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

Form 10-K

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

For the fiscal year ended September 30, 2026

OR

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

Commission File Number 001-35839

ENANTA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE	**04-3205099**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

4 Kingsbury Avenue
Watertown, Massachusetts 02472
(617) 607-0800
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.01 per share	ENTA	Nasdaq

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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

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

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

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

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

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

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

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

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter, March 31, 2026, based on the last reported sale price of the registrant's common stock of $12.63 per share was $264,303,817. The number of shares of the registrant's Common Stock, $0.01 par value, outstanding as of November 6, 2026 was 29,158,815 shares**.**

DOCUMENTS INCORPORATED BY REFERENCE

Information for Part III of this Form 10-K will either (i) be incorporated by reference to portions of the registrant's Definitive Proxy Statement for its 2027 Annual Meeting of Stockholders, or (ii) if the Definitive Proxy is not filed with the Securities and Exchange Commission within 120 days after the registrant's fiscal year end of September 30, 2026, it will be provided by amendment to this Form 10-K.

As used in this Form 10-K, "Enanta," "the Company," "we," "our," and "us" refer to Enanta Pharmaceuticals, Inc., and "MAVYRET/MAVIRET" refers to AbbVie's HCV regimen consisting of tablets of glecaprevir/pibrentasvir, except where the context otherwise requires or as otherwise indicated. MAVYRET®, MAVIRET®, VIEKIRA PAK®, VIEKIRAX® and EXVIERA® are trademarks of AbbVie, Inc.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "potential," "positioned," "seek," "should," "target," "will," "would," and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about overall trends, royalty revenue trends, research and clinical development plans, liquidity and capital needs and other statements of expectations, beliefs, future plans and strategies, anticipated events or trends and similar expressions. These forward-looking statements are based on our management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate and our management's beliefs and assumptions. These forward-looking statements are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this Annual Report on Form 10-K may turn out to be inaccurate. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under "Risk Factors" and discussed elsewhere in this Annual Report on Form 10-K. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future. 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 Annual Report on Form 10-K.

ENANTA PHARMACEUTICALS, INC.

ANNUAL REPORT ON FORM 10-K

For the year ended September 30, 2026

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SUMMARY OF PRINCIPAL RISK FACTORS

This summary briefly states the principal risks and uncertainties facing our business that could affect our common stock, which are only a select portion of those risks. A more complete statement of those risks and uncertainties is set forth in Item 1A, "Risk Factors," of this report. This summary is qualified in its entirety by that more complete statement. You should carefully read the entire "Risk Factors" section when considering the risks and uncertainties as part of your evaluation of an investment in our common stock.

- **We will require substantial additional funding to achieve our goals. If we do not generate sufficient funding from our existing collaboration and any future collaborations, we will need to obtain additional funding to support our operations. A failure to obtain funding when needed could force us to delay, limit, reduce or terminate some or all of our product development efforts, including our Phase 2b/3 study of zelicapavir in adults at high risk of severe outcomes from RSV infection.**
- **Our revenues for the next several years are substantially dependent upon AbbVie's success selling MAVYRET/MAVIRET, which includes our protease inhibitor, glecaprevir, for the treatment of HCV**.
  - AbbVie may experience lower sales volume in future quarters.
  - AbbVie's MAVYRET®/MAVIRET® regimen will have to continue to compete successfully against other products and therapies for HCV, including competition for exclusive arrangements with third-party payors and governmental entities as well as price competition, both in the U.S. and in other markets worldwide.
  - Beginning after June 30, 2023, 54.5% of our reported revenues represent payments that go directly to OMERS following our April 2023 sale of that portion of our MAVYRET/MAVIRET royalties earned through June 30, 2032, subject to a cap on aggregate payments to OMERS equal to 1.42 times the purchase price.
- **Any further changes in royalty revenue earned under our AbbVie agreement or in the level of expenses associated with our research and clinical development programs, or both, will cause our results of operations to fluctuate from period to period. If AbbVie experiences lower sales volumes in future quarters combined with research and development expenses in support of our advancing programs, we expect to have continuing operating losses for the foreseeable future.**
  - Many of the preclinical and clinical development activities required for our product candidates must be contracted out to contract research organizations, or CROs, at significant expense. We expect these expenses to increase substantially in the coming years if we are able to advance any of our compounds into registrational clinical studies, as well as any impact of inflation, the combination of which will likely result in continuing operating losses.
- **There are several companies developing potential therapies for RSV, and many companies developing potential therapies for type 2 immune and mast-cell-driven diseases and other immunology indications, which may result in others discovering, developing or commercializing products before we do or doing so more successfully than we do.**
  - In most of the disease areas currently the subject of our research and development efforts, there are other companies with product candidates that are more advanced than ours.
  - If we are not "first to market" or sufficiently differentiated with one of our product candidates in one or more of our targeted disease indications, such as atopic dermatitis or urticarias, our competitive position could be compromised because it may be more difficult for us to obtain marketing approval for that product candidate and/or market acceptance of that product candidate as a follow-on competitor.
- **Clinical drug development for viral infections and immunology indications involves a lengthy and expensive process with uncertain timelines, uncertain outcomes and evolving clinical endpoints for regulatory approvals. If clinical trials of any of our proprietary product candidates are prolonged or delayed, we may be unable to commercialize our product candidates on a timely basis.**
  - Changes in regulatory requirements, policies and guidelines, including guidelines specifically addressing requirements for the development of treatments for RSV, type 2 immune and mast-cell-driven diseases or other virology and immunology indications could also delay the time required to reach regulatory approval of one or more of our product candidates.

- Disruptions at the FDA and other government agencies, including as a result of staffing reductions, leadership changes, funding shortfalls or government shutdowns, could delay the review of our regulatory submissions and the development of our product candidates.

