability to develop and commercialize products or product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products.

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

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

We are a party to the Takeda License under which we are granted rights to intellectual property that are important to our business and we may enter into additional license agreements in the future with other third parties. The Takeda License imposes, and we expect that any future license agreements where we in-license intellectual property, will impose on us, various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to bankruptcy-related proceedings, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license. Additionally, if a future license agreement includes a sublicense from a third party who is not the original licensor of the intellectual property at issue, then we must rely on our direct licensor to comply with its obligations under the primary license agreements under which such licensor obtained rights in the applicable intellectual property, where we may have no relationship with the original licensor of such rights. If such a licensor fails to comply with its obligations under its upstream license agreement, the original third-party licensor may have the right to terminate the original license, which may terminate our sublicense. If this were to occur, we would no longer have rights to the applicable intellectual property unless we are able to secure our own direct license with the owner of the relevant rights, which we may not be able to do on reasonable terms, or at all, which may impact our ability to continue to develop and commercialize vonoprazan and any future product candidates incorporating the relevant intellectual property.

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

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

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

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

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

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

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

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

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

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

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 vonoprazan 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 development 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 vonoprazan 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 vonoprazan 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 vonoprazan and any future product candidates.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that vonoprazan 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 vonoprazan 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 vonoprazan and any future product candidates may infringe. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Any claims of patent infringement asserted by third parties would be time consuming and could:

- result in costly litigation that may cause negative publicity;

- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing 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 prospectus, others may hold proprietary rights that could prevent vonoprazan and any future product candidates from being marketed.

Any patent-related legal action against us claiming damages and seeking to enjoin activities relating to vonoprazan and any future product candidates or processes could subject us to potential liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or develop vonoprazan 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 vonoprazan and any future product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing vonoprazan 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 vonoprazan 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 vonoprazan 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 vonoprazan and any future product candidates, the defendant could counterclaim that our patent or the patent of our current or future licensor is invalid and/or unenforceable in whole or in part. In patent litigation, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description, non-enablement, or obviousness-type double patenting. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution.

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

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

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

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

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

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

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

Recent 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 vonoprazan 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.

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 vonoprazan 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. For example, a new bill (Terminating the Extension of Rights Misappropriated Act H.R. 3199) percolating through the United States Congress aims to reduce the term of certain drug patents in order to ease generic entry and increase competition. 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 vonoprazan and any future product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering vonoprazan 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 vonoprazan 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 vonoprazan and any future product candidates, our business may be materially harmed.

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

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

Although we have issued patents and pending patent applications in the United States and certain other countries in which we intend to commercialize our products, filing, prosecuting and defending patents in all relevant countries throughout the 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 vonoprazan 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.

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

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

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

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

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

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

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

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

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

We may acquire or license in the future intellectual property rights that have been generated through the use of U.S. government funding or grant. Pursuant to the Bayh-Dole Act of 1980, the U.S. government has certain rights in inventions developed with government funding. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as “march-in rights”). The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. 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 and This Offering

An active, liquid and orderly market for our common stock may not develop, and you may not be able to resell your common stock at or above the public offering price.

Prior to this offering, there has been no public market for our common stock. Although our common stock has been approved for listing on Nasdaq, an active trading market for our common stock may never develop or be sustained following this offering. We and the representatives of the underwriters determined the initial public offering price of our common stock through negotiation. This price does not necessarily reflect the price at which investors in the market will be willing to buy and sell our shares following this offering. In addition, an active trading market may not develop following the consummation of this offering or, if it is developed, may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses or technologies using our shares as consideration, which, in turn, could materially adversely affect our business.

The trading price of the shares of our common stock could be highly volatile, and purchasers of our common stock could incur substantial losses.

Our stock price is likely to be volatile. 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 initial public offering price. The market price for our common stock may be influenced by those factors discussed in this “Risk Factors” section and many others, including:

- our ability to enroll patients in our planned clinical trials;
- results of our clinical trials and preclinical studies, the results of clinical trials conducted by Takeda and others for vonoprazan, and the results of trials of our competitors or those of other companies in our market sector;
- regulatory approval of vonoprazan and any future product candidates, or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process;

- any termination or loss of rights under the Takeda License;
- regulatory developments in the United States and foreign countries;
- changes in the structure of healthcare payment systems, especially in light of current reforms to the U.S. healthcare system;
- the success or failure of our efforts to acquire, license or develop additional product candidates;
- innovations or new products developed by us or our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- manufacturing, supply or distribution delays or shortages;
- any changes to our relationship with any manufacturers, suppliers, licensors, future collaborators or other strategic partners;
- achievement of expected product sales and profitability;
- variations in our financial results or those of companies that are perceived to be similar to us;
- market conditions in the biopharmaceutical sector and issuance of securities analysts' reports or recommendations;
- trading volume of our common stock;
- an inability to obtain additional funding;
- sales of our stock by insiders and stockholders, including Takeda;
- general economic, industry and market conditions other events or factors, many of which are beyond our control;
- additions or departures of key personnel;
- intellectual property, product liability or other litigation against us;
- changes in our capital structure, such as future issuances of securities and the incurrence of additional debt; and
- changes in accounting standards, policies, guidelines, interpretations or principles.

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

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

If, after listing, 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 may allocate the net proceeds from this offering in ways that you and other stockholders may not approve.

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section titled "Use of Proceeds." Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment, and the failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short- and intermediate-term, investment grade interest-bearing instruments. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected results, which could cause our stock price to decline.

You will suffer immediate and substantial dilution in the net tangible book value of the common stock you purchase.

The initial public offering price of our common stock is substantially higher than the pro forma as adjusted net tangible book value per share of our outstanding common stock immediately after the completion of this offering. Purchasers of common stock in this offering will experience immediate dilution of approximately $10.85 per share, based on the initial public offering price of $19.00 per share.

After this offering, our executive officers, directors and principal stockholders, if they choose to act together, will continue to 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.

Following the completion of this offering, our executive officers, directors and greater than 5% stockholders, in the aggregate, will own approximately 45.0% of our outstanding common stock (assuming no exercise of the underwriters' option to purchase additional shares and no exercise of outstanding options, warrants or other rights, and without giving effect to any purchases that these holders may make through our directed share program), based on the initial public offering price of $19.00 per share. Furthermore, many of our current directors were appointed by our principal stockholders. As a result, such persons or their appointees to our board of directors, acting together, will 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. In addition, if any of our executive officers, directors and greater than 5% stockholders purchase shares in this offering, or if any of our other current investors purchase shares in this offering and become greater than 5% stockholders as a result, the ability of such persons, acting together, to control or significantly influence such matters will increase. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

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

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

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

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

Based on shares of common stock outstanding as of June 30, 2019, upon the closing of this offering, we will have outstanding a total of 27,547,593 shares of common stock after this offering, assuming no exercise of the underwriters' option to purchase additional shares and no exercise of outstanding options, warrants or other rights. Of these shares, only the 9,563,157 shares of common stock sold in this offering by us, plus any shares sold upon exercise of the underwriters' option to purchase additional shares, will be freely tradable, without restriction, in the public market immediately following this offering, unless they are purchased by one of our affiliates.

In addition, immediately following the completion of this offering, Takeda will beneficially own 24.7% of our outstanding shares of common stock, including 7,588,000 shares of common stock issuable pursuant to the Takeda Warrant (or 23.7% if the underwriters exercise their option to purchase additional shares in full). The sale by Takeda of a substantial number of shares after this offering, or a perception that such sales could occur, could significantly reduce the market price of our common stock.

Our officers, directors and holders of substantially all of our outstanding securities have entered into lock-up agreements with the underwriters pursuant to which they may not, with limited exceptions, for a period of 180 days from the date of this prospectus, offer, sell or otherwise transfer or dispose of any of our securities, without the prior written consent of Goldman Sachs & Co. LLC, Jefferies LLC and Evercore Group L.L.C. The underwriters may permit our officers, directors and other securityholders who are subject to the lock-up agreements to sell shares prior to the expiration of the lock-up agreements, subject to limitations. Sales of these shares, or perceptions that they will be sold, could cause the trading price of our common stock to decline. After the lock-up agreements expire, up to an additional 17,984,436 shares of common stock will be eligible for sale in the public market of which 13,414,828 shares are held by directors, executive officers and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act.

In addition, as of June 30, 2019, up to 9,819,925 shares of common stock that are either subject to outstanding options, warrants or other rights or reserved for future issuance under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, exercise limitations, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

After this offering, the holders of 12,069,916 shares of our outstanding common stock, or approximately 43.8% of our total outstanding common stock as of June 30, 2019, will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to vesting and the 180-day lock-up agreements described above. In addition, upon the closing of this offering Takeda will be entitled to the same rights with respect to the registration of 7,588,000 shares of our common stock underlying the Takeda Warrant. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

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

We are an emerging growth company, as defined in the JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the completion of this offering. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, our annual gross revenues exceed $1.07 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

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

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

We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

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

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to 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. 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 will depend in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. We do not currently have and may never obtain research coverage by securities and industry analysts. If no securities or industry analysts commence coverage of our company, the trading price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, if one or more of the analysts who covers us downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

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

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

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

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

Our ability to use net operating loss carryforwards and other tax attributes may be limited in connection with this offering or other ownership changes.

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

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

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

The Tax Act has significantly changed the U.S. federal income taxation of U.S. corporations, including by reducing the U.S. corporate income tax rate and revising the rules governing NOLs. Many of these changes became effective beginning in 2018, without any transition periods or grandfathering for existing transactions. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, as well as interpretations and implementing regulations by the U.S. Treasury Department and the IRS, any of which could lessen or increase certain adverse impacts of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities.

There may be other material adverse effects resulting from the legislation that we have not yet identified. While some of the changes made by the tax legislation may adversely affect us in one or more reporting periods and prospectively, other changes may be beneficial on a going forward basis. We continue to work with our tax advisors to determine the full impact that the recent tax legislation as a whole will have on us. We urge our investors to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our common stock.

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 biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, research and development plans, the anticipated timing, costs, design and conduct of our planned clinical trials for vonoprazan, our only product candidate, the timing and likelihood of regulatory filings and approvals for vonoprazan, our ability to commercialize vonoprazan, if approved, the pricing and reimbursement of vonoprazan, if approved, the potential to develop future product candidates, the potential benefits of strategic collaborations and our intent to enter into any strategic arrangements, the timing and likelihood of success, 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.

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 prospectus 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 business, financial condition and results of operations. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions described under the sections titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this prospectus. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. 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 undertake no obligation 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. You should, however, review the factors and risks we describe in the reports we will file from time to time with the SEC after the date of this prospectus. See the section titled “Where You Can Find More Information.”

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to rely unduly upon them.

MARKET AND INDUSTRY DATA

We obtained the industry, market and competitive position data used throughout this prospectus from our own internal estimates and research, as well as from independent market research, industry and general publications and surveys, governmental agencies and publicly available information in addition to research, surveys and studies conducted by third parties. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our knowledge of our industry and market, which we believe to be reasonable. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires. In addition, while we believe the industry, market and competitive position data included in this prospectus is reliable and based on reasonable assumptions, such data involve risks and uncertainties and are subject to change based on various factors, including those discussed in the section titled “Risk Factors.” These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties or by us.

USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of the common stock that we are offering will be approximately $166.2 million (or $191.5 million if the underwriters exercise their option to purchase additional shares in full), based on the initial public offering price of $19.00 per share, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to obtain additional capital to support our operations, to create a public market for our common stock and to facilitate our future access to the public equity markets. We intend to use approximately $100.0 million of the net proceeds from this offering to fund the clinical development of vonoprazan and the remainder for working capital and general corporate purposes, including pre-commercial activities.

We may also use a portion of the remaining net proceeds and our existing cash and cash equivalents to in-license, acquire, or invest in complementary businesses, technologies, products or assets. However, we have no current commitments or obligations to do so.

We believe, based on our current operating plan, that the net proceeds from this offering together with our existing cash and cash equivalents, will be sufficient to fund our operations for at least the next 24 months, although there can be no assurance in that regard. In particular, we expect that the net proceeds from this offering will allow us to complete our planned Phase 3 clinical trials of vonoprazan in the treatment of erosive esophagitis and *H. pylori* infection. However, our expected use of proceeds from this offering described above represents our current intentions based on our present plans and business condition. We cannot predict with certainty all of the particular uses of the net from this offering or the actual amounts that we will spend on the uses set forth above.

The amounts and timing of our actual expenditures will depend on numerous factors, including the time and cost necessary to conduct our planned clinical trials, the results of such trials, and other factors described in the section titled “Risk Factors,” as well as the amount of cash used in our operations and any unforeseen cash needs. Therefore, our actual expenditures may differ materially from the estimates described above. We may find it necessary or advisable to use the net proceeds for other purposes, and we will have broad discretion in the application of the net proceeds.

Pending the uses described above, we plan to invest the net proceeds from this offering in short- and intermediate-term, investment grade interest-bearing instruments.

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.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of June 30, 2019:

- on an actual basis;
- on a pro forma basis to reflect (i) the automatic conversion of the May 2019 Notes into an aggregate of 6,107,918 shares of our common stock immediately prior to the closing of this offering (based on the initial public offering price of $19.00 per share and assuming the conversion occurs on October 29, 2019), (ii) the reclassification of the Takeda Warrant to stockholders' equity (deficit), and (iii) the filing and effectiveness of our amended and restated certificate of incorporation immediately prior to the closing of this offering; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of 9,563,157 shares of our common stock in this offering at the initial public offering price of $19.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this information in conjunction with our combined financial statements and related notes included in this prospectus and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and other financial information contained in this prospectus.

	As of June 30, 2019		
(in thousands, except share and par value data)	**Actual (unaudited)**	**Pro Forma (unaudited)**	**Pro Forma As Adjusted (unaudited)**
Cash and cash equivalents	$ 82,917	$ 82,917	$249,098
Capitalization:			
Convertible promissory notes payable at fair value (including accrued interest)	$ 93,559	$ –	$ –
Warrant liabilities	49,597	426	426
Long-term debt, including final payment fee and net of debt discount	24,512	24,512	24,512
Stockholders' equity (deficit):			
Preferred stock, $0.0001 par value; no shares authorized, issued and outstanding, actual; 40,000,000 shares authorized and no shares issued and outstanding, pro forma and pro forma as adjusted	–	–	–
Common stock, $0.0001 par value; 50,000,000 shares authorized, 11,876,518 shares issued and 7,219,268 shares outstanding, actual; 400,000,000 shares authorized, 17,984,436 shares issued and 13,327,186 shares outstanding, pro forma; 400,000,000 shares authorized, 27,547,593 shares issued and 22,890,343 shares outstanding, pro forma as adjusted	–	1	2
Additional paid-in capital	5,916	148,645	314,825
Accumulated deficit	(90,301)	(90,301)	(90,301)
Total stockholders' equity (deficit)	(84,385)	58,345	224,526
Total capitalization	$ 83,283	$ 83,283	$249,464

The number of shares of common stock issued and outstanding pro forma and pro forma as adjusted in the table above is based on 17,984,436 shares of our common stock outstanding as of June 30, 2019, including 4,657,250 shares subject to forfeiture or our right of repurchase, and gives effect to the automatic conversion of the May 2019 Notes into an aggregate of 6,107,918 shares of our common stock immediately prior to the closing of this offering (based on the initial public offering price of $19.00 per share and assuming the conversion occurs on October 29, 2019), and excludes:

- 7,588,000 shares of common stock issuable to Takeda upon the exercise of the Takeda Warrant as of June 30, 2019, at an exercise price of $0.00004613 per share;
- 1,400,528 shares of common stock issuable upon exercise of stock options granted after June 30, 2019, at a weighted-average exercise price of $9.10 per share;
- 2,700,000 shares of our common stock reserved for future issuance under our 2019 Plan, which became effective in connection with this offering (which number does not include any potential evergreen increases pursuant to the terms of the 2019 Plan);
- 270,000 shares of common stock reserved for future issuance under our ESPP, which became effective in connection with this offering (which number does not include any potential evergreen increases pursuant to the terms of the ESPP); and
- 16,446 shares of our common stock which may become issuable to the lenders under our Loan Agreement upon the exercise of the Lender Warrants, at an exercise price of $15.20 per share (based on the initial public offering price of $19.00 per share), which warrants will only become exercisable if and when we borrow an additional $25.0 million under our Loan Agreement.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

As of June 30, 2019, our historical net tangible book value (deficit) was $(84.4) million, or $(7.11) per share of our common stock, based on 11,876,518 shares of common stock issued and outstanding as of such date, including 4,657,250 shares subject to forfeiture or our right of repurchase as of such date. Our historical net tangible book value per share represents total tangible assets less total liabilities, divided by the number of shares of common stock outstanding at June 30, 2019.

On a pro forma basis, after giving effect to (i) the automatic conversion of the May 2019 Notes into an aggregate of 6,107,918 shares of our common stock immediately prior to the closing of this offering (based on the initial public offering price of $19.00 per share and assuming the conversion occurs on October 29, 2019), and (ii) the reclassification of the Takeda Warrant to stockholders' equity (deficit), our pro forma net tangible book value as of June 30, 2019 would have been approximately $58.3 million, or approximately $3.24 per share of our common stock.

After giving further effect to the sale of 9,563,157 shares of common stock in this offering at the initial public offering price of $19.00 per share, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2019 would have been approximately $224.5 million, or approximately $8.15 per share. This amount represents an immediate increase in pro forma net tangible book value of approximately $4.91 per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of approximately $10.85 per share to new investors purchasing shares of common stock in this offering.

Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution (without giving effect to any exercise by the underwriters of their option to purchase additional shares):

Initial public offering price per share		$19.00
Historical net tangible book value (deficit) per share as of June 30, 2019	$ (7.11)	
Pro forma increase in historical net tangible book value per share as of June 30, 2019 attributable to the pro forma adjustments described above	10.35	
Pro forma net tangible book value per share as of June 30, 2019	3.24	
Increase in pro forma net tangible book value per share attributable to new investors participating in this offering	4.91	
Pro forma as adjusted net tangible book value per share after this offering		8.15
Dilution per share to new investors participating in this offering		$10.85

If the underwriters exercise their option to purchase additional shares of our common stock in full in this offering, the pro forma as adjusted net tangible book value after the offering would be approximately $8.62 per share, the increase in pro forma as adjusted net tangible book value per share to existing stockholders would be approximately $5.38 and the dilution per share to new investors would be $10.38, in each case based upon the initial public offering price of $19.00 per share.

The following table summarizes on the pro forma as adjusted basis described above, as of June 30, 2019, the differences between the number of shares purchased from us, the total consideration paid to us in cash and the average price per share paid by existing stockholders for shares issued prior to this offering and the price to be paid by new investors in this offering. The calculations below are based on the initial public offering price of $19.00 per share, before deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Weighted-Average Price
	Number	Percent	Amount	Percent	Per Share
Existing stockholders before this offering	17,984,436	65%	$ 92,840,000	34%	$ 5.16
New investors participating in this offering	9,563,157	35%	$181,699,983	66%	$ 19.00
Total	27,547,593	100%	$274,539,983	100%	

If the Takeda Warrant and Lender Warrants had been exercised as of June 30, 2019, the pro forma as adjusted net tangible book value after this offering would be approximately $224.8 million, or approximately $6.39 per share, and total dilution per share to new investors would be approximately $12.61 per share.

If the underwriters exercise their option to purchase additional shares of our common stock in full:

- the percentage of shares of common stock held by existing stockholders before this offering will decrease to approximately 62% of the total number of shares of our common stock outstanding after this offering; and
- the number of shares held by new investors participating in this offering will increase to 10,997,630, or approximately 38% of the total number of shares of our common stock outstanding after this offering.

The foregoing tables and calculations on a pro forma and pro forma as adjusted basis are based on 17,984,436 shares of our common stock outstanding as of June 30, 2019, including 4,657,250 shares subject to forfeiture or our right of repurchase, and gives effect to the automatic conversion of the May 2019 Notes into an aggregate of 6,107,918 shares of our common stock immediately prior to the closing of this offering (based on the initial public offering price of $19.00 per share, and assuming the conversion occurs on October 29, 2019) and excludes:

- 7,588,000 shares of common stock issuable to Takeda upon the exercise of the Takeda Warrant as of June 30, 2019, at an exercise price of $0.00004613 per share;
- 1,400,528 shares of common stock issuable upon exercise of stock options granted after June 30, 2019, at a weighted-average exercise price of $9.10 per share;
- 2,700,000 shares of our common stock reserved for future issuance under our 2019 Plan, which became effective in connection with this offering (which number does not include any potential evergreen increases pursuant to the terms of the 2019 Plan);
- 270,000 shares of common stock reserved for future issuance under our ESPP, which became effective in connection with this offering (which number does not include any potential evergreen increases pursuant to the terms of the ESPP); and

- 16,446 shares of our common stock which may become issuable to the lenders under our Loan Agreement upon the exercise of the Lender Warrants, at an exercise price of $15.20 per share (based on the initial public offering price of $19.00 per share), which warrants will only become exercisable if and when we borrow an additional $25.0 million under our Loan Agreement.

To the extent any outstanding options, warrants or other rights are exercised, or we issue additional equity or convertible securities in the future, there will be further dilution to new investors.

SELECTED COMBINED FINANCIAL DATA

The following tables set forth our selected historical combined financial data as of, and for the periods ended on, the dates indicated. The combined financial statements include the accounts of our company and YamadaCo IIA, Inc., both of which were entities under common control prior to the Merger. We have derived the selected combined statements of operations data for the year ended December 31, 2018 and the selected combined balance sheet data as of December 31, 2018 from our audited combined financial statements included elsewhere in this prospectus. We have derived the selected combined statements of operations data for the six months ended June 30, 2018 and 2019 and the selected combined balance sheet data as of June 30, 2019 from our unaudited combined financial statements included elsewhere in this prospectus. The unaudited combined financial statements have been prepared on a basis consistent with our audited combined financial statements included in this prospectus and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, necessary to fairly state our results of operations for the six months ended June 30, 2018 and 2019 and financial position as of June 30, 2019. You should read these data together with our combined financial statements and related notes included elsewhere in this prospectus and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our historical results for any prior period are not necessarily indicative of our future results.

(in thousands, except share and per share data)	Year Ended December 31, 2018	Six Months Ended June 30, 2018 (unaudited)	Six Months Ended June 30, 2019 (unaudited)
Combined Statements of Operations Data:			
Operating expenses:			
Research and development	$ 20	$ –	$ 3,201
In-process research and development	–	–	78,897
General and administrative (includes related party amounts of $321, $124 and $18, respectively)	1,205	506	2,142
Total operating expenses	1,225	506	84,240
Loss from operations	(1,225)	(506)	(84,240)
Other income (expense):			
Interest income	–	–	101
Interest expense (includes related party amounts of $(13), $(4) and $(82), respectively)	(13)	(4)	(1,148)
Change in fair value of warrant liabilities (includes related party amounts of $0, $0 and $(1,277), respectively)	–	–	(1,284)
Change in fair value of convertible promissory notes (includes related party amounts of $(50), $(4) and $(502), respectively)	(50)	(4)	(2,442)
Total other income (expense)	(63)	(8)	(4,773)
Net loss	$ (1,288)	$ (514)	$ (89,013)
Net loss per share, basic and diluted(1)	$ (0.21)	$ (0.10)	$ (13.40)
Weighted-average shares of common stock outstanding, basic and diluted(1)	6,051,675	5,331,270	6,640,394
Pro forma net loss per share, basic and diluted (unaudited)(1)	$ (0.20)		$ (9.85)
Pro forma weighted-average shares of common stock outstanding, basic and diluted (unaudited)(1)	6,098,429		8,578,296

(1) See Note 1 to our combined financial statements included elsewhere in this prospectus for an explanation of the method used to calculate the historical and pro forma net loss per share, basic and diluted, and the number of shares used in the computation of the per share amounts.

(in thousands)	As of December 31, 2018	As of June 30, 2019 (unaudited)
Combined Balance Sheet Data:		
Cash and cash equivalents	$ 879	$ 82,917
Working capital (deficit)[(1)]	(1,286)	(60,210)
Total assets	902	84,879
Convertible promissory notes payable at fair value (including accrued interest)	1,963	93,559
Warrant liabilities	–	49,597
Long-term debt, including final payment fee and net of debt discount	–	24,512
Accumulated deficit	(1,288)	(90,301)
Total stockholders' equity (deficit)	(1,286)	(84,385)

(1) We define working capital (deficit) as current assets less current liabilities. See our combined financial statements included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

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 combined financial statements and related notes included elsewhere in this prospectus. Some of the information contained in this discussion and analysis are set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, and includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the section titled "Risk Factors," our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a late clinical-stage biopharmaceutical company focused on developing and commercializing novel treatments for GI diseases. Our initial product candidate, vonoprazan, is an oral small molecule P-CAB. P-CABs are a novel class of medicines that block acid secretion in the stomach. Vonoprazan has rapid, potent, and durable anti-secretory effects and has demonstrated clinical benefits over the current standard of care as a single agent in the treatment of GERD, and in combination with antibiotics for the treatment of *H. pylori* infection. Takeda developed vonoprazan and has received marketing approval in nine countries in Asia and Latin America. Vonoprazan generated over $500 million in net sales in its fourth full year on the market since its approval in Japan in late 2014. In May 2019, we in-licensed the U.S., European, and Canadian rights to vonoprazan from Takeda. We plan to initiate two pivotal Phase 3 clinical trials of vonoprazan in the fourth quarter of 2019. We believe that the successful completion of our Phase 3 clinical trials, together with the existing clinical data, will support regulatory submissions in 2021 and 2022 for marketing approval for the treatment of *H. pylori* infection and erosive esophagitis, respectively. If approved, we plan to independently commercialize vonoprazan in the United States. We also plan to seek commercial partnerships for vonoprazan in Europe and Canada, expand development of vonoprazan across indications, dosing regimens and alternative formulations and packaging, and in-license or acquire additional clinical or commercial stage product candidates for the treatment of GI diseases in a capital efficient manner.

We commenced our operations in 2018 and have devoted substantially all of our resources to date to organizing and staffing our company, business planning, raising capital, in-licensing our initial product candidate, vonoprazan, meeting with regulatory authorities, preparing for our planned Phase 3 clinical trials of vonoprazan, and providing other general and administrative support for these operations. Our operations to date have been funded primarily through the issuance of convertible promissory notes and commercial bank debt. From our inception through June 30, 2019, we have raised aggregate gross proceeds of $90.3 million from the issuance of convertible promissory notes and $25.0 million of commercial bank debt. As of June 30, 2019, we had cash and cash equivalents of $82.9 million. Based on our current operating plan, we believe that our existing cash and cash equivalents, together with the estimated net proceeds from this offering, will be sufficient to meet our anticipated cash requirements through at least the next 24 months.

We do not have any products approved for sale and have incurred net losses since our inception. Our net losses for the year ended December 31, 2018 and the six months ended June 30, 2019 were $1.3 million and $89.0 million, respectively. As of June 30, 2019, we had an accumulated deficit of $90.3 million. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical development activities, other research and development activities and pre-commercialization activities. We expect our expenses and operating losses will increase substantially as we advance vonoprazan through clinical trials, seek regulatory approval for vonoprazan, expand our clinical, regulatory, quality, manufacturing and commercialization capabilities, incur significant commercialization expenses for marketing, sales, manufacturing and distribution if we obtain marketing approval for vonoprazan, protect our intellectual property, expand our general and administrative support functions, including hiring additional personnel, and incur additional costs associated with operating as a public company.

We have never generated any revenue and do not expect to generate any revenues from product sales unless and until we successfully complete development and obtain regulatory approval for vonoprazan, which will not be for several years, if ever. Accordingly, until such time as we can generate significant revenue from sales of vonoprazan, if ever, we expect to finance our cash needs through equity offerings, our existing Loan Agreement, debt financings, or other capital sources, including potential collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. 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.

Financial Operations Overview

Our combined financial statements include the accounts of Phathom (the receiving entity) and YamadaCo IIA prior to being merged into a single entity effective March 13, 2019. Phathom and YamadaCo IIA were entities under common control of Frazier, as a result of, among other things, Frazier's: (i) ownership of a majority of the outstanding capital stock of both companies; (ii) financing of both companies; (iii) control of the board of directors of both companies; and (iv) management of both companies. Both Phathom and YamadaCo IIA were formed for the purpose of identifying potential assets around which to form an operating company. As the merged entities were under common control, the combined financial statements report the financial position, results of operations and cash flows of Phathom and YamadaCo IIA as though the transfer of net assets and equity interests had occurred at the beginning of 2018. All intercompany accounts and transactions have been eliminated in combination.

License Agreement with Takeda

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

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

We paid Takeda upfront consideration consisting of a cash fee of $25.0 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 represents less than a certain specified percentage of the fully-diluted capitalization, including shares issuable upon conversion of outstanding convertible promissory notes, calculated immediately prior to the closing of our initial public offering. We agreed to make milestone payments to Takeda upon achieving certain tiered aggregate annual net sales of licensed products in the United States, Europe and Canada up a total maximum milestone amount of $250.0 million. We also agreed to make tiered royalty payments at percentages in the very low to mid 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. For additional information regarding the Takeda License, see "Business—Intellectual Property—License Agreement with Takeda Pharmaceutical Company Limited."

Components of Results of Operations

Operating Expenses

Research and Development

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

Research and development expenses include:

- salaries, payroll taxes, employee benefits, and stock-based compensation charges for those individuals involved in research and development efforts;
- external research and development expenses incurred under agreements with contract research organizations, or CROs, and consultants to conduct and support our planned clinical trials of vonoprazan; and
- costs related to manufacturing vonoprazan clinical trials.

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

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

- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;

- the number of doses evaluated in the trials;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the phase of development of the product candidate; and
- the efficacy and safety profile of the product candidate.

In-Process Research and Development

In-process research and development expenses relate to the Takeda License, and include the $78.9 million purchase price of the acquired research and development assets. The purchase price of the Takeda License consisted of the following: (i) $25.0 million in cash; (ii) issuance to Takeda of 1,084,000 shares of our common stock at a fair value of $5.9 million; (iii) issuance of the Takeda Warrant at an initial fair value of $47.9 million; (iv) issuance of the Takeda Warrant Right, with a nominal initial fair value due to the low probability of issuance; and (v) $0.1 million of transaction costs incurred by us. The fair value of the Takeda Warrant and Takeda Warrant Right were determined using the methodologies described below under "Change in Fair Value of Warrant Liabilities," and the fair value of the common stock was determined using the methodologies described below under "Critical Accounting Policies and Significant Judgments and Estimates—Common Stock Valuations."

General and Administrative

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

Interest Income

Interest income consists of interest on our money market fund.

Interest Expense

Interest expense consists of (i) interest on our outstanding convertible promissory notes at per annum interest rates ranging from 1.68% to 6.00% and (ii) interest on our outstanding commercial bank debt at a floating per annum interest rate (7.25% as of June 30, 2019) and amortization of the commercial bank debt discount recorded in connection with the fair value of warrants issued to the lenders, debt issuance costs incurred and the obligation to make a final payment fee.

Change in Fair Value of Warrant Liabilities

In connection with the Takeda License, we issued the Takeda Warrant and Takeda Warrant Right, or together the Takeda Warrants. In connection with our commercial bank debt, we issued the lenders warrants to purchase our capital stock, or the Lender Warrants. The Takeda Warrants are accounted for as liabilities as they do not meet all the conditions for equity classification due to (i) insufficient authorized shares for the Takeda Warrant and (ii) the Takeda Warrant Right is not indexed to our own stock. The Lender Warrants are accounted for as liabilities as they contain a holder put right under which the lenders could require us to pay cash in exchange for the warrants. We adjust the carrying value of our warrant liabilities to their estimated fair value at each reporting date, with any change in fair value of the warrant liabilities recorded as an increase or decrease to change in fair value of warrant liabilities in the combined statements of operations.

The fair value of the Takeda Warrants is derived from the model used to estimate the fair value of our common stock and the fair value of the Lender Warrants is estimated using a probability-weighted model considering initial public offering and non-initial public offering scenarios. The initial public offering scenarios utilize a binomial lattice model to estimate a distribution of total equity values as of a projected initial public offering date. The non-initial public offering scenario utilizes the repurchase price associated with the warrant put right discounted to present value based on venture capital rates of return and the term associated with the put right.

Upon the closing of this offering, (i) the Takeda Warrant will become reclassified to stockholders' equity and require a final adjustment to fair value, (ii) the Takeda Warrant Right (based on the initial public offering price of $19.00 per share) will expire without effect since no fair value has been allocated to it, and (iii) the Lender Warrants, as a result of a put option, will continue as warrant liabilities adjusted to fair value at each reporting date.

Change in Fair Value of Convertible Promissory Notes

We issued convertible promissory notes in 2018 and 2019 for which we have elected the fair value option. We adjust the carrying value of our convertible promissory notes to their estimated fair value at each reporting date, with any change in fair value of the convertible promissory notes recorded as an increase or decrease to change in fair value of convertible promissory notes in our combined statements of operations. All outstanding convertible promissory notes and related accrued interest will convert to shares of our common stock upon the closing of this offering.

Prior to their exchange into convertible promissory notes issued in May 2019, the fair value of convertible promissory notes issued from inception through April 2019 was estimated using a scenario-based analysis that estimated the fair value of the convertible promissory notes based on the probability-weighted present value of expected future investment returns, considering possible outcomes available to the noteholders, including conversions in subsequent equity financings, change of control transactions, settlement and dissolution. The fair value of the convertible promissory notes issued in May 2019 is estimated using a scenario-based analysis that estimates the fair value of the convertible promissory notes based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to the noteholders, including various initial public offering, settlement, equity financing, corporate transaction and dissolution scenarios.

Results of Operations

Comparison of the Six Months Ended June 30, 2018 and 2019

The following table summarizes our results of operations for each of the periods indicated (in thousands):

	Six Months Ended June 30, 2018	Six Months Ended June 30, 2019 (unaudited)	Change
Operating expenses:			
Research and development	$ –	$ 3,201	$ 3,201
In-process research and development	–	78,897	78,897
General and administrative	506	2,142	1,636
Total operating expenses	506	84,240	83,734
Loss from operations	(506)	(84,240)	(83,734)
Other income (expense):			
Interest income	–	101	101
Interest expense	(4)	(1,148)	(1,144)
Change in fair value of warrant liabilities	–	(1,284)	(1,284)
Change in fair value of convertible promissory notes	(4)	(2,442)	(2,438)
Total other income (expense)	(8)	(4,773)	(4,765)
Net loss	$ (514)	$ (89,013)	$ (88,499)

Research and Development Expenses. We had no research and development expenses for the six months ended June 30, 2018 as we had not yet identified or in-licensed a product candidate. The $3.2 million of research and development expenses for the six months ended June 30, 2019 consisted of $3.0 million of clinical development of vonoprazan and $0.2 million of personnel-related expenses.

In-Process Research and Development Expenses. We had no in-process research and development expenses for the six months ended June 30, 2018. The $78.9 million of in-process research and development expenses for the six months ended June 30, 2019 consisted of the purchase price for the research and development assets we acquired as part of the Takeda License.

General and Administrative Expenses. General and administrative expenses were $0.5 million and $2.1 million for the six months ended June 30, 2018 and 2019, respectively. The increase of $1.6 million was due to increases of $0.6 million in legal fees related to corporate and intellectual property matters, $0.4 million in professional services expenses for accounting, audit, tax, valuation and other services, $0.3 million in personnel-related expenses, $0.2 million of consulting services expenses, and $0.1 million of other operating expenses.

Other Income (Expense). Other expense of $8,000 for the six months ended June 30, 2018 consisted of $4,000 of interest expense on our outstanding convertible promissory notes and $4,000 of other expense related to the increase in fair value of those convertible promissory notes. Other expense of $4.8 million for the six months ended June 30, 2019 consisted of $2.4 million of other expense related to the increase in the fair value of our convertible promissory notes, $1.3 million of other expense related to the increase in the fair value of warrant liabilities, $0.9 million of interest expense on our outstanding convertible promissory notes, $0.3 million of interest expense on outstanding commercial bank debt, and partially offset by $0.1 million of interest income.

Liquidity and Capital Resources

We have incurred net losses and negative cash flows from operations since our inception and anticipate we will continue to incur net losses for the foreseeable future. As of June 30, 2019, we had cash and cash equivalents of $82.9 million.

Commercial Bank Debt

On May 14, 2019, we entered into the Loan Agreement with SVB, as administrative and collateral agent, and lenders SVB and WestRiver. We borrowed $25.0 million, or Term Loan A, at the inception of the Loan Agreement and have the right to borrow an additional $25.0 million, or Term Loan B, and which we collectively refer to as the Term Loans. Term Loan B is available through March 31, 2020, provided that (i) we have received at least $150.0 million of net cash proceeds in connection with the issuance and sale, subsequent to April 1, 2019, of our equity securities and subordinated debt, (ii) we have initiated Phase 3 clinical trials for vonoprazan, and (iii) no event of default has occurred. As of June 30, 2019, we had outstanding Term Loans of $25.0 million and accrued interest of $0.2 million.

The Term Loans bear interest at a floating rate of the higher of the Wall Street Journal Prime rate plus 1.75% (7.25% at June 30, 2019) or 7.25%. The monthly payments consist of interest-only through June 1, 2021 or, in the event of positive data with respect to our Phase 3 clinical trials in both indications for vonoprazan sufficient to file an NDA with the FDA, through June 1, 2022. Subsequent to the interest-only period, the Term Loans will be payable in equal monthly installments of principal, plus accrued and unpaid interest through the maturity date of May 1, 2024. In addition, we are obligated to pay a final payment fee of 8.25% of the original principal amount of the Term Loans. We may elect to prepay all or a portion of the Term Loans prior to maturity, subject to a prepayment fee of up to 2.0% of the then outstanding principal balance and payment of a pro rata portion of the final payment fee. After repayment, no Term Loan amounts may be borrowed again. The borrowings under the Loan Agreement are collateralized by substantially all of our assets, excluding intellectual property and certain other assets. We have agreed not to encumber our intellectual property assets without SVB’s prior written consent unless a security interest in the underlying intellectual property is necessary to have a security interest in the accounts and proceeds that are part of the assets securing the Term Loans, in which case our intellectual property will automatically be included within the assets securing the Term Loans.

The Loan Agreement contains certain customary affirmative and negative covenants and events of default. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, 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. Upon the occurrence of an event of default, subject to any specified cure periods, all amounts owed by us would begin to bear interest at a rate that is 4.00% above the rate effective immediately before the event of default and may be declared immediately due and payable by SVB, as collateral agent. As of June 30, 2019, we were in compliance with all applicable covenants under the Loan Agreement.