- **The results of clinical trials are inherently uncertain. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials, if any, including sufficient efficacy and an acceptable safety and tolerability profile**.
  - Several companies in the disease areas we are seeking to address have suffered significant setbacks in advanced clinical trials due to adverse safety profiles or lack of efficacy, notwithstanding promising results in earlier studies.
  - Clinical trials involving our product candidates may be suspended or terminated at any time for a number of safety or efficacy-related reasons. For example, the Phase 2b portion of our Phase 2b/3 clinical trial of zelicapavir may not support the Phase 3 portion. Administering any product candidate to humans may produce undesirable side effects not identified in preclinical studies.
  - We may choose to test any of our clinical candidates preclinically and/or clinically in combination with other compounds with different mechanisms of action. Any adverse results from such testing may have adverse consequences for the further development potential of not only the combination but also the clinical candidate itself as a monotherapy or in combination with other mechanisms of action.
- **We may delay or terminate the development of a product candidate at any time if we believe the perceived market or commercial opportunity does not justify further investment.**
- **We could be unsuccessful in obtaining or maintaining adequate patent protection for one or more of our product candidates.**
  - We are competing to develop intellectual property in areas of small-molecule drug development that are highly competitive.
  - We cannot be certain that patents will be issued or granted with respect to our patent applications that are currently pending, or that issued or granted patents will not later be found to be invalid and/or unenforceable, be interpreted in a manner that does not adequately protect our products, or otherwise fail to provide us with any competitive advantage.
  - We cannot be certain that we were the first to file patent applications on our product candidates or for their uses, or that our product candidates will not infringe patents that are currently issued or that are issued in the future.
- **We rely on third parties to manufacture our clinical drug supplies, monitor, support, conduct and/or oversee clinical trials of our product candidates that we develop independently.**

PART I

ITEM 1. BUSINESS

BUSINESS

Overview

We are a biotechnology company that uses our robust, chemistry-driven approach and drug discovery capabilities to discover and develop small molecule drugs with an emphasis on viral infections and immunological diseases.

Virology

We discovered glecaprevir, the second of two antiviral protease inhibitors developed through our collaboration with AbbVie for the treatment of acute or chronic infection with hepatitis C virus, or HCV. Glecaprevir is co-formulated as part of AbbVie's leading brand of direct-acting antiviral, or DAA, combination treatment for HCV, which has been marketed under the tradenames MAVYRET® (U.S.) and MAVIRET® (ex-U.S.) (glecaprevir/pibrentasvir) since 2017 for the treatment of chronic HCV. MAVYRET®/MAVIRET® were also approved as the first and only treatments for acute HCV infection in the United States and the European Union in June 2025 and June 2026, respectively, as well as several other countries including Canada and Australia.

Our active development programs in virology are focused on respiratory syncytial virus, or RSV, the most common cause of bronchiolitis and pneumonia and a leading cause of U.S. hospitalization in young children and a significant cause of respiratory illness in older adults. Populations at high risk for severe RSV infection include infants and young children, adults older than 65 years of age, and those with comorbidities such as chronic heart or lung disease, diabetes, kidney disease, immunodeficiency and others. Estimates from the United States Centers for Disease Control and Prevention, or CDC, for the 2024-2025 RSV season indicate that RSV led to up to 6.8 million outpatient visits, approximately 370,000 hospitalizations, and up to 24,000 deaths, in the United States. We estimate a global market opportunity of between $2.5 billion and $3.5 billion for an oral RSV antiviral for children and all high-risk adults, with a potential total addressable population of up to 4 million patients in the United States. Additionally, we believe that the recent FDA approval of at-home combination self-tests capable of detecting RSV, influenza A & B, and COVID-19 will further drive RSV diagnosis and potentially enable a test-to-treat model for zelicapavir.

We also have a clinical-stage program in virology for SARS-CoV-2, the virus that causes COVID-19.

Immunology

In immunology, we are designing and developing highly potent and selective oral small molecule inhibitors for the treatment of type 2 inflammatory diseases by targeting key mechanisms of the immune response. An overactive response is a primary driver of a number of inflammatory diseases for which there is an enduring unmet need including atopic dermatitis, or AD, urticaria, asthma, prurigo nodularis, or PN, chronic rhinosinusitis with nasal polyps, or CRSwNP, as well as some forms of chronic obstructive pulmonary disease, or COPD, eosinophilic esophagitis, or EoE, allergic rhinoconjunctivitis, or ARC, and other conditions. Based on industry reports, by 2032 the market is projected to be approximately $37 billion for urticaria and AD, approximately $47 billion for the combined market of asthma, COPD, CRSwNP, EoE, ARC and PN and could include an additional $40 billion or greater taking into account potential expansion into gastrointestinal and neurology indications thought to be associated with mast cells.

Our initial immunology targets involve the following mechanisms:

- KIT, a receptor tyrosine kinase, critical for regulating mast cell survival and activation, including release of potent inflammatory mediators such as histamine, which is a primary driver of inflammation and implicated in multiple allergic diseases;
- STAT6, a transcription factor uniquely responsible for interleukin-4, or IL-4, and interleukin-13, or IL-13, cell signaling, which drives a type 2 dominant phenotype and downstream inflammation; and
- MRGPRX2, a non-canonical G-protein-coupled-receptor, or GPCR, expressed predominantly on mast cells, which upon activation triggers degranulation and release of inflammation-mediating components, leading to an inflammatory response that is a driver in multiple allergic diseases, and potentially implicated in migraine.

These mechanisms are implicated, along with others, in several diseases, and it is not uncommon for an efficacious treatment for one disease to be tested and approved for other immunology indications. In addition, these mechanisms are orthogonal approaches that may provide additive or complementary benefit if used in combination. We currently plan to focus our initial immunology drug development proof-of-concept efforts on the following disease indications:

- Urticaria, including chronic spontaneous urticaria, or CSU, a severely debilitating, chronic inflammatory skin disease manifested by hives, angioedema, which is swelling of soft tissues, or both, but with no identified triggers, which has an estimated global prevalence of between 0.5% – 1% of the population, resulting in approximately 1.75 – 3.5 million people with this condition at any given time in the U.S. alone and chronic inducible urticaria (CIndU) of various forms with a variety of known triggers; and
- Atopic dermatitis, or AD, a chronic dermatological disease characterized by dry, red, inflamed, irritated and itchy skin with significant quality of life impacts such as leading a limited lifestyle, avoidance of social interactions and a reduced range of activities, with AD affecting 7.3% of the U.S. adult population, of whom approximately 40% have moderate to severe disease.

As of September 30, 2026, we had $194.5 million in cash, cash equivalents and marketable securities. Based on our operating plan, we believe that our existing cash, cash equivalents and marketable securities as of September 30, 2026, as well as our retained portion of future HCV royalties, will enable us to fund our operating expenses and capital expenditure requirements into fiscal 2029. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "Liquidity and Capital Resources."

Because of the numerous risks and uncertainties associated with clinical development and commercialization, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. Until such time, if ever, as we can generate substantial revenue sufficient to achieve profitability, we expect to finance our operations through a combination of equity offerings, non-dilutive financings, collaborations, strategic alliances or licensing agreements. We may be unable to raise additional funds or enter into such other agreements or arrangements, when needed, on favorable terms, or at all. If we are unable to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the further development and commercialization efforts of one or more of our products, or may be forced to reduce or terminate our operations.

Our Wholly-Owned Programs

All of our development programs are wholly-owned, including our RSV and immunology programs.

RSV. We have two clinical-stage candidates for RSV – zelicapavir (EDP-938) and EDP-323, both of which have Fast Track designation from the U.S. Food and Drug Administration, or FDA. Both candidates inhibit viral replication and the production of new virions for both major subgroups of RSV, and differ from fusion inhibitors, which act only at viral entry. Zelicapavir is an inhibitor of the RSV N-protein and EDP-323 is an inhibitor of the RSV L-protein.

- *Zelicapavir - N-protein Inhibitor Candidate.* Zelicapavir is a once-daily, oral, direct-acting antiviral selectively targeting the N-protein. We believe that zelicapavir has the greatest potential to show optimal efficacy in high-risk populations since these patients have reduced RSV immunity or other comorbidities, which manifest in a higher and longer duration of viral replication and greater disease severity, allowing a bigger window to realize the full potential of zelicapavir. Our development program is focused on evaluating zelicapavir in these high-risk populations, including high-risk adults and pediatric patients, all of which have significant unmet need:
  - *RESOLVE (High-Risk Adults Study).* In October 2026, following an End-of-Phase 2 meeting with the FDA, we dosed the first patient in RESOLVE, a global, registrational Phase 2b/3 clinical trial of zelicapavir in adults at high-risk for severe RSV disease, including patients aged 75 years or older and those with chronic obstructive pulmonary disease or congestive heart failure. The study will evaluate time to complete resolution of 13 RSV symptoms as measured by RiiQ™, while secondary endpoints include reduction in hospitalization rate, additional clinical efficacy measures, virology and safety. The Phase 2b portion of the study will include a minimum of 200 patients and is designed to confirm the treatment effect size on the primary and key secondary endpoints in the targeted population. Topline data from the Phase 2b portion of RESOLVE are expected in 2027. If the Phase 2b portion is successful, we expect to continue with the Phase 3 portion of RESOLVE and may adjust sizing if necessary, depending on the Phase 2b data.
  - *LOTUS (Pediatric Study).* In the fourth quarter of 2026, we completed enrollment in LOTUS, a Phase 2b study of zelicapavir in pediatric patients with RSV. LOTUS is designed to evaluate time to complete resolution of RSV signs and symptoms, as measured by RESOLVE-P, together with the safety and antiviral activity of zelicapavir. Topline data from LOTUS are expected in the first quarter of 2027.

  Across clinical studies to date, zelicapavir has demonstrated a favorable safety profile in over 700 subjects.

- *EDP-323 - L-protein Inhibitor Candidate.* Our second clinical RSV candidate, EDP-323, is an oral, once-daily, direct-acting antiviral selectively targeting the RSV L-protein, a viral RNA-dependent RNA polymerase enzyme that contains multiple enzymatic activities required for RSV replication. EDP-323 is not expected to have cross-resistance to other classes of inhibitors and has the potential to be used alone, or in combination with other RSV mechanisms, to broaden the treatment window or addressable patient populations. EDP-323 demonstrated statistically significant reductions in RSV viral load and symptoms in a Phase 2a challenge study of healthy adults infected with RSV. In addition, a post-exposure prophylaxis analysis was performed in subjects who were not infected by Day 5 after RSV exposure and showed the potential for EDP-323 to be effective in preventing RSV infection when initiated up to five days after RSV exposure.

Immunology. We are leveraging our expertise in developing small molecule inhibitors to design and develop highly potent and selective oral medicines targeting the following mechanisms of immune response:

- KIT Inhibitors. We have a clinical-stage program to develop an oral KIT inhibitor for the treatment of CSU and potentially other mast cell-associated indications by depleting mast cells, thereby addressing a primary driver of these diseases. We have selected EDP-978 as our clinical candidate. EDP-978 demonstrates potent nanomolar activity in both binding and cellular function assays, sub-nanomolar activity *in vivo*, and high selectivity for KIT versus other kinases. EDP-978 also demonstrates good *in vitro* and *in vivo* absorption, distribution, metabolism and excretion, or ADME, properties, supporting once-daily dosing. In April 2026, we dosed our first participant in a randomized, double-blind, placebo-controlled, first-in-human Phase 1 clinical trial. The trial is expected to enroll approximately 98 healthy adult volunteers, ranging in age from 18 to 65 years old, to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics, including serum tryptase, of EDP-978. The trial includes a single ascending dose (SAD) phase, with a two-part food-effect cohort, and a multiple ascending dose (MAD) phase with a 14-day treatment period. We expect to complete dosing in the study by year-end and now plan to report topline data in the first quarter of 2027.
- STAT6 Inhibitors. We have a preclinical stage program to develop oral inhibitors of the signal transducer and activator of transcription 6 transcription factor, known as STAT6, for the treatment of type 2 immune-driven diseases. STAT6 is responsible for IL-4/IL-13 signaling, the pathway targeted by dupilumab, an IL-4 and IL-13 monoclonal antibody marketed as DUPIXENT®. We are initially focusing on atopic dermatitis, or AD, for a proof-of-concept clinical study, and subsequently other indications where dupilumab is approved or has shown clinical activity. EDP-903 is our lead clinical candidate, which has demonstrated nanomolar potency in both binding and cellular assays and is highly selective for STAT6 versus other STATs. EDP-903 results in a rapid, continuous and complete (>90%) inhibition of phosphorylated STAT6 after oral dosing in mice. Importantly, EDP-903 shows in vivo efficacy comparable to dupilumab, or an anti-mouse IL-4/IL-13 antibody, in multiple disease models of asthma (ovalbumin, house dust mite) and AD (MC903). EDP-903 displays favorable in vitro and in vivo ADME properties, supportive of once-daily dosing potential. While Investigational New Drug, or IND, enabling activities are complete, due to a delay in drug manufacturing, we are now targeting an IND filing in the second quarter of 2027.
- MRGPRX2 Inhibitors. In January 2026, we announced a preclinical program targeting MRGPRX2, a GPCR expressed predominantly on mast cells, for the treatment of type 2 immune driven diseases and migraine. MRGPRX2 inhibitors act through non-depleting mast cell modulation, including IgE-independent pathways, and may have the potential to address multiple chronic inflammatory diseases, including atopic dermatitis, asthma and others, as well as potential in migraine. We recently selected EPS-5336 as our development candidate. EPS-5336 is a potent inhibitor of MRGPRX2 signaling *in vitro* and *in vivo*, with subnanomolar potency (EC_{50} of 0.2-0.6 nM) in cellular assays, via the preferred noncompetitive mechanism of inhibition and prevention of skin mast cell activation in humanized MRGPRX2 mouse models. Further, EPS-5336 shows potent activity across multiple MRGPRX2 agonists and inhibits MRGPRX2-induced degranulation in migraine-relevant meningeal mast cells. EPS-5336 is highly selective for MRGPRX2 versus other GPCRs. EPS-5336 also demonstrates favorable *in vitro* and *in vivo* ADME properties, supportive of once-daily dosing potential. We are conducting IND-enabling activities with the goal of filing an IND in the fourth quarter of 2027.