In connection with the Loan Agreement, we issued the Lender Warrants, which become exercisable only if we borrow Term Loan B, and the number, class and per share exercise price of the shares subject to the warrants is dependent on the terms of certain future equity financing transactions of the Company, including an initial public offering. The Lender Warrants expire ten years from the date of issuance, subject to earlier termination on September 30, 2020 if we do not draw down Term Loan B on or before March 31, 2020. The Lender Warrants include a put option pursuant to which, in the event that we do not draw down Term Loan B on or before March 31, 2020, the warrant holders may require us to repurchase the warrants for a total aggregate repurchase price of $0.5 million. The put right is exercisable through September 30, 2020.

Convertible Note Financings

From January 2018 to April 2019, we issued an aggregate of $2.4 million of convertible promissory notes to Frazier, or the Frazier Notes, bearing interest at per annum rates ranging from 1.68% to 2.55%. In May 2019, these notes and related accrued interest were exchanged, at their then fair value of $2.4 million, for the May 2019 convertible promissory notes described below.

On May 7, 2019, we entered into a note purchase agreement under which we issued an aggregate of $90.3 million of unsecured convertible promissory notes, or the May 2019 Notes, resulting in gross proceeds to us of $87.8 million in cash and $2.4 million related to the exchange of the Frazier Notes. Including the conversion of the Frazier Notes, Frazier purchased $20.0 million of the May 2019 Notes. The May 2019 Notes bear interest at a rate of 6% per annum and are subordinated to borrowings under our Loan Agreement. The May 2019 Notes become payable upon demand of the holders of at least 60% of the outstanding principal amount of the May 2019 Notes, including Frazier, on May 7, 2020, or the Maturity Date, and become due and payable on May 7, 2022, subject to earlier conversion or repayment in the event we complete certain equity financings or a change of control. The note purchase agreement includes certain customary covenants and events of default. The May 2019 Notes will automatically convert into shares of our common stock immediately prior to the completion of this offering.

Funding Requirements

Based on our current operating plan, we believe that our existing cash and cash equivalents, together with the estimated net proceeds from this offering, will be sufficient to meet our anticipated cash requirements through at least the next 24 months. In particular, we expect the net proceeds from this offering will allow us to complete our planned Phase 3 clinical trials of vonoprazan in the treatment of erosive esophagitis and *H. pylori* infection. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. Additionally, the process of testing product candidates in clinical trials is costly, and the timing of progress and expenses in these trials is uncertain.

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

- the initiation, type, number, scope, results, costs and timing of, our clinical trials of vonoprazan, and preclinical studies or clinical trials of other potential product candidates we may choose to pursue in the future, including feedback received from regulatory authorities;
- the costs and timing of manufacturing for vonoprazan or any future product candidates, including commercial scale manufacturing if any product candidate is approved;
- the costs, timing and outcome of regulatory review of vonoprazan or any future product candidates;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;

- the costs associated with hiring additional personnel and consultants as our business grows, including additional executive officers and clinical development personnel;
- the timing and amount of the milestone or other payments we must make to Takeda and any future licensors;
- the costs and timing of establishing or securing sales and marketing capabilities if vonoprazan or any future product candidate is approved;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements; and
- costs associated with any products or technologies that we may in-license or acquire.

Until such time, if ever, as we can generate substantial product revenues to support our cost structure, we expect to finance our cash needs through equity offerings, the Loan Agreement, debt financings, or other capital sources, including potential collaborations, licenses and other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, or other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves. We have prepared cash flow forecasts which indicate that based on our expected operating losses and negative cash flows, there is substantial doubt about our ability to continue as a going concern without raising additional capital within 12 months after the date that the combined financial statements for the year ended December 31, 2018 and for the six months ended June 30, 2019 are issued. Our independent registered public accounting firm also included an explanatory paragraph in its report on our combined financial statements as of and for the year ended December 31, 2018 indicating that there is substantial doubt about our ability to continue as a going concern.

Cash Flows

The following table sets forth a summary of the net cash flow activity for each of the periods indicated (in thousands):

	Year Ended December 31, 2018	Six Months Ended June 30, 2018	Six Months Ended June 30, 2019
		(unaudited)	(unaudited)
Net cash provided by (used in):			
Operating activities	$ (1,023)	$ (452)	$ (6,018)
Investing activities	–	–	(25,118)
Financing activities	1,902	552	113,174
Net increase in cash	$ 879	$ 100	$ 82,038

Operating Activities

Net cash used in operating activities was approximately $1.0 million for the year ended December 31, 2018, and $0.5 million and $6.0 million for the six months ended June 30, 2018 and 2019, respectively. The net cash used in operating activities for the year ended December 31, 2018 and the six months ended June 30, 2018 was primarily due to our net loss in each period. The net cash used in operating activities for the six months ended June 30, 2019 was due to our net loss of $89.0 million, adjusted for $82.7 million of noncash charges and a $0.3 million net change in operating assets and liabilities. Noncash charges consisted of our in-process research and development charges of $78.9 million related to the Takeda License, $2.4 million related to the change in fair value of convertible promissory notes, $1.3 million related to the change in fair value of warrant liabilities, and $0.1 million of amortization of debt discounts on our commercial bank debt. The net change in operating assets and liabilities related to a $1.0 million increase in accrued interest on our outstanding convertible promissory notes and commercial bank debt and a $0.9 million increase in accounts payable and accrued expenses in support of the growth in our operating activities, partially offset by a $1.6 million increase in prepaid clinical activities.

Investing Activities

Net cash used in investing activities for the six months ended June 30, 2019 was primarily due to the cash we paid, including transaction costs, to acquire the Takeda License. We had no investing activities for the year ended December 31, 2018.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2018 and the six months ended June 30, 2018 was primarily due to proceeds from our issuance of convertible promissory notes. Net cash provided by financing activities for the six months ended June 30, 2019 was $113.2 million, due to $88.3 million of net proceeds from our issuance of convertible promissory notes and $24.9 million of net proceeds from our commercial bank debt.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of June 30, 2019 (in thousands):

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Long-term debt, including interest and final payment fee(1)	$ 33,425	$ 1,843	$12,372	$19,210	$ –
Convertible promissory notes, including interest(2)	95,680	95,680	–	–	–
Total	$129,105	$97,523	$12,372	$19,210	$ –

(1) Our outstanding long-term debt bears interest at a variable rate. The interest amounts included herein are based on the interest rate in effect as of June 30, 2019.
(2) Our outstanding convertible promissory notes become payable upon demand of the holders of at least 60% of the outstanding principal amount of the notes on May 7, 2020, and become due and payable on May 7, 2022, subject to earlier conversion or repayment in the event we complete certain equity financings or a change of control. The amounts herein assume repayment on May 7, 2020.

Under the Takeda License, we have milestone payment obligations that are contingent upon the achievement of specified levels of product sales and are required to make certain royalty payments in connection with the sale of products developed under the agreement. As of June 30, 2019, we are unable to estimate the timing or likelihood of achieving the milestones or making future product sales and, therefore, any related payments are not included in the table above.

We enter into contracts in the normal course of business for 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 and not included in the table above.

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 combined financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of our combined financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our combined 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 combined financial statements included elsewhere in this prospectus, we believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

Accrued Research and Development Expenses

As part of the process of preparing our combined financial statements, we are required to estimate our accrued expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. We make estimates of our accrued expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments, if necessary. The significant estimates in our accrued research and development expenses include the costs incurred for services performed by our vendors in connection with research and development activities for which we have not yet been invoiced.

We base our expenses related to research and development activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid expense accordingly. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

In-Process Research and Development

We evaluate whether acquired intangible assets are a business under applicable accounting standards. Additionally, we evaluate whether the acquired assets have a future alternative use. Intangible assets that do not have future alternative use, such as the Takeda License, are considered acquired in-process research and development. When the acquired in-process research and development assets are not part of a business combination, the value of the consideration paid is expensed on the acquisition date. Future costs to develop these assets are recorded to research and development expense as they are incurred.

Fair Value of Warrant Liabilities and Convertible Promissory Notes

As described above, our warrant liabilities and convertible promissory notes are revalued at each reporting period with changes in the fair value of the liabilities recorded as a component of other income (expense) in the combined statements of operations. There are significant judgments and estimates inherent in the determination of the fair value of these liabilities. If we had made different assumptions including, among others, those related to the timing and probability of various corporate scenarios, discount rates, volatilities and exit valuations, the carrying values of our warrant liabilities and convertible promissory notes, and our net loss and net loss per common share could have been significantly different.

Stock-Based Compensation Expense

Stock-based compensation expense represents the cost of the grant date fair value of equity awards recognized over the requisite service period of the awards (generally the vesting period) on a straight-line basis with forfeitures recognized as they occur. Through June 30, 2019, our stock-based compensation expense primarily consisted of our issuance of restricted stock awards, or RSAs, for which the fair value is determined based on the fair value of the underlying common stock. As of June 30, 2019, the unrecognized stock-based compensation expense was $59,000, which is expected to be recognized as expense over a weighted-average period of approximately 0.7 years.

Common Stock Valuations

Prior to obtaining the Takeda License in May 2019 and entering into the May 2019 Notes, the fair value of our common stock was nominal because we were not sufficiently capitalized and held no assets that could be used to generate future revenues. Subsequent to obtaining the Takeda License and entering into the May 2019 Notes, we estimated the fair value of our common stock using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants Accounting and Valuation Guide: *Valuation of Privately Held Company Equity Securities Issued as Compensation*, or the Practice Aid. The Practice Aid prescribes several valuation approaches for setting the value of an enterprise, such as the cost, income and market approaches, and various methodologies for allocating the value of an enterprise to its common stock. We utilized a scenario-based analysis that estimated the fair value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, including various initial public offering, stay private and dissolution scenarios, and applying a discount for lack of marketability. We considered various stay private scenarios using the income approach and allocated the indicated equity value to each class of equity based on the current-value method. We also considered various initial public offering scenarios based on expected equity values in an initial public offering and allocated the indicated equity value to each class of equity on a fully-diluted basis considering the dilutive impacts of the May 2019 Notes and the Lender Warrants.

We considered various objective and subjective factors to determine the fair value of our common stock, including:

- valuations of our common stock performed with the assistance of independent third-party valuation specialists;
- our stage of development and business strategy, including the status of research and development efforts of vonoprazan, and the material risks related to our business and industry;
- our results of operations and financial position, including our levels of available capital resources;
- the valuation of publicly-traded companies in the life sciences and biotechnology sectors;
- the lack of marketability of our common stock as a private company;
- the likelihood of achieving a liquidity event for the holders of our common stock, such as an initial public offering or a sale of our company, given prevailing market conditions;
- trends and developments in our industry; and
- external market conditions affecting the life sciences and biotechnology industry sectors.

There are significant judgments and estimates inherent in the determination of the fair value of our common stock. These judgments and estimates include assumptions regarding our future operating performance, the time to complete an initial public offering or other liquidity event and the determination of the appropriate valuation methods. If we had made different assumptions, our net loss and net loss per common share could have been significantly different.

Following the completion of this offering, the fair value of our common stock will be based on the closing price as reported on the date of grant on the primary stock exchange on which our common stock is traded.

JOBS Act

As an emerging growth company under the JOBS Act, we can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. We intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of Sarbanes-Oxley.

We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of the consummation of this offering, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 billion, (iii) the last day of the fiscal year in which we are deemed to be a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year, or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

Recent Accounting Pronouncements

See Note 1 to our combined financial statements included elsewhere in this prospectus.

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.

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 portfolio is relatively insensitive to interest rate changes. Our outstanding convertible promissory notes bear interest at a fixed rate. 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.

BUSINESS

Overview

We are a late clinical-stage biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal, or GI, diseases. Our initial product candidate, vonoprazan, is an oral small molecule potassium competitive acid blocker, or P-CAB. P-CABs are a novel class of medicines that block acid secretion in the stomach. Vonoprazan has shown rapid, potent, and durable anti-secretory effects and has demonstrated clinical benefits over standard of care treatments as a single agent in the treatment of gastroesophageal reflux disease, or GERD, and in combination with antibiotics for the treatment of *Helicobacter pylori,* or *H. pylori,* infection. Takeda Pharmaceutical Company Limited, or Takeda, developed vonoprazan and has received marketing approval in nine countries in Asia and Latin America. Vonoprazan generated over $500 million in net sales in its fourth full year on the market since its approval in Japan in late 2014. In May 2019, we in-licensed the U.S., European, and Canadian rights to vonoprazan from Takeda. We intend to initiate two pivotal Phase 3 clinical trials of vonoprazan in the fourth quarter of 2019.

We believe we can leverage Takeda's extensive clinical data, including results from 17 Phase 3 clinical trials, to advance vonoprazan through pivotal trials in the United States and Europe. We plan to initiate two pivotal Phase 3 clinical trials in the fourth quarter of 2019 for vonoprazan: one for the treatment of erosive GERD, also known as erosive esophagitis, and a second for the treatment of *H. pylori* infection. We expect to report top-line data from both trials in 2021. We believe that the successful completion of our Phase 3 clinical trials, together with the existing clinical data, will support regulatory submissions in 2021 and 2022 for marketing approval for the treatment of *H. pylori* infection and erosive esophagitis, respectively. In August 2019, we received qualified infectious disease product, or QIDP, designation from the U.S. Food and Drug Administration, or FDA, for vonoprazan in combination with certain antibiotics for the treatment of *H. pylori* infection which provides, among other benefits, extension of any regulatory exclusivity and potential eligibility for priority review. Vonoprazan has the potential to be the first gastric anti-secretory agent from a novel class approved in the United States, Europe, or Canada in over 30 years.

GERD and *H. pylori* infection are two of the most common acid-related GI diseases and impact millions of people. The prevalence of GERD is estimated to be 20% of the U.S. population and 15% of the population in the five major countries in the European Union (France, Germany, Italy, Spain and the United Kingdom, or the EU5). GERD is a disease that develops when the reflux of acidic stomach contents causes troublesome symptoms and/or complications. Approximately 30% of GERD patients have erosive esophagitis. *H. pylori* is a bacterial pathogen that infects approximately 35% of the U.S. population and 45% of the EU5 population. As a result of the chronic inflammation induced by *H. pylori* infection, approximately 20% of infected patients will develop a range of pathologies, including dyspepsia, peptic ulcer disease, gastric cancer, and mucosa-associated lymphoid tissue (MALT) lymphoma.

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

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

PPIs reduce gastric acid secretion by irreversibly binding to and inhibiting active proton pumps expressed on the parietal cells. PPIs require activation by gastric acid, but they are unstable in the presence of acid. This instability, combined with the short circulating half-life of PPIs, limits their efficacy. Additionally, because proton pumps continuously switch between active and inactive states, multiple doses of PPIs are required to inhibit enough proton pumps to achieve a clinical benefit. As a result, PPIs have a relatively slow onset of action and limited potency and duration of effect, which may result in patients experiencing only partial relief, increasing PPI dosage, and/or cycling through multiple PPIs seeking relief.

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

- does not require activation by gastric acid;
- is stable in the presence of acid;
- binds with a slow dissociation rate to both active and inactive proton pumps; and
- has a long plasma half-life that replenishes the drug at the site of action over the course of the day.

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

We believe that vonoprazan's anti-secretory profile may demonstrate clinically meaningful advantages over PPIs, such as:

- faster, more complete, and more durable healing of erosive esophagitis;
- faster, more complete, and more durable control of GERD symptoms;
- higher *H. pylori* eradication rates in combination with antibiotics compared to standard of care triple therapy and the potential for antibiotic-sparing dual therapy; and
- more flexible dosing, including dosing independent of food and time of day, and the potential for rapid symptom relief through on-demand dosing.

Vonoprazan has demonstrated clinical advantages over PPIs in the treatment of erosive esophagitis and *H. pylori* infection in completed Phase 3 clinical trials conducted in Japan and other Asian countries.

Erosive esophagitis. In two Phase 3 clinical trials conducted in Japan assessing vonoprazan versus the PPI lansoprazole in the healing and maintenance of healing of erosive esophagitis, vonoprazan met its primary endpoint in demonstrating non-inferiority to lansoprazole. In a post hoc analysis of the healing trial, vonoprazan demonstrated faster healing and a superior overall healing rate compared to lansoprazole in patients with more severe erosive esophagitis. After two weeks of treatment, 88% of erosive esophagitis patients with more severe disease were healed after treatment with vonoprazan versus 64% with lansoprazole (p=0.0008). In the maintenance of healing trial, vonoprazan demonstrated lower recurrence rates of erosive esophagitis six months after treatment versus lansoprazole across all grades of severity of erosive esophagitis. Vonoprazan achieved a 2% recurrence rate compared to 17% for lansoprazole (p<0.0001).

H. pylori. A Phase 3 clinical trial was conducted in Japan assessing vonoprazan in combination with the antibiotics amoxicillin and clarithromycin versus lansoprazole in combination with these same antibiotics in first line treatment of *H. pylori* infection. In this trial, the vonoprazan-based regimen met its primary endpoint in demonstrating a non-inferior eradication rate of 93% compared to 76% for lansoprazole-based regimen (p<0.0001) and was also superior in a post hoc analysis of this trial (p<0.0001). In patients who failed first line therapy, vonoprazan in combination with the antibiotics metronidazole and amoxicillin demonstrated a 98% eradication rate as second line therapy. A p-value is the probability that the reported result was achieved purely by chance, such that a p-value of less than or equal to 0.05 or 0.01 means that there is a 5.0% or 1.0% or less probability, respectively, that the difference between the control group and the treatment group is purely due to chance. A p-value of 0.05 or less typically represents a statistically significant result.

We have used this clinical experience to inform our planned Phase 3 clinical development program in these indications.

Our company was founded as a collaboration between Takeda and Frazier Healthcare Partners. Our founders and management team have deep expertise in developing GI therapeutics, including anti-secretory agents, and direct experience developing vonoprazan at Takeda. Our Chairman, Tadataka (Tachi) Yamada, M.D., is the former Chief Medical Officer and Chief Scientific Officer at Takeda. He is the former President of the American Gastroenterological Association and former Chief of Gastroenterology and Internal Medicine at the University of Michigan. Our Chief Executive Officer, David Socks, is the former Chief Executive Officer of Outpost Medicine, LLC, a GI and urology focused company. Mr. Socks was also President and Chief Operating Officer of Incline Therapeutics Inc. through its sale to the Medicines Company in 2013, and Senior Vice President, Corporate Development and Strategy of Cadence Pharmaceuticals, Inc. Azmi Nabulsi, M.D., M.P.H., our Chief Operating Officer, is the former Deputy Chief Medical and Scientific Officer at Takeda. Our Head of Regulatory, Tom Harris, is the former Senior Vice President and Head of Global Regulatory at Takeda. Dr. Yamada, Dr. Nabulsi, and Mr. Harris were extensively involved with the development of vonoprazan at Takeda. Our investors include Frazier Healthcare Partners, Medicxi, RA Capital Management, Abingworth, certain accounts managed by Janus Henderson Investors and BVF Partners LP.

As part of a planned transition, we expect that Terrie Curran, a member of our board of directors, will succeed Mr. Socks as Chief Executive Officer effective upon the closing of the acquisition of her current employer, Celgene Corporation, by Bristol-Myers Squibb Company. Ms. Curran has served as President, Global Inflammation and Immunology (I&I) Franchise and as a member of the Executive Committee at Celgene since 2017. Ms. Curran joined Celgene in 2013 as the U.S. Commercial Head of the I&I Franchise and built the capabilities and recruited the teams that executed the launch of OTEZLA. Following Ms. Curran’s appointment as CEO, Mr. Socks will serve as interim Chief Financial Officer and continue to serve as a member of our board of directors.

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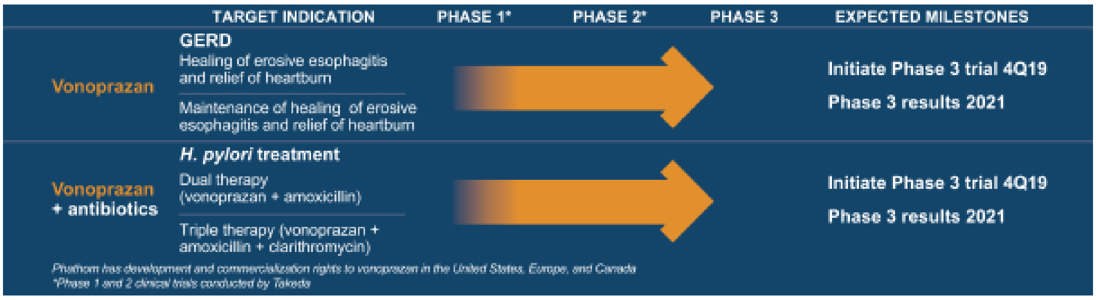
Our Pipeline

The following chart summarizes our current development programs.



Our Strategy

Our goal is to be a leader in the development and commercialization of novel treatments for GI diseases. Our strategy is initially focused on developing and commercializing vonoprazan as a potential first-in-class P-CAB in the United States, Europe, and Canada for the treatment of acid-related GI diseases. Key elements of this strategy include:

- ***Advance the clinical development of vonoprazan in erosive esophagitis and H. pylori infection and seek marketing approval****.* We believe we can leverage the existing clinical data and post-marketing experience, as well as our management team's experience with vonoprazan, to advance vonoprazan through our planned pivotal Phase 3 clinical trials. We plan to initiate a single pivotal Phase 3 clinical trial of vonoprazan in each of erosive esophagitis and *H. pylori* infection beginning in the fourth quarter of 2019. We expect to report top-line data from both trials in 2021, and if successful, file regulatory submissions for marketing approval for the treatment of *H. pylori* infection in 2021 and for erosive esophagitis in 2022. If approved by the FDA as a new chemical entity, vonoprazan would receive a five-year period of marketing exclusivity within the United States and vonoprazan's QIDP designation would extend the U.S. marketing exclusivity for an additional five years.
- ***Commercialize vonoprazan in the United States****.* We plan to independently commercialize vonoprazan, if approved, in the United States by building a leading specialty gastroenterology commercial infrastructure to support the adoption of vonoprazan. We believe we can successfully launch vonoprazan in the United States with a focused specialty sales force targeting high prescribers of PPIs, particularly gastroenterologists. PPI prescribing is highly concentrated, with approximately 1.5% of U.S. PPI prescribers (approximately 12,000 total) accounting for approximately 20% of PPI prescriptions and approximately 6.0% of U.S. PPI prescribers (approximately 50,000 total) accounting for approximately 50% of PPI prescriptions, according to IQVIA. We believe we have an opportunity to achieve significant share of voice and exposure to physicians given the scarcity of actively marketed anti-secretory medicines. Given the limitations of PPIs and current unmet need, we believe the commercial opportunity for vonoprazan is substantial.
- ***Seek commercial partnerships to maximize the vonoprazan opportunity outside of the United States****.* We believe there is a significant commercial opportunity for vonoprazan in Europe and Canada. To address these markets, we plan to seek one or more partners with existing commercial infrastructure and expertise in these markets. We believe this strategy will allow us to realize the value of the market opportunity in Europe and Canada while focusing our resources on the U.S. market.

- ***Expand the development of vonoprazan across indications, dosing regimens, and alternative formulations and packaging***. We plan to pursue vonoprazan lifecycle extension strategies in areas with clear unmet need, clinical rationale, and commercial justification. These strategies may include: (i) additional indications, including treatment of gastric ulcers and duodenal ulcers, Barrett's esophagus, and eosinophilic esophagitis; (ii) flexible dosing regimens, such as on-demand therapy for symptom relief of GERD; and (iii) alternative formulations and packaging, such as orally disintegrating tablets and other oral dosage forms for patients with difficulty swallowing, an intravenous formulation for in-hospital applications, and pre-packaged convenience packs for the treatment of *H. pylori* infection. Additionally, we believe that vonoprazan has the ideal profile for an OTC product, including the potential for on-demand symptom relief and a well-tolerated safety profile.
- ***In-license or acquire additional clinical or commercial stage product candidates for the treatment of GI diseases in a capital efficient manner***. We intend to take advantage of our management team's GI expertise to opportunistically in-license or acquire additional innovative therapies for diseases treated by gastroenterologists. We plan to leverage our development and planned commercial infrastructure to support multiple assets targeting GI indications.

Acid-Related GI Diseases

Overview

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

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

Prevalence

The prevalence of GI diseases is high. Approximately 20% to 40% of Western adults report chronic heartburn or regurgitation symptoms potentially related to GERD. We estimate that there are approximately 65 million individuals in the United States and 50 million individuals in the EU5 with GERD. In the United States, GERD is the most common gastroenterology-related outpatient diagnosis. Additionally, approximately 35% of the U.S. population and 45% of the EU5 population are infected with *H. pylori*. We estimate that there are approximately 115 million individuals in the United States and 145 million individuals in the EU5 infected with *H. pylori*.

Prevalence of GERD and *H. pylori* Infection

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

Treatments

Treatments of acid-related GI diseases aim to provide relief of acute symptoms, healing of damaged tissue, and prevention of long-term clinical sequelae associated with chronic acid exposure. Gastric acidity is measured by the pH scale, a logarithmic scale where 7.0 describes a neutral state and lower levels indicate a higher level of acidity. The pH of the stomach typically ranges from 1.5 to 3.5. In patients with acid-related GI diseases, increasing gastric pH has been shown to improve mucosal healing rates and provide more rapid symptom relief for patients. For example, the duration of time that intra-gastric acidity is greater than pH 3.0 correlates with the healing of duodenal and gastric ulcers, and pH greater than 4.0 is correlated with the healing of erosive esophagitis. Similarly, in patients with *H. pylori* infection, a more neutral gastric pH of 5.0 to 7.6 preserves antibiotic function and is optimal for successful eradication.

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

Antacids

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

Histamine Receptor Antagonists (H2RAs)

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

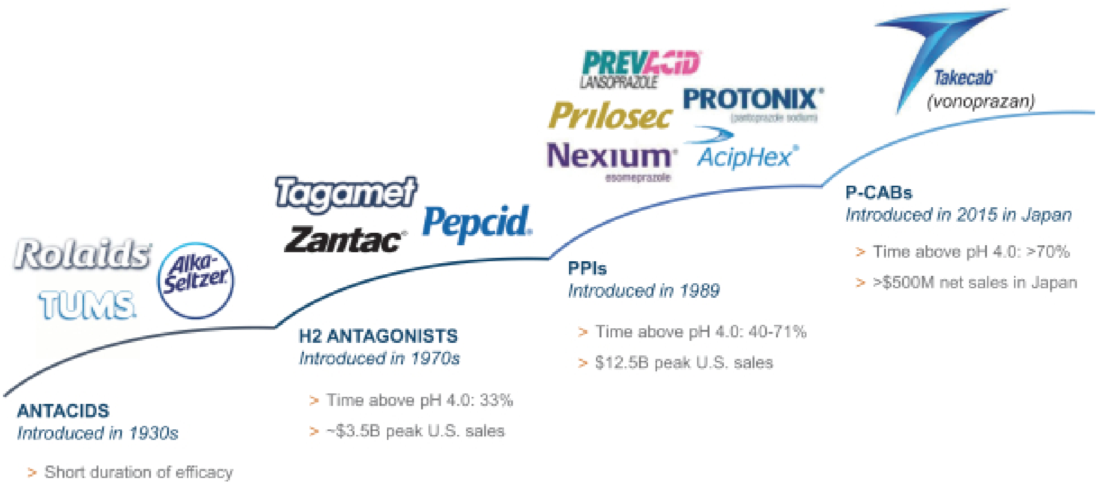
Proton Pump Inhibitors (PPIs)

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

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

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

History of Pharmaceutical Agents for Control of Gastric Acid



PPI Limitations

While PPIs provide clinically meaningful symptom relief and healing for millions of patients suffering from acid-related GI diseases, they are inadequate for many patients. The suboptimal anti-secretory profile of PPIs results in slow onset of symptom relief, breakthrough nighttime or postprandial heartburn, and treatment failure. Approximately 15% to 45% of GERD patients are inadequately treated with PPIs, experiencing persistent, troublesome symptoms, such as heartburn and regurgitation. In approximately two thirds of symptomatic GERD patients, reflux symptoms are not adequately controlled after the first dose of a PPI, and nearly 50% of patients still suffer from symptoms three days later. Given these limitations, more than 20% of GERD patients on PPI therapy take their PPI twice daily, which is not FDA approved, or purchase OTC heartburn treatments in addition to their prescription medicine. In a survey of approximately 1,000 GERD patients and 1,000 physicians, approximately one third of GERD patients reported persistent symptoms and were dissatisfied with PPI therapy and 35% of physicians perceived patients as somewhat satisfied to completely dissatisfied with PPI treatment. In addition, in July 2019 we conducted a U.S. market research study of 100 gastroenterologists and 100 primary care physicians who commonly prescribe PPIs and treat patients with GERD and *H. pylori* infection. Surveyed physicians reported that approximately 25% of patients are not satisfied on PPIs.

In patients with more severe grades of erosive esophagitis, studies with PPIs have reported failure rates of healing of esophageal erosions exceeding 25%. Additionally, recurrence of erosions is common in healed erosive esophagitis patients receiving maintenance PPI therapy. One study reported recurrence in 15% to 23% of patients with less severe erosive esophagitis and 24% to 41% of patients with more severe erosive esophagitis. We believe that these limitations of PPIs are in part driven by their mechanism of action and pharmacokinetics.

Mechanistic Differences Between PPIs and Vonoprazan

PPIs

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

Vonoprazan

Vonoprazan has a differentiated mechanism of action from PPIs. When vonoprazan reaches gastric parietal cells from the bloodstream, it accumulates in the secretory canaliculus where the proton pumps are present in their active state. In contrast to most PPIs, vonoprazan does not require gastric acid for activation, is stable in the presence of gastric acid, reversibly binds to proton pumps in both their inactive and active states, and remains in the secretory canaliculus where it continues to inhibit acid secretion over an extended period. Vonoprazan's prolonged effect is also maintained through a slow dissociation rate from the proton pumps and resupply from the bloodstream due to its seven-hour half-life. These characteristics allow vonoprazan to rapidly achieve target 24-hour acid suppression within two hours of a single dose, unlike PPIs that require three to five days to achieve stable acid suppression. In addition, vonoprazan is primarily metabolized by CYP3A4/5, an enzyme which has less genetic variability than CYP2C19, and may exhibit more consistent activity than PPIs across U.S. and European populations.

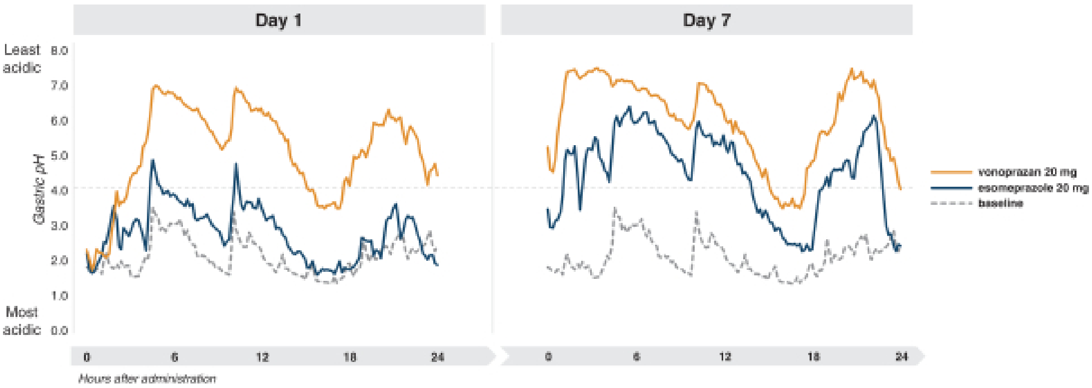
The mechanistic and pharmacologic differences of PPIs and vonoprazan are summarized in the table below.

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

Vonoprazan Pharmacodynamics vs. PPIs

Vonoprazan's more rapid, potent, and durable anti-secretory effects versus the PPI esomeprazole (Nexium) were demonstrated in a randomized, open-label, crossover clinical trial comparing 20 mg of once daily, or QD, vonoprazan to 20 mg QD of esomeprazole in 20 healthy volunteers. As shown below, vonoprazan achieved rapid and potent pH control on Day 1 relative to esomeprazole (left). Vonoprazan maintained pH approximately 1 to 2 units higher than esomeprazole at Day 7 (right), which represents a 10-to-100-fold reduction in acidity.

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



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

Improved Time Above pH 4.0 of Vonoprazan vs. Esomeprazole at Day 1 and Day 7

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

Vonoprazan for the Potential Treatment of Acid-Related GI Diseases

Given the shortcomings of PPI therapy, we believe that there is a significant unmet medical need for a safe and effective anti-secretory agent with rapid, potent, and durable activity. Vonoprazan was developed in markets outside of the United States by Takeda through an extensive clinical program, including 17 Phase 3 clinical trials. As of December 2018, 6,683 subjects were exposed to vonoprazan in completed and ongoing clinical trials. In head-to-head Phase 3 trials versus a PPI, vonoprazan demonstrated faster onset of healing in more severe erosive esophagitis patients, lower recurrence rates of erosions in erosive esophagitis patients across all levels of severity, and a superior eradication rate in combination with antibiotics in patients with *H. pylori* infection than PPI-based triple therapy. Vonoprazan received marketing approval in Japan in late 2014 and generated over $500 million in net sales in its fourth full year on the market in Japan. We plan to initiate a single pivotal Phase 3 clinical trial of vonoprazan in each of erosive esophagitis and *H. pylori* infection in the fourth quarter of 2019. We expect to report top-line data from both trials in 2021, and if successful, file regulatory submissions for marketing approval for the treatment of *H. pylori* infection in 2021 and for erosive esophagitis in 2022.

Vonoprazan in GERD

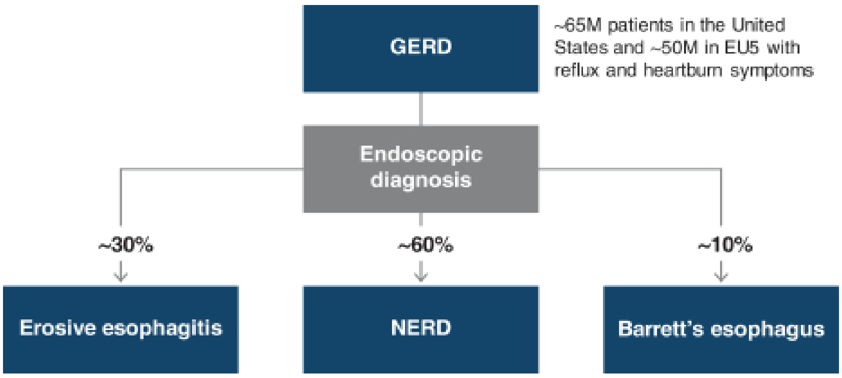
Based on the significant unmet medical need, previous Phase 3 trial results, and commercial potential, we have prioritized the development of vonoprazan in GERD in:

- the healing of erosive esophagitis and relief of heartburn; and
- the maintenance of healing of erosive esophagitis and relief of heartburn.

GERD Disease Overview

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

- ***Erosive esophagitis***: Approximately 30% of GERD patients have erosive esophagitis, which is classified by erosions in the gastric mucosa caused by acidic reflux of stomach contents into the esophagus. Erosive esophagitis is commonly graded by the Los Angeles classification system, which characterizes the extent of erosions in the esophagus and is graded on a scale of increasing severity from A to D, with D being the most severe. Approximately 10% to 20% of erosive esophagitis patients have the more severe Los Angeles Class C or D disease.
- ***Non-erosive reflux disease (NERD)***: Approximately 60% of GERD patients have NERD, which is classified by an endoscopically normal esophagus, but abnormal gastric acid exposure in the esophagus and persistent symptoms.
- ***Barrett's esophagus***: Approximately 10% of GERD patients have Barrett's esophagus, which is classified by endoscopic and histological evidence of metaplasia or dysplasia in the mucosal cell lining in the lower portion of the esophagus; approximately 1% of patients annually progress to esophageal cancer.



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

GERD Treatment Paradigm

Approximately 80% of GERD patients are pharmacologically treated with prescription or OTC medications. PPIs are currently the most effective anti-secretory agents available in the United States and Europe for relieving GERD symptoms and healing erosions in gastric mucosa. Our market research suggests that approximately 80% of patients who are pharmacologically treated receive PPIs, and approximately 75% of PPI use is prescription rather than OTC. The majority of PPI use is chronic, with more than 70% of patients prescribed PPIs for daily use. According to IQVIA NDTI, there were approximately 120 million oral PPI prescriptions written in the United States and 6.1 billion doses prescribed for the 12 months ended May 31, 2019.

While PPIs provide clinically meaningful symptom relief and healing for millions of patients suffering from acid-related GI diseases, they are inadequate for many patients. The suboptimal anti-secretory profile of PPIs results in slow onset of symptom relief, breakthrough nighttime or postprandial heartburn, and treatment failure. Approximately 15% to 45% of GERD patients are inadequately treated with PPIs, experiencing persistent, troublesome symptoms, such as heartburn and regurgitation. In approximately two thirds of symptomatic GERD patients, reflux symptoms are not adequately controlled after the first dose of a PPI, and nearly 50% of patients still suffer from symptoms three days later. Given these limitations, more than 20% of GERD patients on PPI therapy are taking their PPI twice daily, which is not FDA approved, or purchasing OTC heartburn treatments in addition to their prescription medicine. In a survey of approximately 1,000 GERD patients and 1,000 physicians, approximately one-third of GERD patients reported persistent symptoms and were dissatisfied with PPI therapy and 35% of physicians perceived patients as somewhat satisfied to completely dissatisfied with PPI treatment. In our U.S. market research study, physicians highlighted control of nighttime and daytime heartburn symptoms and efficacy in the healing and maintenance of healing of esophageal erosions as key unmet needs in GERD and reported that approximately 25% of patients are not satisfied on PPIs.

There are few treatment options for GERD patients who are inadequately managed on PPI therapy. Our U.S. market research survey reported that 26% of patients who are unsatisfied with therapy on a given PPI will switch to a different PPI to improve symptom control or heal esophageal erosions; however, physicians surveyed did not believe there are meaningful differences in outcomes between PPIs. Even though safety and efficacy of twice daily dosing of PPIs has not been evaluated in large controlled clinical studies and is not included on the label for any PPIs, surveyed physicians reported that 23% of patients resort to this dosing regimen given dissatisfaction of once daily PPIs. A limited number of patients proceed to a surgical procedure, such as Nissen fundoplication. However, this procedure results in postoperative morbidity of 5% to 20%, as well as a two- to six-week recovery period and a median hospital stay of two days.

Vonoprazan has the potential to be the first gastric anti-secretory agent from a novel class approved in the United States, Europe, or Canada in over 30 years. Our U.S. market research survey reported that physicians would prefer to use vonoprazan in 59% of all of their GERD patients and believe that vonoprazan’s mechanism of action and gastric pH control is meaningfully improved over PPIs, that vonoprazan could be a more effective treatment than PPIs in healing and maintenance of healing of esophageal erosions, and that vonoprazan would improve their ability to treat GERD patients.