We have utilized our internal chemistry and drug discovery capabilities to generate all of our development-stage programs. We continue to invest substantial resources in research programs to discover compounds targeting new disease areas.

Our Out-Licensed Products

HCV. Two protease inhibitors developed through our Collaborative Development and License Agreement with AbbVie have been clinically tested, manufactured, and commercialized by AbbVie as part of its combination regimens for HCV. We have received the full $330.0 million of contractual milestone payments under the agreement related to clinical development and commercialization regulatory approvals of these regimens in major markets, and we continue to earn royalties on sales of the second-generation regimen.

Glecaprevir is the HCV protease inhibitor we discovered that was developed by AbbVie in a fixed-dose combination with its NS5A inhibitor, pibrentasvir, for the treatment of chronic HCV. This product was also approved by the FDA and European Commission as the first and only treatment for acute HCV infection in June 2025 and June 2026, respectively, as well as several other countries including Canada and Australia. This patented combination, currently marketed under the brand names MAVYRET® (U.S.) and MAVIRET® (ex-U.S.), is referred to in this report as MAVYRET/MAVIRET. This regimen is a once-daily, all-oral, fixed-dose, ribavirin-free treatment for HCV genotypes 1-6, or GT1-6, which is referred to as being pan-genotypic. In the U.S., EU and Japan, it is approved as an 8-week treatment for patients with and without compensated cirrhosis and new to treatment. Today, these patients are estimated to represent the majority of HCV patients in over 50 countries where MAVYRET/MAVIRET is sold by AbbVie and where MAVYRET/MAVIRET remains the only 8-week pan-genotypic HCV treatment. The first protease inhibitor developed through this collaboration, paritaprevir, is part of AbbVie's initial HCV regimens, which have been almost entirely replaced by MAVYRET/MAVIRET.

Since August 2017, substantially all of our royalty revenue has been derived from AbbVie's net sales of MAVYRET/MAVIRET. Our ongoing royalty revenues from this regimen consist of annually tiered, double-digit, per-product royalties on 50% of the calendar year net sales of the glecaprevir/pibrentasvir combination in MAVYRET/MAVIRET. The annual royalty tiers return to the lowest tier for sales on and after each January 1. In April 2023, we sold 54.5% of our future MAVYRET/MAVIRET royalties to an affiliate of OMERS, a Canadian public employee pension fund, for a $200.0 million cash payment, subject to a cap of total royalties sold equal to 1.42 times the cash payment.

Our Strategy

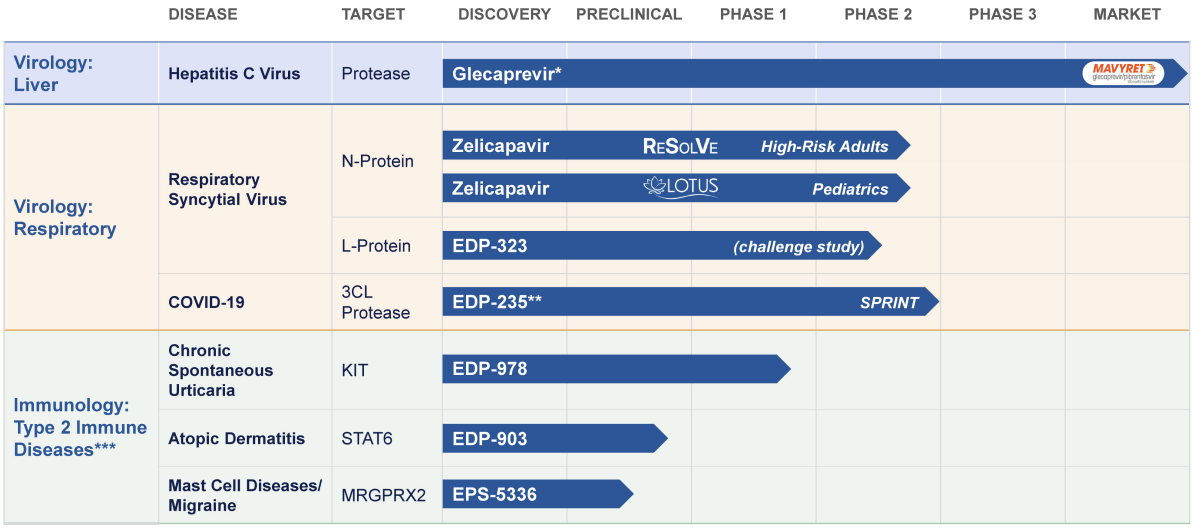
Our primary objective is to become a leader in the discovery and development of small molecule drugs with an emphasis on first-in-disease treatments for RSV and best-in-class small molecule treatments for diseases with significant unmet medical needs in immunology. Our strategy includes the following key elements:

- *Advance clinical development of novel virology product candidates for RSV.* We have completed clinical studies of two compounds discovered in our research program for RSV, a viral infection for which there is currently no safe and effective treatment and, as such, there exists a substantial unmet medical need. We are continuing to evaluate zelicapavir in high-risk populations in our RESOLVE and LOTUS studies. In parallel, we are continuing to evaluate potential partnership opportunities to advance our RSV programs.
- *Advance our preclinical and clinical immunology portfolio of novel, oral inhibitors.* We are evaluating EDP-978, our oral KIT inhibitor, in a Phase 1 clinical trial, with an initial focus on CSU. We also have ongoing discovery and preclinical efforts targeting additional mechanisms of the immune response, including MRGPRX2, addressing mast-cell-driven diseases, with an initial focus on CSU and potentially migraine, and the STAT6 pathway, with an initial focus on AD.
- *Invest in research and development of compounds against other immunology targets*. We are continuing to invest resources in our research programs to identify and advance novel compounds to additional targets that have the potential to address significant unmet medical needs in immunology. We may also seek to augment our product candidate pipeline through the acquisition or in-licensing of external assets and/or technologies in one or more of our disease areas of focus.
- *Collaborate or out-license, where and when appropriate, with pharmaceutical partners to accelerate the development and commercialization of our proprietary compounds and/or create combination therapies*. We may choose to collaborate with other companies to accelerate the global clinical development of one or more of our product candidates, including our RSV and immunology programs. We are also prepared to combine efforts, where and when appropriate, with collaborators where there is the potential for better treatments with combination therapies, as we did in HCV. Our decisions regarding our proprietary programs will be based on the results of our studies and the potential for collaborations, including combinations with one or more drugs targeting other mechanisms of action in these diseases.

- *Continue to use our existing resources and future cash flow from our AbbVie collaboration to fund our research and development activities*. Based on our operating plan, we believe our existing financial resources, as well as our retained portion of future HCV royalties will enable us to fund our operating expenses and capital expenditure requirements into fiscal 2029. These resources will allow us to continue to advance compounds in clinical development and to progress the most promising candidates at least through proof-of-concept trials. Further development of any compound as a monotherapy or in combinations with other therapeutic agents when we believe such combinations will provide the most promising opportunities will require additional financial resources.

Our Research and Development Pipeline

The following table summarizes our product development pipeline in our virology and immunology programs:



*Fixed-dose antiviral combination contains glecaprevir and AbbVie's NS5A inhibitor, pibrentasvir. Marketed by AbbVie as MAVYRET® (U.S.) and MAVIRET® (ex-U.S.).
**Continued development dependent on a future collaboration.
***Initial indications. Potential future indications include Asthma, Chronic Inducible Urticaria (CIndU), COPD, Eosinophilic Esophagitis (EoE); Prurigo Nodularis (PN), Migraine and others.

Our RSV Program

Background and Overview of RSV

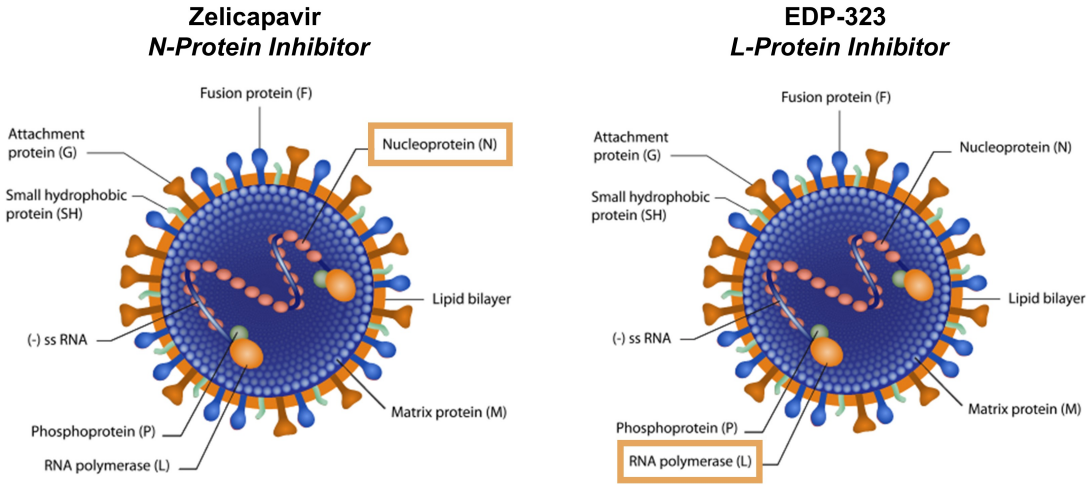
Respiratory syncytial virus, or RSV, is a virus that infects the lungs and is the most common cause of bronchiolitis and pneumonia and a leading cause of U.S. hospitalization in young children, and a significant cause of respiratory illness in older adults, with CDC estimates from the United States of approximately 370,000 hospitalizations and up to 6.8 million outpatient visits during the 2024-2025 RSV season. Populations at high risk for severe RSV infection include infants and young children, adults older than 65 years of age, and those with comorbidities such as chronic heart or lung disease, diabetes, kidney disease, immunodeficiency and others. There are currently no safe and effective therapies for RSV infection.

There are several prophylaxis options on the market or in development. AstraZeneca/Sanofi (BEYFORTUS®) and Merck (ENFLONSIA™) have approved long-acting monoclonal antibodies for prophylaxis use in infants, and Pfizer has an approved maternal vaccine (ABRYSVO®), all of which provide passive, short-term immunity to infants. There are also three approved RSV vaccines, each administered as a single-dose, for high-risk adults age 18–59 years and for all adults age 60 years and above (Pfizer/ABRYSVO®, GSK/AREXVY® and Moderna/mRESVIA®).