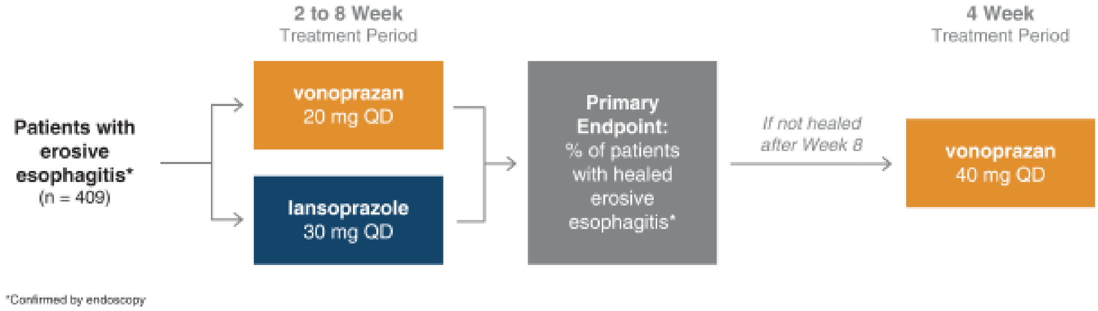
Clinical Data for Vonoprazan in GERD

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

Healing of Erosive Esophagitis Clinical Trials in Japan and Asia

In a Phase 3 multicenter, randomized, double-blind, parallel group trial, 409 patients in Japan with endoscopically confirmed erosive esophagitis were randomized to receive vonoprazan 20 mg QD or lansoprazole 30 mg QD for up to eight weeks. The primary endpoint was the non-inferiority of the percent of patients with healed erosive esophagitis up to Week 8, as assessed by endoscopy. Non-inferiority is intended to show that the effect of a new treatment is not worse than the active control by more than a specified margin, while superiority is intended to show that one treatment is more effective than a comparator by any margin.

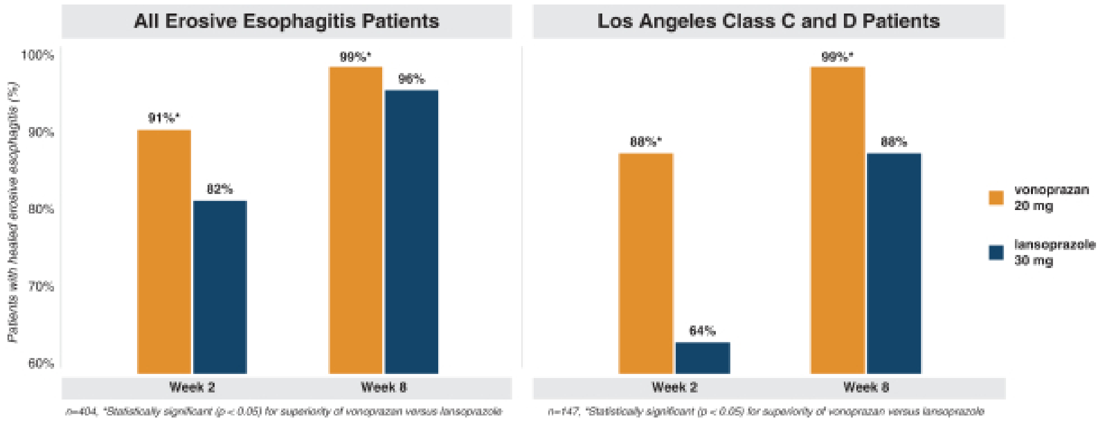
Design of Japan Phase 3 Clinical Trial for the Healing of Erosive Esophagitis



Vonoprazan achieved the primary endpoint of non-inferiority versus lansoprazole on the percent of patients with healed erosive esophagitis up to Week 8 (99% vs. 96%, $p<0.0001$). Further, a post hoc analysis demonstrated that vonoprazan was superior to lansoprazole on the percent of patients with healed erosive esophagitis up to Week 8 ($p=0.0337$). In the subset of 147 patients with more severe erosive esophagitis of Los Angeles Class C or D, vonoprazan healing was also shown to be superior (99% vs. 88%, $p=0.0082$). We believe this result is due to the improved acid control of vonoprazan over lansoprazole, and we believe lansoprazole is representative of the PPI class.

Vonoprazan further demonstrated a more rapid clinical effect versus lansoprazole with a superior healing rate at Week 2 (91% vs. 82%, $p<0.0001$ for non-inferiority and $p=0.0132$ in a post hoc superiority analysis). The treatment effect was more pronounced in the more severe patients with Los Angeles Class C or D disease (88% vs. 64%, $p=0.0008$ for superiority). Of the seven patients who failed lansoprazole treatment and continued into the additional treatment period, six healed with four weeks of treatment of 40 mg vonoprazan QD.

Results of Japan Phase 3 Clinical Trial in the Healing of Erosive Esophagitis



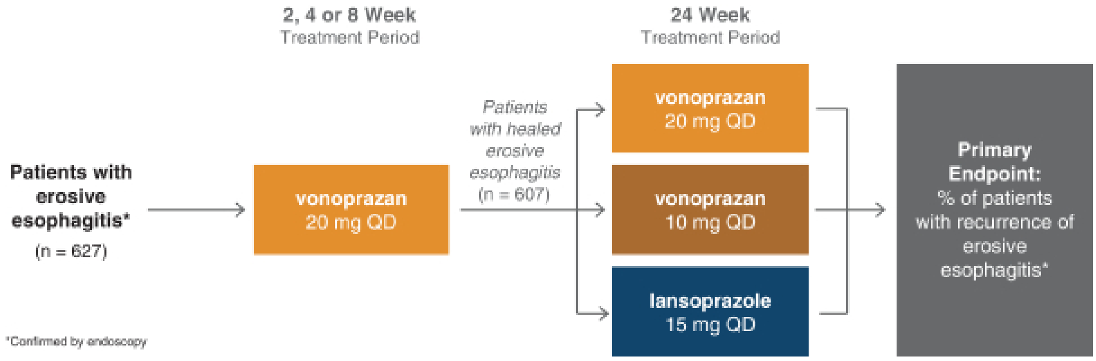
In addition, in the lead-in period of the Japan Phase 3 maintenance of healing clinical trial discussed below, patients were treated with vonoprazan 20 mg for up to eight weeks before proceeding into treatment for the maintenance of healing of erosive esophagitis. The healing rate at Week 2 and through Week 8 during this lead-in healing period was 91% and 99%, respectively.

In another multicenter, randomized, double-blind, parallel group Phase 3 clinical trial in China, Taiwan, Korea, and Malaysia, 481 patients with endoscopically confirmed erosive esophagitis were randomized to receive vonoprazan 20 mg QD or lansoprazole 30 mg QD for eight weeks. Vonoprazan achieved the primary endpoint of non-inferiority versus lansoprazole on the percent of patients with healed erosive esophagitis up to Week 8, 92% and 91%, respectively (95% confidence interval of treatment difference of -3.8% to 6.1%). The difference in healing rates of 1% between the treatment groups had a confidence interval of -3.8 to 6.1, which means that statistically there is 95% certainty that the true difference in healing rates lies within this range of values. Non-inferiority was established in this trial as the lower bound (-3.8%) of the confidence interval was greater than the pre-established non-inferiority margin of -10%.

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

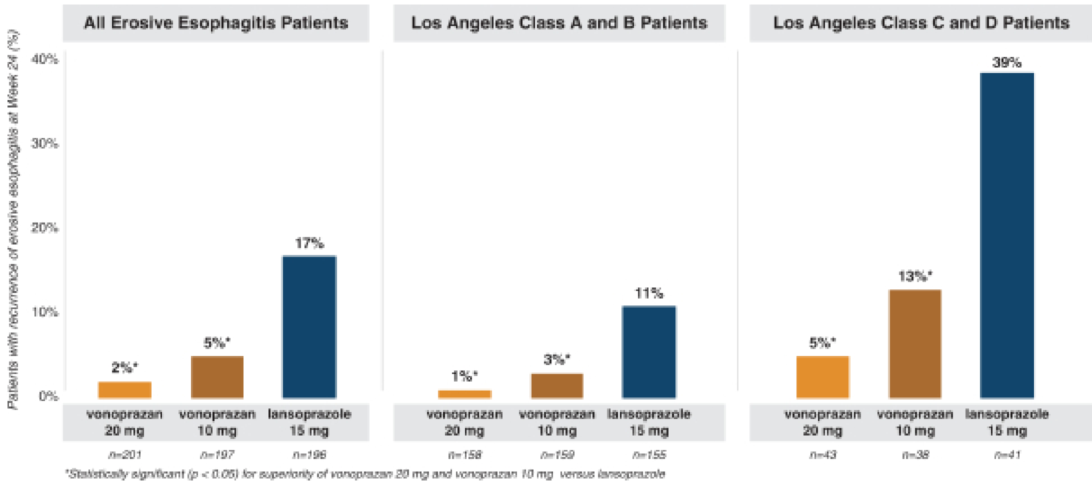
In a multicenter, randomized, double-blind, parallel-group Phase 3 clinical trial in Japan, 627 patients with erosive esophagitis were treated with vonoprazan 20 mg QD for two, four, or eight weeks. After this lead-in period, a total of 607 patients with healed erosive esophagitis, of whom 124 had Los Angeles Class C or D disease, were randomized to receive vonoprazan 10 mg QD, vonoprazan 20 mg QD, or lansoprazole 15 mg QD for 24 weeks. The primary endpoint was the percent of patients with recurrence of erosive esophagitis at Week 24 as assessed by endoscopy.

Design of Japan Phase 3 Clinical Trial in Maintenance of Healing of Erosive Esophagitis



Vonoprazan achieved the primary endpoint of non-inferiority versus lansoprazole on the percent of patients with recurrence of erosive esophagitis during the 24-week maintenance period. Patients on lansoprazole had a 17% recurrence rate of erosive esophagitis after 24 weeks of daily treatment, versus 5% for patients on vonoprazan 10 mg and 2% for patients on vonoprazan 20 mg (p<0.0001 for non-inferiority of both vonoprazan doses vs. lansoprazole). Both vonoprazan doses were superior to lansoprazole in a post hoc analysis (p=0.0002 for vonoprazan 10 mg and p<0.0001 for vonoprazan 20 mg). As shown below, the superiority of each dose of vonoprazan to lansoprazole was demonstrated in both Los Angeles Class A and B patients, as well as the more severe Los Angeles Class C and D patients. We believe this result demonstrates the improved potency and durability of vonoprazan versus lansoprazole in all patients with erosive esophagitis.

Results of Japan Phase 3 Clinical Trial in Maintenance of Healing of Erosive Esophagitis

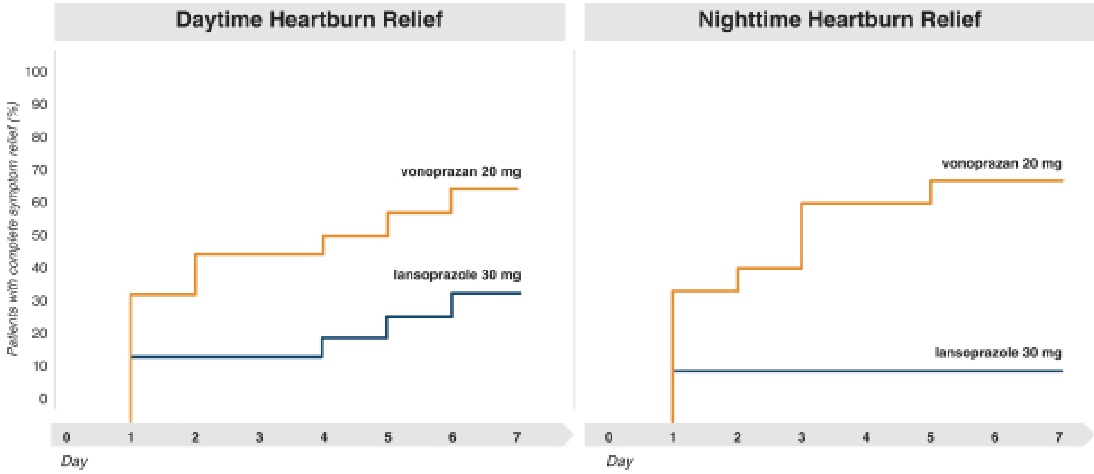


A second multicenter, randomized, double-blind, parallel group Phase 3 clinical trial was conducted in China, Taiwan, and Korea in 703 patients with healed erosive esophagitis, who were randomized to receive vonoprazan 20 mg QD, vonoprazan 10 mg QD, or lansoprazole 15 mg QD for 24 weeks. This trial has been completed, but final results are not yet available.

Symptom Relief

We believe the rapid pharmacodynamic effects of vonoprazan may provide complete and sustained heartburn relief more quickly compared to PPIs. A double-blind, randomized, investigator-sponsored clinical trial in 32 patients with erosive esophagitis compared the effects of vonoprazan 20 mg and lansoprazole 30 mg on the time to achieve complete heartburn relief, defined as seven days without heartburn symptoms. Vonoprazan demonstrated a faster time to complete heartburn relief than lansoprazole, and this complete relief was most pronounced for nighttime heartburn. The results of the trial are summarized below. We plan to evaluate a similar endpoint in our planned Phase 3 clinical trial.

Faster Onset and Higher Rate of Complete Heartburn Relief



On-Demand Dosing

We believe the rapid onset of action of vonoprazan may also enable on-demand, or as needed, use for the relief of symptoms as an alternative to chronic daily treatment. In two open-label, investigator-sponsored clinical trials in Japan, one in erosive esophagitis and a second in NERD, the effectiveness of vonoprazan as an on-demand therapy was compared to that of daily PPI therapy with a number of different PPIs. In both clinical trials, patients utilized approximately 80% fewer doses of vonoprazan compared to PPIs but demonstrated similar levels of patient satisfaction.

Our Erosive Esophagitis Phase 3 Program

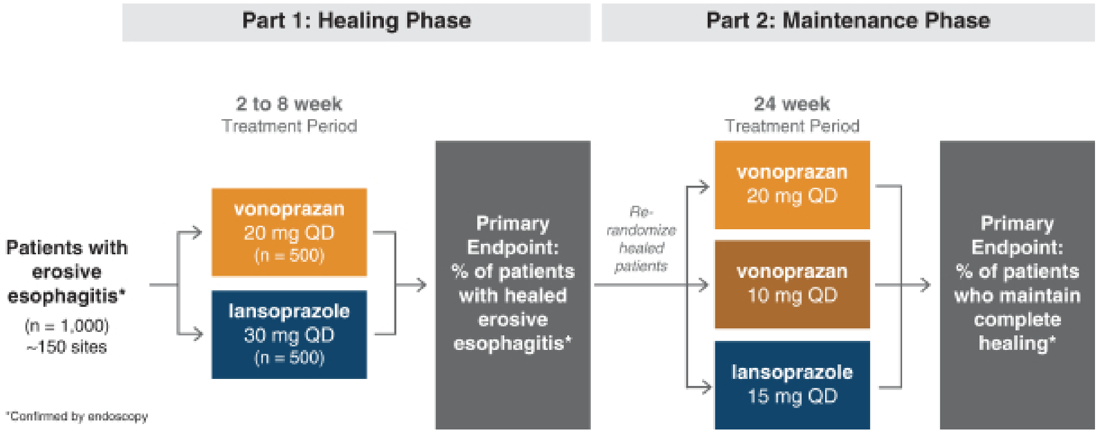
We plan to initiate a single Phase 3 clinical trial of vonoprazan to assess the healing of erosive esophagitis and relief of heartburn, and the maintenance of healing of erosive esophagitis and relief of heartburn in the fourth quarter of 2019. Our IND for vonoprazan in erosive esophagitis was accepted by the FDA in September 2019.

We plan to enroll approximately 1,000 patients with endoscopically confirmed erosive esophagitis in this clinical trial and enrich the clinical trial for more severe patients, targeting 30% Los Angeles Class C or D patients. The clinical trial will have both a healing phase and a maintenance phase. As patients will be re-randomized between the healing phase and the maintenance phase, each phase will be analyzed independently and have independent primary and secondary endpoints.

- ***Healing phase**:* During the healing phase, patients will be randomized 1:1 to receive either vonoprazan 20 mg QD or lansoprazole 30 mg QD for up to eight weeks. The lansoprazole 30 mg QD dose is recommended in the FDA prescribing information for lansoprazole. The primary endpoint for this phase will be the percentage of patients with complete healing of erosive esophagitis by Week 8 as assessed by endoscopy with a primary analysis of non-inferiority. If non-inferiority is demonstrated, then an analysis for superiority will also be performed. Key secondary endpoints will include: the percentage of patients with complete healing of erosive esophagitis at Week 2; percentage of patients with Los Angeles Class C or D erosive esophagitis disease with complete healing at Week 2 and Week 8; percentage of patients with onset of complete heartburn relief by Day 3 of treatment; and the percentage of 24-hour heartburn free days over the healing phase.
- ***Maintenance phase**:* Patients with complete healing of erosive esophagitis at Week 2 or Week 8 in the healing phase will be re-randomized 1:1:1 into the maintenance phase. During this phase, patients will receive either vonoprazan 10 mg QD, vonoprazan 20 mg QD, or lansoprazole 15 mg QD for 24 weeks. The lansoprazole 15 mg QD dose is recommended in the FDA prescribing information for the maintenance of healing indication. The primary endpoint for this phase will be the percent of patients who maintain complete healing after 24 weeks as assessed by endoscopy with a primary analysis of non-inferiority. If non-inferiority is demonstrated, then an analysis for superiority will also be performed. Key secondary endpoints will include the percentage of patients with Los Angeles Class C or D erosive esophagitis disease who maintain complete healing after 24 weeks and the percentage of 24-hour heartburn free days over the maintenance phase.

Our Phase 3 trial design is modeled after the successful Phase 3 clinical trials conducted in Japan and Asia with limited differences other than combining both the healing and maintenance of erosive esophagitis into a single study. In Japan and Asia, separate clinical trials were conducted for each of these indications. We believe we can simplify patient recruitment by conducting a single clinical trial and re-randomizing patients between phases.

Design for Planned Phase 3 Erosive Esophagitis Clinical Trial



We expect to report top-line data from this trial in 2021 and, if successful, file a regulatory submission for marketing approval in 2022.

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

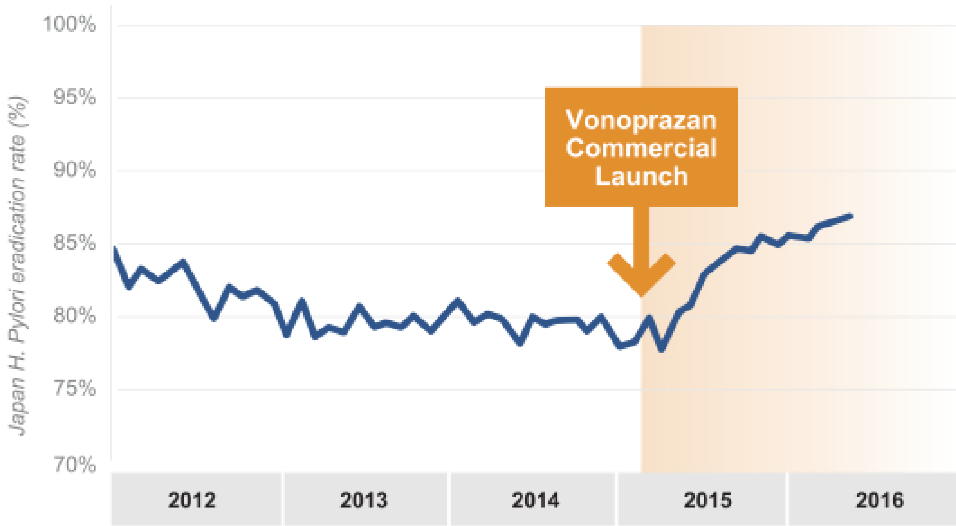
Disease Burden and Outcomes

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

H. pylori eradication rates have fallen from >90% in the 1990s to current rates of <80% due to increasing antibiotic resistance. In 2017, the World Health Organization (WHO) listed *H. pylori* among the 16 antibiotic-resistant bacteria that pose the greatest threat to human health and designated *H. pylori* as a Class 1 carcinogen, meaning that it is a definite known cause of cancer. In 2014, the FDA added *H. pylori* to the agency's list of qualifying pathogens that have the potential to pose a serious threat to public health under the GAIN Act. We believe that vonoprazan-based treatment regimens have the potential to restore eradication rates to greater than 90% in the United States and Europe given the clinical and post-marketing experience in the Japanese market.

A recent study compiled real-world health insurance claims data in Japan from 2008 to 2016 for *H. pylori* eradication. Prior to vonoprazan's approval in late 2014, the *H. pylori* eradication rate across Japan fell to below 80% as shown in the figure below. Approximately one year after vonoprazan's launch, the eradication rate increased to greater than 85%. From January 2015 to March 2016, the eradication rate with PPI-containing regimens in Japan was between 78% and 82% while the eradication rate with vonoprazan-containing regimens was 91% across all claims in this analysis.

Eradication Rate of *H. pylori* Infection in Japan Before and After Launch of Vonoprazan



In Japan, vonoprazan-containing regimens have become the most common first line treatment. One-year post launch, approximately 80% of all treated *H. pylori*-infected patients received vonoprazan-based regimens as shown below.

Current Treatment Paradigm in the United States and Europe

The ACG treatment guidelines for *H. pylori* infection recommend using PPIs in conjunction with antibiotics to improve antibiotic efficacy against *H. pylori* infection. The use of anti-secretory agents enhances the effect of antibiotics in two ways. First, anti-secretory agents increase gastric pH, which in turn increases the stability of the antibiotics. For example, amoxicillin and clarithromycin are chemically unstable at the low pH typically found in the human stomach. Second, several antibiotics, including amoxicillin and clarithromycin, are most potent against *H. pylori* at the time of maximum bacterial replication, which occurs at pH 6.0 to 7.0. *H. pylori* is in a dormant state at lower pH values, which reduces the effectiveness of the antibiotics.

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

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

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

A triple therapy regimen (PPI, clarithromycin, and either amoxicillin or metronidazole) is the most commonly used in clinical practice for the first-line treatment of *H. pylori* infection. However, *H. pylori* eradication rates with PPI triple therapy have fallen from >90% in the 1990s to current levels of <80%, primarily due to increased resistance of *H. pylori* to clarithromycin and metronidazole. A recent meta-analysis indicates that U.S. resistance rates measured from 2012 to 2016 were 20% for clarithromycin, 29% for metronidazole, and 19% for levofloxacin. These figures represent a marked increase from 2009 to 2011 for both clarithromycin and metronidazole, for which resistance was 9% for clarithromycin, 21% for metronidazole, and 11% for levofloxacin. *H. pylori* resistance to amoxicillin remains low despite its use in most triple therapy regimens; resistance is generally <2% among isolates in the United States and Europe. There is a similar trend of increasing resistance to key antibiotics in Europe.

Given the declining eradication rates for *H. pylori,* quadruple therapy is recommended as first-line treatment in areas with known high rates of clarithromycin or metronidazole resistance; however, our U.S. market research study reported that physicians prescribe quadruple therapy to only 17% of first-line patients. The surveyed physicians are concerned with patient adherence to treatment and patient compliance and tolerability issues associated with dosing multiple drugs at multiple times throughout the day. Further, geographic patterns of resistance in the United States are poorly understood and treatment is largely empiric, with susceptibility testing rarely conducted prior to first-line treatment. Our U.S. market research study reported that only 8% and 16% of physicians conduct resistance testing prior to prescribing treatment for first-line and second-line *H. pylori* infection, respectively.

In our U.S. market research study, physicians highlighted the need for more effective and simpler first-line treatment options. For the treatment of *H. pylori* infection, surveyed physicians highlighted the declining eradication rate and low patient compliance rate with treatment regimens as key unmet needs, and 93% of these physicians believe that vonoprazan offers clinically meaningful benefits over PPIs. Surveyed physicians reported that they would prefer to use vonoprazan dual or triple therapy in, on average, 67% of first-line and 69% of second-line patients with *H. pylori* infection.

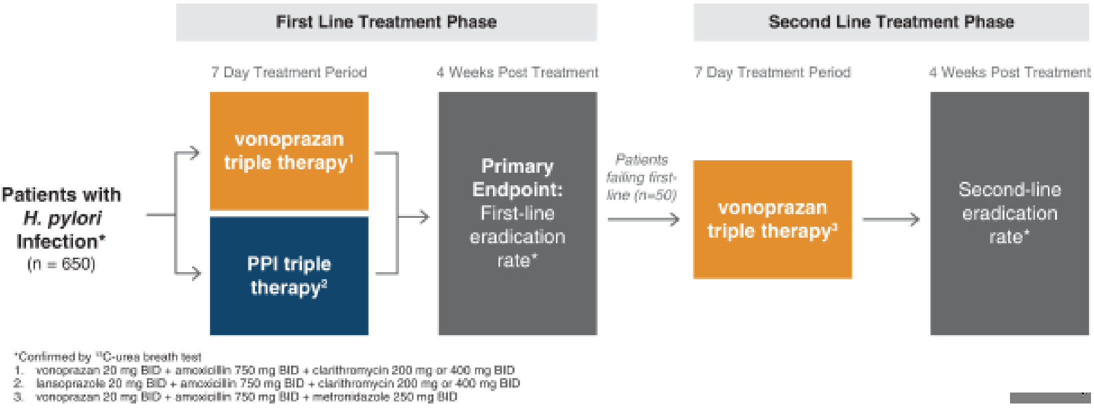
Phase 3 Clinical Trial in Japan of Vonoprazan in Combination with Antibiotics to Treat H. pylori Infection

A randomized, double-blind, multicenter Phase 3 clinical trial in *H. pylori*-positive patients was completed in Japan. Patients with *H. pylori* infection and a history of gastric or duodenal ulcer who had not previously received *H. pylori* treatment were eligible for inclusion in the clinical trial. A total of 650 patients were randomized to receive seven days of:

- ***vonoprazan triple therapy***: vonoprazan 20 mg twice daily, or BID, amoxicillin 750 mg BID, and clarithromycin (200 mg or 400 mg) BID; or
- ***lansoprazole triple therapy***: lansoprazole 30 mg BID, amoxicillin 750 mg BID, and clarithromycin (200 mg or 400 mg) BID.

Patients who did not achieve *H. pylori* eradication after first-line treatment received a second-line regimen of vonoprazan 20 mg BID, amoxicillin 750 mg BID, and metronidazole 250 mg BID for seven days.

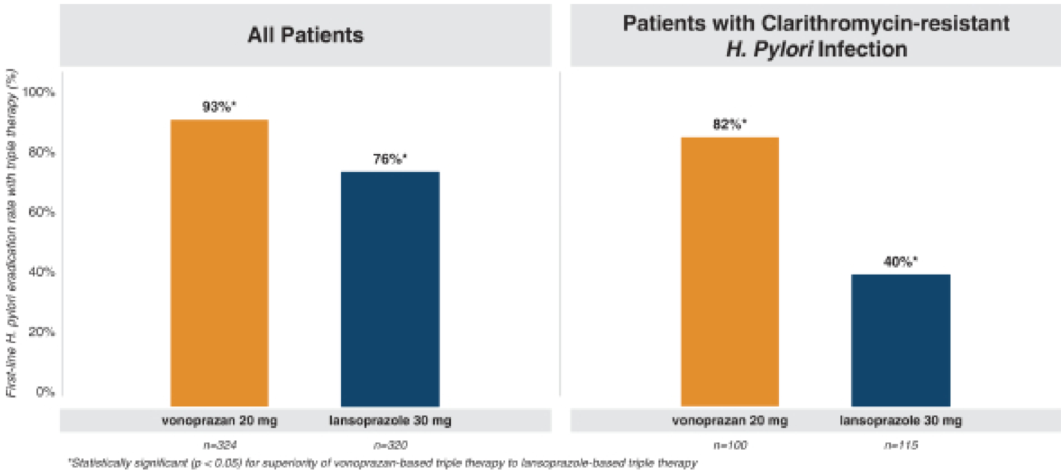
Design of Japan Phase 3 *H. pylori* Treatment Clinical Trial



The primary endpoint of the clinical trial was confirmed *H. pylori* eradication determined by ^{13}C-urea breath test, a standard test for the diagnosis of *H. pylori*, four weeks after the completion of treatment. The primary analysis was non-inferiority, and key secondary endpoints included the second line eradication rate and eradication rate in antibiotic-resistant subgroups.

Vonoprazan-based triple therapy demonstrated a non-inferior eradication rate of 93% compared to 76% for lansoprazole-based triple therapy (p<0.0001). Post hoc analyses indicated that vonoprazan-based triple therapy was superior to lansoprazole-based triple therapy (p<0.0001). Patients who were not eradicated on vonoprazan-based triple therapy or lansoprazole-based triple therapy were treated with a triple therapy regimen of vonoprazan, amoxicillin, and metronidazole. In this second-line setting, the *H. pylori* eradication rate with vonoprazan triple therapy was 98%. Across first- and second-line patients, the *H. pylori* eradication rate in clarithromycin resistant strains was higher with vonoprazan-based triple therapy (82%) than with lansoprazole-based triple therapy (40%) as shown below. We believe that this result is significant, as *H. pylori* antibiotic resistance testing is rare in the United States, and *H. pylori* treatment is generally empiric.

Results of Japan Phase 3 Clinical Trial in the Treatment of *H. pylori* Infection

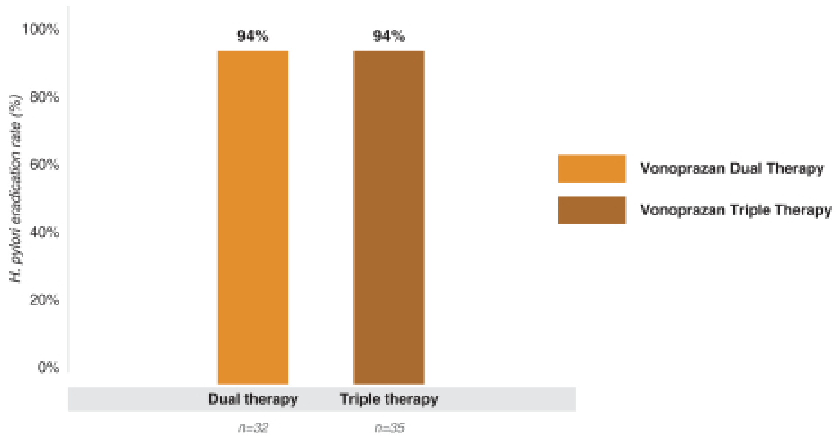


Other Studies of Vonoprazan in H. pylori Treatment

A meta-analysis of 14 studies in Japan with over 14,636 patients found that the pooled eradication rates of vonoprazan-containing regimens were superior to those of PPI-containing regimens in a first-line setting (85% vs. 68%, p<0.00001). Subgroup analysis further indicated the superiority of vonoprazan in patients with either clarithromycin-resistant strains (82% vs. 41%, p<0.00001) or clarithromycin-susceptible strains (95% vs 90%, p=0.006). A second study retrospectively confirmed that empiric vonoprazan-based triple therapy was non-inferior to PPI-based triple therapy based on *H. pylori* antibiotic susceptibility testing.

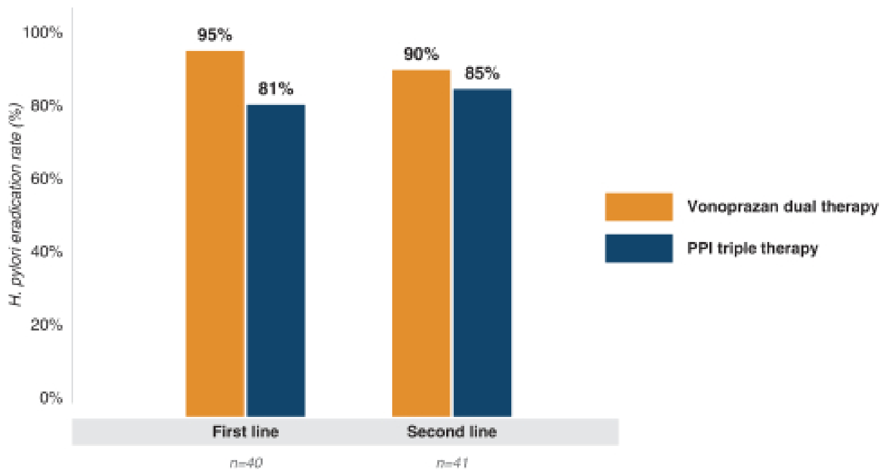
In addition to demonstrating superiority to PPIs in triple therapy regimens, vonoprazan was studied in a dual therapy regimen with amoxicillin in two investigator-initiated clinical trials in Japan. The first trial involving 67 Japanese patients assessed vonoprazan dual therapy (vonoprazan 20 mg BID in combination with amoxicillin 500 mg three times daily, or TID, for seven days) compared to vonoprazan triple therapy (vonoprazan 20 mg BID in combination with amoxicillin 750 mg BID and clarithromycin 200 mg BID for seven days). As shown below, vonoprazan dual therapy was similarly efficacious to vonoprazan triple therapy (eradication rates of 94% in both treatment arms).

Results of Vonoprazan Dual and Triple Therapy in the Treatment of *H. pylori* Infection



A second clinical trial compared vonoprazan-based dual therapy to esomeprazole or rabeprazole PPI-based triple therapy. This clinical trial enrolled 81 Japanese patients including 40 first-line treatment patients and 41 second-line treatment patients who had failed standard therapy and compared vonoprazan dual therapy and PPI triple therapy in both first- and second-line therapy. Patients assigned to vonoprazan dual therapy were treated with vonoprazan 20 mg BID in combination with amoxicillin 500 mg TID for seven days. Patients assigned to PPI triple therapy were treated first-line with esomeprazole 20 mg or rabeprazole 10 mg BID, amoxicillin 750 mg BID, and clarithromycin 200 mg BID or second-line with esomeprazole 20 mg or rabeprazole 10 mg BID, amoxicillin 750 mg BID, and metronidazole 250 mg BID for seven days. As shown below, dual therapy with vonoprazan was efficacious in both first- and second-line therapy with eradication rates of 95% and 90%, respectively, versus 81% and 85% for PPI-based triple therapies.

Results of Vonoprazan Dual and PPI Triple Therapy in the Treatment of *H. pylori* Infection



Antibiotic resistance is a significant clinical issue, and we believe that vonoprazan has the potential to address the growing resistance to *H. pylori* by eradicating infection after first-line of treatment. Vonoprazan dual therapy has further potential for improved convenience and compliance over triple or quadruple therapy regimens, and importantly, spares the use of clarithromycin, metronidazole, and levofloxacin, representing an opportunity both for effective treatment and sound antibiotic stewardship through the avoidance of additional antibiotics to which *H. pylori* is known to acquire resistance. Less frequent use of these antibiotics, which have important roles aside from the treatment of *H. pylori* infection, may help to limit the spread of resistance among other pathogenic bacteria within populations.

Our H. pylori Phase 3 Program

We plan to initiate a Phase 3 clinical trial of vonoprazan for the treatment of *H. pylori* infection. Our INDs for vonoprazan in treatment of *H. pylori* infection were accepted by the FDA in September 2019. In August 2019, we received QIDP designation from the FDA for vonoprazan in combination with both amoxicillin and clarithromycin and in combination with amoxicillin alone for the treatment of *H. pylori* infection. Subject to limited exceptions, QIDP designation extends any non-patent marketing exclusivity by an additional five years, and also provides potential eligibility for priority review and fast track designation.

We plan to enroll approximately 975 patients with *H. pylori* infection as assessed by ^{13}C-urea breath test in this clinical trial. The clinical trial will compare vonoprazan dual therapy and vonoprazan triple therapy regimens each head-to-head with a standard of care lansoprazole triple therapy regimen. Patients will be randomized in a 1:1:1 manner into the three treatment arms as follows:

- ***vonoprazan dual therapy***: vonoprazan 20 mg BID and amoxicillin 1 g TID for 14 days;
- ***vonoprazan triple therapy***: vonoprazan 20 mg BID, amoxicillin 1 g BID and clarithromycin 500 mg BID for 14 days; and
- ***PPI triple therapy***: lansoprazole 30 mg BID, amoxicillin 1 g BID and clarithromycin 500 mg BID for 14 days.

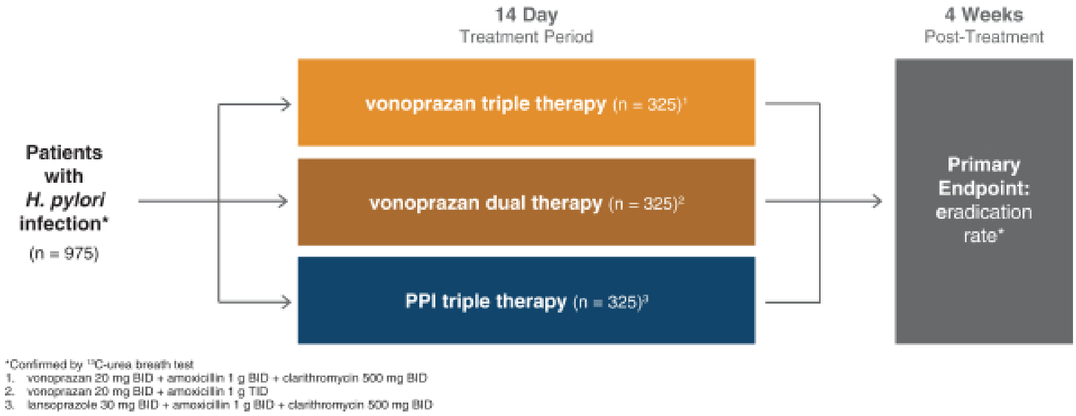
The primary endpoint for this trial will be the percentage of patients with successful eradication of *H. pylori* infection as assessed by ^{13}C-urea breath test four weeks after completion of treatment. The primary analysis will assess the non-inferiority of vonoprazan dual therapy to lansoprazole triple therapy and vonoprazan triple therapy to lansoprazole triple therapy excluding patients who have *H. pylori* infection that is resistant to clarithromycin or amoxicillin. We will also conduct secondary analyses for superiority in all patients regardless of antibiotic resistance and in patients with clarithromycin-resistant *H. pylori* infection.

Our Phase 3 trial design is modeled after the successful Phase 3 clinical trial conducted in Japan. Key differences include:

- ***Inclusion of patients with H. pylori infection and dyspeptic symptoms****.* Our clinical trial will enroll patients with active *H. pylori* infection and dyspeptic symptoms. The Japan Phase 3 trial enrolled patients with *H. pylori* infection and a history of gastric or duodenal ulcers;
- ***Treatment duration and antibiotic doses****.* Standard of care regimens in Western countries include higher doses of antibiotics and a longer duration of treatment (typically 14 days) than in Japan (typically seven days); and
- ***Inclusion of dual therapy arm****.* Vonoprazan dual therapy has only been studied in investigator-initiated clinical trials and not yet in a pivotal trial.

Our clinical trial design conforms to standard of care treatment regimens in the United States and Europe and follows the ACG treatment guidelines.

Design for Planned Phase 3 *H. pylori* Clinical Trial

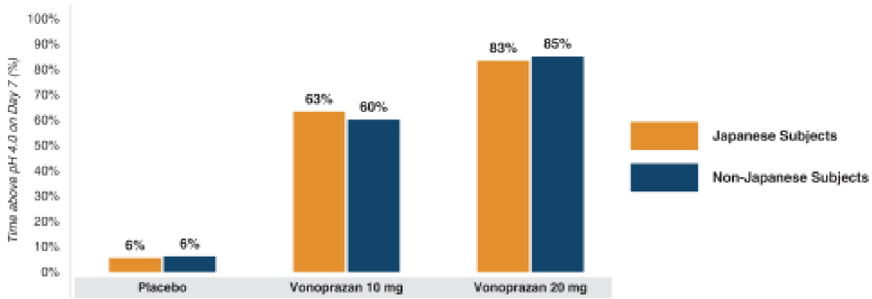


We expect to report top-line data from this trial in 2021 and, if successful, file a regulatory submission for marketing approval in 2021.

Vonoprazan Pharmacokinetics and Pharmacodynamics in Japanese vs. non-Japanese Subjects

The vonoprazan pharmacokinetic and pharmacodynamic profile is similar between Japanese and non-Japanese subjects as assessed in two randomized, double-blind, placebo-controlled Phase 1 clinical trials in healthy volunteers. Sixty Japanese subjects in the first study and 48 non-Japanese subjects in the second study, of whom 85% were Caucasian, received doses from 10 mg up to 40 mg QD for seven consecutive days. At all doses, pharmacokinetics between the two populations were similar. In addition, the pharmacodynamics were similar between Japanese and non-Japanese subjects as shown in the figure below. On Day 7, mean time above pH 4.0 for vonoprazan 20 mg QD was 83% for Japanese subjects and 85% for non-Japanese subjects. Night-time 12-hour time above pH 4.0 was 73% for Japanese subjects and 75% for non-Japanese subjects. We believe that these results show that vonoprazan has a similar profile in Japanese and non-Japanese subjects.

Comparative Pharmacodynamics of Vonoprazan in Japanese and non-Japanese Subjects



Summary of Vonoprazan Safety Data

Safety in Clinical Studies

As of December 2018, 6,683 subjects have been exposed to vonoprazan in completed and ongoing Phase 1 to 3 clinical trials. The doses studied have ranged from 1 to 120 mg with durations up to one year. The most commonly reported adverse events, or AEs, in the clinical development program for vonoprazan, as reflected in the Japanese prescribing information published by Japan's Pharmaceuticals and Medical Devices Agency, or PMDA, were diarrhea, constipation, nausea, elevated liver enzymes, rash, and eosinophilia. All such events had an incidence rate of less than 5.0% other than diarrhea in the treatment of *H. pylori* which had an incidence rate of 10.6% in combination with antibiotics. No dose-related increase in treatment-emergent AEs, or TEAEs, or serious AEs was observed. The safety profile of vonoprazan and incidence of TEAEs, drug-related TEAEs, and TEAEs leading to drug discontinuation were similar between vonoprazan and lansoprazole across studies.

Certain earlier generation P-CABs previously under development by other companies may have been discontinued in-part due to their hepatic safety profile. These hepatic safety concerns may be compound-specific and not generalizable to the P-CAB class. It is notable that vonoprazan is based on a pyrrole chemical structure and is chemically distinct from previously discontinued P-CABs that were based on an imidazole structure. Vonoprazan has had a similar hepatic safety profile to lansoprazole across all clinical studies conducted by Takeda, in which 1.0% of subjects treated with vonoprazan 10 mg or 20 mg and 0.8% of subjects treated with lansoprazole 15 mg or 30 mg had ALT or AST elevations greater than three times the upper limit of normal or bilirubin elevations greater than two times the upper limit of normal.

Vonoprazan Post-Marketing Safety in Japan

The most recent post-marketing safety report from December 2018 includes an estimated 23 million patients who have received vonoprazan in Japan since its launch. Based on the post-marketing experience, the clinically significant adverse reactions section of the Japanese prescribing information for vonoprazan was updated to include skin reactions such as toxic epidermal necrolysis, Steven-Johnson syndrome, and erythema multiforme. The incidence of these skin reactions was considered extremely rare (less than 1 in 100,000 patients) and a causal relationship to vonoprazan could not be ruled out.

Serious hepatic adverse events have also been observed among patients exposed to vonoprazan in Japan in the post-marketing setting. These cases were typically confounded by comorbidities or other concomitant medications and believed to be idiosyncratic reactions. The incidence of these events was considered extremely rare (less than 1 in 100,000 patients). The post-marketing safety data, including the December 2018 post-marketing safety report and the reported hepatic safety events, have been submitted to the PMDA. To date, there have been no changes to the Japan prescribing information related to hepatic safety.

Vonoprazan Launch in Japan

Vonoprazan Regulatory Status

Vonoprazan first received approval in Japan on December 26, 2014 as TAKECAB® for the following indications:

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

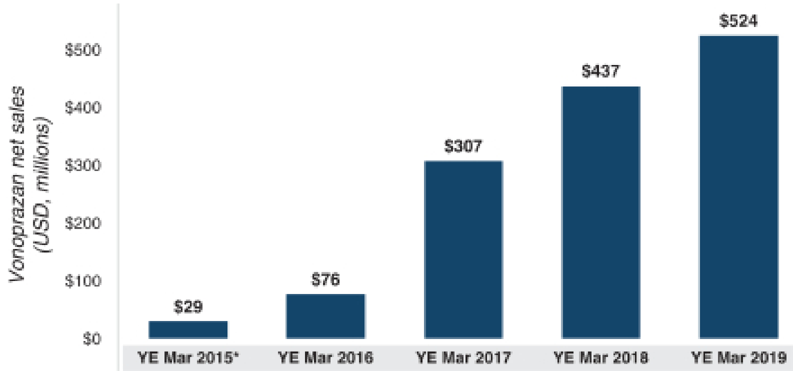
- Prevention of recurrence of gastric ulcer or duodenal ulcer during nonsteroidal anti-inflammatory drug (NSAID) administration.

Vonoprazan was subsequently approved in Japan in February 2016 for the treatment of *H. pylori* in combination packs with antibiotics (Vonosap Pack 400, Vonosap Pack 800, and Vonopion Pack), and as VOCINTI in the Philippines (October 2017), Singapore (March 2018), Thailand (July 2018), Argentina (September 2018), Peru (September 2018), South Korea (March 2019), Taiwan (March 2019), and Malaysia (May 2019). Vonoprazan is currently under review for approval by regulatory authorities in additional countries in Latin America and Asia, including China.

Vonoprazan Commercialization in Japan

Vonoprazan was approved in Japan in December 2014. In its fourth full year on the market vonoprazan generated $524 million in net sales, a 20% increase over the prior year. In addition, in the quarter ended June 30, 2019, vonoprazan generated $164.7 million in net sales, a 28% increase over the corresponding quarter from the prior fiscal year.

Vonoprazan Net Sales Since Approval



* Vonoprazan was approved in Japan in December 2014

We believe that the market dynamic for anti-secretory agents in Japan is similar to that in the United States. In both countries, the anti-secretory market is largely genericized. Ahead of the vonoprazan launch in Japan, all PPIs, other than Nexium, were available as generics. As of 2017, generic drugs in Japan represent approximately 70% of the market by volume, compared to the United States where generics are approximately 90% of the market by volume. Additionally, the Japanese government set a goal to increase generic use to 80% by 2020. Although vonoprazan and Dexilant are priced at a premium to generic PPIs in Japan and the United States, respectively, both have experienced commercial success.

Vonoprazan Commercial Opportunity and Strategy

The market for prevention and treatment of acid-related GI diseases in the United States and Europe is large. There were approximately 120 million oral PPI prescriptions written in the United States and 6.1 billion doses prescribed for the 12 months ended May 31, 2019. We estimate there are approximately 65 million individuals with GERD in the United States and 50 million individuals with GERD in the EU5, of whom 15% to 45% are inadequately treated with PPIs. In addition, we estimate that there are approximately 115 million individuals in the United States, of which 2.5 million are treated each year, and 145 million individuals in the EU5 infected with *H. pylori*.

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

As recently as 2015, the last branded PPI, Dexilant, reached approximately $530 million in sales in the United States despite limited differentiation from other PPIs. As of June 30, 2019, Dexilant was priced at a significant premium to generic PPIs on the market. Even with premium pricing, Dexilant obtained broad insurance coverage and favorable access. As of June 30, 2019, approximately 90% of commercially covered lives and 80% of Medicare covered lives had access to Dexilant. Furthermore, of those commercially covered lives, 65% had unrestricted access to the drug without prior authorization or step edits and 35% of patients had access at the lowest branded cost tier. We believe that, if approved in our markets, vonoprazan will be the first of the next generation of anti-secretory therapies to improve the standard of care for acid-related GI diseases by providing a safe and effective treatment option for the millions of patients in need of more potent, rapid, or durable acid suppression. Additionally, we believe the potential differentiation of vonoprazan compared to PPIs could result in attractive market access and formulary positioning.

In July 2019, we conducted a U.S. market research study which surveyed 100 gastroenterologists and 100 primary care physicians who commonly prescribe PPIs and treat patients with GERD and *H. pylori* infection. For the treatment of GERD, surveyed physicians highlighted control of nighttime and daytime heartburn symptoms and efficacy in the healing and maintenance of healing of esophageal erosions as key unmet needs. These physicians reported that vonoprazan's mechanism of action and gastric pH control is considered meaningfully improved over PPIs and that vonoprazan could be a more effective treatment than PPIs in healing and maintenance of healing of esophageal erosions. These physicians would prefer to use vonoprazan in, on average, 59% of all of their GERD patients. For the treatment of *H. pylori* infection, surveyed physicians highlighted the declining eradication rate and low patient compliance rate with treatment regimens as key unmet needs, and 93% of these physicians believe that vonoprazan offers clinically meaningful benefits over PPIs. Surveyed physicians reported that they would prefer to use vonoprazan dual or triple therapy in, on average, 67% of first-line and 69% of second-line patients with *H. pylori* infection.

Sales and Marketing

We do not currently have our own marketing, sales, or distribution capabilities. We plan to independently commercialize vonoprazan in the United States by building a leading specialty gastroenterology-focused commercial infrastructure to support the adoption of vonoprazan. We believe we can successfully launch vonoprazan in the United States with a focused specialty sales force targeting high prescribers of PPIs, particularly gastroenterologists. PPI prescribing is highly concentrated with approximately 1.5% of U.S. PPI prescribers (approximately 12,000 total) accounting for approximately 20% of PPI prescriptions and approximately 6.0% of U.S. PPI prescribers (approximately 50,000 total) accounting for approximately 50% of PPI prescriptions, according to IQVIA. We believe we have an opportunity to achieve significant share of voice and exposure to physicians given the scarcity of actively marketed anti-secretory medicines.

To address the commercial opportunity for vonoprazan in Europe and Canada, we plan to seek one or more partners with existing commercial infrastructure and expertise in these markets. Additional clinical trials of vonoprazan may be required to obtain regulatory approval and/or ensure access to these markets.

Additional Vonoprazan Development Opportunities

Indications

While we are initially focused on the development of vonoprazan for the treatment of erosive esophagitis and the treatment of *H. pylori* infection, we believe there are opportunities to expand the use of vonoprazan to other indications in our licensed territories. For example, in Japan, vonoprazan is also approved for the treatment of gastric ulcers, treatment of duodenal ulcers, prevention of recurrence of gastric ulcer or duodenal ulcer during low-dose aspirin administration, and prevention of recurrence of gastric ulcer or duodenal ulcer during NSAID administration.

In addition to those indications for which vonoprazan is approved in Japan, we believe there are additional opportunities to develop vonoprazan for the treatment of GI diseases.

NERD. We believe that there is opportunity to broadly position vonoprazan's use in GERD with an indication in NERD, also known as symptomatic GERD, in addition to an indication in erosive esophagitis. We may develop vonoprazan in NERD with daily and/or on-demand, or as-needed, dosing regimens. We believe the rapid onset of action of vonoprazan may enable on-demand use for the management of GERD-related symptoms as an alternative to chronic daily treatment with PPIs. An on-demand dosing regimen may be especially attractive in NERD, as NERD patients have symptoms related to acid, but do not have esophageal erosions which require chronic treatment for healing. In an open-label, investigator-sponsored clinical trial in Japan in NERD patients, on-demand treatment with vonoprazan was compared to daily treatment with PPIs. Patients utilized approximately 80% fewer doses of vonoprazan compared to PPIs, but demonstrated similar levels of satisfaction.

Takeda conducted two Phase 3 multicenter, randomized, double-blind, parallel group trials with vonoprazan in Japanese patients with endoscopically confirmed NERD. In the first clinical trial, vonoprazan demonstrated a significant reduction in symptom severity versus placebo ($p=0.0139$), and in the second trial, vonoprazan demonstrated a faster onset of symptom relief versus placebo ($p=0.0003$). However, the studies did not show a statistically significant difference in the primary endpoint of proportion of days over a 4-week period without heartburn between vonoprazan and placebo ($p=0.0504$ and $p=0.0643$). In the first clinical trial, Takeda enrolled patients with symptoms including a three-week history of heartburn or regurgitation with two or more days of heartburn per week, or a three-week history of any acid-reflux symptoms of moderate or higher severity. In the second clinical trial, patients with a three-week history of recurrent heartburn with two or more days of heartburn per week were enrolled. We believe that these results may be due to the selection of patients with a limited history of symptoms, a low threshold for frequency of symptoms of two or more days per week, and with mostly mild to moderate symptoms rather severe symptoms. In contrast, all PPIs approved for NERD in the United States enrolled subjects with greater than six-month history of heartburn and heartburn on at least four of the seven days immediately preceding randomization.

In addition, in a Phase 2 clinical trial in European patients with NERD who were partial responders to high dose PPIs, vonoprazan did not demonstrate superiority versus esomeprazole in the primary endpoint of the percentage of heartburn free days over the four-week treatment period. We believe this result may have been due to inclusion of patients with GI disorders unrelated to acid.

Other Indications. Barrett's esophagus and Zollinger Ellison syndrome are severe diseases related to acid secretion where PPIs are the current standard of care. The improved acid control of vonoprazan relative to PPIs may lead to improved results over PPIs.

Eosinophilic esophagitis is an autoimmune disease with significant unmet need. Although not approved for this indication, PPIs are prescribed for the treatment of eosinophilic esophagitis. Vonoprazan demonstrated similar efficacy to PPIs in an investigator-sponsored clinical trial in Japan. In this clinical trial, 112 patients with eosinophilic esophagitis were treated with vonoprazan, or the PPI rabeprazole or esomeprazole. Of patients treated with vonoprazan, 82% had complete relief of symptoms compared to 70% for esomeprazole and 76-78% for rabeprazole. Similarly, 35% of patients treated with vonoprazan demonstrated complete remission of eosinophilic esophagitis by histology, compared to 37% for esomeprazole and 31-38% for rabeprazole.

Formulations and Packaging

Orally Disintegrating Tablet*.* An orally disintegrating tablet, or ODT, formulation for vonoprazan is currently in development by Takeda. We may conduct one or more Phase I trials to support potential approval of the ODT formulation. We believe that the ODT represents a meaningful commercial opportunity for patients with difficulty swallowing, as estimated peak U.S. sales of the lansoprazole ODT formulation were over $450 million.

Intravenous Formulation*.* We are exploring the potential to develop an intravenous formulation of vonoprazan for use in acute bleeding, critically ill patients, or other in-hospital applications. Several PPIs have approved intravenous formulations.

Pediatric Formulation*.* We are exploring the potential to develop an oral formulation, in addition to an ODT formulation, for pediatric use.

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

Over the Counter Use

We believe that vonoprazan has the ideal profile for an OTC product, including the potential for on-demand symptom relief and a well-tolerated safety profile. The market for OTC heartburn relief is substantial, with 2018 sales of $3.2 billion in the United States.

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. If vonoprazan receives marketing approval in the United States, Europe or Canada, it will compete with existing therapies and new therapies that may become available in the future.

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

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

We expect that vonoprazan, if approved for the treatment of erosive esophagitis and treatment of *H. pylori* infection, will primarily compete with generic PPIs marketed by multiple pharmaceutical companies in both the prescription and OTC markets. Additionally, RedHill Biopharma Ltd. is developing Talicia, a co-formulated capsule comprising generic omeprazole, amoxicillin, and rifabutin for the treatment of *H. pylori* infection, and filed a new drug application, or NDA, in the United States in May 2019. Ironwood Pharmaceuticals, Inc. is developing IW-3718, a bile acid sequestrant, currently in Phase 3 clinical trials as an adjunct to PPIs for the treatment of patients with persistent GERD.

We are also aware of other P-CABs in territories outside of the United States that, if developed and approved in our territories, may compete with vonoprazan. Revaprazan is marketed by Yuhan Corporation in South Korea. Tegoprazan is marketed by CJ Healthcare Corp. in South Korea and is currently in Phase 3 development in Japan by RaQualia Pharma, Inc. Daewoong Pharmaceutical Co., Ltd.'s DWP14012 has been studied in Phase 2 clinical trials in South Korea, and Cinclus Pharma AG's X842 has completed a Phase 1 clinical trial in Europe. To our knowledge, none of these compounds have demonstrated superiority to PPIs on clinical endpoints.

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

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 currently rely on Takeda to supply us with vonoprazan drug product for clinical use. We intend to enter into a commercial supply agreement with Takeda, and we are exploring additional options for commercial supply of vonoprazan from other third party contract manufacturers.

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

Intellectual Property

Intellectual property, including patents, trade secrets, trademarks and copyrights, is important to our business. Our commercial success depends in part on our ability to obtain and maintain proprietary intellectual property protection for vonoprazan, as well as for future product candidates and novel discoveries, product development technologies, and know-how. Our commercial success also depends in part on our ability to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to develop and maintain protection of our proprietary position by, among other methods, licensing or filing U.S. and foreign patents and applications relating to our technology, inventions, and improvements that are important to the development and implementation of our business.

Our patent portfolio, comprising patents and patent applications exclusively licensed to us, is built with a goal of establishing broad protection that generally includes, for the product candidate compound, claims directed to composition of matter, pharmaceutical compositions or formulations, methods of synthesis, and methods of treatment using such pharmaceutical compositions or formulations. As of September 30, 2019, our patent portfolio covering vonoprazan consists solely of exclusively licensed patents and patent applications from Takeda. Subject to the terms of the license agreement we entered into with Takeda on May 7, 2019, or the Takeda License, we have licensed from Takeda exclusive rights in the United States, Europe, and Canada to patents and patent applications covering the composition of matter, formulation, use and/or manufacture of vonoprazan. Our patent portfolio comprises 11 distinct patent families protecting the technology relating to the compound vonoprazan and its synthetic intermediates, methods of synthesizing vonoprazan and related compounds, various formulations of vonoprazan products, as well as methods of treating diseases with vonoprazan and related compounds. As of September 30, 2019, our portfolio consists of approximately 17 issued U.S. patents, 6 pending U.S. applications, 9 issued European patents subsequently validated in individual European countries, 6 pending European applications, 3 issued Canadian patents, 5 pending Canadian applications, and one pending PCT application. The issued patents and pending applications have nominal expiration dates ranging from 2024 to 2038, without accounting for any available patent term adjustments or extensions. The issued U.S. patent covering the composition of matter of vonoprazan is expected to expire in August 2028, not including patent term extension. The issued U.S. patent covering the formulation of vonoprazan is expected to expire in August 2030, not including patent term extension.

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

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

Further, patents and other intellectual property rights in the pharmaceutical and biotechnology space are evolving and involve many risks and uncertainties. For example, third parties may have blocking patents that could be used to prevent us from commercializing vonoprazan and any future product candidates and practicing our proprietary technology, and any issued patents may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or could limit the term of patent protection that otherwise may exist for vonoprazan and any future product candidates. In addition, the scope of the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies that are outside the scope of the rights granted under any issued patents. For these reasons, we may face competition with respect to vonoprazan and any future product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any patent protection for such product may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides.

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

Further, we have filed for and are pursuing trademark protection for our company name “Phathom Pharmaceuticals” in the United States and foreign jurisdictions.

License Agreement with Takeda Pharmaceutical Company Limited

On May 7, 2019, we and Takeda entered into the Takeda License. Pursuant to the Takeda License, 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 $25.0 million, 1,084,000 shares of common stock and a warrant to purchase 7,588,000 shares of common stock, or the Takeda Warrant. In the event that Takeda's fully-diluted ownership, including the Takeda Warrant, represents less than a certain specified percentage of our fully-diluted capitalization, including shares issuable upon conversion of outstanding convertible promissory notes, calculated immediately prior to the closing of this offering, we further agreed to issue an additional warrant to purchase shares of common stock such that Takeda would hold a certain specified percentage of the fully-diluted capitalization immediately before the closing of this offering. We agreed to make milestone payments to Takeda upon achieving certain tiered aggregate annual net sales of licensed products in the United States, Europe and Canada up a total maximum milestone amount of $250.0 million. We also agreed to make tiered royalty payments in the low double digits to the mid-teens on net sales of licensed products, subject to specified offsets and reductions. Royalties will be payable, on a product-by-product and country-by-country basis from the first commercial sale of such product in such country, until the latest of expiration of the licensed patents covering the applicable product, expiration of regulatory exclusivity in such country, or 15 years following first commercial sale in such country.

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

In connection with the Takeda License, we entered into a clinical manufacturing and supply agreement with Takeda whereby Takeda provides certain quantities of vonoprazan.

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. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

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

- completion of preclinical laboratory tests, animal studies and formulation studies in accordance with Good Laboratory Practice, or GLP, regulations and other applicable regulations;
- submission to the FDA of an 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 GMP, or cGMP, requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; 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. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The sponsor will also include a protocol detailing, among other things, the objectives of the first phase of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the first phase lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns about on-going or proposed clinical trials or non-compliance with specific FDA requirements, and the trials may not begin or continue until the FDA notifies the sponsor that the hold has been lifted. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. They must be 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, and timely safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events. 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.

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 and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain an early indication of its effectiveness. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients. Sponsors sometimes designate their Phase 1 clinical trials as Phase 1a or Phase 1b. Phase 1b clinical trials are typically aimed at confirming dosing, pharmacokinetics and safety in larger number of patients. Some Phase 1b studies evaluate biomarkers or surrogate markers that may be associated with efficacy in patients with specific types of diseases.
- ***Phase 2***: This phase involves clinical trials in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and appropriate dosage.
- ***Phase 3***: Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population, generally at geographically dispersed clinical study 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.

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.

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

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

While the IND is active and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report 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 same or similar drugs, findings from animal or *in vitro* testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

There are also requirements governing the reporting of ongoing clinical trials and completed trial results to public registries. Sponsors of certain clinical trials of FDA-regulated products are required to register and disclose specified clinical trial information, which is publicly available at www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved.

NDA Review and Approval Process

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 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 the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, 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 it the application is submitted. The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP requirements.

After the FDA evaluates an NDA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the NDA identified by the FDA and may require additional clinical data, such as an additional pivotal Phase 3 trial or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the sponsor must resubmit the NDA or, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require a sponsor to conduct Phase 4 testing, which involves clinical trials designed 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. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Marketing approval may be withdrawn for non-compliance with regulatory requirements or if problems occur following initial marketing.

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

Expedited Development and Review Programs

A sponsor may seek approval of its product candidate under programs designed to accelerate FDA's review and approval of new drugs and biological products that meet certain criteria. The FDA has a fast track designation program that is intended to expedite or facilitate the process for reviewing new drug products that meet certain criteria. Specifically, new drugs are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Unique to a fast track product, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

Any product submitted to the FDA for approval, including a product with a fast track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious disease or condition. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of new molecular entity NDAs under its current PDUFA review goals. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

In addition, a product may be eligible for accelerated approval. Drug products intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. FDA may withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product.

The FDA can also designate a drug as a "breakthrough therapy." A sponsor may seek FDA designation of a product candidate as a "breakthrough therapy" if the product is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If the FDA designates a breakthrough therapy, it may take actions appropriate to expedite the development and review of the application, which may include holding meetings with the sponsor and the review team throughout the development of the therapy; providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review; assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and considering alternative clinical trial designs when scientifically appropriate, which may result in smaller trials or more efficient trials that require less time to complete and may minimize the number of patients exposed to a potentially less efficacious treatment. The designation includes all of the fast track program features, which means that the sponsor may file sections of the NDA for review on a rolling basis if certain conditions are satisfied, including an agreement with FDA on the proposed schedule for submission of portions of the application and the payment of applicable user fees before the FDA may initiate a review. The breakthrough therapy designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met. If a product is designated as breakthrough therapy, the FDA will work to expedite the development and review of such drug.

Fast track designation, priority review and breakthrough therapy designation do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We may explore some of these opportunities for vonoprazan and any future product candidates as appropriate.

Post-Approval Requirements

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

Any drug products manufactured or distributed by us or our partners pursuant to FDA approvals will be 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.

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 after 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.

Marketing Exclusivity

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 marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity 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 approve or even 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 marketing 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 marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials.

Additionally, under the GAIN Act, the FDA may designate a product as a “qualified infectious disease product,” or 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. A sponsor must request such designation before submitting a marketing application. FDA granted QIDP designation for vonoprazan for the treatment of *H. pylori* infection in combination with both amoxicillin and clarithromycin, and with amoxicillin alone, respectively.

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 marketing exclusivity period awarded, such as a five-year exclusivity period awarded for a new molecular 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 the 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, data privacy and security laws, and physician payment transparency laws. In addition to the federal laws summarized below, we may also be subject to similar state and local laws and regulations that 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 payors, including private insurers, or by patients themselves.

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. 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 and the civil monetary penalties statute.

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.

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 payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation.

In addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, imposes certain requirements relating to the privacy, security and transmission of protected health information on HIPAA covered entities, which include certain healthcare providers, health plans and healthcare clearinghouses, and their business associates who conduct certain activities for or on their behalf involving protected health information on their behalf.

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 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 payors, 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; state and local laws that require the registration of pharmaceutical sales representatives; and state and local laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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 payors, which include government health programs such as Medicare, Medicaid, TRICARE and the Veterans Administration, as well as managed care organizations and private health insurers. Prices at which we or our customers seek reimbursement for vonoprazan and any future product candidates can be subject to challenge, reduction or denial by third-party payors.

The process for determining whether a third-party payor will provide coverage for a product is typically separate from the process for setting the reimbursement rate that the payor will pay for the product. In the United States, there is no uniform policy among payors for coverage or reimbursement. Decisions regarding whether to cover any of a product, the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. Third-party payors 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 payor to payor. 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 payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Third-party payors 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 payors may not consider vonoprazan and 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 payor not to cover a product could reduce physician usage and patient demand for the product.

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 payors in the United States, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the Patient Protection and Affordable Care Act, or the Affordable Care Act, was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the pharmaceutical industry. The Affordable Care Act, increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; required collection of rebates for drugs paid by Medicaid managed care organizations; required manufacturers to participate in a coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs, implemented a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected; expanded eligibility criteria for Medicaid programs; creates 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 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. For example, the Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act, on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the Affordable Care Act, are invalid as well. While the Texas District Court Judge, as well as the Trump Administration and CMS, have stated that the ruling will have no immediate effect, and on December 30, 2018 the Texas District Court Judge issued an order staying the judgment pending appeal, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act, will impact the Affordable Care Act.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018, will remain in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Moreover, there has recently 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. Further, the Trump Administration released a “Blueprint” to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of pharmaceutical products paid by consumers. Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs and suppliers will be included in their healthcare programs Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

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.

To market a medicinal product in the European Economic Area, or EEA (which is comprised of the 28 Member States of the EU plus Norway, Iceland and Liechtenstein), we must obtain a Marketing Authorization, or MA. There are two types of marketing authorizations:

- the Community MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use of the EMA and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced therapy products, and medicinal products containing a new active substance indicated for the treatment certain diseases, such as AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU; and

- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, 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 above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Data and marketing exclusivity

In the EEA, new products authorized for marketing, or reference products, qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. 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 marketing authorization 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 authorization of the reference product in the EU. The 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 marketing authorization 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.

Pediatric investigation plan

In the EEA, marketing authorization applications for new medicinal products not authorized have to include the results of studies 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 marketing authorization 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 is 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 marketing authorization is obtained in all Member States of the EU and study results are included in the product information, even when negative, the product is eligible for six months’ supplementary protection certificate extension.

Clinical trials

Clinical trials of medicinal products in the European Union must be conducted in accordance with European Union and national regulations and the International Conference on Harmonization, or ICH, guidelines on GCPs. Additional GCP guidelines from the European Commission, focusing in particular on traceability, apply to clinical trials of advanced therapy medicinal products. If the sponsor of the clinical trial is not established within the European Union, it must appoint an entity within the European Union to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU countries, the sponsor is liable to provide 'no fault' compensation to any study subject injured in the clinical trial.

Prior to commencing a clinical trial, the sponsor must obtain a clinical trial authorization from the competent authority, and a positive opinion from an independent ethics committee. The application for a clinical trial authorization 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. Currently, clinical trial authorization applications must be submitted to the competent authority in each EU Member State in which the trial will be conducted. Under the new Regulation on Clinical Trials, which is currently expected to take effect in 2019, there will be a centralized application procedure where one national authority takes the lead in reviewing the application and the other national authorities have only a limited involvement. Any substantial changes to the trial protocol or other information submitted with the clinical trial applications must be notified to or approved by the relevant competent authorities and ethics committees. Medicines used in clinical trials must be manufactured in accordance with cGMP. Other national and European Union-wide regulatory requirements also apply.

Privacy and data protection laws

We are also subject to laws and regulations in non-U.S. countries covering data privacy and the protection of health-related and other personal information. EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. Laws and regulations in these jurisdictions apply broadly to the collection, use, storage, disclosure, processing and security of personal information that identifies or may be used to identify an individual, such as names, contact information, and sensitive personal data such as health data. These laws and regulations are subject to frequent revisions and differing interpretations, and have generally become more stringent over time.

As of May 25, 2018, Regulation 2016/676, known as the General Data Protection Regulation, or GDPR, replaced the Data Protection Directive with respect to the processing of personal data in the European Union. The GDPR imposes many requirements for controllers and processors of personal data, including, for example, higher standards for obtaining consent from individuals to process their personal data, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention and secondary use of information, increased requirements pertaining to health data and pseudonymised (i.e., key-coded) data and additional obligations when we contract third-party processors in connection with the processing of the personal data. The GDPR allows EU member states to make additional laws and regulations further limiting the processing of genetic, biometric or health data. Failure to comply with the requirements of GDPR and the applicable national data protection laws of the EU member states may result in fines of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties.

Employees

As of September 30, 2019, we had 16 full-time employees, 3 of whom have a Ph.D. or M.D. 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.

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.

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MANAGEMENT

Executive Officers and Directors

The following table sets forth the name, age and position of each of our executive officers and directors as of September 30, 2019.

Name	Age	Position
Executive Officers		
David Socks	45	President, Chief Executive Officer, Treasurer, Secretary and Director
Azmi Nabulsi, M.D., M.P.H.	60	Chief Operating Officer
Aditya Kohli, Ph.D.	31	Chief Business Officer
Non-Employee Directors		
Tadataka Yamada, M.D.(1)(3)	74	Chairman
Michael F. Cola(1)(2)	60	Director
Terrie Curran	50	Director
Jonathan Edwards, Ph.D.(1)(3)	35	Director
Heidi Kunz(2)	64	Director
Chris Slavinsky(2)	47	Director
James Topper, M.D., Ph.D.(1)(3)	57	Director

(1) Member of the compensation committee
(2) Member of the audit committee
(3) Member of the nominating and corporate governance committee

Executive Officers

David Socks is our co-founder and has served as our Chief Executive Officer, Treasurer and Secretary, and as a member of our board of directors since January 2018, and as our President since March 2019. As part of a planned transition, Terrie Curran, a member of our board of directors, will succeed Mr. Socks as Chief Executive Officer effective upon the closing of the acquisition of her current employer, Celgene Corporation, by Bristol-Myers Squibb Company. Following Ms. Curran's appointment as CEO, Mr. Socks will serve as interim Chief Financial Officer and continue to serve as a member of our board of directors. Since August 2014, Mr. Socks has been a Venture Partner at Frazier Healthcare Partners, or Frazier, a venture capital firm. In this capacity, he co-founded Arcutis, Inc., Nexcida Therapeutics, Inc., Outpost Medicine, LLC, Passage Bio, Inc., Recida Therapeutics, Inc., and Scout Bio, Inc. Mr. Socks served as Chief Executive Officer of Nexcida Therapeutics, Outpost Medicine and Scout Bio. Mr. Socks also serves as Executive Chairman of the board of directors of Recida Therapeutics and as a board member of Outpost Medicine. Prior to joining Frazier, Mr. Socks co-founded Incline Therapeutics, Inc. in 2010 and served as its President and Chief Operating Officer from 2010 until its sale to The Medicines Company in 2013. He also co-founded Cadence Pharmaceuticals, Inc. in 2004 and served as its Vice President of Business Development and then as its Senior Vice President, Corporate Development and Strategy from 2004 until 2010. From 2000 to 2004, Mr. Socks was a Venture Partner at Windamere Venture Partners, a venture capital firm founding and investing in early stage life science companies, where he co-founded several biopharmaceutical companies including Avera Pharmaceuticals, Inc. and Kanisa Pharmaceuticals, Inc. Previously, he worked at Neurocrine Biosciences, EFO Holdings, L.P., an investment firm, and Kaiser Associates, Inc., a strategic management consulting firm. Mr. Socks holds a B.S. from Georgetown University and an M.B.A. from Stanford University. Mr. Socks' knowledge of our business and significant experience as a biopharmaceutical executive and board member, contributed to our board of directors' conclusion that he should serve as a director of our company.

Azmi Nabulsi, M.D., M.P.H. is our co-founder and has served as our Chief Operating Officer since March 2019. Dr. Nabulsi has been an entrepreneur-in-residence at Frazier since October 2018. Also, since January 2019, Dr. Nabulsi has served as a business and clinical advisor to Saama Technologies, Inc., a clinical data and analytics company. Previously, through October 2018, Dr. Nabulsi spent fourteen years at Takeda. Dr. Nabulsi held a number of leadership positions at Takeda, most recently as the Deputy Chief Medical & Scientific Officer and Head of Global Development from 2014 until October 2018. In his roles at Takeda, Dr. Nabulsi oversaw global drug development for both early and late stage product candidates and led global medical, analytic and operational functions responsible for bringing new medicines in multiple therapeutic areas to many markets. Prior to joining Takeda, Dr. Nabulsi held numerous positions at Abbott Laboratories, including Head of Immunology and Oncology Ventures from 1998 to 2002. Dr. Nabulsi has an M.D. from Ain-Shams University in Cairo and a M.P.H. from the University of Minnesota.

Aditya Kohli, Ph.D. is our co-founder and has served as our Chief Business Officer since March 2019. Since January 2018, Dr. Kohli has served as Vice President of Frazier. From September 2016 to December 2017, Dr. Kohli served as Senior Associate of Frazier. In this capacity, he has co-founded Passage Bio, Scout Bio, and Recida Therapeutics, Inc., and also served as VP, Business Development and serves on the board of directors of Scout Bio. Prior to joining Frazier, Dr. Kohli worked at McKinsey & Company as an Engagement Manager from June 2016 until September 2016 and as an Associate from September 2014 until May 2016, where he consulted with biopharmaceutical companies on business development, research and development, and marketing and sales strategy. Dr. Kohli received his Ph.D. from the UC Berkeley and UC San Francisco joint graduate program in bioengineering and holds B.S. and M.Eng. degrees in biological engineering from the Massachusetts Institute of Technology.

Non-Employee Directors

Tadataka Yamada, M.D. has served as Chairman of our board of directors since March 2019. Dr. Yamada currently serves as a Venture Partner on the Life Sciences team of Frazier. From June 2011 to June 2015, Dr. Yamada served as the Chief Medical and Scientific Officer and as a member of the board of directors of Takeda. Dr. Yamada has served since 2011 as a member of the board of directors of Agilent Technologies, a global scientific instrument manufacturing and clinical diagnostics company listed on the New York Stock Exchange. Since June 2016, Dr. Yamada has served on the board of directors of CSL Limited, a biotechnology company that is publicly traded on the Australian Securities Exchange. Dr. Yamada previously served as President of the Global Health Program of the Bill & Melinda Gates Foundation from June 2006 to June 2011. From 2000 to 2006, Dr. Yamada was Chairman of Research and Development and a member of the board of directors of GlaxoSmithKline Inc. and prior to that, he held research and development positions at SmithKline Beecham. Prior to joining SmithKline Beecham, Dr. Yamada was Chairman of the Department of Internal Medicine at the University of Michigan Medical School and Physician-in-Chief of the University of Michigan Medical Center. Dr. Yamada serves as chair of the board of directors at the Clinton Health Access Initiative and a member of the National Academy of Medicine. He is also a Fellow of the Imperial College of Medicine, a Master of the American College of Physicians, a Fellow of the Royal College of Physicians, a Member of the American Academy of Arts and Sciences and a past-President of the American Gastroenterological Association and the Association of American Physicians. Dr. Yamada received his M.D. from New York University School of Medicine and a B.A. in History from Stanford University. He has authored over 150 manuscripts in peer reviewed journals and is the editor of The Textbook of Gastroenterology. He has been the recipient of numerous awards including the Distinguished Achievement Award in Gastrointestinal Physiology from the American Physiological Society, the Friedenwald Medal from the American Gastroenterological Association, and the Watanabe Prize in Translational Research from Indiana University and Eli Lilly & Co. Dr. Yamada's extensive research and experience in gastrointestinal drug development, particularly his involvement in the development of vonoprazan at Takeda, as well as his service as a director or officer of other healthcare companies, contributed to our board of directors' conclusion that he should serve as Chairman of our board of directors.