While prophylaxis options have recently become available, there is still a significant unmet need for safe and effective antiviral treatments in patients at high-risk for serious RSV outcomes. The adoption of adult RSV vaccines has declined year over year, especially as the CDC recommendation is restricted to high-risk adults age 50-74 years and for all adults 75 years and above, which is narrower than the FDA-approved labeling. Even with adoption, breakthrough infections will still occur, as vaccine efficacy is not complete, and efficacy wanes over time and the recommendation is currently for only a single RSV vaccine dose. In the pediatric population, both the maternal vaccine and the prophylactic antibody approaches provide only passive immunity, which lasts for a limited period of time (approximately 4-5 months) and will generally shift the time of first RSV infection to the next season. Recent data shows that, while hospitalization rates have declined in the infant population, rates have increased for older children. Similarly, uptake of these options will not be optimal and breakthrough infections will still occur in the population that does receive them. Finally, the antibody approach has a low barrier to the development of clinical resistance. Thus, despite these options for prophylaxis, antiviral treatments are urgently needed.

Scientific Background

RSV is a single-stranded, negative-sense RNA virus. There are two major subgroups of RSV, designated RSV-A and RSV-B, each of which contains numerous genotypes. Both groups are viewed as capable of causing RSV infections that can result in hospitalization. The RSV genome consists of ten genes that encode for 11 proteins, namely NS1, NS2, N, P, M, SH, G, F, M2-1, M2-2, and L. The F and G proteins are the predominant target proteins for RSV vaccines. Similarly, small molecule therapeutics have focused primarily on the F (or fusion) protein, while some efforts have targeted the N (nucleocapsid) and L (contains viral RNA polymerase) proteins. Fusion inhibitors work by blocking viral entry, a mechanism that may be less ideal when treatment begins at a time when massive amounts of viral replication is already ongoing. Additionally, fusion inhibitors have been generally shown to have a lower barrier to the development of viral resistance when in clinical use. Replication inhibitors (e.g., N and L inhibitors) work by blocking viral replication at its source, stopping production of new virions. They have demonstrated a higher bar to the emergence of viral resistance. While certain companies are developing potential approaches geared toward the F-protein (or fusion protein, responsible for mediating viral entry of RSV into host cells), we are focused on mechanisms, such as the N-protein and L-protein inhibitors, that target the replication process of RSV directly.



Competitive Landscape

Several companies have developed or are seeking to develop antiviral treatments for RSV infection in adult and pediatric patients, including Ark Biosciences and Shionogi, both of which have compounds in later-stage clinical development.

There are several prophylaxis options on the market or in development. AstraZeneca/Sanofi (BEYFORTUS®) and Merck (ENFLONSIA™) have approved long-acting monoclonal antibodies for prophylaxis use in infants, and Pfizer has an approved maternal vaccine (ABRYSVO®), all of which provide passive, short-term immunity to infants. There are also three approved RSV vaccines, each administered as a single-dose, for high-risk adults age 18–59 years and for all adults age 60 years and above (Pfizer/ABRYSVO®, GSK/AREXVY® and Moderna/mRESVIA®).

Zelicapavir, Our N-Protein Inhibitor

Through our internal chemistry efforts, we identified our lead clinical candidate, zelicapavir. During preclinical studies, zelicapavir demonstrated a greater than 4-log reduction in viral load in an animal model challenged with RSV. Further, zelicapavir maintained nanomolar antiviral potency across all clinical isolates tested *in vitro*, as well as virus that was resistant to fusion inhibitors. The compound inhibited RSV at a post-entry replication step and maintained its activity *in vitro* when given 24 hours post infection. It was also shown to have a high barrier to viral resistance. In addition, combination studies of zelicapavir with other types of RSV inhibitors, such as L-protein and fusion inhibitors, showed synergistic antiviral effects.

To date, we have studied zelicapavir in a Phase 1 study and four Phase 2 studies. The first Phase 2 trial was a human challenge study that demonstrated statistically significant ($p<0.001$) reductions in viral load and clinical symptoms, as well as a high barrier to the development of clinical resistance. Subsequently, a Phase 2 study in otherwise healthy, young adults did not show a clinical benefit with zelicapavir, because in this low-risk patient population, RSV results in a mild, self-resolving upper respiratory tract infection that resolves quickly on its own. We believe these data support the idea that an RSV antiviral treatment, including zelicapavir, has the greatest potential to show optimal efficacy in high-risk populations, which have significant unmet need. These patients have reduced RSV immunity which manifests in a higher and longer duration of viral load and greater disease severity, allowing a bigger window to realize the full potential of zelicapavir.

The most recent Phase 2 studies of zelicapavir were proof-of-concept studies conducted in patients at high risk for developing severe outcomes from RSV infection leading to hospitalization or death, including the studies in high-risk adults and pediatric patients described below. To date, zelicapavir has been well-tolerated in more than 700 patients.