Michael F. Cola has served as a member of our board of directors since September 2019. Mr. Cola has served as Chief Executive Officer and President of Aevi Genomic Medicine, Inc. since September 2013. Mr. Cola served as President of Shire plc's Specialty Pharmaceuticals business from 2007 until April 2012. Mr. Cola joined Shire in July 2005 as Executive Vice President for Global Therapeutic Business Units and Portfolio Management prior to being named President of the Specialty Pharmaceuticals business. Prior to joining Shire, Mr. Cola spent more than five years at Safeguard Scientifics, where he served as President of the Life Sciences Group. As part of his role with Safeguard Scientifics, Mr. Cola served as Chairman and CEO of Clarient, a cancer diagnostics company, and Chairman of Laureate Pharma, a full service contract manufacturing organization serving research based biologics companies. Prior to joining Safeguard Scientifics, Mr. Cola held progressively senior positions in product development and commercialization at AstraMerck, and later with AstraZeneca. Mr. Cola currently serves on the board of directors of Aevi Genomic Medicine, Inc., Sage Therapeutics, Inc. and Vanda Pharmaceuticals Inc. Mr. Cola received his Bachelor of Arts degree in biology and physics from Ursinus College and his Master of Science degree in biomedical science from Drexel University. Mr. Cola's executive experience in the biopharmaceutical industry, knowledge of our business and service as a director of other biopharmaceutical companies contributed to our board of directors' conclusion that he should serve as a director of our company.

Terrie Curran has served as a member of our board of directors since August 2019. As part of a planned transition, Ms. Curran will succeed Mr. Socks as Chief Executive Officer effective upon the closing of the acquisition of her current employer, Celgene Corporation, by Bristol-Myers Squibb Company. Ms. Curran has served as the President, Global Inflammation and Immunology Franchise at Celgene and a member of the Executive Committee since April 2017. Ms. Curran joined Celgene in 2013 as the U.S. Commercial Head of the I&I Franchise and built the capabilities and recruited the teams that executed the successful launch of OTEZLA, before becoming Head of Worldwide Markets. Prior to joining Celgene, she served as Senior Vice President and General Manager - Global Women's Health at Merck & Co. Before joining Merck, Ms. Curran held a number of Country General Manager positions at Schering-Plough and Pharmacia across Europe and Asia Pacific. She currently serves on the board of Myovant Sciences Ltd., a biotechnology company, and previously served on the board of H. Lundbeck A/S, a global pharmaceutical company. Ms. Curran holds a Graduate Diploma of Marketing and a Bachelor of Applied Science (B.A.S.) from the University of Technology, Sydney. Ms. Curran's extensive 22 year biopharmaceutical industry experience contributed to our board of directors' conclusion that she should serve as a director of our company.

Jon Edwards, Ph.D. has served as a member of our board of directors since May 2019. Dr. Edwards is a Partner at Medicxi, a life sciences-focused investment firm. Dr. Edwards was part of the Medicxi co-founding team and joined the firm's investment team as an Associate in February 2016. Prior to joining Medicxi, Dr. Edwards was an Associate in the investment team at Index Ventures, a venture capital firm, from September 2014 until February 2016. Dr. Edwards currently serves on the board of a number of private U.S. and European biotechnology and biopharmaceutical companies, including Palladio Biosciences Inc., Xenikos B.V., UltraHuman Limited, Breakpoint Therapeutics GmbH and Sydnexis Inc. Prior to joining Index Ventures, Dr. Edwards was a life sciences strategy consultant at ClearView Healthcare Partners from January 2013 until September 2014. Dr. Edwards received a Ph.D. in Biochemistry and Biophysics from the University of North Carolina at Chapel Hill and conducted postdoctoral research at the Massachusetts Institute of Technology. Dr. Edwards' knowledge of our business and prior service as a director of multiple biopharmaceutical and biotechnology companies contributed to our board of directors' conclusion that he should serve as a director of our company.

Heidi Kunz has served as a member of our board of directors since September 2019. Ms. Kunz served as Executive Vice President and Chief Financial Officer of Blue Shield of California from

September 2003 until her retirement in December 2012. Prior to joining Blue Shield of California, she served as Executive Vice President and Chief Financial Officer of Gap, Inc. from 1999 to January 2003. From 1995 to 1999, Ms. Kunz served as the Chief Financial Officer of ITT Industries, Inc. She has also held senior financial management positions at General Motors Corporation, including Vice President and Treasurer during her 16-year tenure from 1979 to 1995. Ms. Kunz currently serves as a director of Agilent Technologies Inc., a global scientific instrument manufacturing and clinical diagnostics company and Avanos Medical, Inc., a public medical device company, and previously served as a director of Financial Engines, Inc., an investment advisement company. Ms. Kunz received an MBA in Finance and Accounting from Columbia Business School and a bachelor's degree in Russian Language from Georgetown University. Ms. Kunz's extensive experience as a chief financial officer and service as a director of other public companies contributed to our board of directors' conclusion that she should serve as a director of our company.

Chris Slavinsky has served as a member of our board of directors since August 2019. Since December 2018, Mr. Slavinsky has served as Vice President, Takeda Center for External Innovation as well as Head, Gastroenterology Business Development, Externalization and Special Projects at Takeda. From June 2003 to December 2018, Chris served in a number of capacities at Pfizer, Inc., including as Chief Counsel of several Pfizer business units starting in 2011. Mr. Slavinsky received a J.D. from the Washington University in St. Louis School of Law, an M.S. in biochemistry and molecular biology from Thomas Jefferson University (Philadelphia), and a B.S. in biochemistry from the State University of New York at Stony Brook. Mr. Slavinsky's knowledge of our business and experience in the biopharmaceutical industry has contributed to our board of directors' conclusion that he should serve as director of our company.

James Topper, M.D., Ph.D. has served as a member of our board of directors since January 2018. Since 2005, Dr. Topper has also served as the Managing General Partner at Frazier with whom he served as a Partner from 2003 to 2005. Prior to that, from 2002 to 2003, Dr. Topper served as head of the Cardiovascular Research and Development Division at Millennium Pharmaceuticals, Inc., a biopharmaceutical company. Dr. Topper has served as a member of the board of directors of Allena Pharmaceuticals, Inc., a biopharmaceutical company, since September 2011, Alpine Immunosciences Inc., a biotechnology company, since June 2016, Aptinyx Inc., a biopharmaceutical company, since May 2016, and Amunix Pharmaceuticals, Inc., a pharmaceutical company, since October 2018. In addition, from April 2014 to March 2017, Dr. Topper served as a member of the board of directors of Sierra Oncology, Inc. (formerly ProNai Therapeutics, Inc.), an oncology company, and since 2007, Dr. Topper has served as a member of the board of directors of AnaptysBio, Inc., a biotechnology company. From March 2011 to December 2013, Dr. Topper served as a member of the board of directors of Portola Pharmaceuticals, Inc., a biopharmaceutical company, and from 2004 to April 2015 as a member of the board of directors of Amicus Therapeutics, Inc., a biopharmaceutical company. Dr. Topper received a B.S. in Biology from the University of Michigan and an M.D. and a Ph.D. in Biophysics from the Stanford University School of Medicine. He did his postgraduate training in internal medicine and cardiovascular disease at the Brigham and Women's Hospital in Boston and was board certified in both disciplines. Dr. Topper's extensive service as a director of other biopharmaceutical companies contributed to our board of directors' conclusion that he should serve as a director of our company.

Board Composition and Election of Directors

Director Independence

Our board of directors currently consists of eight members. Our board of directors has determined that Dr. Yamada, Mr. Cola, Dr. Edwards, Ms. Kunz and Dr. Topper are independent directors in accordance with the listing requirements of the Nasdaq Global Select Market, or Nasdaq.

The Nasdaq independence definition includes a series of objective tests, including that the director is not, and has not been for at least three years, one of our employees and that neither the director nor any of his or her family members has engaged in various types of business dealings with us. In addition, as required by Nasdaq rules, our board of directors has made a subjective determination as to each independent director that no relationships exist, which, in the opinion of our board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of the director. In making these determinations, our board of directors reviewed and discussed information provided by the directors and us with regard to each director's business and personal activities and relationships as they may relate to us and our management. There are no family relationships among any of our directors or executive officers.

Classified Board of Directors

In accordance with the terms of our amended and restated certificate of incorporation that will go into effect immediately prior to the closing of this offering, our board of directors will be divided into three classes with staggered, three-year terms. At each annual meeting of stockholders, the directors whose terms then expire will be eligible for reelection until the third annual meeting following reelection. Effective upon the closing of this offering, our directors will be divided among the three classes as follows:

- the Class I directors will be Terrie Curran and Jonathan Edwards, Ph.D., and their terms will expire at our first annual meeting of stockholders following this offering;
- the Class II directors will be Michael F. Cola, Chris Slavinsky and James Topper, M.D., Ph.D., and their terms will expire at our second annual meeting of stockholders following this offering; and
- the Class III directors will be Heidi Kunz, David Socks and Tadataka Yamada, M.D., and their terms will expire at our third annual meeting of stockholders following this offering.

Our amended and restated certificate of incorporation that will go into effect immediately prior to the closing of this offering will provide that the authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our board of directors or a change in control of our company. Our directors may be removed only for cause by the affirmative vote of the holders of at least two-thirds of our outstanding voting stock then entitled to vote in an election of directors.

Board Leadership Structure

Our board of directors is currently led by its chairman, Dr. Yamada. Our board of directors recognizes that it is important to determine an optimal board leadership structure to ensure the independent oversight of management as the company continues to grow. We separate the roles of chief executive officer and chairman of the board of directors in recognition of the differences between the two roles. The chief executive officer is responsible for setting the strategic direction for our company and the day-to-day leadership and performance of our company, while the chairman of the board of directors provides guidance to the chief executive officer and presides over meetings of the full board of directors. We believe that this separation of responsibilities provides a balanced approach to managing the board of directors and overseeing our company.

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

Role of Board in Risk Oversight Process

Our board of directors has responsibility for the oversight of our risk management processes and, either as a whole or through its committees, regularly discusses with management our major risk exposures, their potential impact on our business and the steps we take to manage them. The risk oversight process includes receiving regular reports from board committees and members of senior management to enable our board of directors to understand our risk identification, risk management and risk mitigation strategies with respect to areas of potential material risk, including operations, finance, legal, regulatory, strategic and reputational risk.

The audit committee reviews information regarding liquidity and operations, and oversees our management of financial risks. Periodically, the audit committee reviews our policies with respect to risk assessment, risk management, loss prevention and regulatory compliance. Oversight by the audit committee includes direct communication with our external auditors, and discussions with management regarding significant risk exposures and the actions management has taken to limit, monitor or control such exposures. The compensation committee is responsible for assessing whether any of our compensation policies or programs has the potential to encourage excessive risk-taking. The nominating and corporate governance committee manages risks associated with the independence of the board of directors, corporate disclosure practices and potential conflicts of interest. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, the entire board of directors is regularly informed through committee reports about such risks. Matters of significant strategic risk are considered by our board of directors as a whole.

Board Committees and Independence

Our board of directors has established three standing committees—audit, compensation and nominating and corporate governance—each of which operates under a charter that has been approved by our board of directors.

Audit Committee

The audit committee's main function is to oversee our accounting and financial reporting processes and the audits of our financial statements. This committee's responsibilities include, among other things:

- appointing our independent registered public accounting firm;
- evaluating the qualifications, independence and performance of our independent registered public accounting firm;
- approving the audit and non-audit services to be performed by our independent registered public accounting firm;
- reviewing the design, implementation, adequacy and effectiveness of our internal accounting controls and our critical accounting policies;
- discussing with management and the independent registered public accounting firm the results of our annual audit and the review of our quarterly unaudited combined financial statements;
- reviewing, overseeing and monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to financial statements or accounting matters;
- reviewing on a periodic basis, or as appropriate, any investment policy and recommending to our board of directors any changes to such investment policy;

- reviewing with management and our auditors any earnings announcements and other public announcements regarding our results of operations;
- preparing the report that the SEC requires in our annual proxy statement;
- reviewing and approving any related party transactions and reviewing and monitoring compliance with our code of conduct and ethics; and
- reviewing and evaluating, at least annually, the performance of the audit committee and its members including compliance of the audit committee with its charter.

The members of our audit committee are Ms. Kunz, Mr. Cola and Mr. Slavinsky. Ms. Kunz serves as the chairperson of the committee. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and Nasdaq. Our board of directors has determined that Ms. Kunz is an "audit committee financial expert" as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable Nasdaq listing standards. Our board of directors has determined each of Ms. Kunz and Mr. Cola is independent under the applicable rules of the SEC and Nasdaq. Under the applicable Nasdaq rules, we are permitted to phase in our compliance with the independent audit committee requirements of Nasdaq on the same schedule as we are permitted to phase in our compliance with the independent audit committee requirements pursuant to Rule 10A-3 under the Exchange Act, which requires all members to be independent within one year of listing. We will comply with the phase-in requirements of the Nasdaq rules and within one year of our listing on Nasdaq, all members of our audit committee will be independent under Nasdaq rules and Rule 10A-3. Upon the listing of our common stock on Nasdaq, the audit committee will operate under a written charter that satisfies the applicable standards of the SEC and Nasdaq.

Compensation Committee

Our compensation committee approves policies relating to compensation and benefits of our officers and employees. The compensation committee approves corporate goals and objectives relevant to the compensation of our Chief Executive Officer and other executive officers, evaluates the performance of these officers in light of those goals and objectives and approves the compensation of these officers based on such evaluations. The compensation committee also approves the issuance of stock options and other awards under our equity plans. The compensation committee will review and evaluate, at least annually, the performance of the compensation committee and its members, including compliance by the compensation committee with its charter.

The members of our compensation committee are Mr. Cola, Dr. Edwards, Dr. Topper and Dr. Yamada. Mr. Cola serves as the chairperson of the committee. Our board of directors has determined that each member of this committee is independent under the applicable Nasdaq listing standards, is a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act. Upon the listing of our common stock on Nasdaq, the compensation committee will operate under a written charter, which the compensation committee will review and evaluate at least annually.

Nominating and Corporate Governance Committee

The nominating and corporate governance committee is responsible for assisting our board of directors in discharging the board of directors' responsibilities regarding the identification of qualified candidates to become board members, the selection of nominees for election as directors at our annual meetings of stockholders (or special meetings of stockholders at which directors are to be elected), and the selection of candidates to fill any vacancies on our board of directors and any committees thereof. In addition, the nominating and corporate governance committee is responsible for overseeing our corporate governance policies, reporting and making recommendations to our board of directors concerning governance matters and oversight of the evaluation of our board of directors. The members of our nominating and corporate governance committee are Dr. Edwards, Dr. Topper and Dr. Yamada. Dr. Edwards serves as the chairperson of the committee. Our board of directors has determined that each member of this committee is independent under the applicable Nasdaq listing standards. Upon the listing of our common stock on Nasdaq, the nominating and corporate governance committee will operate under a written charter, which the nominating and corporate governance committee will review and evaluate at least annually.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee has ever been one of our officers or employees. None of our executive officers currently serves, or has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

Board Diversity

Upon the closing of this offering, our nominating and corporate governance committee will be responsible for reviewing with the board of directors, on an annual basis, the appropriate characteristics, skills and experience required for the board of directors as a whole and its individual members. In evaluating the suitability of individual candidates (both new candidates and current members) for election or appointment, the nominating and corporate governance committee and the board of directors will take into account many factors, including the following:

- personal and professional integrity, ethics and values;
- experience in corporate management, such as serving as an officer or former officer of a publicly-held company;
- experience as a board member or executive officer of another publicly-held company;
- strong finance experience;
- diversity of expertise and experience in substantive matters pertaining to our business relative to other board members;
- diversity of background and perspective, including, but not limited to, with respect to age, gender, race, place of residence and specialized experience;
- experience relevant to our business industry and with relevant social policy concerns; and
- relevant academic expertise or other proficiency in an area of our business operations.

Currently, our board of directors evaluates, and following the closing of this offering will evaluate, each individual in the context of the board of directors as a whole, with the objective of assembling a group that can best maximize the success of the business and represent stockholder interests through the exercise of sound judgment using its diversity of experience in these various areas.

Code of Conduct and Ethics

We have adopted a written code of conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, which will be effective upon the closing of this offering. Upon the closing of this offering, our code of conduct and ethics will be available under the Corporate Governance section of our website at www.phathompharma.com. In addition, we intend to post on our website all disclosures that are required by law or the listing standards of Nasdaq concerning any amendments to, or waivers from, any provision of the code. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this prospectus.

EXECUTIVE AND DIRECTOR COMPENSATION

This section discusses the material components of the executive compensation program for our named executive officer who is named in the "Summary Compensation Table" below.

For 2018, our only "named executive officer" was David Socks, our President, Chief Executive Officer, Treasurer and Secretary, and member of our board of directors.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt following the closing of this offering may differ materially from the currently planned programs summarized in this discussion.

We are an "emerging growth company," as that term is used in the JOBS Act, and have elected to comply with the reduced compensation disclosure requirements available to emerging growth companies under the JOBS Act.

Summary Compensation Table

The following table presents summary information regarding the total compensation that was awarded to, earned by or paid to our named executive officer for services rendered during the year ended December 31, 2018.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	All Other Compensation ($)[1]	Total ($)
David Socks *President, Chief Executive Officer, Treasurer, Secretary and Director*	2018	153,333	–	–	16,812	170,145

(1) Represents benefit costs paid on behalf of Mr. Socks by our company.

Narrative Disclosure to Summary Compensation Table

Annual Base Salary

The compensation of our executive officers is generally determined and approved at the time of their commencement of employment by our board of directors or the compensation committee.

The annual base salary for Mr. Socks for his service as our Chief Executive Officer was $160,000 for 2018.

In connection with the Takeda License and Mr. Socks' increased responsibilities as our President and Chief Executive Officer, our board of directors increased his base salary to $340,000, effective May 1, 2019.

Bonus Compensation

From time to time our board of directors or compensation committee may approve bonuses for our executive officers based on individual performance, company performance or as otherwise determined appropriate. No formal bonus plan was in effect during 2018.

Equity-Based Incentive Awards

Our equity-based incentive awards are designed to align our interests and the interests of our stockholders with those of our employees and consultants, including our named executive officer. Our board of directors or the compensation committee approves equity grants.

On February 13, 2018, we issued and sold to Mr. Socks, 1,686,704 shares of our common stock for a per share purchase price of $0.0002958.

On March 13, 2019, we entered into a stock restriction agreement with Mr. Socks whereby Mr. Socks' previously-acquired 1,686,704 shares of our common stock were subjected to new vesting conditions, such that 421,676 shares were deemed vested as of March 13, 2019 and the remaining 1,265,028 shares were converted into unvested shares of restricted stock that vest in equal monthly installments over the 48 months thereafter ending on March 13, 2023, subject, in each case, to continued employment or status as a service provider. Any unvested shares held by Mr. Socks upon a termination of employment or service (after giving effect to any accelerated vesting provisions described further below), will be subject to repurchase by us at the original purchase price.

Under Mr. Socks' stock restriction agreement, 100% of any unvested shares will automatically accelerate and vest upon (i) a termination of service by us without cause or by him for good reason following a change in control, or (ii) the refusal by us to enter into a consulting agreement with him in connection with his resignation, subject to his continued employment or service through the date of such event.

Defined Terms Applicable to Stock Restriction Agreement

For purposes of the stock restriction agreement with Mr. Socks, "change in control" generally has the same meaning given to such term in our Existing Incentive Plan, as described below.

For purposes of the stock restriction agreement with Mr. Socks, "good reason" means the occurrence of any of the following events or conditions without his consent: (i) a material diminution in authority, duties or responsibilities; (ii) a material diminution in base compensation, unless such reduction is imposed across-the-board to senior management of the Company; (iii) a material change in the geographic location at which he must perform his duties (and the parties acknowledge that a relocation of our principal executive offices to a location more than fifty (50) miles from our then-current offices at which the individual is providing services (excepting reasonable travel on business) shall constitute a material change for purposes of this clause (iii)); or (iv) any other action or inaction that constitutes a material breach by us or any successor or affiliate of our obligations to him under the stock restriction agreement.

For purposes of the stock restriction agreement with Mr. Socks, "cause" means one or more of the following has occurred, as determined in good faith by us in our reasonable discretion: (i) conviction of, or plea of nolo contendere to, any felony or of any crime involving either moral turpitude or dishonesty; (ii) intentional participation in a fraud or intentional act of dishonesty against our company or any of our customers or business partners; (iii) material breach of duties; (iv) material breach of any written agreement with us if such breach has not been cured, or services ceased, within thirty (30) days of receiving written notice thereof; and (v) failure to comply with the reasonable and lawful directives of management.

Employment Letters with our Executive Officers

In 2018, none of our executive officers were parties to employment agreements or other similar arrangements with us. Each of our executive officers' employment is "at will" and may be terminated at any time, subject to our contractual obligations to them as described below.

Employment Letter with David Socks

We entered into an employment letter with Mr. Socks setting forth the terms of his employment, effective May 7, 2019 in connection with entering into the Takeda License.

The employment letter for Mr. Socks provides for an annual base salary of $340,000, and an annual bonus with a target amount equal to 50% of Mr. Socks' annual base salary. Under the employment letter for Mr. Socks, he will devote at least 80% of his time to our company. Additionally, under the employment letter, Mr. Socks is eligible to participate in all employee benefit plans and programs generally available to similarly situated employees of our company and is entitled to vacation benefits in accordance with our policies.

Employment Letter with Terrie Curran

We have entered into an employment letter with Ms. Curran, pursuant to which we have appointed her as a member of our board of directors and offered her employment as our Chief Executive Officer. Under the terms of the employment letter, Ms. Curran must commence full-time employment with us as our Chief Executive Officer within two weeks after the completion of the planned acquisition of her current employer but in no event later than December 31, 2019, or the Start Date Deadline. In the event Ms. Curran has not commenced full-time employment with us as our Chief Executive Officer prior to such deadline, the employment offer will cease to be outstanding.

The employment letter for Ms. Curran provides for an initial annual base salary of $500,000, and an annual bonus with a target amount equal to 50% of her annual base salary. Her annual bonus for 2019 will be pro-rated based on the portion of the year she is employed by us. Additionally, under the employment letter, Ms. Curran will be eligible to participate in all employee benefit plans and programs generally available to similarly situated employees of our company and is entitled to vacation benefits in accordance with our policies.

Effective August 29, 2019, we appointed Ms. Curran to our board of directors. In connection with her appointment to the board, we granted her stock options to purchase 867,200 shares of our common stock under the Existing Incentive Plan. The stock options have a ten-year term and an exercise price of $6.95 per share, which our board of directors determined was equal to the fair market value per share of our common stock on the date of grant. Ms. Curran's options will vest over a four-year period, with 25% of the stock options vesting on the first anniversary of her commencement of employment with us and the remaining stock options vesting in 36 equal monthly installments thereafter, subject to her continued employment or service on each vesting date. In the event Ms. Curran does not commence employment with us as our Chief Executive Officer prior to the Start Date Deadline, all of the stock options granted to her in connection with her appointment to the board will terminate immediately, regardless of her continued service on the board of directors.

Regardless of the manner in which Ms. Curran's employment terminates, she will be entitled to receive amounts previously earned during her term of employment, including unpaid salary and accrued but unused vacation. In addition, Ms. Curran will be entitled to certain severance benefits under her employment letter, subject to her execution of a release of claims, returning of all company property, compliance with post-termination obligations and resignation from positions with us.

Ms. Curran’s employment letter provides for severance benefits for certain terminations that arise during and outside a change in control period (as defined below). Upon a termination without cause or resignation for good reason outside of a change in control period, Ms. Curran will be entitled to: (1) continuation of her base salary for 12 months (such applicable period, the “severance period”), (2) a lump sum equal to her target bonus for the year during which such termination occurs, plus any unpaid annual bonus for the calendar year prior to the year in which her termination occurs, to the extent she is entitled to such bonus and if such bonus has not already been paid, (3) payment of the COBRA premiums for her and her eligible dependents until the earliest of (a) the end the severance period, (b) expiration of her eligibility under for continuation coverage under COBRA, or (c) the date she becomes eligible for health insurance coverage in connection with her new employment, and (4) acceleration of the vesting of all outstanding equity awards that would have vested during the severance period.

Upon a termination without cause or resignation for good reason that occurs during the period that is three months prior to or any time on or after a change in control (such period, the “change in control period”), Ms. Curran will be entitled to all of the same severance benefits described above, except (1) the severance period is increased from 12 months to 18 months, (2) Ms. Curran will be entitled to a lump sum payment equal to 1.5 times her target bonus for the year during which such termination occurs, plus any unpaid annual bonus for the calendar year prior to the year in which her termination occurs, to the extent she is entitled to such bonus and if such bonus has not already been paid, and (3) all unvested and outstanding equity awards will become fully vested on the later of the date her release of claims becomes effective or the date of the change in control.

For purposes of Ms. Curran’s employment letter:

- “cause” means (1) her commission of an act of fraud, embezzlement or dishonesty, or the commission of some other illegal act, that has a demonstrable adverse impact on us or any successor or affiliate thereof; (2) her conviction of, or plea of “guilty” or “no contest” to, a felony or any crime involving fraud, dishonesty or moral turpitude under the laws of the United States or any state thereof; (3) any intentional, unauthorized use or disclosure by her of the confidential information or trade secrets of the company or any successor or affiliate thereof; (4) her gross negligence, insubordination or material violation of any duty of loyalty to us or any successor or affiliate thereof, or any other demonstrable material misconduct on her part; (5) her ongoing and repeated failure or refusal to perform or neglect of her duties as required by the employment letter or her ongoing and repeated failure or refusal to comply with the instructions given to her by the board of directors, which failure, refusal or neglect continues for 15 days following her receipt of written notice from the board of directors stating with specificity the nature of such failure, refusal or neglect; or (6) her willful, material breach of any material company policy or any material provision of the employment letter or her proprietary information and inventions assignment agreement.
- “change in control” has the same meaning given to such term in our Existing Incentive Plan; and
- “good reason” means any of the following without her written consent: (1) a material diminution in her authority, duties or responsibilities; (2) a material diminution in her base compensation (and any diminution of 10% or more shall be considered material for this purpose, regardless of whether such diminution occurs due to a single reduction or a series of reductions in her base compensation), unless such a reduction is imposed across-the-board to senior management; (3) a material change in the geographic location at which she must perform her duties; or (4) any other action or inaction that constitutes a material breach by us or any successor or affiliate of its obligations to her under the employment letter.

Employment Letters with Other Executives

We have also entered into employment letters with each of our other executive officers, Aditya Kohli, Ph.D., our Chief Business Officer, and Azmi Nabulsi, M.D., M.P.H., our Chief Operating Officer. Each employment letter sets forth the terms of their employment, each effective on May 7, 2019 in connection with entering into the Takeda License.

The employment letters for Drs. Kohli and Nabulsi each provide for an annual base salary of $180,000 and $470,000, respectively, and an annual bonus with a target amount equal to 35% and 40% of the executive's annual base salary, respectively. Pursuant to his employment letter, Dr. Kohli's base salary will increase to $220,000, effective August 1, 2019. Under his employment letter, Dr. Nabulsi will work for our company on a full-time basis. Under his employment letter, Dr. Kohli will devote at least 80% of his time to our company. Additionally, under the employment letters, each executive is eligible to participate in all employee benefit plans and programs generally available to similarly situated employees of our company and is entitled to vacation benefits in accordance with our policies.

In September 2019, we amended and restated the employment letter for Dr. Nabulsi to provide certain severance benefits under his employment letter, subject to his execution of a release of claims, returning of all company property, compliance with post-termination obligations and resignation from positions with us.

Dr. Nabulsi's amended and restated employment letter provides for severance benefits for certain terminations that arise during and outside a change in control period (as defined below). Upon a termination without cause or resignation for good reason outside of a change in control period, Dr. Nabulsi will be entitled to: (1) continuation of his base salary for 9 months (such applicable period, the "severance period"), (2) a lump sum equal to his prorated target bonus for the year during which such termination occurs, plus any unpaid annual bonus for the calendar year prior to the year in which his termination occurs, to the extent he is entitled to such bonus and if such bonus has not already been paid, (3) payment of the COBRA premiums for him and his eligible dependents until the earliest of (a) the end the severance period, (b) expiration of his eligibility under for continuation coverage under COBRA, or (c) the date he becomes eligible for health insurance coverage in connection with his new employment, and (4) acceleration of the vesting of all outstanding equity awards that would have vested during the severance period.

Upon a termination without cause or resignation for good reason that occurs during the period that is three months prior to or the 24 months following a change in control (such period, the "change in control period"), Dr. Nabulsi will be entitled to all of the same severance benefits described above, except (1) the severance period is increased from 9 months to 12 months, (2) Dr. Nabulsi will be entitled to a lump sum payment equal to his target bonus for the year during which such termination occurs, plus any unpaid annual bonus for the calendar year prior to the year in which his termination occurs, to the extent he is entitled to such bonus and if such bonus has not already been paid, and (3) all unvested and outstanding equity awards will become fully vested on the later of the date his release of claims becomes effective or the date of the change in control.

For purposes of Dr. Nabulsi's amended and restated offer letter, "cause", "change in control" and "good reason" have the same definitions as set forth in Ms. Curran's employment letter described above.

Outstanding Equity Awards at Fiscal Year-End

Our named executive officer did not hold any unvested equity awards granted as of December 31, 2018.

Other Elements of Compensation

Perquisites, Health, Welfare and Retirement Benefits

We generally do not maintain employee benefit plans or provide perquisites or personal benefits to our executive officers. We do, however, reimburse certain of our executive officers for costs related to health and welfare benefits they receive pursuant to other sources. Our board of directors may elect to adopt qualified or non-qualified benefit plans in the future if it determines that doing so is in our best interests.

Nonqualified Deferred Compensation

We do not maintain nonqualified defined contribution plans or other nonqualified deferred compensation plans. Our board of directors may elect to provide our officers and other employees with non-qualified defined contribution or other nonqualified deferred compensation benefits in the future if it determines that doing so is in our best interests.

Change in Control Benefits

Our named executive officer may become entitled to certain benefits or enhanced benefits in connection with a change in control of our company. The stock restriction agreement with our named executive officer provides for accelerated vesting of all outstanding equity awards upon a qualifying termination in connection with a change in control of our company.

Incentive Award Plans

2019 Incentive Award Plan

Our board of directors and stockholders have adopted the 2019 Plan, which became effective in connection with this offering. Under the 2019 Plan, we may grant cash and equity incentive awards to eligible employees, directors and consultants in order to attract, motivate and retain the talent for which we compete. The material terms of the 2019 Plan are summarized below.

Eligibility and Administration

Our employees, consultants and directors, and employees and consultants of our subsidiaries, will be eligible to receive awards under the 2019 Plan. Following our initial public offering, the 2019 Plan will generally be administered by our board of directors with respect to awards to non-employee directors and by our compensation committee with respect to other participants, each of which may delegate its duties and responsibilities to committees of our directors and/or officers (referred to collectively as the plan administrator below), subject to certain limitations that may be imposed under the 2019 Plan, Section 16 of the Exchange Act and/or stock exchange rules, as applicable. The plan administrator will have the authority to make all determinations and interpretations under, prescribe all forms for use with, and adopt rules for the administration of, the 2019 Plan, subject to its express terms and conditions. The plan administrator will also set the terms and conditions of all awards under the 2019 Plan, including any vesting and vesting acceleration conditions.

Limitation on Awards and Shares Available

An aggregate of 2,700,000 shares of our common stock will initially be available for issuance under awards granted pursuant to the 2019 Plan. 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 our existing 2019 Equity Incentive Plan, or the Existing Incentive Plan, that expire or otherwise terminate without having been exercised in full after the effective date of the 2019 Plan and unvested shares issued pursuant to awards granted under our Existing Incentive Plan, that are forfeited to or repurchased by us 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 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 our board of directors. No more than 40,000,000 shares of common stock may be issued upon the exercise of incentive stock options under the 2019 Plan. Shares issued under the 2019 Plan may be authorized but unissued shares, shares purchased in the open market or treasury shares.

If an award under the 2019 Plan or the Existing Incentive Plan expires, lapses or is terminated, exchanged for cash, surrendered, repurchased, canceled without having been fully exercised or forfeited, any shares subject to such award will, as applicable, become or again be available for new grants under the 2019 Plan. Further, shares delivered to us to satisfy the applicable exercise or purchase price of an award under the 2019 Plan or the Existing Incentive Plan and/or to satisfy any applicable tax withholding obligations (including shares retained by us from the award under the 2019 Plan or the Existing Incentive Plan being exercised or purchased and/or creating the tax obligation) will become or again be available for award grants under the 2019 Plan. Awards granted under the 2019 Plan upon the assumption of, or in substitution for, awards authorized or outstanding under a qualifying equity plan maintained by an entity with which we enter into a merger or similar corporate transaction will not reduce the shares available for grant under the 2019 Plan.

Awards

The 2019 Plan provides for the grant of stock options, including incentive stock options, or ISOs, and nonqualified stock options, or NSOs, restricted stock, dividend equivalents, restricted stock units, or RSUs, stock appreciation rights, or SARs, and other stock or cash-based awards. Certain awards under the 2019 Plan may constitute or provide for a deferral of compensation, subject to Section 409A of the Code, which may impose additional requirements on the terms and conditions of such awards. All awards under the 2019 Plan will be set forth in award agreements, which will detail the terms and conditions of the awards, including any applicable vesting and payment terms and post-termination exercise limitations. A brief description of each award type follows.

Stock Options. Stock options provide for the purchase of shares of our common stock in the future at an exercise price set on the grant date. ISOs, by contrast to NSOs, may provide tax deferral beyond exercise and favorable capital gains tax treatment to their holders if certain holding period and other requirements of the Code are satisfied. The exercise price of a stock option will not be less than 100% of the fair market value of the underlying share on the date of grant (or 110% in the case of ISOs granted to certain significant stockholders), except with respect to certain substitute options granted in connection with a corporate transaction. The term of a stock option may not be longer than ten years (or five years in the case of ISOs granted to certain significant stockholders). Vesting conditions determined by the plan administrator may apply to stock options and may include continued service, performance and/or other conditions. ISOs generally may be granted only to our employees and employees of our parent or subsidiary corporations, if any.

SARs. SARs entitle their holder, upon exercise, to receive from us an amount equal to the appreciation of the shares subject to the award between the grant date and the exercise date. The exercise price of a SAR will not be less than 100% of the fair market value of the underlying share on the date of grant (except with respect to certain substitute SARs granted in connection with a corporate transaction), and the term of a SAR may not be longer than ten years. Vesting conditions determined by the plan administrator may apply to SARs and may include continued service, performance and/or other conditions.

Restricted Stock and RSUs. Restricted stock is an award of nontransferable shares of our common stock that remain forfeitable unless and until specified conditions are met, and which may be subject to a purchase price. RSUs are contractual promises to deliver shares of our common stock in the future, which may also remain forfeitable unless and until specified conditions are met and may be accompanied by the right to receive the equivalent value of dividends paid on shares of our common stock prior to the delivery of the underlying shares. Delivery of the shares underlying RSUs may be deferred under the terms of the award or at the election of the participant, if the plan administrator permits such a deferral. Conditions applicable to restricted stock and RSUs may be based on continuing service, the attainment of performance goals and/or such other conditions as the plan administrator may determine.

Other Stock or Cash-Based Awards. Other stock or cash-based awards are awards of cash, fully vested shares of our common stock and other awards valued wholly or partially by referring to, or otherwise based on, shares of our common stock. Other stock or cash-based awards may be granted to participants and may also be available as a payment form in the settlement of other awards, as standalone payments and as payment in lieu of base salary, bonus, fees or other cash compensation otherwise payable to any individual who is eligible to receive awards. The plan administrator will determine the terms and conditions of other stock or cash-based awards, which may include vesting conditions based on continued service, performance and/or other conditions.

Performance Awards

Performance awards include any of the foregoing awards that are granted subject to vesting and/or payment based on the attainment of specified performance goals or other criteria the plan administrator may determine, which may or may not be objectively determinable. Performance criteria upon which performance goals are established by the plan administrator may include: net earnings or losses (either before or after one or more of interest, taxes, depreciation, amortization and non-cash equity-based compensation expense); gross or net sales or revenue or sales or revenue growth; net income (either before or after taxes) or adjusted net income; profits (including, but not limited to, gross profits, net profits, profit growth, net operation profit or economic profit), profit return ratios or operating margin; budget or operating earnings (either before or after taxes or before or after allocation of corporate overhead and bonus); cash flow (including operating cash flow and free cash flow or cash flow return on capital); return on assets; return on capital or invested capital; cost of capital; return on stockholders' equity; total stockholder return; return on sales; costs, reductions in costs and cost control measures; expenses; working capital; earnings or loss per share; adjusted earnings or loss per share; price per share or dividends per share (or appreciation in or maintenance of such price or dividends); regulatory achievements or compliance; implementation, completion or attainment of objectives relating to research, development, regulatory, commercial or strategic milestones or developments; market share; economic value or economic value added models; division, group or corporate financial goals; customer satisfaction/growth; customer service; employee satisfaction; recruitment and maintenance of personnel; human resources management; supervision of litigation and other legal matters; strategic partnerships and transactions; financial ratios (including those measuring liquidity, activity, profitability or leverage); debt levels or reductions; sales-related goals; financing and other capital raising transactions; cash on hand; acquisition activity; investment sourcing activity; and marketing initiatives, any of which may be measured in absolute terms or as compared to any incremental increase or decrease. Such performance goals also may be based solely by reference to our performance or the performance of a subsidiary, division, business segment or business unit, or based upon performance relative to performance of other companies or upon comparisons of any of the indicators of performance relative to performance of other companies.

Provisions of the 2019 Plan Relating to Director Compensation

The 2019 Plan provides that the plan administrator may establish compensation for non-employee directors from time to time subject to the 2019 Plan's limitations. Prior to commencing this offering, our stockholders approved the initial terms of our non-employee director compensation program, which is described below under the heading "—Director Compensation." Our board of directors or its authorized committee may modify the non-employee director compensation program from time to time in the exercise of its business judgment, taking into account such factors, circumstances and considerations as it shall deem relevant from time to time, provided that the sum of any cash compensation or other compensation and the grant date fair value (as determined in accordance with ASC 718, or any successor thereto) of any equity awards granted as compensation for services as a non-employee director during any fiscal year may not exceed $750,000, increased to $1,000,000, in the fiscal year of a non-employee director's initial service as a non-employee director. The plan administrator may make exceptions to this limit for individual non-employee directors in extraordinary circumstances, as the plan administrator may determine in its discretion, provided that the non-employee director receiving such additional compensation may not participate in the decision to award such compensation or in other contemporaneous compensation decisions involving non-employee directors.

Certain Transactions

In connection with certain transactions and events affecting our common stock, including a change in control, or change in any applicable laws or accounting principles, the plan administrator has broad discretion to take action under the 2019 Plan to prevent the dilution or enlargement of intended benefits, facilitate such transaction or event, or give effect to such change in applicable laws or accounting principles. This includes canceling awards in exchange for either an amount in cash or other property with a value equal to the amount that would have been obtained upon exercise or settlement of the vested portion of such award or realization of the participant's rights under the vested portion of such award, accelerating the vesting of awards, providing for the assumption or substitution of awards by a successor entity, adjusting the number and type of shares available, replacing awards with other rights or property or terminating awards under the 2019 Plan. In the event of a change in control where the acquirer does not assume awards granted under the 2019 Plan, awards issued under the 2019 Plan shall be subject to accelerated vesting such that 100% of the awards will become vested and exercisable or payable, as applicable, and which may be subject to such terms and conditions as apply generally to holders of common stock under the change in control documents. In addition, in the event of certain non-reciprocal transactions with our stockholders, or an "equity restructuring," the plan administrator will make equitable adjustments to the 2019 Plan and outstanding awards as it deems appropriate to reflect the equity restructuring.