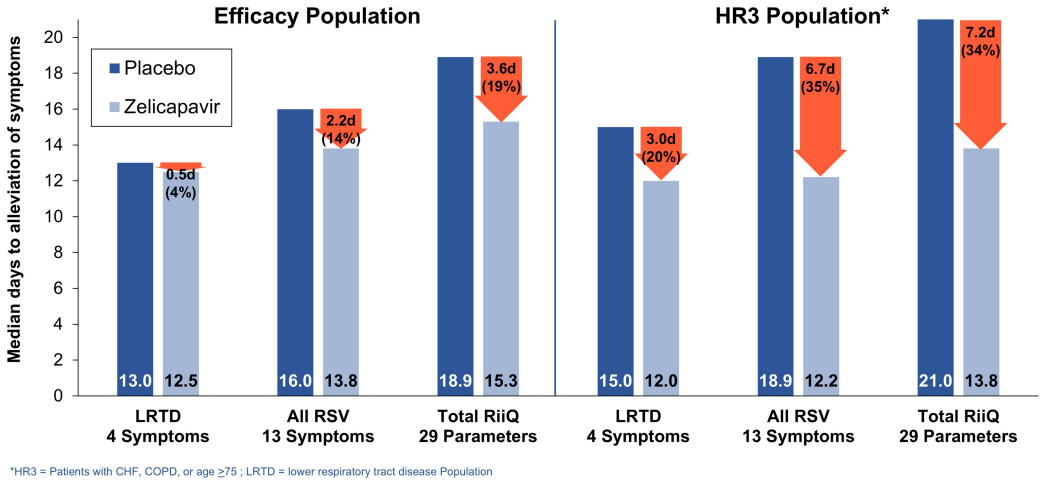
High-Risk Adults Study of Zelicapavir

On September 29, 2025, we announced positive topline results from RSVHR, our Phase 2b high-risk adult study of zelicapavir for the treatment of RSV. This Phase 2b study was a randomized, double-blind, placebo-controlled study of RSV infection in non-hospitalized adults who are at high risk of complications, including those 65 years of age and older and/or those with congestive heart failure, or CHF, chronic obstructive pulmonary disease, or COPD, or asthma. The proportion of patients aged 65-74 years or those with asthma was capped at 20% of the total population. Patients were enrolled within 72 hours of symptom onset and received 800 milligrams, or mg, of zelicapavir or placebo once daily for 5 days. The goal of this proof-of-concept, signal-finding study was to inform the design of a Phase 3 trial, including populations and endpoints, as well as give an indication of a treatment effect on symptoms that could be confirmed in a larger registrational study. Symptoms were measured using the Respiratory Infection Intensity and Impact Questionnaire, or RiiQ™, scale, which evaluates a total of 29 parameters, including 13 RSV symptoms, four of which are lower respiratory tract disease, or LRTD, symptoms, and three other impact of disease components (daily activities, emotions, and social relationships). The primary endpoint evaluated the time to resolution of the LRTD subset of four symptoms to mild. Predefined analyses of complete resolution, defined by all symptoms absent, were also conducted. Multiple secondary endpoints, including all 13 RSV symptoms, total RiiQ™ score, additional patient reported outcomes (e.g., PGI-S), virology, safety, and hospitalization rate, were assessed.

A total of 186 subjects received 800mg of zelicapavir (n=121) or placebo (n=65) orally, once daily for 5 days and were evaluated for 28 days thereafter (safety population). An efficacy population of 175 patients was further defined as those who were polymerase chain reaction, or PCR, positive for RSV at a central laboratory. A high-risk population (HR3) was defined as those who had CHF, COPD, or were age 75 or older, which represented 81% of the efficacy population. Demographics and baseline characteristics were balanced across treatment groups, with the majority of patients being enrolled within 48 hours of symptom onset.

- Zelicapavir demonstrated a favorable safety profile over the initial 5-day dosing period and through 28 days of follow-up, with adverse events, or AEs, being similar between zelicapavir and placebo. No AEs led to treatment discontinuation or study withdrawal in the zelicapavir group. The majority of AEs were mild with diarrhea and asthma being the most common AEs on zelicapavir at 3.3% and 2.5%, respectively.
- No effect was observed on the time to partial resolution of symptoms (defined as mild or absent), including the primary endpoint of time to resolution of the LRTD subset of four symptoms in the efficacy population.

- A clinically meaningful improvement in time to complete resolution (defined as all symptoms absent) of all 13 RSV symptoms was observed for zelicapavir compared to placebo, with a benefit of 2.2 days for the overall efficacy population and 6.7 days for the HR3 population. Zelicapavir also showed an improvement in time to complete resolution on the 29-parameter total RiiQ™ symptom scale of 3.6 days for the efficacy population and 7.2 days for the HR3 population compared to placebo. Additionally, there was a 3.0-day faster time to complete resolution of LRTD symptoms in the HR3 population.



*HR3 = Patients with CHF, COPD, or age ≥75 ; LRTD = lower respiratory tract disease Population

- A statistically significant improvement in RiiQ™ RSV 13-symptom score in the HR3 population at Days 9 (p=0.0403) and 14 (p=0.0247) was observed in a post hoc analysis for zelicapavir compared to placebo.
- Furthermore, the study met a key secondary endpoint with zelicapavir treatment resulting in a statistically significant 2-day faster improvement in a Patient Global Impression of Severity, or PGI-S, score compared to placebo in both the efficacy population (p=0.0446) and the HR3 population (p=0.0465).
- Importantly, a lower hospitalization rate was observed for patients treated with zelicapavir (1.7%) compared to placebo (5.0%). Blinded attribution by investigators judged none (0%) of the hospitalizations on zelicapavir and all (5.0%) of the hospitalizations on placebo to be related to RSV. Post hoc attribution suggested RSV-relatedness of 0.9% for the patients on zelicapavir compared to 5.0% on placebo.
- The study met key secondary virology endpoints showing a robust antiviral effect, with a statistically significantly greater proportion of zelicapavir patients having an undetectable viral load at the end of treatment compared with placebo. In the efficacy population, undetectable viral load at the end of treatment was 23.5% vs. 10.0% in placebo (p=0.0198), and in the HR3 population was 23.9% vs. 10.0% in placebo (p=0.0292). Treatment with zelicapavir resulted in a 4- or 5-day faster median time to undetectable viral load and a 0.6 or 0.7 log decline in viral load at the end of treatment compared to placebo for the efficacy and HR3 populations, respectively.

Pediatric Study of Zelicapavir

In December 2024, we announced positive topline results from the first-in-pediatrics Phase 2 randomized, double-blind, placebo-controlled study evaluating zelicapavir in 96 hospitalized and non-hospitalized children aged 28 days to 36 months with RSV. The first part of the study included dose ranging in two different age cohorts, and focused on safety and pharmacokinetics (PK), while the second part of the study focused on virology outcomes from a single dose selected from the first part of the study.