For purposes of the 2019 Plan, a "change in control" means and includes each of the following: (i) a transaction or series of transactions (other than an offering of our common stock to the general public through a registration statement filed with the SEC or a transaction or series of transactions that meets the requirements of clauses (x) and (y) of clause (iii) below) whereby any "person" or related "group" of "persons" (as such terms are used in Sections 13(d) and 14(d)(2) of the Exchange Act) (other than us, any of our subsidiaries, an employee benefit plan maintained by us or any of our subsidiaries or a "person" that, prior to such transaction, directly or indirectly controls, is controlled by, or is under common control with, us) directly or indirectly acquires beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of our securities possessing more than 50% of the total combined voting power of our securities outstanding immediately after such acquisition; or (ii) during any period of two consecutive years, individuals who, at the beginning of such period, constitute the board of directors together with any new director(s) (other than a director designated by a person who shall have entered into an agreement with us to effect a transaction described in clauses

(i) or (iii)) whose election by the board of directors or nomination for election by our stockholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of the two-year period or whose election or nomination for election was previously so approved, cease for any reason to constitute a majority thereof; or (iii) the consummation by us (whether directly involving us or indirectly involving us through one or more intermediaries) of (a) a merger, consolidation, reorganization, or business combination or (b) a sale or other disposition of all or substantially all of our assets in any single transaction or series of related transactions or (c) the acquisition of assets or stock of another entity, in each case other than a transaction: (x) which results in our voting securities outstanding immediately before the transaction continuing to represent (either by remaining outstanding or by being converted into our voting securities or the voting securities of a successor entity, directly or indirectly, at least a majority of the combined voting power of our outstanding voting securities or the successor entity's outstanding voting securities immediately after the transaction, and (y) after which no person or group beneficially owns voting securities representing 50% or more of the combined voting power of us or the successor entity (provided that no person will be treated as beneficially owning 50% or more of the combined voting power of us or the successor entity for purposes of this clause (y) solely as a result of the voting power held in us prior to the consummation of the transaction).

Foreign Participants, Claw-Back Provisions, Transferability and Participant Payments

With respect to foreign participants, the plan administrator may modify award terms, establish subplans and/or adjust other terms and conditions of awards, subject to the share limits described above. All awards will be subject to the provisions of any claw-back policy implemented by our company to the extent set forth in such claw-back policy or in the applicable award agreement. With limited exceptions for estate planning, domestic relations orders, certain beneficiary designations and the laws of descent and distribution, awards under the 2019 Plan are generally non-transferable prior to vesting and are exercisable only by the participant. With regard to tax withholding obligations arising in connection with awards under the 2019 Plan and exercise price obligations arising in connection with the exercise of stock options under the 2019 Plan, the plan administrator may, in its discretion, accept cash, wire transfer, or check, shares of our common stock that meet specified conditions, a "market sell order" or such other consideration as it deems suitable or any combination of the foregoing.

Plan Amendment and Termination

Our board of directors may amend or terminate the 2019 Plan at any time; however, except in connection with certain changes in our capital structure, stockholder approval will be required for any amendment that increases the number of shares available under the 2019 Plan. The plan administrator will have the authority, without the approval of our stockholders, to amend any outstanding stock option or SAR to reduce its exercise price per share. No award may be granted pursuant to the 2019 Plan after the tenth anniversary of the date on which our board of directors adopted the 2019 Plan.

Securities Laws

The 2019 Plan is intended to conform to all provisions of the Securities Act, and the Exchange Act and any and all regulations and rules promulgated by the SEC thereunder, including, without limitation, Rule 16b-3. The 2019 Plan will be administered, and awards will be granted and may be exercised, only in such a manner as to conform to such laws, rules and regulations.

Federal Income Tax Consequences

The material federal income tax consequences of the 2019 Plan under current federal income tax law are summarized in the following discussion, which deals with the general tax principles applicable to the 2019 Plan. The following discussion is based upon laws, regulations, rulings and decisions now in effect, all of which are subject to change. Foreign, state and local tax laws, and employment, estate and gift tax considerations are not discussed due to the fact that they may vary depending on individual circumstances and by locality.

Stock Options and SARs. A 2019 Plan participant generally will not recognize taxable income and we generally will not be entitled to a tax deduction upon the grant of a stock option or SAR. The tax consequences of exercising a stock option and the subsequent disposition of the shares received upon exercise will depend upon whether the option qualifies as an ISO or an NSO. Upon exercising an NSO when the fair market value of our stock is higher than the exercise price of the option, a 2019 Plan participant generally will recognize taxable income at ordinary income tax rates equal to the excess of the fair market value of the stock on the date of exercise over the purchase price, and we (or our subsidiaries, if any) generally will be entitled to a corresponding tax deduction for compensation expense, in the amount equal to the amount by which the fair market value of the shares purchased exceeds the purchase price for the shares. Upon a subsequent sale or other disposition of the option shares, the participant will recognize a short-term or long-term capital gain or loss in the amount of the difference between the sales price of the shares and the participant's tax basis in the shares.

Upon exercising an ISO, a 2019 Plan participant generally will not recognize taxable income, and we will not be entitled to a tax deduction for compensation expense. However, upon exercise, the amount by which the fair market value of the shares purchased exceeds the purchase price will be an item of adjustment for alternative minimum tax purposes. The participant will recognize taxable income upon a sale or other taxable disposition of the option shares. For federal income tax purposes, dispositions are divided into two categories: qualifying and disqualifying. A qualifying disposition generally occurs if the sale or other disposition is made more than two years after the date the option was granted and more than one year after the date the shares are transferred upon exercise. If the sale or disposition occurs before these two periods are satisfied, then a disqualifying disposition generally will result.

Upon a qualifying disposition of ISO shares, the participant will recognize long-term capital gain in an amount equal to the excess of the amount realized upon the sale or other disposition of the shares over their purchase price. If there is a disqualifying disposition of the shares, then the excess of the fair market value of the shares on the exercise date (or, if less, the price at which the shares are sold) over their purchase price will be taxable as ordinary income to the participant. If there is a disqualifying disposition in the same year of exercise, it eliminates the item of adjustment for alternative minimum tax purposes. Any additional gain or loss recognized upon the disposition will be recognized as a capital gain or loss by the participant.

We will not be entitled to any tax deduction if the participant makes a qualifying disposition of ISO shares. If the participant makes a disqualifying disposition of the shares, we should be entitled to a tax deduction for compensation expense in the amount of the ordinary income recognized by the participant.

Upon exercising or settling a SAR, a 2019 Plan participant will recognize taxable income at ordinary income tax rates, and we should be entitled to a corresponding tax deduction for compensation expense, in the amount paid or value of the shares issued upon exercise or settlement. Payments in shares will be valued at the fair market value of the shares at the time of the payment, and upon the subsequent disposition of the shares the participant will recognize a short-term or long-term capital gain or loss in the amount of the difference between the sales price of the shares and the participant's tax basis in the shares.

Restricted Stock and RSUs. A 2019 Plan participant generally will not recognize taxable income at ordinary income tax rates and we generally will not be entitled to a tax deduction upon the grant of restricted stock or RSUs. Upon the termination of restrictions on restricted stock or the payment of RSUs, the participant will recognize taxable income at ordinary income tax rates, and we should be entitled to a corresponding tax deduction for compensation expense, in the amount paid to the participant or the amount by which the then fair market value of the shares received by the participant exceeds the amount, if any, paid for them. Upon the subsequent disposition of any shares, the participant will recognize a short-term or long-term capital gain or loss in the amount of the difference between the sales price of the shares and the participant's tax basis in the shares. However, a 2019 Plan participant granted restricted stock that is subject to forfeiture or repurchase through a vesting schedule such that it is subject to a "risk of forfeiture" (as defined in Section 83 of the Code) may make an election under Section 83(b) of the Code to recognize taxable income at ordinary income tax rates, at the time of the grant, in an amount equal to the fair market value of the shares of common stock on the date of grant, less the amount paid, if any, for such shares. We will be entitled to a corresponding tax deduction for compensation, in the amount recognized as taxable income by the participant. If a timely Section 83(b) election is made, the participant will not recognize any additional ordinary income on the termination of restrictions on restricted stock, and we will not be entitled to any additional tax deduction.

Other Stock or Cash-Based Awards. A 2019 Plan participant will not recognize taxable income and we will not be entitled to a tax deduction upon the grant of other stock or cash-based awards until cash or shares are paid or distributed to the participant. At that time, any cash payments or the fair market value of shares that the participant receives will be taxable to the participant at ordinary income tax rates and we should be entitled to a corresponding tax deduction for compensation expense. Payments in shares will be valued at the fair market value of the shares at the time of the payment, and upon the subsequent disposition of the shares, the participant will recognize a short-term or long-term capital gain or loss in the amount of the difference between the sales price of the shares and the participant's tax basis in the shares.

Existing Equity Incentive Plan

On May 6, 2019, our board of directors and our stockholders approved the adoption of the Existing Incentive Plan.

A total of 2,231,739 shares of our common stock are reserved for issuance under the Existing Incentive Plan. As of June 30, 2019, 16,260 shares of our common stock were subject to outstanding restricted stock awards under the Existing Incentive Plan and 2,215,479 shares of our common stock remained available for future issuance under the Existing Incentive Plan. Since June 30, 2019, options to purchase a total of 1,400,528 shares of our common stock have been granted under the Existing Incentive Plan.

After the effective date of the 2019 Plan, no additional awards will be granted under the Existing Incentive Plan. However, the Existing Incentive Plan will continue to govern the terms and conditions of the outstanding awards granted under it. Shares of our common stock subject to awards granted under the Existing Incentive Plan that expire, lapse or are terminated, exchanged for cash, surrendered, repurchased or forfeited following the effective date of the Existing Incentive Plan will be available for issuance under the Existing Incentive Plan in accordance with its terms.

Administration. Our board of directors administers the Existing Incentive Plan, unless it delegates authority for administration of the plan. Subject to the terms and conditions of the Existing Incentive Plan, the administrator has the authority to select the persons to whom awards are to be made, to determine the type or types of awards to be granted to each person, determine the number of awards to grant, determine the number of shares to be subject to such awards, and the terms and conditions of such awards, and make all other determinations and decisions and to take all other actions necessary or advisable for the administration of the Existing Incentive Plan. The plan administrator is also authorized to establish, adopt, amend or revise rules relating to administration of the Existing Incentive Plan, subject to certain restrictions.

Eligibility. Awards under the Existing Incentive Plan may be granted to individuals who are then our employees, consultants and members of our board of directors and our subsidiaries. Only employees may be granted ISOs.

Awards. The Existing Incentive Plan provides that our administrator may grant or issue stock options (including NSOs and ISOs), restricted stock, RSUs, other stock-based awards, or any combination thereof. The administrator considers each award grant subjectively, considering factors such as the individual performance of the recipient and the anticipated contribution of the recipient to the attainment of our long-term goals. Each award is set forth in a separate agreement with the person receiving the award and indicates the type, terms and conditions of the award.

Corporate Transactions. The plan administrator has broad discretion to equitably adjust the provisions of the Existing Incentive Plan and the terms and conditions of existing and future awards, including with respect to aggregate number and type of shares subject to the Existing Incentive Plan and awards granted pursuant to the Existing Incentive Plan, to prevent the dilution or enlargement of intended benefits and/or facilitate necessary or desirable changes in the event of certain transactions and events affecting our common stock, such as stock dividends, stock splits, mergers, acquisitions, consolidations and other corporate transactions. The plan administrator may also provide for the acceleration, cash-out, termination, assumption, substitution or conversion of awards in the event of a change in control or certain other unusual or nonrecurring events or transactions. In addition, in the event of certain non-reciprocal transactions with our stockholders, or an “equity restructuring,” the plan administrator will make equitable adjustments to the Existing Incentive Plan and outstanding awards as it deems appropriate to reflect the equity restructuring.

In the event of a change of control where the acquirer does not assume awards granted under the Existing Incentive Plan, awards issued under the Existing Incentive Plan held by persons who have not experienced a termination of service will be subject to accelerated vesting such that 100% of the awards will become vested and exercisable or payable, as applicable, immediately prior to the change in control. Under the Existing Incentive Plan, a change of control is generally defined as: (i) a merger or consolidation of our company with or into any other corporation or other entity or person; (ii) a sale, lease, exchange or other transfer in one transaction or a series of related transactions of all or substantially all of our company’s assets; or (iii) any other transaction, including the sale by us of new shares of our capital stock or a transfer of existing shares of our capital stock, the result of which is that a third party that is not an affiliate of us or our stockholders (or a group of third parties not affiliated with us or our stockholders) immediately prior to such transaction acquires or holds capital stock representing a majority of our outstanding voting power immediately following such transaction; provided that the following events shall not constitute a “change in control” under the Existing Incentive Plan: (a) a transaction (other than a sale of all or substantially all of our assets) in which the holders of our voting securities immediately prior to the merger or consolidation hold, directly or indirectly, at least a majority of the voting securities in the successor corporation or its parent immediately after the merger or consolidation; (b) a sale, lease, exchange or other transaction in one transaction or a series of related transactions of all or substantially all of our assets to an affiliate of ours; (c) an initial public offering of any of our securities or any other transaction principally for bona fide equity financing purposes; (d) a reincorporation solely to change our jurisdiction; or (e) a transaction undertaken for the primary purpose of creating a holding company that will be owned in substantially the same proportion by the persons who held our securities immediately before such transaction.

Amendment and Termination of the Existing Incentive Plan. Our board of directors may terminate, amend or modify the Existing Incentive Plan. However, stockholder approval of any amendment to the Existing Incentive Plan must be obtained to the extent necessary and desirable to comply with any applicable law, regulation or stock exchange rule, or for any amendment to the Existing Incentive Plan that increases the number of shares available under the Existing Incentive Plan. If not terminated earlier by the compensation committee or the board of directors, the Existing Incentive Plan will terminate on May 6, 2029.

Securities Laws and Federal Income Tax Consequences. The Existing Incentive Plan is designed to comply with applicable securities laws in the same manner as described above in the description of the 2019 Plan under the heading "—2019 Incentive Award Plan —Securities Laws." The general federal tax consequences of awards under the Existing Incentive Plan are the same as those described above in the description of the 2019 Plan under the heading "—2019 Incentive Award Plan—Federal Income Tax Consequences."

2019 Employee Stock Purchase Plan

Our board of directors and our stockholders have approved the ESPP, which became effective in connection with this offering. The material terms of the ESPP are summarized below.

Shares Available; Administration. A total of 270,000 shares of our common stock are initially reserved for issuance under our 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 our board of directors. In no event will more than 10,000,000 shares of our common stock be available for issuance under the ESPP.

Our board of directors or its committee will have authority to interpret the terms of the ESPP and determine eligibility of participants. We expect that the compensation committee will be the initial administrator of the ESPP.

Eligibility. Our employees are eligible to participate in the ESPP if they meet the eligibility requirements under the ESPP established from time to time by the plan administrator. However, an employee may not be granted rights to purchase stock under our ESPP if such employee, immediately after the grant, would own (directly or through attribution) stock possessing 5% or more of the total combined voting power or value of all classes of our common or other class of stock.

Grant of Rights. The ESPP is intended to qualify under Section 423 of the Code and stock will be offered under the ESPP during offering periods. The length of the offering periods under the ESPP will be determined by the plan administrator and may be up to 27 months long. Employee payroll deductions will be used to purchase shares on each purchase date during an offering period. The number of purchase periods within, and purchase dates during each offering period will be established by the plan administrator prior to the commencement of each offering period. Offering periods under the ESPP will commence when determined by the plan administrator. The plan administrator may, in its discretion, modify the terms of future offering periods.

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 us, including overtime payments and excluding sales commissions, incentive compensation, bonuses, expense reimbursements, fringe benefits and other special payments. The plan administrator will establish a maximum number of shares that may be purchased by a participant during any offering period or purchase period, which, in the absence of a contrary designation, will be

100,000 shares. In addition, no employee will be permitted to accrue the right to purchase stock under the ESPP at a rate in excess of $25,000 worth of shares during any calendar year during which such a purchase right is outstanding (based on the fair market value per share of our common stock as of the first day of the offering period).

On the first trading day of each offering period, each participant will automatically be granted an option to purchase shares of our common stock. The option will be exercised on the applicable purchase date(s) during the offering period, to the extent of the payroll deductions accumulated during the applicable purchase period. The purchase price of the shares, in the absence of a contrary determination by the plan administrator, will be 85% of the lower of the fair market value of our common stock on the first trading day of the offering period or on the applicable purchase date, which will be the final trading day of the applicable purchase period. Participants may voluntarily end their participation in the ESPP at any time at least one week prior to the end of the applicable offering period (or such shorter or longer period specified by the plan administrator), and will be paid their accrued payroll deductions that have not yet been used to purchase shares of common stock. Participation ends automatically upon a participant's termination of employment.

A participant may not transfer rights granted under the ESPP other than by will, the laws of descent and distribution or as otherwise provided under the ESPP.

Certain Transactions. In the event of certain transactions or events affecting our common stock, such as any stock dividend or other distribution, change in control, reorganization, merger, consolidation or other corporate transaction, the plan administrator will make equitable adjustments to the ESPP and outstanding rights. In addition, in the event of the foregoing transactions or events or certain significant transactions, including a change in control, the plan administrator may provide for (i) either the replacement of outstanding rights with other rights or property or termination of outstanding rights in exchange for cash, (ii) the assumption or substitution of outstanding rights by the successor or survivor corporation or parent or subsidiary thereof, if any, (iii) the adjustment in the number and type of shares of stock subject to outstanding rights, (iv) the use of participants' accumulated payroll deductions to purchase stock on a new purchase date prior to the next scheduled purchase date and termination of any rights under ongoing offering periods or (v) the termination of all outstanding rights. Under the ESPP, a change in control has the same definition as given to such term in the Existing Incentive Plan.

Plan Amendment; Termination. The plan administrator may amend, suspend or terminate the ESPP at any time. However, stockholder approval of any amendment to the ESPP will be obtained for any amendment which increases the aggregate number or changes the type of shares that may be sold pursuant to rights under the ESPP, changes the corporations or classes of corporations whose employees are eligible to participate in the ESPP or changes the ESPP in any manner that would cause the ESPP to no longer be an employee stock purchase plan within the meaning of Section 423(b) of the Code. The ESPP will remain in effect until terminated by our board of directors.

Securities Laws. The ESPP has been designed to comply with various securities laws in the same manner as described above in the description of the 2019 Plan under the heading "—2019 Incentive Award Plan—Securities Laws.".

Federal Income Taxes. The material federal income tax consequences of the ESPP under current federal income tax law are summarized in the following discussion, which deals with the general tax principles applicable to the ESPP. The following discussion is based upon laws, regulations, rulings and decisions now in effect, all of which are subject to change. Foreign, state and local tax laws, and employment, estate and gift tax considerations are not discussed due to the fact that they may vary depending on individual circumstances and from locality to locality.

The ESPP, and the right of participants to make purchases thereunder, is intended to qualify under the provisions of Section 423 of the Code. Under the applicable Code provisions, no income will be taxable to a participant until the sale or other disposition of the shares purchased under the ESPP. This means that an eligible employee will not recognize taxable income on the date the employee is granted an option under the ESPP (i.e., the first day of the offering period). In addition, the employee will not recognize taxable income upon the purchase of shares. Upon such sale or disposition, the participant will generally be subject to tax in an amount that depends upon the length of time such shares are held by the participant prior to disposing of them. If the shares are sold or disposed of more than two years from the first day of the offering period during which the shares were purchased and more than one year from the date of purchase, or if the participant dies while holding the shares, the participant (or his or her estate) will recognize ordinary income measured as the lesser of: (i) the excess of the fair market value of the shares at the time of such sale or disposition over the purchase price; or (ii) an amount equal to 15% of the fair market value of the shares as of the first day of the offering period. Any additional gain will be treated as long-term capital gain. If the shares are held for the holding periods described above but are sold for a price that is less than the purchase price, there is no ordinary income and the participating employee has a long-term capital loss for the difference between the sale price and the purchase price.

If the shares are sold or otherwise disposed of before the expiration of the holding periods described above, the participant will recognize ordinary income generally measured as the excess of the fair market value of the shares on the date the shares are purchased over the purchase price and we will be entitled to a tax deduction for compensation expense in the amount of ordinary income recognized by the employee. Any additional gain or loss on such sale or disposition will be long-term or short-term capital gain or loss, depending on how long the shares were held following the date they were purchased by the participant prior to disposing of them. If the shares are sold or otherwise disposed of before the expiration of the holding periods described above but are sold for a price that is less than the purchase price, the participant will recognize ordinary income equal to the excess of the fair market value of the shares on the date of purchase over the purchase price (and we will be entitled to a corresponding deduction), but the participant generally will be able to report a capital loss equal to the difference between the sales price of the shares and the fair market value of the shares on the date of purchase.

Director Compensation

Historically, we have not paid cash or stock-based compensation to directors for their service on our board of directors.

On January 23, 2018, YamadaCo IIA issued and sold to Dr. Yamada, 1,686,704 shares of common stock of YamadaCo IIA for a per share purchase price of $0.0002958.

On March 13, 2019, we entered into a stock restriction agreement with Dr. Yamada whereby Dr. Yamada’s previously-acquired 1,686,704 shares of our common stock were subjected to new vesting conditions, such that 421,676 shares were deemed vested as of March 13, 2019 and the remaining 1,265,028 shares were converted into unvested shares of restricted stock that vest in equal monthly installments over the 48 months thereafter ending on March 13, 2023, subject, in each case, to continued employment or status as a service provider. Any unvested shares held by Dr. Yamada upon a termination of employment or service (after giving effect to any accelerated vesting provisions described further below), will be subject to repurchase by us at the original purchase price.

Under Dr. Yamada’s stock restriction agreement, 100% of any unvested shares will automatically accelerate and vest upon (i) a termination of service by us without cause or by him for good reason following a change in control, or (ii) the refusal by us to enter into a consulting agreement with him in connection with his resignation, subject to his continued employment or service through the date of such event.

The defined terms “change in control,” “cause” and “good reason” have the same meanings in Dr. Yamada’s stock restriction agreement as given to such terms in Mr. Socks’ stock restriction agreement and described above under “Executive and Director Compensation—Equity-Based Incentive Awards.”

On May 7, 2019, we entered into an offer letter with Dr. Yamada, our Chairman of the board of directors. Pursuant to Dr. Yamada’s offer letter, Dr. Yamada will be paid an annual cash fee of $100,000, paid quarterly, for his services as Chairman. Additionally, as a member of our board of directors, we will reimburse Dr. Yamada for reasonable travel and other expenses to attend board meetings and other board-related functions.

Effective August 29, 2019, we appointed Terrie Curran to our board of directors. In connection with Ms. Curran’s appointment to our board of directors, we granted to her stock options to purchase 867,200 shares of our common stock under the Existing Incentive Plan. For a description of the stock options granted to Ms. Curran, see “—Employment Letter with Terrie Curran” above.

Effective September 26, 2019, we entered into an offer letter with each of Heidi Kunz and Michael Cola in connection with their appointment to our board of directors. Pursuant to each offer letter, Ms. Kunz and Mr. Cola will be paid an annual cash retainer of $40,000, paid quarterly, which retainer will commence immediately. Additionally, as a member of our board of directors, we will reimburse Ms. Kunz and Mr. Cola for reasonable travel and other expenses to attend board meetings and other board-related functions. Pursuant to their offer letters, we also granted each of Ms. Kunz and Mr. Cola stock options to purchase 43,360 shares of our common stock. The stock options have a ten-year term and an exercise price of $13.04 per share, which our board of directors determined was equal to the fair market value per share of our common stock on the date of grant. The options will vest over a three-year period, with one-third vesting on the first anniversary of the date of grant and the remainder vesting quarterly over the 24 months thereafter, subject to continued service with us on each vesting date. Such stock options will accelerate in full upon a change in control of our company.

In connection with this offering, our board of directors and our stockholders have approved a non-employee director compensation program. The material terms of the non-employee director compensation program are summarized below.

The non-employee director compensation program will provide for annual retainer fees and/or long-term equity awards for our non-employee directors. Each non-employee director will receive an annual retainer of $40,000. Non-employee directors serving as the chairs of the audit, compensation and nominating and corporate governance committees will receive additional annual retainers of $20,000, $15,000 and $10,000, respectively. Non-employee directors serving as members of the audit, compensation and nominating and corporate governance committees will receive additional annual retainers of $10,000, $7,500 and $5,000, respectively. Additionally, the non-executive chairman of the board will receive an additional annual retainer of $40,000. The non-employee directors will also receive initial grants of options to purchase 20,000 shares of our common stock upon election to the board of directors, one-third of which will vest on the first anniversary of the grant date and the remainder of which will vest in quarterly installments over the following 24 months, and thereafter annual grants of options to purchase 10,000 shares of our common stock, vesting on the first to occur of (i) the first anniversary of the grant date or (ii) the next occurring annual meeting of our stockholders, in each case, subject to the non-employee director continuing in service on our board of directors through such vesting date.

Compensation under our non-employee director compensation program will be subject to the annual limits on non-employee director compensation set forth in the 2019 Plan, as described above. Our board of directors or its authorized committee may modify the non-employee director compensation program from time to time in the exercise of its business judgment, taking into account such factors, circumstances and considerations as it shall deem relevant from time to time, subject to the annual limit on non-employee director compensation set forth in the 2019 Plan. As provided in the 2019 Plan, our board of directors or its authorized committee may make exceptions to this limit for individual non-employee directors in extraordinary circumstances, as the board of directors or its authorized committee may determine in its discretion, provided that the non-employee director receiving such additional compensation may not participate in the decision to award such compensation or in other compensation decisions involving non-employee directors.

Limitations of Liability and Indemnification Matters

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that we will indemnify our directors and officers to the fullest extent permitted by the Delaware General Corporation Law, which prohibits our amended and restated certificate of incorporation from limiting the liability of our directors for the following:

- any breach of the director’s duty of loyalty to us or our stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit.

Our amended and restated certificate of incorporation and our amended and restated bylaws also provide that if Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law, as so amended. This limitation of liability does not apply to liabilities arising under the federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated certificate of incorporation and our amended and restated bylaws also provide that we shall have the power to indemnify our employees and agents to the fullest extent permitted by law. Our amended and restated bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in this capacity, regardless of whether our amended and restated bylaws would permit indemnification. We have obtained directors’ and officers’ liability insurance.

We have entered into separate indemnification agreements with our directors and executive officers, in addition to indemnification provided for in our amended and restated certificate of incorporation and amended and restated bylaws. These agreements, among other things, provide for indemnification of our directors and executive officers for expenses, judgments, fines and settlement amounts incurred by this person in any action or proceeding arising out of this person’s services as a director or executive officer or at our request. We believe that these provisions in our amended and restated certificate of incorporation and amended and restated bylaws and indemnification agreements are necessary to attract and retain qualified persons as directors and executive officers.

The above description of the indemnification provisions of our amended and restated certificate of incorporation, our amended and restated bylaws and our indemnification agreements is not complete and is qualified in its entirety by reference to these documents, each of which is filed as an exhibit to the registration statement of which this prospectus is a part.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Insofar as indemnification for liabilities under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

The following includes a summary of transactions since our inception to which we have been a party in which the amount involved exceeded or will exceed the lesser of $120,000 and one percent of the average of our total assets at year-end for the last two completed fiscal years, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under “Executive and Director Compensation.” The transactions below also include transactions of YamadaCo IIA, Inc. prior to the Merger. We also describe below certain other transactions with our directors, executive officers and stockholders.

Convertible Promissory Note Financings

Prior Convertible Promissory Note Financings with Frazier Life Sciences IX, L.P.

In January 2018, YamadaCo IIA, Inc. entered into a convertible promissory note purchase agreement with Frazier Life Sciences IX, L.P., or FLS IX, pursuant to which from January 2018 to December 2018 YamadaCo IIA issued and sold to FLS IX three convertible promissory notes, or the YamadaCo Notes, in the aggregate principal amount of $1.5 million. The YamadaCo Notes accrued interest at the then applicable federal rate (1.68%, 2.38% and 2.55%, respectively) per annum, and were due and payable upon demand by FLS IX nine months from the date of issuance, subject to earlier conversion or repayment in the event YamadaCo IIA completed an equity financing or a change of control.

In January 2018, we entered into a convertible promissory note purchase agreement with FLS IX, pursuant to which from January 2018 to April 2019, we issued and sold to FLS IX three convertible promissory notes, or the Phathom Notes, in the aggregate principal amount of $0.9 million. The Phathom Notes accrued interest at the then applicable federal rate (1.68%, 2.42% and 2.52%, respectively) per annum, and were due and payable upon demand by FLS IX nine months from the date of issuance, subject to earlier conversion or repayment in the event we completed an equity financing or a change of control.

The YamadaCo Notes and Phathom Notes, in the aggregate amount of $2.4 million, including accrued interest thereon, were cancelled and exchanged for May 2019 Notes issued in the May 2019 convertible note financing described below.

The general partner of FLS IX is FHMLS IX, L.P., and the general partner of FHMLS IX, L.P. is FHMLS IX, L.L.C. James Topper, M.D., Ph.D., a member of our board of directors, is one of the managing members of FHMLS IX, L.L.C.

May 2019 Convertible Promissory Note Financing

In May 2019, we entered into a convertible promissory note purchase agreement with certain investors, or the 2019 Note Purchase Agreement, pursuant to which in May 2019 we issued and sold to such investors convertible promissory notes, or the May 2019 Notes, in the aggregate principal amount of approximately $90.3 million. The May 2019 Notes accrue interest at a rate of 6% per annum and become payable upon demand of the holders of at least 60% of the outstanding principal amount of the May 2019 Notes one year from the date of issuance, subject to earlier conversion or repayment in the event we complete an equity financing or a change of control. We have not paid any interest on the May 2019 Notes to date. The participants in this May 2019 Note financing included the following 5% or greater stockholders and or entities affiliated with members of our board of directors.

Participants	Aggregate Principal Amount of May 2019 Notes
Frazier Life Sciences IX, L.P.(1)	$ 20,000,000
Entities affiliated with Medicxi Growth(2)	$ 15,000,000

(1) Consists of convertible promissory notes held by FLS IX, or the Frazier May 2019 Notes. Additional details regarding FLS IX and its equity holdings are provided under the section titled “Principal Stockholders.” James Topper, M.D., Ph.D., a member of our board of directors, is one of the managing members of FHMLS IX, L.L.C, which is an affiliate of FLS IX.

(2) Consists of convertible promissory notes, or the Medicxi Notes, held by Medicxi Growth I LP and Medicxi Growth Co-Invest I LP, collectively Medicxi Growth. Jonathan Edwards, Ph.D., a member of our board of directors, is a Partner of Medicxi, an affiliate of Medicxi Growth.

The outstanding principal and unpaid accrued interested due on the Frazier May 2019 Notes and the Medicxi Notes will automatically convert into an aggregate of 1,353,640 shares and 1,015,230 shares of our common stock, respectively, immediately prior to the closing of this offering, each based on the initial public offering price of $19.00 per share and assuming the conversion occurs on October 29, 2019.

The May 2019 Notes are subordinated to borrowings under our Loan Agreement with Silicon Valley Bank and WestRiver Innovation Lending Fund VIII, L.P.

Investor Rights Under the 2019 Note Purchase Agreement

Registration Rights

The 2019 Note Purchase Agreement provides FLS IX, Takeda, and all holders of the May 2019 Notes with specified registration rights relating to the registration of shares of common stock held by such entities, including shares of our common stock issuable upon conversion of the May 2019 Notes and shares of our common stock issuable upon the exercise or conversion of any securities exercisable or convertible into shares of our common stock.

The registration rights terminate upon the earlier of: (i) five years after the closing of this offering or (ii) with respect to a particular holder, such time at which such holder can sell all shares held by it in compliance with Rule 144 under the Securities Act.

See the section titled “Description of Capital Stock—Registration Rights” for more information regarding these registration rights.

Voting Rights

The 2019 Note Purchase Agreement provides for rights relating to the election of members to serve on our board of directors. Pursuant to the 2019 Note Purchase Agreement, as amended in

September 2019, the following directors were each elected to serve as members on our board of directors and, as of the date of this prospectus, continue to so serve: David Socks, Tadataka Yamada, M.D., Michael F. Cola, Terrie Curran, Jonathan Edwards, Ph.D., Heidi Kunz, Chris Slavinsky, and James Topper, M.D., Ph.D. Mr. Socks, our President and Chief Executive Officer, was initially selected to serve on our board of directors in his role as Chief Executive Officer. Dr. Yamada was initially selected to serve on our board of directors as a representative of holders of our common stock, as designated by a majority of our common stockholders. Dr. Topper was initially selected to serve on our board of directors as a representative of holders of our common stock, as designated by FLS IX. Dr. Edwards was initially selected to serve on our board of directors as a representative of the holders of the May 2019 Notes. Mr. Cola, Ms. Curran, Ms. Kunz, and Mr. Slavinsky were initially selected to serve on our board of directors as representatives of holders of our common stock, with Mr. Slavinsky being designated by Takeda.

The 2019 Note Purchase Agreement provides that Takeda may designate a member to serve on our board of directors as a representative of holders of our common stock, provided that such right does not apply at any time the board of directors consists of fewer than five individuals that are not affiliated with Takeda. In connection with our appointment of Ms. Curran to our board of directors in August 2019, at which time we had five directors serving on our board, we also appointed Mr. Slavinsky to our board pursuant this right.

The voting rights provisions of the 2019 Note Purchase Agreement will terminate upon the closing of this offering, and members previously elected to our board of directors pursuant to this agreement will continue to serve as directors until they resign, are removed or their successors are duly elected by holders of our common stock. The composition of our board of directors after this offering is described in more detail under “Management—Board Composition and Election of Directors.”

Other Rights

The 2019 Note Purchase Agreement provides certain holders of our May 2019 Notes with various additional rights including, among others, information rights, pre-emptive rights, drag along rights, rights of first refusal, co-sale rights, and certain additional covenants made by us. Except as set forth above, all rights under the 2019 Note Purchase Agreement will terminate upon the closing of this offering.

Takeda Agreements

License Agreement and Clinical Manufacturing and Supply Agreement

On May 7, 2019, we and Takeda, one of our 5% stockholders, entered into the Takeda License and a clinical manufacturing and supply agreement. Such agreements are described in “Business—Intellectual Property—License Agreement with Takeda Pharmaceutical Company Limited.”

In connection with the Takeda License, we (i) entered into a Stock Issuance Agreement with Takeda, pursuant to which we issued Takeda 1,084,000 shares of our common stock, (ii) issued the Takeda Warrant to purchase 7,588,000 shares of common stock at an exercise price of $0.00004613 per share and (iii) granted the Takeda Warrant Right, pursuant to which Takeda has a right to receive an additional common stock warrant upon the closing of this offering if Takeda’s fully-diluted ownership represents less than a specified percentage of our fully-diluted capitalization, including shares issuable upon conversion of outstanding convertible promissory notes, calculated immediately prior to the closing of this offering, each as partial consideration under the Takeda License. The Takeda Warrant expires ten years from its date of issuance, subject to its earlier termination upon the completion of certain mergers, acquisitions and similar transactions. The Takeda Warrant Right will expire upon the closing of this offering based on the initial public offering price of $19.00 per share. See the section titled “Description of Capital Stock—Warrants” for more information regarding the Takeda Warrant and the Takeda Warrant Right. In connection with the Takeda License, we provided Takeda with various investor rights, including pre-emptive rights, drag along rights, voting rights and certain registration rights. See “—Investor Rights Under the 2019 Note Purchase Agreement” above for more information regarding these voting rights and registration rights.

Merger

Initial Founder Equity Issuances

On January 23, 2018, YamadaCo IIA issued and sold to Tadataka Yamada, M.D., our Chairman, 1,686,704 shares of YamadaCo IIA common stock at a purchase price of $0.0002958 per share, after giving effect to the merger described below. On February 14, 2018, YamadaCo IIA issued and sold to FLS IX 1,693,463 shares of YamadaCo IIA common stock at a purchase price of $0.0002958 per share, after giving effect to the merger described below.

On February 13, 2018, we issued and sold to David Socks, our President and Chief Executive Officer and a member of our board of directors, 1,686,704 shares of our common stock at a purchase price of $0.0002958 per share. On February 14, 2018, we issued and sold to FLS IX 1,693,463 shares of our common stock at a purchase price of $0.0002958 per share.

On March 13, 2019, we entered into stock restriction agreements with each of Mr. Socks and Dr. Yamada providing for vesting and a company right to repurchase the unvested shares held by Mr. Socks and Dr. Yamada upon the occurrence of certain events.

For more information regarding these stock issuances to Dr. Yamada and Mr. Socks, see the section in this prospectus entitled “Executive and Director Compensation—Equity-Based Incentive Awards” and “Executive and Director Compensation—Narrative Disclosure to Summary Compensation Table—Director Compensation.”

Merger Agreement

On March 13, 2019, YamadaCo IIA merged with and into our company, with our company surviving the merger, or the Merger. Immediately prior to the Merger, we effected a 1,559.1183-for-1 forward stock split for each outstanding share of our common stock. Effective upon the closing of the Merger, each issued and outstanding share of YamadaCo IIA was converted into 1,559.1183 shares of our common stock.

Additional Equity Issuances

Following the Merger, on March 13, 2019, we issued and sold to FLS IX 1,491,072 shares of our common stock at a purchase price of $0.0002958 per share.

Additional Executive Officer Equity Issuances

Following the Merger, on March 13, 2019, we issued and sold to each of Azmi Nabulsi, M.D., M.P.H., our Chief Operating Officer, and Aditya Kohli, Ph.D., our Chief Business Officer, 867,200 and 843,352 shares of our common stock, respectively, at a purchase price of $0.0002958 per share.

Shared Operating Expenses

Frazier is a principal stockholder of our company and is represented on our board of directors.

For the year ended December 31, 2018 and the six months ended June 30, 2019, we conducted our operations within office space controlled by Frazier and Frazier allocated a portion of the costs associated with this office to us. In addition, Frazier paid for various goods and services, such as employee wages, insurance and expense reimbursements and various administrative services associated with our operations and charged us for those expenses. For the year ended December 31, 2018 and the six months ended June 30, 2018 and 2019, we incurred $0.3 million, $0.1 million and $0.1 million, respectively, of shared operating expenses.

Employment Arrangements

We have entered into employment letter agreements with our executive officers. For more information regarding these employment agreements, see the section in this prospectus entitled “Executive and Director Compensation—Employment Letters with our Executive Officers.”

Director and Officer Indemnification

We have entered into indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us or will require us to indemnify each director (and in certain cases their related venture capital funds) and executive officer to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys’ fees, judgments, fines and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person’s services as a director or executive officer.

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that we will indemnify each of our directors and officers to the fullest extent permitted by the Delaware General Corporation Law. Further, we have purchased a policy of directors’ and officers’ liability insurance that insures our directors and officers against the cost of defense, settlement or payment of a judgment under certain circumstances. For further information, see “Executive and Director Compensation—Limitations of Liability and Indemnification Matters.”

Directed Share Program

At our request, the underwriters have reserved up to 3.0% of the shares of common stock to be offered by this prospectus for sale, at the initial public offering price, to certain of our directors, officers, employees, and their friends and family members through a directed share program. We do not currently know whether any of our directors, officers, or their affiliates, or holders of more than 5% of our common stock will purchase more than $120,000 in value of such reserved shares of our common stock in this offering. See “Underwriting—Directed Share Program.”

Policies and Procedures for Related Person Transactions

Our board of directors has adopted a written related person transaction policy, to be effective upon the closing of this offering, setting forth the policies and procedures for the review and approval or ratification of related-person transactions. This policy will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships in which we were or are to be a participant, where the amount involved exceeds $120,000, and a related person had or will have a direct or indirect material interest, including, without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm’s length transaction and the extent of the related person’s interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

PRINCIPAL STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common stock as of September 30, 2019, and as adjusted to reflect the sale of shares of common stock in this offering, by:

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

The number of shares beneficially owned by each stockholder is determined under rules issued by the SEC. Under these rules, beneficial ownership includes any shares as to which a person has sole or shared voting power or investment power. Applicable percentage ownership prior to this offering is based on 11,876,518 shares of common stock outstanding on September 30, 2019, which includes 4,455,525 shares subject to forfeiture or a right of repurchase. Applicable percentage ownership after this offering is based on the sale of 9,563,157 shares of common stock in this offering and gives effect to the automatic conversion of the May 2019 Notes into an aggregate of 6,107,918 shares of our common stock immediately prior to the closing of this offering (based on the initial public offering price of $19.00 per share and assuming the conversion occurs on October 29, 2019). In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock subject to options, warrants or other rights held by such person that are currently exercisable or will become exercisable within 60 days of September 30, 2019 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person.

Unless otherwise indicated, the address of each beneficial owner listed below is c/o Phathom Pharmaceuticals, Inc., 2150 E. Lake Cook Road, Suite 800, Buffalo Grove, Illinois 60089. We believe, based on information provided to us, that each of the stockholders listed below has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

Name of Beneficial Owner	Beneficial Ownership Prior to this Offering Number	Beneficial Ownership Prior to this Offering Percent	Beneficial Ownership After this Offering Number	Beneficial Ownership After this Offering Percent
5% or Greater Stockholders				
Takeda Pharmaceutical Company Limited(1)	1,084,000	9.1%	8,672,000	24.7%
Frazier Life Sciences IX, L.P.(2)	4,877,998	41.1%	6,231,638	22.6%
Executive Officers and Directors				
David Socks(3)	1,686,704	14.2%	1,686,704	6.1%
Tadataka Yamada, M.D.(4)	1,686,704	14.2%	1,686,704	6.1%
Michael F. Cola	—	*	—	*
Terrie Curran	—	*	—	*
Azmi Nabulsi, M.D., M.P.H.(5)	867,200	7.3%	867,200	3.1%
Aditya Kohli, Ph.D.(6)	843,352	7.1%	843,352	3.1%
James Topper, M.D., Ph.D.(2)	4,877,998	41.1%	6,231,638	22.6%
Jonathan Edwards, Ph.D	—	*	—	*
Heidi Kunz	—	*	—	*
Chris Slavinsky	—	*	—	*
All executive officers and directors as a group (10 persons)(7)	9,961,958	83.9%	11,315,598	41.1%

* Less than 1%.

(1) The number of shares beneficially owned before the offering does not include 7,588,000 shares of common stock issuable upon exercise of the Takeda Warrant, which becomes exerciseable upon the closing of this offering. The number of shares beneficially owned after the offering includes 7,588,000 shares of common stock issuable upon the exercise of the Takeda Warrant. The address for Takeda Pharmaceutical Company Limited is 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645, Japan.

(2) The shares are held directly by Frazier Life Sciences IX, L.P., or FLS IX. The general partner of FLS IX is FHMLS IX, L.P., and the general partner of FHMLS IX, L.P. is FHMLS IX, L.L.C. James Topper, M.D., Ph.D., and Patrick Heron are the sole managing members of FHMLS IX, L.L.C. and share voting and investment power of the securities held by FLS IX. Dr. Topper and Mr. Heron disclaim beneficial ownership of such securities except to the extent of their pecuniary interest therein. The number of shares beneficially owned after the offering includes 1,353,640 shares of common stock issuable upon the conversion of May 2019 Notes in the aggregate principal amount of $20,000,000 plus accrued interest held by Frazier Life Sciences IX, L.P. immediately prior to the closing of this offering (based on the initial public offering price of $19.00 per share and assuming the conversion occurs on October 29, 2019). The address for FLS IX is 601 Union Street, Suite 3200, Seattle, WA 98101.

(3) Consists of 1,686,704 shares of common stock held by the David A. Socks 2013 Revocable Trust, 1,106,900 of which were subject to a right of repurchase by us as of September 30, 2019. David Socks is a trustee of the David A. Socks 2013 Revocable Trust and in such capacity has the sole power to vote and dispose of such shares.

(4) Consists of 1,686,704 shares of common stock held by Dr. Yamada, 1,106,900 of which were subject to a right of repurchase by us as of September 30, 2019.

(5) Consists of 867,200 shares of common stock held by Dr. Nabulsi, all of which were subject to a right of repurchase by us as of September 30, 2019,

(6) Consists of 843,352 shares of common stock held by Dr. Kohli, 553,450 of which were subject to a right of repurchase by us as of September 30, 2019.

(7) Consists of the shares held by the executive officers and directors described in footnotes 2 through 6 above.

DESCRIPTION OF CAPITAL STOCK

General

The following description summarizes some of the terms of our amended and restated certificate of incorporation and amended and restated bylaws and of the Delaware General Corporation Law. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description you should refer to our amended and restated certificate of incorporation and amended and restated bylaws, copies of which have been filed as exhibits to the registration statement of which the prospectus is a part.

Following the closing of this offering, our authorized capital stock will consist of 400,000,000 shares of common stock, $0.0001 par value per share, and 40,000,000 shares of preferred stock, $0.0001 par value per share.

Common Stock

As of June 30, 2019, there were 11,876,518 shares of our common stock outstanding, including 4,657,250 shares of restricted common stock which are subject to forfeiture or our right of repurchase as of June 30, 2019, and held of record by 20 stockholders. Based on the number of shares of common stock outstanding as of June 30, 2019, and assuming (i) the automatic conversion of the May 2019 Notes into an aggregate of 6,107,918 shares of our common stock immediately prior to the closing of this offering (based on the initial public offering price of $19.00 per share and assuming the conversion occurs on October 29, 2019) and (ii) the issuance by us of 9,563,157 shares of common stock in this offering, there will be 27,547,593 shares of common stock outstanding upon the closing of this offering. Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders, including the election of directors, and do not have cumulative voting rights. Accordingly, the holders of a majority of the outstanding shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they so choose, other than any directors that holders of any preferred stock we may issue may be entitled to elect. Subject to the supermajority votes for some matters, other matters shall be decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter. Our amended and restated certificate of incorporation and amended and restated bylaws also provide that our directors may be removed only for cause and only by the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon. In addition, the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon is required to amend or repeal, or to adopt any provision inconsistent with, several of the provisions of our amended and restated certificate of incorporation. See below under "—Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws—Amendment of Charter Provisions."

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared by the board of directors out of legally available funds. In the event of our liquidation, dissolution or winding up, the holders of common stock will be entitled to share ratably in the assets legally available for distribution to stockholders after the payment of or provision for all of our debts and other liabilities, subject to the prior rights of any preferred stock then outstanding. Holders of common stock have no preemptive or conversion rights or other subscription rights and there are no redemption or sinking funds provisions applicable to the common stock. All outstanding shares of common stock are, and the common stock to be outstanding upon the closing of this offering will be, duly authorized, validly issued, fully paid and nonassessable. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Preferred Stock

As of the date of this prospectus, we do not have shares of preferred stock authorized or outstanding. Under the terms of our amended and restated certificate of incorporation, which became effective immediately prior to the closing of this offering, our board of directors has the authority, without further action by our stockholders, to issue up to 40,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the dividend, voting and other rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deterring or preventing a change in our control and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

Warrants

In May 2019, in connection with the Takeda License, we issued the Takeda Warrant to purchase 7,588,000 shares of our common stock with an exercise price of $0.00004613 per share. The Takeda Warrant contains a net exercise provision under which Takeda may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares of our common stock based on the fair market value of our common stock at the time of the net exercise of the warrant after deduction of the aggregate exercise price. The Takeda Warrant expires ten years from its date of issuance, subject to its earlier termination upon the completion of certain mergers, acquisitions and similar transactions.

In May 2019, in connection with the Takeda License, we granted to Takeda the Takeda Warrant Right, pursuant to which Takeda has a right to right to receive an additional common stock warrant should Takeda's fully-diluted ownership represent less than a certain specified percentage of our fully-diluted capitalization, including shares issuable upon conversion of the outstanding May 2019 Notes in connection with this offering, calculated immediately prior to the closing of this offering. The Takeda Warrant Right will expire upon the closing of this offering (based on the initial public offering price of $19.00 per share).

In May 2019, in connection with the entry into the Loan Agreement, we issued to the lenders the Lender Warrants to purchase an aggregate of 16,446 shares of our common stock with an exercise price equal to $15.20 per share (based on the initial public offering price of $19.00 per share). The Lender Warrants only become exercisable if and when we borrow Term Loan B under our Loan Agreement. The Lender Warrants expire ten years from the date of issuance, subject to their earlier termination on September 30, 2020 if we do not draw down on Term Loan B on or before March 31, 2020. The Lender Warrants also include a put option pursuant to which, in the event that we do not draw down on Term Loan B on or before March 31, 2020, the lenders may require us to repurchase the Lender Warrants for a total aggregate repurchase price of $500,000.

Registration Rights

As of June 30, 2019, upon the closing of this offering holders of 12,069,916 shares of our common stock, which includes all of the shares of common stock issuable upon the automatic conversion of the May 2019 Notes, or their transferees, will be entitled to the following rights with respect to the registration of such shares for public resale under the Securities Act, pursuant to the 2019 Note Purchase Agreement by and among us and certain investors. In addition, upon the closing of this offering, Takeda will be entitled to the same rights with respect to the registration of 7,588,000 shares of our common stock underlying the Takeda Warrant. The registration of shares of common stock as a result of the following rights being exercised would enable holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective.

Demand Registration Rights

Form S-1. If at any time beginning six months following the effective date of the registration statement of which this prospectus forms a part, the holders of at least 25% of the registrable securities request in writing that we effect a registration with respect to all or a part of the registrable securities then outstanding where the price to the public of the offering is $10.0 million or more, we may be required to provide notice to all holders of registrable securities and to use commercially reasonable efforts to effect such registration; provided, however, that we will not be required to effect such a registration if, within the preceding 12 months, we have already effected two registrations for the holders of registrable securities in response to these demand registration rights, subject to certain exceptions.

Form S-3. If at any time we become entitled under the Securities Act to register our shares on Form S-3, the holders of at least 20% of the registrable securities request in writing that we effect a registration with respect to all or a part of the registrable securities then outstanding where the price to the public of the offering is $3.0 million or more, we may be required to provide notice to all holders of registrable securities and to use commercially reasonable efforts to effect such registration; provided, however, that we will not be required to effect such a registration if, within the preceding 12 months, we have already effected two registrations on Form S-3 for the holders of registrable securities.

If the holders requesting registration intend to distribute their shares by means of an underwriting, the underwriter of such offering will have the right to limit the numbers of shares to be underwritten for reasons related to the marketing of the shares.

Piggyback Registration Rights

If at any time following the closing of this offering we propose to register any shares of our common stock under the Securities Act, subject to certain exceptions, the holders of registrable securities will be entitled to notice of the registration and to include their shares of registrable securities in the registration. If our proposed registration involves an underwriting, the managing underwriter of such offering will have the right to limit the number of shares to be underwritten for reasons related to the marketing of the shares.

Indemnification

The 2019 Note Purchase Agreement contains customary cross indemnification provisions, under which we are obligated to indemnify holders of registrable securities in the event of material misstatements or omissions in a registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions attributable to them.

Expenses

Ordinarily, other than underwriting discounts and commissions, we will be required to pay all expenses incurred by us related to any registration effected pursuant to the exercise of these registration rights. These expenses may include all registration and filing fees, printing expenses, fees and disbursements of our counsel, reasonable fees and disbursements of a counsel for the selling securityholders, blue sky fees and expenses and the expenses of any special audits incident to the registration.

Termination of Registration Rights

The registration rights terminate upon the earlier of: (i) five years after the closing of this offering or (ii) with respect to a particular holder, such time at which such holder can sell all shares held by it in compliance with Rule 144 under the Securities Act.

Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws

Some provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Undesignated Preferred Stock

The ability of our board of directors, without action by the stockholders, to issue up to 40,000,000 shares of undesignated preferred stock with voting or other rights or preferences as designated by our board of directors could impede the success of any attempt to change control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

Stockholder Meetings

Our amended and restated bylaws provide that a special meeting of stockholders may be called only by our chairman of the board of directors, chief executive officer or president, or by a resolution adopted by a majority of our board of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of Stockholder Action by Written Consent

Our amended and restated certificate of incorporation and amended and restated bylaws eliminate the right of stockholders to act by written consent without a meeting.

Staggered Board of Directors

Our board of directors is divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders. For more information on the classified board of directors, see "Management—Board Composition and Election of Directors." This system of electing and removing directors may tend to discourage a third party from attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Removal of Directors

Our amended and restated certificate of incorporation provides that no member of our board of directors may be removed from office except for cause and, in addition to any other vote required by law, upon the approval of not less than two thirds of the total voting power of all of our outstanding voting stock then entitled to vote in the election of directors.

Stockholders Not Entitled to Cumulative Voting

Our amended and restated certificate of incorporation does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits persons deemed to be "interested stockholders" from engaging in a "business combination" with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

Choice of Forum

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative form, the Court of Chancery of the State of Delaware will be the sole and exclusive forum under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders, creditors or other constituents; (iii) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our amended and restated certificate of incorporation or amended and restated bylaws; (iv) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; or (v) any action asserting a claim governed by the internal affairs doctrine. The 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. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. In any case, stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. 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. Our amended and restated certificate of incorporation also provides that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to this choice of forum provision.

Amendment of Charter Provisions

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock, would require approval by holders of at least two thirds of the total voting power of all of our outstanding voting stock.

The provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board of directors and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock will be Computershare Trust Company, N.A. The transfer agent and registrar's address is 250 Royall Street, Canton, Massachusetts 02021.

The Nasdaq Global Select Market Listing

Our common stock has been approved for listing on the Nasdaq Global Select Market under the symbol "PHAT."

Limitations of Liability and Indemnification Matters

For a discussion of liability and indemnification, see "Executive and Director Compensation—Limitations of Liability and Indemnification Matters."

SHARES ELIGIBLE FOR FUTURE SALE

Immediately prior to this offering, there was no public market for our common stock. Future sales of substantial amounts of common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock. Although our common stock has been approved for listing on the Nasdaq Global Select Market, we cannot assure you that there will be an active public market for our common stock.

Based on the number of shares of our common stock outstanding as of June 30, 2019, and assuming (i) the issuance of 9,563,157 shares in this offering, (ii) the automatic conversion of the May 2019 Notes into an aggregate of 6,107,918 shares of our common stock immediately prior to the closing of this offering (based on the initial public offering price of $19.00 per share and assuming the conversion occurs on October 29, 2019), (iii) no exercise of the underwriters' option to purchase additional shares of common stock, and (iv) no exercise of outstanding options, warrants, or other rights we will have outstanding an aggregate of 27,547,593 shares of common stock.

Of these shares, all shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act. Shares purchased by our affiliates would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

The remaining 17,984,436 shares of common stock will be "restricted securities," as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rule 144 or 701 under the Securities Act, each of which is summarized below. We expect that substantially all of these shares will be subject to the 180-day lock-up period under the lock-up agreements described below.

In addition, 7,588,000 shares of common stock issuable to Takeda upon the exercise of the Takeda Warrant became exercisable upon the closing of this offering. Upon exercise of the Takeda Warrant, these shares of common stock will be eligible for sale subject to the lock–up agreements described below and Rules 144 and 701 under the Securities Act.

Lock-Up Agreements

We, our officers, directors and holders of substantially all of our securities, have agreed with the underwriters that for a period of 180 days, after the date of this prospectus, subject to specified exceptions, we or they will not offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to sale of, or otherwise dispose of or transfer any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock, request or demand that we file a registration statement related to our common stock or enter into any swap or other agreement that transfers to another, in whole or in part, directly or indirectly, the economic consequence of ownership of the common stock. Upon expiration of the lock-up period, certain of our stockholders will have the right to require us to register their shares under the Securities Act. See "—Registration Rights" below and "Description of Capital Stock—Registration Rights."

Goldman Sachs & Co. LLC, Jefferies LLC, and Evercore Group L.L.C. may, in their sole discretion and at any time or from time to time before the termination of the lock-up period, in certain cases without public notice, release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our stockholders who will execute a lock-up agreement providing consent to the sale of shares prior to the expiration of the lock-up period.

Upon the expiration of the lock-up period, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above.

Rule 10b5-1 Trading Plans

Following the closing of this offering, certain of our officers, directors and significant stockholders may adopt written plans, known as Rule 10b5-1 trading plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis to diversify their assets and investments. Under these 10b5-1 trading plans, a broker may execute trades pursuant to parameters established by the officer, director or stockholder when entering into the plan, without further direction from such officer, director or stockholder. Such sales would not commence until the expiration of the applicable lock-up agreements entered into by such officer, director or stockholder in connection with this offering.

Rule 144

Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days before a sale, who has beneficially owned shares of our common stock for at least six months would be entitled to sell in "broker's transactions" or certain "riskless principal transactions" or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 275,475 shares immediately after this offering; or
- the average weekly trading volume in our common stock on the Nasdaq Global Select Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of $50,000, the seller must file a notice on Form 144 with the SEC and the Nasdaq Global Select Market concurrently with either the placing of a sale order with the broker or the execution of a sale directly with a market maker.

Non-Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock for at least six months but less than a year, is entitled to sell such shares subject only to the availability of current public information about us. If such person has held our shares for at least one year, such person can resell under Rule 144(b)(1) without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement.

Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

Rule 701

In general, under Rule 701, any of an issuer's employees, directors, officers, consultants or advisors who purchases shares from the issuer in connection with a compensatory stock or option plan or other written agreement before the effective date of a registration statement under the Securities Act is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

Equity Plans

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of common stock subject to outstanding stock options and common stock issued or issuable under our equity incentive plans and employee stock purchase plan. We expect to file the registration statement covering shares offered pursuant to these stock plans shortly after the date of this prospectus, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market subject to compliance with the resale provisions of Rule 144.

Registration Rights

As of June 30, 2019, upon the closing of this offering holders of 12,069,916 shares of our common stock, which includes all of the shares of common stock issuable upon the automatic conversion of the May 2019 Notes, or their transferees will be entitled to various rights with respect to the registration of these shares under the Securities Act. In addition, upon the closing of this offering, Takeda will be entitled to the same rights with respect to the registration of 7,588,000 shares of our common stock underlying the Takeda Warrant. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration. See “Description of Capital Stock—Registration Rights” for additional information. Shares covered by a registration statement will be eligible for sale in the public market upon the expiration or release from the terms of the lock-up agreement.

MATERIAL UNITED STATES FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following discussion is a summary of the material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder of our common stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder's particular circumstances, including the impact of the alternative minimum tax or the Medicare contribution tax on net investment income. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- brokers, dealers or traders in securities;
- "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- persons subject to special tax accounting rules as a result of any item of gross income with respect to our common stock being taken into account in an "applicable financial statement" (as defined in the Code);
- tax-qualified retirement plans; and
- "qualified foreign pension funds" as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds.

If an entity treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

THIS DISCUSSION IS FOR INFORMATION PURPOSES ONLY AND IS NOT TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of a Non-U.S. Holder

For purposes of this discussion, a "Non-U.S. Holder" is any beneficial owner of our common stock that is neither a "U.S. person" nor an entity treated as a partnership for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (i) is subject to the primary supervision of a U.S. court and the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code), or (ii) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

Distributions

As described in the section entitled "Dividend Policy," we do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder's adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under "—Sale or Other Taxable Disposition."

Subject to the discussion below on effectively connected income, dividends paid to a Non-U.S. Holder of our common stock will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate). If a Non-U.S. Holder holds the stock through a financial institution or other agent acting on the Non-U.S. Holder's behalf, the Non-U.S. Holder will be required to provide appropriate documentation to the agent, who then will be required to provide certification to the applicable withholding agent, either directly or through other intermediaries. A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such dividends are attributable), the Non-U.S. Holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Sale or Other Taxable Disposition

A Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such gain is attributable);
- the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest, or USRPI, by reason of our status as a U.S. real property holding corporation, or USRPHC, for U.S. federal income tax purposes.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

Gain described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty), which may be offset by U.S. source capital losses of the Non-U.S. Holder (even though the Non-U.S. Holder is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and do not anticipate becoming, a USRPHC. Because the determination of whether we are a USRPHC depends, however, on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we currently are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a Non-U.S. Holder of our common stock will not be subject to U.S. federal income tax if our common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market, and such Non-U.S. Holder owned, actually or constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period. If we are a USRPHC and either our common stock is not regularly traded on an established securities market or a Non-U.S. Holder holds, or is treated as holding, more than 5% of our outstanding common stock, directly or indirectly, during the applicable testing period, such Non-U.S. Holder will generally be taxed on any gain in the same manner as gain that is effectively connected with the conduct of a U.S. trade or business, except that the branch profits tax generally will not apply. If we are a USRPHC and our common stock is not regularly traded on an established securities market, a Non-U.S. Holder’s proceeds received on the disposition of shares will also generally be subject to withholding at a rate of 15%. Prospective investors are encouraged to consult their own tax advisors regarding the possible consequences to them if we are, or were to become, a USRPHC.

Non-U.S. Holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Payments of dividends on our common stock will not be subject to backup withholding, provided the applicable withholding agent does not have actual knowledge or reason to know the holder is a United States person and the holder either certifies its non-U.S. status, such as by furnishing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any dividends on our common stock paid to the Non-U.S. Holder, regardless of whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting, if the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that such holder is a United States person, or the holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder’s U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections are commonly referred to as the Foreign Account Tax Compliance Act, or FATCA) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on, or subject to the proposed Treasury Regulations discussed below, gross proceeds from the sale or other disposition of, our common stock paid to a “foreign financial institution” or a “non-financial foreign entity” (each as defined in the Code), unless (i) the foreign financial institution undertakes certain diligence and reporting obligations, (ii) the non-financial foreign entity either certifies it does not have any “substantial United States owners” (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (iii) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in clause (i) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain “specified United States persons” or “United States owned foreign entities” (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends on our common stock. While withholding under FATCA would also have applied to payments of gross proceeds from the sale or other disposition of stock on or after January 1, 2019, recently proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

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UNDERWRITING

We and the underwriters named below have entered into an underwriting agreement with respect to the shares being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the number of shares indicated in the following table. Goldman Sachs & Co. LLC, Jefferies LLC, and Evercore Group L.L.C. are the representatives of the underwriters.

Underwriters	Number of Shares
Goldman Sachs & Co. LLC	3,825,263
Jefferies LLC	2,868,947
Evercore Group L.L.C.	2,390,789
Needham & Company, LLC	478,158
Total	9,563,157

The underwriters are committed to take and pay for all of the shares being offered, if any are taken, other than the shares covered by the option described below unless and until this option is exercised.

The underwriters have an option to buy up to an additional 1,434,473 shares from us to cover sales by the underwriters of a greater number of shares than the total number set forth in the table above. They may exercise that option for 30 days. If any shares are purchased pursuant to this option, the underwriters will severally purchase shares in approximately the same proportion as set forth in the table above.

The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters by us. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase 1,434,473 additional shares.

	No Exercise	Full Exercise
Per Share	$ 1.33	$ 1.33
Total	$ 12,718,999	$ 14,626,848

Shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover page of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to $0.798 per share from the initial public offering price. After the initial offering of the shares, the representatives may change the offering price and the other selling terms. The offering of the shares by the underwriters is subject to receipt and acceptance and subject to the underwriters' right to reject any order in whole or in part.

We and our officers, directors, and holders of substantially all of our securities have agreed with the underwriters, subject to certain exceptions, not to dispose of or hedge any of their common stock or securities convertible into or exchangeable for shares of common stock during the period from the date of this prospectus continuing through the date 180 days after the date of this prospectus, except with the prior written consent of the representatives. This agreement does not apply to any existing employee benefit plans. See "Shares Eligible for Future Sale" for a discussion of certain transfer restrictions.

Prior to the offering, there has been no public market for the shares. The initial public offering price was negotiated among our company and the representatives. Among the factors considered in determining the initial public offering price of the shares, in addition to prevailing market conditions, was our historical performance, estimates of our business potential and earnings prospects, an assessment of our management and the consideration of the above factors in relation to market valuation of companies in related businesses.

Our common stock has been approved for listing on the Nasdaq Global Select Market under the symbol "PHAT."

In connection with the offering, the underwriters may purchase and sell shares of our common stock in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering, and a short position represents the amount of such sales that have not been covered by subsequent purchases. A "covered short position" is a short position that is not greater than the amount of additional shares for which the underwriters' option described above may be exercised. The underwriters may cover any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to cover the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase additional shares pursuant to the option described above. "Naked" short sales are any short sales that create a short position greater than the amount of additional shares for which the option described above may be exercised. The underwriters must cover any such naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of our stock, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of the common stock. As a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on the Nasdaq Global Select Market, in the OTC market or otherwise.

We estimate that our share of the total expenses of the offering, excluding underwriting discounts and commissions, will be approximately $2.8 million. We have also agreed to reimburse the underwriters for certain expenses incurred by them in connection with the offering in an amount up to $40,000.

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act.

At our request, the underwriters have reserved up to 3.0% of the shares of common stock to be offered by this prospectus for sale, at the initial public offering price, to certain of our directors, officers, employees, and their friends and family members through a directed share program. Goldman Sachs & Co. LLC will administer our directed share program. The number of shares available for sale to the general public in the offering will be reduced to the extent these persons purchase the reserved shares. Any reserved shares not so purchased will be offered by the underwriters to the general public on the same terms as the other shares offered by this prospectus. The underwriters will receive the same discount from such reserved shares as they will from other shares of our common stock sold to the public in this offering. We have agreed to indemnify the underwriters against certain liabilities and expenses, including liabilities under the Securities Act, in connection with sales of the reserved shares.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Certain of the underwriters and their respective affiliates have provided, and may in the future provide, a variety of these services to the issuer and to persons and entities with relationships with the issuer, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to assets, securities and/or instruments of the issuer (directly, as collateral securing other obligations or otherwise) and/or persons and entities with relationships with the issuer. The underwriters and their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

European Economic Area

In relation to each Member State of the European Economic Area (each a “Member State”), no shares of common stock (the “Shares”) have been offered or will be offered pursuant to the offering to the public in that Member State prior to the publication of a prospectus in relation to the Shares which has been approved by the competent authority in that Member State or, where appropriate, approved in another Member State and notified to the competent authority in that Member State, all in accordance with the Prospectus Regulation), except that offers of Shares may be made to the public in that Member State at any time under the following exemptions under the Prospectus Regulation:

(a) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or

(c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of Shares shall require the company or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an “offer to the public” in relation to any Shares in any Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any Shares to be offered so as to enable an investor to decide to purchase or subscribe for any Shares, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129.

United Kingdom

Each Underwriter has represented and agreed that:

(a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000 (FSMA)) received by it in connection with the issue or sale of the Shares in circumstances in which Section 21(1) of the FSMA does not apply to the company or the underwriter; and

(b) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the Shares in, from or otherwise involving the United Kingdom.

Canada

The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions, and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption form, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Hong Kong

The shares may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32 of the Laws of Hong Kong) ("Companies (Winding Up and Miscellaneous Provisions) Ordinance") or which do not constitute an invitation to the public within the meaning of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong) ("Securities and Futures Ordinance"), or (ii) to "professional investors" as defined in the Securities and Futures Ordinance and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance, and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" in Hong Kong as defined in the Securities and Futures Ordinance and any rules made thereunder.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor (as defined under Section 4A of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA")) under Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to conditions set forth in the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor, the securities (as defined in Section 239(1) of the SFA) of that corporation shall not be transferable for 6 months after that corporation has acquired the shares under Section 275 of the SFA except: (i) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (ii) where such transfer arises from an offer in that corporation's securities pursuant to Section 275(1A) of the SFA, (iii) where no consideration is or will be given for the transfer, (iv) where the transfer is by operation of law, (v) as specified in Section 276(7) of the SFA, or (vi) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore ("Regulation 32").

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a trust (where the trustee is not an accredited investor (as defined in Section 4A of the SFA)) whose sole purpose is to hold investments and each beneficiary of the trust is an accredited investor, the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferable for 6 months after that trust has acquired the shares under Section 275 of the SFA except: (i) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (ii) where such transfer arises from an offer that is made on terms that such rights or interest are acquired at a consideration of not less than S$200,000 (or its equivalent in a foreign currency) for each transaction (whether such amount is to be paid for in cash or by exchange of securities or other assets), (iii) where no consideration is or will be given for the transfer, (iv) where the transfer is by operation of law, (v) as specified in Section 276(7) of the SFA, or (vi) as specified in Regulation 32.

Japan

The securities have not been and will not be registered under the Financial Instruments and Exchange Act of Japan (Act No. 25 of 1948, as amended), or the FIEA. The securities may not be offered or sold, directly or indirectly, in Japan or to or for the benefit of any resident of Japan (including any person resident in Japan or any corporation or other entity organized under the laws of Japan) or to others for reoffering or resale, directly or indirectly, in Japan or to or for the benefit of any resident of Japan, except pursuant to an exemption from the registration requirements of the FIEA and otherwise in compliance with any relevant laws and regulations of Japan.

Australia

This prospectus is not a disclosure document for the purposes of Australia's Corporations Act 2001 (Cth) of Australia, or Corporations Act, has not been lodged with the Australian Securities &

Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus in Australia:

You confirm and warrant that you are either:

- a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act;
- a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to the Company which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made;
- a person associated with the Company under Section 708(12) of the Corporations Act; or
- a "professional investor" within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Corporations Act any offer made to you under this prospectus is void and incapable of acceptance.

You warrant and agree that you will not offer any of the securities issued to you pursuant to this prospectus for resale in Australia within 12 months of those securities being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

Israel

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Securities Law, and has not been filed with or approved by the Israel Securities Authority. In Israel, this prospectus is being distributed only to, and is directed only at, and any offer of the shares is directed only at, (i) a limited number of persons in accordance with the Israeli Securities Law and (ii) investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and "qualified individuals," each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case, purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors are required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

Switzerland

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("SIX") or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to the offering, our company or the securities have been or will be filed with or approved by any Swiss regulatory authority.

In particular, this prospectus will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes ("CISA"). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Latham & Watkins LLP, San Diego, California. The underwriters are being represented by Cooley LLP, San Diego, California.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our combined financial statements at December 31, 2018 and for the year then ended, as set forth in their report (which contains an explanatory paragraph describing conditions that raise substantial doubt about Phathom Pharmaceuticals, Inc.'s ability to continue as a going concern as described in Note 1 to the combined financial statements). We have included our combined financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and the common stock offered hereby, we refer you to the registration statement and the exhibits and schedules filed thereto. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. Upon the closing of this offering, we will be required to file periodic reports, proxy statements and other information with the SEC pursuant to the Exchange Act. The SEC maintains an Internet website that contains reports, proxy statements and other information about registrants, like us, that file electronically with the SEC. The address of that site is www.sec.gov.

Upon the closing of this offering, we will become subject to the information and periodic reporting requirements of the Exchange Act and, in accordance therewith, will file periodic reports, proxy statements and other information with the SEC. Such periodic reports, proxy statements and other information will be available at the website of the SEC referred to above. We maintain a website at www.phathompharma.com. Upon the closing of this offering, you may access our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge at our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The reference to our website address does not constitute incorporation by reference of the information contained on our website, and you should not consider the contents of our website in making an investment decision with respect to our common stock.

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PHATHOM PHARMACEUTICALS, INC.

INDEX TO COMBINED 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 combined balance sheet of Phathom Pharmaceuticals, Inc. (the Company) as of December 31, 2018, the related combined statement of operations, stockholders' deficit and cash flows for the year then ended, and the related notes (collectively referred to as the "combined financial statements"). In our opinion, the combined financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018, and the results of its operations and its cash flows for the year then ended in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying combined financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred net losses and negative cash flows from operating activities since its inception, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The combined financial statements do not include any adjustments that might result from the outcome of these uncertainties.

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 audit. 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether 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 audit 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2019.

San Diego, California
July 26, 2019
except for the last paragraph in Note 8, as to which the date is
October 15, 2019

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PHATHOM PHARMACEUTICALS, INC.
COMBINED BALANCE SHEETS
(in thousands, except share and par value data)

	December 31, 2018	June 30, 2019 (unaudited)	Pro Forma June 30, 2019 (unaudited)
Assets			
Current assets:			
Cash and cash equivalents	$ 879	$ 82,917	
Prepaid expenses and other current assets (including related party amounts of $19 and $15, respectively)	23	1,625	
Total current assets	902	84,542	
Other assets	–	337	
Total assets	$ 902	$ 84,879	
Liabilities and Stockholders' Deficit			
Current liabilities:			
Accounts payable (including related party amounts of $45 and $31, respectively)	$ 55	$ 450	
Accrued expenses (including related party amounts of $2 and $19, respectively)	170	995	
Accrued interest (including related party amounts of $13 and $82, respectively)	13	967	$ 151
Convertible promissory notes payable at fair value (including related party amounts of $1,950 and $20,552, respectively)	1,950	92,743	–
Warrant liabilities (including related party amounts of ($0 and $49,171, respectively)	–	49,597	426
Total current liabilities	2,188	144,752	
Long-term debt, net of discount	–	22,449	
Other long-term liabilities	–	2,063	
Total liabilities	2,188	169,264	
Commitments and contingencies (Note 3)			
Stockholders' deficit:			
Common stock, $0.0001 par value; authorized shares—50,000,000 at June 30, 2019 (unaudited); issued shares—11,876,518 at June 30, 2019 (unaudited); outstanding shares—7,219,268 at June 30, 2019 (unaudited); 17,984,436 and 13,327,186 shares issued and outstanding, respectively, pro forma (unaudited)	–	–	1
Additional paid-in capital	2	5,916	148,645
Accumulated deficit	(1,288)	(90,301)	(90,301)
Total stockholders' deficit	(1,286)	(84,385)	$ 58,345
Total liabilities and stockholders' deficit	$ 902	$ 84,879	

See accompanying notes.

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PHATHOM PHARMACEUTICALS, INC.
COMBINED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)

	Year Ended December 31, 2018	Six Months Ended June 30, 2018	Six Months Ended June 30, 2019
		(unaudited)	(unaudited)
Operating expenses:			
Research and development	$ 20	$ –	$ 3,201
In-process research and development	–	–	78,897
General and administrative (includes related party amounts of $321, $124 and $18, respectively)	1,205	506	2,142
Total operating expenses	1,225	506	84,240
Loss from operations	(1,225)	(506)	(84,240)
Other income (expense):			
Interest income	–	–	101
Interest expense (includes related party amounts of $(13), $(4) and $(82), respectively)	(13)	(4)	(1,148)
Change in fair value of warrant liabilities (includes related party amounts of $0, $0 and $(1,277), respectively)	–	–	(1,284)
Change in fair value of convertible promissory notes (includes related party amounts of $(50), $(4) and $(502), respectively)	(50)	(4)	(2,442)
Total other income (expense)	(63)	(8)	(4,773)
Net loss	$ (1,288)	$ (514)	$ (89,013)
Net loss per share, basic and diluted	$ (0.21)	$ (0.10)	$ (13.40)
Weighted-average shares of common stock outstanding, basic and diluted	6,051,675	5,331,270	6,640,394
Pro forma net loss per share, basic and diluted (unaudited)	$ (0.20)		$ (9.85)
Pro forma weighted-average shares of common stock outstanding, basic and diluted (unaudited)	6,098,429		8,578,296

See accompanying notes.

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PHATHOM PHARMACEUTICALS, INC.
COMBINED STATEMENTS OF STOCKHOLDERS' DEFICIT
(in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount			
Combined balance at January 1, 2018	–	$ –	$ –	$ –	$ –
Issuance of common stock to founders	–	–	2	–	2
Net loss	–	–	–	(1,288)	(1,288)
Combined balance at December 31, 2018	–	–	2	(1,288)	(1,286)
Merger of entities under common control into the Company (unaudited)	6,760,334	–	–	–	–
Vesting restrictions placed on previously issued and outstanding common stock (unaudited)	(3,373,408)	–	–	–	–
Issuance of common stock (unaudited)	1,491,072	–	–	–	–
Issuance of common stock in connection with license agreement (unaudited)	1,084,000	–	5,885	–	5,885
Vesting of restricted shares (unaudited)	1,257,270	–	–	–	–
Stock-based compensation (unaudited)	–	–	29	–	29
Net loss (unaudited)	–	–	–	(89,013)	(89,013)
Balance at June 30, 2019 (unaudited)	7,219,268	$ –	$ 5,916	$ (90,301)	$ (84,385)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount			
Combined balance at January 1, 2018	–	$ –	$ –	$ –	$ –
Issuance of common stock to founders (unaudited)	–	–	2	–	2
Net loss (unaudited)	–	–	–	(514)	(514)
Combined balance at June 30, 2018 (unaudited)	–	$ –	$ 2	$ (514)	$ (512)

See accompanying notes.

PHATHOM PHARMACEUTICALS, INC.
COMBINED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31, 2018	Six Months Ended June 30, 2018	Six Months Ended June 30, 2019
		(unaudited)	
Cash flows from operating activities			
Net loss	$ (1,288)	$ (514)	$ (89,013)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	–	–	29
Amortization of debt discount	–	–	81
Acquired in-process research and development	–	–	78,897
Change in fair value of warrant liabilities (includes related party amounts of $0, $0 and $1,277, respectively)	–	–	1,284
Change in fair value of convertible promissory notes (includes related party amounts of $50, $4 and $502, respectively)	50	4	2,442
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets (includes related party amounts of $(19), $(13) and $4, respectively)	(23)	(18)	(1,602)
Accounts payable and accrued expenses (includes related party amounts of $47, $54 and $3, respectively)	225	72	883
Accrued interest (includes related party amounts of $13, $4 and $82, respectively)	13	4	981
Net cash used in operating activities	(1,023)	(452)	(6,018)
Cash flows from investing activities			
Cash paid for purchased in-process research and development	–	–	(25,118)
Net cash used in investing activities	–	–	(25,118)
Cash flows from financing activities			
Proceeds from issuance of common stock	2	2	–
Proceeds from issuance of convertible promissory notes	1,900	550	88,324
Proceeds from issuance of long-term debt	–	–	24,850
Net cash provided by financing activities	1,902	552	113,174
Net increase in cash	879	100	82,038
Cash and cash equivalents—beginning of period	–	–	879
Cash and cash equivalents—end of period	$ 879	$ 100	$ 82,917
Supplemental disclosure of cash flow information			
Interest paid	$ –	$ –	$ 86
Supplemental disclosure of noncash investing and financing activities			
Exchange of accrued interest for convertible promissory notes	$ –	$ –	$ 27
Issuance of Takeda Warrants in connection with Takeda License	$ –	$ –	$ 47,894
Issuance of common stock in connection with Takeda License	$ –	$ –	$ 5,885
Issuance of common stock warrants in connection with long-term debt	$ –	$ –	$ 419
Unpaid initial public offering costs	$ –	$ –	$ 337
Final interest payment fee	$ –	$ –	$ 2,063

See accompanying notes.

PHATHOM PHARMACEUTICALS, INC.
NOTES TO COMBINED FINANCIAL STATEMENTS
(Information as of June 30, 2019 and thereafter and for the six months ended June 30, 2018 and 2019 is unaudited)

1. Organization, Basis of Presentation and Summary of Significant Accounting Policies

Organization

Phathom Pharmaceuticals, Inc. (the “Company” or “Phathom”) was incorporated in the state of Delaware in January 2018 under the name North Bridge IV, Inc. On March 13, 2019, the Company changed its name to Phathom Pharmaceuticals, Inc. and merged with YamadaCo IIA, Inc. (“YamadaCo”), a Delaware corporation formed in September 2017, with Phathom being the surviving entity (the “Merger”). All activities of YamadaCo prior to 2018 related to formation and were insignificant. The Company is a late clinical-stage biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal diseases.

Stock Split and Conversion

During 2018, without consideration of the forward stock split described in Note 8, both the Company and YamadaCo issued 1,000 shares of common stock at a purchase price of $1.00 per share, and had no other capital transactions prior to the Merger. Immediately prior to the Merger, the Company effected a 1,559.1183-for-1 forward stock split for each outstanding share of its common stock and, effective upon the closing of the Merger, each issued and outstanding share of YamadaCo was converted into 1,559.1183 shares of the Company’s common stock. Upon completion of the Merger, the Company had 6,760,334 shares of common stock outstanding, with the prior stockholders of each YamadaCo and Phathom holding an equal number of shares. The accompanying combined financial statements and notes to the combined financial statements give retroactive effect to the forward stock split and conversion for all periods presented.

Basis of Presentation

The Company’s combined financial statements are prepared in accordance with U.S. generally accepted accounting principles (“GAAP”). The accompanying combined financial statements include the accounts of the Company (the receiving entity) and YamadaCo, prior to the Merger. The Company and YamadaCo were entities under the common control of Frazier Life Sciences IX, L.P. (“Frazier”) as a result of, among others, Frazier’s; (i) ownership of a majority of the outstanding capital stock of both companies, (ii) financing of both companies, (iii) control of board of directors of both companies, and (iv) management of both companies. Both the Company and YamadaCo were formed for the purpose of identifying potential assets around which to form an operating company. As the merged entities were under common control, the combined financial statements report the financial position, results of operations and cash flows of the Company and YamadaCo as though the transfer of net assets and equity interests had occurred at the beginning of 2018. All intercompany accounts and transactions have been eliminated in combination.

Liquidity and Capital Resources

From inception to June 30, 2019, the Company has devoted substantially all of its efforts to organizing and staffing the Company, business planning, raising capital, in-licensing its initial product candidate, vonoprazan, meeting with regulatory authorities, and preparing for the planned Phase 3 clinical trials of vonoprazan. The Company has a limited operating history, has never generated any revenue, and the sales and income potential of its business is unproven. The Company has incurred net losses and negative cash flows from operating activities since its inception and expects to continue to incur net losses into the foreseeable future as it continues the development and commercialization of vonoprazan. From inception to June 30, 2019, the Company has funded its operations through the issuance of convertible promissory notes and commercial bank debt.

The accompanying combined 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 that may result from the outcome of this uncertainty. 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 has prepared cash flow forecasts which indicate that based on the Company's expected operating losses, negative cash flows and maturities of outstanding convertible promissory notes, there is substantial doubt about the Company's ability to continue as a going concern for twelve months after the date the combined financial statements for the year ended December 31, 2018 and the six months ended June 30, 2019 are issued.

The Company's ability to continue as a going concern is dependent upon its ability to raise additional funding. Management plans to raise additional capital through equity offerings, the Company's existing loan and security agreement, debt financings, or other capital sources, including potential collaborations, licenses and other similar arrangements. While management believes this plan to raise additional funds will alleviate the conditions that raise substantial doubt, these plans are not entirely within its control and cannot be assessed as being probable of occurring. The Company may not be able to secure additional financing in a timely manner or on favorable terms, if at all. Furthermore, if the Company issues equity securities to raise additional funds, its existing stockholders may experience dilution, and the new equity securities may have rights, preferences and privileges senior to those of the Company's existing stockholders. If the Company raises additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to its potential products on terms that are not favorable to the Company. If the Company is unable to raise capital when needed or on attractive terms, it would be forced to delay, reduce or eliminate its research and development programs or other operations. If any of these events occur, the Company's ability to achieve the development and commercialization goals would be adversely affected.

Use of Estimates

The preparation of the Company's combined financial statements requires it to make estimates and assumptions that impact the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in the Company's combined financial statements and accompanying notes. The most significant estimates in the Company's combined financial statements relate to accruals for research and development expenses, and the valuation of convertible promissory notes, warrant liabilities and various other equity instruments. 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.

Unaudited Interim Financial Information

The accompanying interim balance sheet as of June 30, 2019, the combined statements of operations and cash flows for the six months ended June 30, 2018 and 2019 and the combined

PHATHOM PHARMACEUTICALS, INC.
NOTES TO COMBINED FINANCIAL STATEMENTS—(CONTINUED)
(Information as of June 30, 2019 and thereafter and for the six months ended June 30, 2018 and 2019 is unaudited)

statement of stockholders' deficit for the six months ended June 30, 2018 and 2019 and the related footnote disclosures are unaudited. In management's opinion, the unaudited interim financial statements have been prepared on the same basis as the audited combined financial statements and include all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of June 30, 2019 and its results of operations and cash flows for the six months ended June 30, 2018 and 2019 in accordance with GAAP. The results for the six months ended June 30, 2019 are not necessarily indicative of the results expected for the full fiscal year or any other interim period.

Unaudited Pro Forma Balance Sheet Information

The unaudited pro forma balance sheet information as of June 30, 2019 in the accompanying combined balance sheet gives effect to: (i) the automatic conversion of all outstanding convertible promissory notes and related accrued interest (see Note 4) into 6,107,918 shares of common stock (assuming the initial public offering ("IPO") price of $19.00 per share and assuming the conversion occurs on October 29, 2019), the expected closing date of the Company's IPO, and (ii) the reclassification of the Takeda Warrant to stockholders' equity. Shares of common stock issued in the IPO and any related net proceeds are excluded from the pro forma information.

Fair Value Option

As permitted under Accounting Standards Codification ("ASC") 825, *Financial Instruments*, ("ASC 825"), the Company has elected the fair value option to account for its convertible promissory notes issued since inception. In accordance with ASC 825, the Company records these convertible promissory notes at fair value with changes in fair value recorded in the combined statements of operations. As a result of applying the fair value option, direct costs and fees related to the convertible promissory notes were recognized in earnings as incurred and not deferred.

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 classified within the Level 1 designation discussed above, prepaid and other current assets, accounts payable, and accrued liabilities, approximate fair value due to their short maturities. Warrant liabilities and convertible promissory notes are recorded at fair value on a recurring basis.

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.

Liabilities measured at fair value on a recurring basis are as follows (in thousands):

		Fair Value Measurements at Reporting Date Using:		
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
As of December 31, 2018:				
Convertible promissory notes	$ 1,950	$ –	$ –	$ 1,950
As of June 30, 2019:				
Warrant liabilities	$ 49,597	$ –	$ –	$ 49,597
Convertible promissory notes	92,743	–	–	92,743
Total	$ 142,340	$ –	$ –	$ 142,340

The warrant liabilities consist of an issued and outstanding common stock warrant (the "Takeda Warrant") and a right to receive an additional common stock warrant (the "Takeda Warrant Right", and together with the Takeda Warrant, the "Takeda Warrants") issued to Takeda Pharmaceutical Company Limited ("Takeda") in connection with a May 2019 license agreement (see Note 3) and warrants (the "Lender Warrants") issued in connection with a loan and security agreement for commercial bank debt (see Note 5). The Takeda Warrants are accounted for as liabilities as they do not meet all the conditions for equity classification due to (i) insufficient authorized shares for the Takeda Warrant and (ii) the Takeda Warrant Right is not indexed to the Company's own stock. The Lender Warrants are accounted for as liabilities as they contain a holder put right under which the lenders could require the Company to pay cash in exchange for the warrants. The fair value of the Takeda Warrants is derived from the model used to estimate the fair value the Company's common stock (see Note 6). The fair value of the Lender Warrants is estimated using a probability-weighted model considering IPO and non-IPO scenarios. The IPO scenarios utilize a binomial lattice model to estimate a distribution of total equity values as of a projected IPO date. The non-IPO scenario utilizes the repurchase price associated with the warrant put right discounted to present value based on venture capital rates of return and the term associated with the put right. As of June 30, 2019, the fair value of the Takeda Warrants was $49.2 million and the fair value of the Lender Warrants was $0.4 million.

As further described in Note 4, the Company issued convertible promissory notes to Frazier (the "Frazier Notes") from January 2018 to April 2019 and issued convertible promissory notes in May 2019 (the "May 2019 Notes") to investors including Frazier. The Company has elected the fair value option for each of its convertible promissory note issuances. The fair value of the Frazier Notes was estimated using a scenario-based analysis that estimated the fair value of the convertible promissory notes based on the probability-weighted present value of expected future investment returns, considering possible

PHATHOM PHARMACEUTICALS, INC.
NOTES TO COMBINED FINANCIAL STATEMENTS—(Continued)
(Information as of June 30, 2019 and thereafter and for the six months ended June 30, 2018 and 2019 is unaudited)

outcomes available to the noteholders, including conversions in subsequent equity financings, change of control transactions, settlement and dissolution. The fair value of the May 2019 Notes is estimated using a scenario-based analysis that estimates the fair value of the convertible promissory notes based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to the noteholders, including various IPO, settlement, equity financing, corporate transaction and dissolution scenarios. As of December 31, 2018, the fair value of the Frazier Notes was $2.0 million and the Frazier Notes were exchanged for May 2019 Notes in May 2019. As of June 30, 2019, the fair value of the May 2019 Notes was $92.7 million.

The Company adjusts the carrying value of its warrant liabilities and convertible promissory notes to their estimated fair value at each reporting date, with any related increases or decreases in the fair value recorded as change in fair value of warrant liabilities and change in fair value of convertible promissory notes, respectively, in the combined statements of operations.

The following table summarizes information about the significant unobservable inputs used in the fair value measurements for the Takeda Warrants and the May 2019 Notes:

Liability	Fair value as of initial valuation date (in thousands)	Fair value as of June 30, 2019 (in thousands)	Fair value method as of initial valuation date (and relative weighting)	Fair value method as of June 30, 2019 (and relative weighting)	Key unobservable inputs	Range
Takeda Warrants	$ 47,894	$ 49,171	Financing transactions (40%) Income approach (60%)	Financing transactions (40%) Income approach (60%)	Transaction prices per share Estimated time to liquidity Discount rate	$9.33-$10.56 0.29-1.73 years 13%
May 2019 Notes	$ 90,250	$ 92,743	Financing transactions (40%) Income approach (60%)	Financing transactions (40%) Income approach (60%)	Estimated time to liquidity Volatility Discount rate	0.29-1.73 years 70% 22.6%-25%

There are significant judgments, assumptions and estimates inherent in the determination of the fair value of each of the instruments described above. These include determination of a valuation method and selection of the possible outcomes available to the Company, including the determination of timing and expected future investment returns for such scenarios. The Company considered the equity value of an initial public offering using market transactions and have determined the expected value of various stay private and dissolution scenarios using the income approach, which is based on assumptions regarding the Company's future operating performance. The related judgments, assumptions and estimates are highly interrelated and changes in any one assumption could necessitate changes in another. In particular, any changes in the probability of a particular outcome would require a related change to the probability of another outcome. In addition, the fair value of the May 2019 Notes is derived using assumptions that are consistent with the assumptions used to value the Company's common stock and the Takeda Warrants, and the concluded fair value of the May 2019 Notes is used in the determination of both the fair value of the Company's common stock and the Takeda Warrants. In the future, depending on the valuation approaches used and the expected timing and weighting of each, the inputs described above, or other inputs, may have a greater or lesser impact on the Company's estimates of fair value.

PHATHOM PHARMACEUTICALS, INC.
NOTES TO COMBINED FINANCIAL STATEMENTS—(Continued)
(Information as of June 30, 2019 and thereafter and for the six months ended June 30, 2018 and 2019 is unaudited)

The following table provides a reconciliation of all liabilities measured at fair value using Level 3 significant unobservable inputs (in thousands):

	Warrant Liabilities	Convertible Promissory Notes
Balance at January 1, 2018	$ –	$ –
Issuance of convertible promissory notes	–	1,900
Change in fair value	–	50
Balance at December 31, 2018	–	1,950
Issuance of convertible promissory notes	–	90,750
Exchange of convertible promissory notes (Note 4)	–	(2,399)
Issuance of warrants	48,313	–
Change in fair value	1,284	2,442
Balance at June 30, 2019	$49,597	$ 92,743

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.

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.

Deferred Offering Costs

The Company has deferred offering costs consisting of legal, accounting and other fees and costs directly attributable to its planned IPO. The deferred offering costs will be offset against the proceeds received upon the completion of the planned IPO. In the event the planned IPO is terminated, all of the deferred offering costs will be expensed within the Company's statements of operations. As of June 30, 2019, $0.3 million of deferred offering costs were recorded within other long-term assets on the balance sheet. No such costs were included on the combined balance sheet as of December 31, 2018.

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 and consultants to conduct and support the Company's planned clinical trials of vonoprazan, and costs related to manufacturing vonoprazan for clinical trials.

PHATHOM PHARMACEUTICALS, INC.
NOTES TO COMBINED FINANCIAL STATEMENTS—(Continued)
(Information as of June 30, 2019 and thereafter and for the six months ended June 30, 2018 and 2019 is unaudited)

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 performance are reflected in the accompanying balance sheets as prepaid expenses or accrued liabilities. The Company records accruals for estimated costs incurred for ongoing research and development activities. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the services, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates may be made in determining the prepaid or accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates.

In-Process Research and Development

The Company evaluates whether acquired intangible assets are a business under applicable accounting standards. Additionally, the Company evaluates whether the acquired assets have a future alternative use. Intangible assets that do not have future alternative use are considered acquired in-process research and development. When the acquired in-process research and development assets are not part of a business combination, the value of the consideration paid is expensed on the acquisition date. Future costs to develop these assets are recorded to research and development expense as they are incurred.

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. The Company recognizes forfeitures as they occur.

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 statement 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.

Comprehensive Loss

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. The Company's comprehensive loss was the same as its reported net loss for all periods presented.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker in making decisions on how to allocate resources and assess performance. The Company views its operations and manages its business as one operating segment.

Net Loss Per Share

For the year ended December 31, 2018 and the six months ended June 30, 2018 and 2019, the net loss per share was recast to include in the numerator the net losses of both the Company and YamadaCo and include in the denominator the combined weighted-average outstanding shares of both the Company and YamadaCo. Basic net loss per share is computed by dividing the combined net loss by the weighted-average number of common shares outstanding for the period, without consideration for potentially dilutive securities. The Company has excluded weighted-average unvested shares of 2,728,593 shares from the weighted-average number of common shares outstanding for the six months ended June 30, 2019. No shares of common stock were unvested during the year ended December 31, 2018. Diluted net loss per share is computed by dividing the combined 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, warrants and convertible promissory notes. For all 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 would be antidilutive.

Unaudited Pro Forma Net Loss Per Share

The unaudited pro forma basic and diluted net loss per share reflects (i) the automatic conversion of all outstanding convertible promissory notes and related accrued interest into 6,107,918 shares of common stock (at the IPO price of $19.00 per share and assuming the conversion occurs on October 29, 2019, the expected closing date of the Company's IPO), and (ii) the reclassification of the Takeda Warrant to stockholders' equity, each as of the beginning of the period presented or the issuance date, if later.

The unaudited pro forma basic and diluted net loss per share amounts do not give effect to the issuance of common stock issued in the IPO nor do they give effect to potential dilutive securities where the impact would be anti-dilutive.

PHATHOM PHARMACEUTICALS, INC.
NOTES TO COMBINED FINANCIAL STATEMENTS—(Continued)
(Information as of June 30, 2019 and thereafter and for the six months ended June 30, 2018 and 2019 is unaudited)

The following table summarizes the Company’s unaudited pro forma net loss per share (in thousands, except share and per share data):

	Year Ended December 31, 2018	Six Months Ended June 30, 2019
Numerator		
Net loss	$ (1,288)	$ (89,013)
Interest expense on convertible promissory notes	13	831
Change in fair value of Takeda Warrant	–	1,277
Change in fair value of convertible promissory notes	50	2,442
Pro forma net loss	$ (1,225)	$ (84,463)
Denominator		
Weighted-average shares of common stock outstanding, basic and diluted	6,051,675	6,640,394
Pro forma adjustments to reflect assumed weighted-average effect of conversion of convertible promissory notes	46,754	1,937,902
Pro forma weighted-average shares of common stock outstanding, basic and diluted	6,098,429	8,578,296
Pro forma net loss per share, basic and diluted	$ (0.20)	$ (9.85)

Recently Adopted Accounting Pronouncements

In June 2018, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*. This guidance expands the scope of Topic 718, *Compensation—Stock Compensation*, which currently only includes share-based payments to employees, to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. This ASU supersedes Subtopic 505-50, *Equity—Equity-Based Payments to Non-Employees* and is effective for public companies for annual periods beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted as long as ASU No. 2014-09 has been adopted by the Company. The Company adopted this guidance effective January 1, 2018, and the adoption did not have a material impact on the Company’s financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, which requires a lessee to recognize a lease liability and a right-of-use asset for all leases with lease terms of more than 12 months. Additionally, certain qualitative and quantitative disclosures will be required in the financial statements. This guidance is effective for annual reporting periods beginning after December 15, 2018, including interim periods within those fiscal years, and early adoption is permitted. Companies may adopt this guidance using a modified retrospective approach for leases that exist or are entered into after the beginning of the earliest comparative period in the financial statements. The Company adopted this guidance effective January 1, 2018, and the adoption did not have any impact on the Company’s financial statements as the Company did not have any leases through June 30, 2019. As

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the Company enters into future, material lease agreements, the adoption of this guidance is expected to result in a significant increase in the total assets and liabilities reported on the balance sheets.

Recently Issued Accounting Pronouncements

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement,* which eliminates, modifies and adds disclosure requirements on fair value measurements. The standard is effective for annual periods beginning after December 15, 2019, including interim periods within those fiscal years, and early adoption is permitted. The Company is currently evaluating the impact the adoption of ASU No. 2018-13 will have on the Company's financial statements.

2. Related Party Transactions

Frazier is a principal stockholder of the Company and is represented on the Company's board of directors. For the year ended December 31, 2018 and the six months ended June 30, 2019, the Company conducted its operations within office space controlled by Frazier and Frazier allocated a portion of the costs associated with this office to the Company. In addition, Frazier paid for various goods and services, such as employee wages, insurance and expense reimbursements and various administrative services associated with the operations of the Company and charged the Company for those expenses. As of December 31, 2018 and June 30, 2019, the Company had outstanding accounts payable balances due to Frazier of $45,000 and $50,000, respectively, related to these shared operating expenses. For the year ended December 31, 2018 and the six months ended June 30, 2018 and 2019, the Company incurred $0.3 million, $0.1 million and $0.1 million, respectively, of shared operating expenses. In addition to the shared operating expenses, the Company issued convertible promissory notes to Frazier during 2018 and 2019 (see Note 4).

Mountain Field LLC ("Mountain Field") is an entity owned by the chairman of the Company's board of directors. During the year ended December 31, 2018 and the six months ended June 30, 2019, the Company charged Mountain Field for certain rent and payroll related expenses. These shared expenses were allocated based on usage of the related facilities and time incurred by personnel. As of December 31, 2018 and June 30, 2019, the Company had an outstanding accounts receivable balance from Mountain Field of $19,000 and $15,000, respectively, related to shared operating expenses. For the year ended December 31, 2018 and the six months ended June 30, 2018 and 2019, the Company charged Mountain Field $4,000, $3,000 and $0.1 million, respectively, for shared expenses.

Takeda became a common stockholder of the Company as of May 7, 2019 in connection with the May 2019 license agreement (see Note 3).

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 (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 $25.0 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 the Takeda Warrant Right to receive an additional common stock warrant 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 outstanding convertible promissory notes, calculated immediately before the closing of the Company's IPO, with a nominal initial fair value due to the low probability of issuance. In addition, the Company is obligated to pay Takeda up to an aggregate of $250.0 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 Company incurred $0.1 million of transaction costs in connection with the Takeda License. The Takeda Warrant has an exercise price of $0.00004613 per share, expires on May 7, 2029 and becomes exercisable upon (i) certain change of control transactions of the Company or (ii) the consummation of an IPO by the Company.

The transaction has been accounted for as an asset acquisition as substantially all of the fair value is concentrated in a group of similar assets. The $78.9 million fair value of the consideration paid for these research and development assets, which have no alternative future use, was recorded as in-process research and development in the Company's combined statement of operations for the six months ended June 30, 2019.

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. Convertible Promissory Notes

Frazier Convertible Note Financing

From January 2018 to April 2019, the Company issued the Frazier Notes for an aggregate of $2.4 million and bearing interest at per annum rates ranging from 1.68% to 2.55%. Of the Frazier Notes, $1.9 million were issued in 2018 and $0.5 million were issued in April 2019. Due to certain embedded features within the Frazier Notes, the Company elected to account for these notes and all their embedded features under the fair value option. The Company recorded changes in the fair value of the Frazier Notes in the combined statements of operations until May 2019, when the Frazier Notes and related accrued interest were exchanged, at their then fair value of $2.4 million, for the May 2019

Notes. For the year ended December 31, 2018 and the six months ended June 30, 2018, the Company recognized $50,000 and $4,000, respectively, of change in fair value of convertible promissory notes in the combined statements of operations related to increases in the fair value of the Frazier Notes. For the six months ended June 30, 2019, the Company recognized $50,000 of other income in the combined statements of operations related to decreases in the fair value of the Frazier Notes. For the year ended December 31, 2018 and the six months ended June 30, 2018 and 2019, the Company recognized $13,000, $4,000 and $15,000, respectively, of interest expense in connection with the Frazier Notes.

May 2019 Convertible Note Financing

On May 7, 2019, the Company entered into a note purchase agreement under which it issued the unsecured May 2019 Notes for an aggregate of $90.3 million, resulting in gross proceeds to the Company of $87.8 million in cash and $2.4 million related to the exchange of the Frazier Notes and related accrued interest for the May 2019 Notes. Including the conversion of the Frazier Notes, Frazier purchased $20.0 million of the May 2019 Notes. The May 2019 Notes bear interest at a rate of 6% per annum and are subordinated to borrowings under the Company's loan and security agreement (see Note 5). The May 2019 Notes become payable upon demand of the holders of at least 60% of the outstanding principal amount of the May 2019 Notes, including Frazier, on May 7, 2020 (the "Maturity Date"), and become due and payable on May 7, 2022, subject to earlier conversion or repayment in the event the Company completes certain equity financings or a change of control. The May 2019 Notes can be converted/redeemed as follows (i) automatically converted upon a qualified equity financing, with a conversion price of the lesser of 80% of the price paid per share in such financing or the conversion cap price per share, (ii) optionally converted upon a non-qualified equity financing with a conversion price of 80% of the price paid per share in such financing, (iii) optionally converted any time after the Maturity Date, with a conversion price per share of the conversion cap price per share, (iv) automatically upon an IPO with a conversion price per share of the lesser of 80% of the IPO price per share, or the conversion cap price per share, and (v) upon certain corporate transactions, receive cash equal to the greater of (A) two times the then outstanding principal and accrued interest and (B) an amount equal to the amount that would be received as if the May 2019 Notes were converted with a conversion price of the conversion cap price per share. The conversion cap price per share is defined as $500.0 million less the outstanding principal and accrued interest divided by the total of (1) the total number of common shares outstanding immediately prior to conversion, (2) the number of common shares issuable upon exercise or conversion of exercisable or convertible securities, and (3) the number of shares of capital stock reserved for issuance under the Company's equity incentive plan.

The note purchase agreement includes, among others, covenants related to delivery of certain financial reports, certain registration rights, voting provisions regarding the composition of the Company's board of directors, and limitations on the Company's ability to pay dividends, incur additional indebtedness or consummate certain changes of control. The note purchase agreement also contains customary events of default, including bankruptcy, the failure to make payments when due, and certain material adverse changes. 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. As of June 30, 2019, the Company was in compliance with all applicable covenants under the note purchase agreement.

Due to certain embedded features within the May 2019 Notes, the Company elected to account for these notes and all their embedded features under the fair value option. For the six months ended

June 30, 2019, the Company recognized $2.5 million of other expense in the combined statements of operations related to increases in the fair value of the May 2019 Notes. For the six months ended June 30, 2019, the Company recognized $0.8 million of interest expense in connection with the May 2019 Notes. As of June 30, 2019, the outstanding principal and accrued interest on the May 2019 Notes was $90.3 million and $0.8 million, respectively.

5. Long-Term Debt

Long-term debt consists of the following (in thousands):

	June 30, 2019
Long-term debt	$ 25,000
Unamortized debt discount	(2,551)
Long-term debt, net of debt discount	$ 22,449

On May 14, 2019, the Company entered into a loan and security agreement (the “Loan Agreement”, and all amounts borrowed thereunder the “Term Loans”) with Silicon Valley Bank (“SVB”), as administrative and collateral agent, and lenders including SVB and WestRiver Innovation Lending Fund VIII, L.P. (“WestRiver”). The Company borrowed $25.0 million (“Term Loan A”) at the inception of the Loan Agreement and has the right to borrow an additional $25.0 million (“Term Loan B”). Term Loan B is available through March 31, 2020, provided that (i) the Company has received at least $150.0 million of net cash proceeds in connection with the issuance and sale, subsequent to April 1 2019, of its equity securities and subordinated debt, (ii) the Company has initiated Phase 3 clinical trials for vonoprazan, and (iii) no event of default has occurred.

The Term Loans bear interest at a floating rate of the higher of the Wall Street Journal Prime rate plus 1.75% (7.25% at June 30, 2019) or 7.25%. The monthly payments consist of interest-only through June 1, 2021 or, in the event of positive data with respect to the Company’s Phase 3 clinical trial in both indications for Vonoprazan sufficient to file an NDA with the FDA, through June 1, 2022. Subsequent to the interest-only period, the Term Loans will be payable in equal monthly installments of principal, plus accrued and unpaid interest through the maturity date of May 1, 2024. In addition, the Company is obligated to pay a final payment fee of 8.25% of the original principal amount of the Term Loans. As of June 30, 2019, the final payment fee of $2.1 million has been recorded as an other long-term liability.

The Company may elect to prepay all or a portion of the Term Loans prior to maturity, subject to a prepayment fee of up to 2.0% of the then outstanding principal balance and payment of a pro rata portion of the final payment fee. After repayment, no Term Loan amounts may be borrowed again.

The borrowings under the Loan Agreement are collateralized by substantially all of the Company’s assets, excluding intellectual property and certain other assets. The Loan Agreement includes affirmative and negative covenants. The affirmative covenants include, among others, covenants requiring the Company to maintain its legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and satisfy certain requirements regarding its operating accounts. The negative covenants include, among others, limitations on the Company’s

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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. The Loan Agreement also contains customary events of default, including bankruptcy, the failure to make payments when due, and a material adverse change. Upon the occurrence of an event of default, subject to any specified cure periods, all amounts owed by the Company would begin to bear interest at a rate that is 4.00% above the rate effective immediately before the event of default and may be declared immediately due and payable by SVB, as collateral agent. As of June 30, 2019, the Company was in compliance with all applicable covenants under the Loan Agreement.

In connection with the Loan Agreement, the Company issued the Lender Warrants to purchase stock of the Company. The Lender Warrants become exercisable only if the Company borrows Term Loan B, and the number, class and per share price of the shares subject to the warrants is dependent on the terms of certain future equity financing transactions of the Company, including an IPO. The Lender Warrants expire ten years from the date of issuance, subject to earlier termination on September 30, 2020 if the Company does not draw down Term Loan B on or before March 31, 2020. The Lender Warrants include a put option pursuant to which, in the event that the Company does not draw down Term Loan B on or before March 31, 2020, the warrant holders may require that the Company repurchase the warrants for a total aggregate repurchase price of $0.5 million. The put right is exercisable through September 30, 2020.

The initial $0.4 million fair value of the Lender Warrants, the $2.1 million final payment fee and $0.2 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 Loans. For the six months ended June 30, 2019, the Company recognized $0.3 million of interest expense, including amortization of the debt discount, in connection with the Loan Agreement. As of June 30, 2019, the Company had outstanding Term Loans of $25.0 million and accrued interest of $0.2 million.

Future minimum principal and interest payments under the Term Loans, including the final payment fee, as of June 30, 2019 are as follows (in thousands):

Year ending December 31:	
2019	$ 921
2020	1,843
2021	6,609
2022	9,533
2023	8,920
2024	5,599
Total principal and interest payments	33,425
Less interest and final payment fee	(8,425)
Long-term debt	$ 25,000

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6. Stockholders' Deficit

Common Stock

In March 2019, subsequent to the Merger, the Company sold 1,491,072 shares of the Company's common stock to Frazier.

In March 2019, the founders granted the Company a repurchase right for the 3,373,408 shares of common stock originally purchased in 2018. The Company has the right, but not the obligation, to repurchase unvested shares in the event the founder's relationship with the Company is terminated, subject to certain limitations, at the original purchase price of the stock. The repurchase right lapses for 843,352 shares in March 2019 and the repurchase right for the remaining 2,530,056 shares lapses in equal monthly amounts over the following 48-month period ending in March 2023. The fair value of the founder shares at the date the repurchase right was granted is being recognized as stock-based compensation expense on a straight-line basis over the vesting period. As of June 30, 2019, 2,371,928 shares of common stock were subject to repurchase by the Company and the associated repurchase liability was not significant. The amount of recognized and unrecognized stock-based compensation related to the founder stock was immaterial for all periods presented.

In May 2019, the Company issued Takeda 1,084,000 shares of common stock in connection with the Takeda License.

For the period from January 1, 2019 to May 6, 2019, the Company issued 2,524,852 shares of common stock to various employees and consultants of the Company for aggregate proceeds of approximately $1,000. Upon issuance, these shares were subject to a repurchase option by the Company at the original purchase price of the shares. The repurchase rights generally lapse as to 25% of the shares on the first anniversary of the vesting commencement date, and the repurchase right lapses as to 1/48th of the shares each one-month period thereafter, subject to the purchaser remaining continuously an employee, consultant or director of the Company.

Equity Incentive Plan

The Company's 2019 Equity Incentive Plan (the "Existing Incentive Plan") provides for the grant of incentive stock options, nonstatutory 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. As of June 30, 2019, the Company had 2,231,739 shares of common stock authorized for issuance under the Existing Incentive Plan, of which 2,215,479 shares remained available for grant. In May 2019, the Company issued 16,260 shares of common stock under a restricted stock award, of which 10,840 were unvested as of June 30, 2019. For the six months ended June 30, 2019, the Company recognized $29,000 of stock-based compensation expense related to restricted stock awards under the Existing Incentive Plan and the grant date fair value of the award was $5.43 per share, the grant date fair value of the Company's common stock.

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A summary of the Company’s unvested shares is as follows:

Balance at January 1, 2019	–
Vesting restrictions placed on previously issued shares	3,373,408
Sale of unvested common stock	2,524,852
Issuance of unvested restricted stock awards	16,260
Share vesting	(1,257,270)
Balance at June 30, 2019	4,657,250

For accounting purposes, unvested shares of common stock are considered issued, but not outstanding until they vest.

Stock-Based Compensation Expense

Stock-based compensation expense recognized for all equity awards, including founder stock, has been reported in the combined statements of operations as follows (in thousands):

	Six Months Ended June 30, 2019
Research and development expense	$ –
General and administrative expense	29
Total	$ 29

As of June 30, 2019, the Company had $59,000 of unrecognized stock-based compensation expense, which is expected to be recognized over a weighted-average period of 0.7 years. For the six months ended June 30, 2019, the vested fair value of the restricted stock awards was $29,000. There was no stock-based compensation expense for the year ended December 31, 2018.

Valuation of Common Stock

Prior to obtaining the Takeda License on May 7, 2019, the fair value of the Company’s common stock was nominal since the Company was not sufficiently capitalized and held no assets that could be used to generate future revenues. Subsequent to obtaining the Takeda License and issuing the May 2019 Notes, the Company estimated the fair value of its common stock using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants Accounting and Valuation Guide: *Valuation of Privately Held Company Equity Securities Issued as Compensation* (the “Practice Aid”). The Practice Aid prescribes several valuation approaches for setting the value of an enterprise, such as the cost, income and market approaches, and various methodologies for allocating the value of an enterprise to its common stock. The Company’s 2019 valuations utilized a scenario-based analysis that estimated the fair value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to the Company, including various IPO, stay private and dissolution scenarios, and applying a discount for lack of marketability. The Company considered various stay private scenarios using the income approach and allocated the indicated equity value to each class of equity based on the current-value method. The Company also considered various IPO scenarios based on expected equity values in an IPO and allocated the indicated equity value to each class of equity on a fully-diluted basis considering the dilutive impacts of the May 2019 Notes and the Lender Warrants.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consists of the following:

	June 30, 2019
Common stock warrants	7,588,000
Shares available for issuance under the Existing Incentive Plan	2,215,479
Total	9,803,479

As of December 31, 2018, no shares of common stock were reserved for future issuance.

7. Income Taxes

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

	Year Ended December 31, 2018
Tax computed at federal statutory rate	$ (271)
Permanent differences	14
Change in valuation allowance	257
Provision for income taxes	$ –

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

	December 31, 2018
Deferred tax assets:	
Net operating loss carryforwards	$ 5
Accruals and reserves	16
Intangible assets	236
Total deferred tax assets	257
Valuation allowance	(257)
Net deferred taxes	$ –

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, 2018.

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As of December 31, 2018, the Company had federal net operating loss carryforwards of approximately $23,000, which do not expire, and no material federal or California research and development credits.

Pursuant to Internal Revenue Code Sections 382 and 383, annual use of the Company's net operating loss and research and development tax credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. The Company has not completed a Section 382 study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since the Company's formation. If eliminated, the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance. Due to the existence of the valuation allowance, limitations created by future ownership changes, if any, will not impact the Company's effective tax rate.

As of December 31, 2018, there were no material unrecognized tax benefits recorded in the combined financial statements and the Company does not anticipate any significant changes in its unrecognized tax benefits over the next 12 months.

The Company is subject to taxation in the United States federal and state jurisdictions. The Company has not yet filed federal income tax and state income tax returns, but upon filing will be subject to examination by federal and state tax authorities due to the carryforward of unutilized net operating losses and research and development credits. The Company is not currently under examination by any tax authority. The Company's policy is to recognize interest and penalties related to income tax matters as a component of income tax expense. The Company has not recognized interest or penalties in its combined statements of operations since inception.

8. Subsequent Events

For purposes of the financial statements as of December 31, 2018 and for the year then ended, and the interim financial statements as of June 30, 2019 and for the six months then ended, the Company has completed an evaluation of all subsequent events through July 26, 2019 to ensure these financial statements include appropriate disclosure of events both recognized in the financial statements and events which occurred but were not recognized in the financial statements. The Company has further evaluated subsequent events for disclosure purposes through October 15, 2019. Except as described below, the Company has concluded that no subsequent event has occurred that requires disclosure.

2019 Incentive Award Plan

In October 2019, the board of directors adopted, and the Company's stockholders approved the 2019 Equity Incentive Plan (the "2019 Plan"), which will become effective in connection with this offering. Under the 2019 Plan, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units and other awards to individuals who are then employees, officers, non-employee directors or consultants of the Company or its subsidiaries. An aggregate of 2,700,000 shares of the Company's common stock will initially be available for issuance under awards granted pursuant to the 2019 Plan. The number of shares initially available for issuance will be increased by (i) the number of shares subject to stock options or similar awards granted under the Existing Incentive Plan that expire or otherwise terminate without having been exercised in full after the effective date of the 2019 Plan and unvested shares issued pursuant to awards granted under the Existing Incentive Plan that are forfeited to or repurchased by the Company after the effective date of the 2019 Plan, with the maximum number of shares to be added to the 2019 Plan pursuant to clause (i) above 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.

Approval of the Employee Stock Purchase Plan

In October 2019, the board of directors adopted, and the Company's stockholders approved, the Employee Stock Purchase Plan (the "ESPP"), which will become effective in connection with this offering. 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 is 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.

Forward Stock Split

On October 11, 2019, the Company effected a 2.168-for-1 forward stock split of its common stock (the "Forward Stock Split"). The par value of the common stock was not adjusted as a result of the Forward Stock Split and the authorized shares were increased to 50,000,000 shares of common stock in connection with the Forward Stock Split. The accompanying combined financial statements and notes to the combined financial statements give retroactive effect to the Forward Stock Split for all periods presented, unless otherwise indicated.

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9,563,157 Shares

Phathom Pharmaceuticals, Inc.

Common Stock

Goldman Sachs & Co. LLC	**Jefferies**	**Evercore ISI**

Needham & Company

Through and including November 18, 2019 (the 25th day after the date of this prospectus) all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.