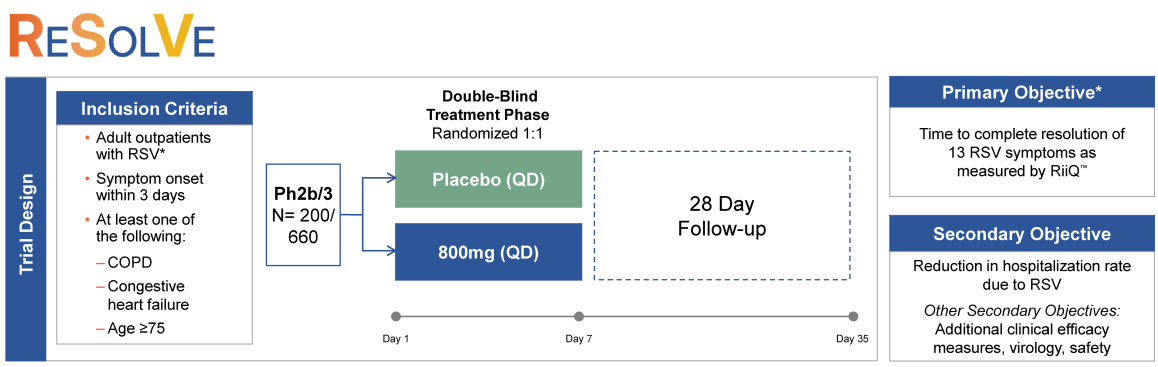
- Zelicapavir demonstrated a favorable safety profile over the 5-day dosing period and through 23 days of follow-up. There were no adverse events leading to treatment discontinuation or study withdrawal.
- Zelicapavir achieved target drug exposure levels across all age groups and dosing cohorts. Exposure was similar across cohorts and doses, and all patients received a therapeutic dose. A dose of 5mg/kg was selected for patients aged ≥28 days to <12 months, and a dose of 7.5mg/kg was selected for patients aged ≥12 months to ≤36 months.
- An antiviral effect was observed for the primary and secondary virology endpoints in the overall pooled efficacy population, with the viral load decline peaking at 0.7 log on Day 9 compared to placebo. The primary endpoint for Part 2 of the study showed a more pronounced effect, with a viral load decline of 1.0 log at Day 3 and 1.4 log at Day 5 compared to placebo. Additionally, a rapid and robust antiviral effect was observed in the prespecified subset of patients who were randomized within 3 days of symptom onset, which represents about 40% of patients in the study (n=38/96). In these patients, a viral load decline of 0.9 log at Day 3 and 1.2 log at Day 5 was observed compared to placebo. Furthermore, zelicapavir treatment resulted in a greater proportion of patients having undetectable viral load at Days 5 and 9 compared to placebo and improvements in area under the curve (AUC) of change from baseline for viral load at all timepoints. Qualitative improvement in time to undetectable viral load was observed at early timepoints, although median time to undetectable viral load was similar between groups. Overall, virology results were similar regardless of age or whether patients were enrolled from a hospitalized or outpatient setting.

In a post hoc analysis of this Phase 2 study, zelicapavir demonstrated that treatment with zelicapavir resulted in a shorter time to complete resolution of RSV-related symptoms, as measured by ReSViNET, a parent/guardian clinical scoring system. Caregivers reported the severity of RSV-related symptoms daily from baseline through Day 14. A post hoc analysis of time to complete resolution of symptoms (defined as absent and discharged from hospital), showed an estimated Kaplan-Meier median of 6.99 days for zelicapavir versus 8.60 days for placebo.

Ongoing Studies in High-Risk Populations

We are continuing to evaluate zelicapavir in high-risk adult and pediatric populations, all of which have significant unmet need:

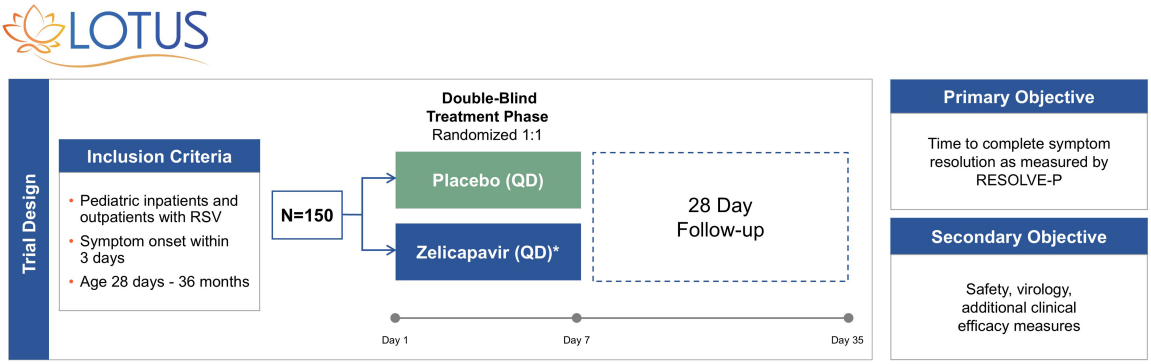
- *RESOLVE*. In October 2026, following an End-of-Phase 2 meeting with the FDA, we dosed the first patient in RESOLVE, a Phase 2b/3 global, registrational trial of zelicapavir in adults at high-risk for severe RSV disease, including patients aged 75 years or older and those with COPD or CHF. These risk factors are the same as the HR3 population in our Phase 2b RSVHR trial. Patients will receive an oral dose of 800mg of zelicapavir or placebo once daily for 7 days and be evaluated for 28 days thereafter. The primary endpoint is the time to complete resolution of all 13 RSV symptoms as measured by the RiiQ™ tool. A key secondary endpoint will evaluate hospitalization rate, with other secondary endpoints of additional clinical efficacy measures, antiviral activity and safety of zelicapavir. The Phase 2b portion of the study will include a minimum of 200 patients and is designed to confirm the treatment effect size on the primary and key secondary endpoints in the targeted population. Topline data from the Phase 2b portion of RESOLVE are expected in 2027. If the Phase 2b portion is successful, we expect to continue with the Phase 3 portion of RESOLVE, which is estimated to enroll approximately 660 patients.



Study initiated in 4Q 2026; Phase 2b data in 2027 to confirm endpoints and sizing

* Patients who have received an RSV vaccine are capped at 10%; Primary endpoint is on MITT of unvaccinated patients (vaccinated patients included in a separate supportive ITT analysis)
COPD: Chronic Obstructive Pulmonary Disease; PGI-S: Patient Global Impression of Severity; QD: Once-daily; RiiQ: Respiratory Infection Intensity and Impact Questionnaire

- *LOTUS*. In the fourth quarter of 2026, we completed enrollment in LOTUS, a Phase 2b, double-blind, placebo-controlled, multicenter trial in pediatric patients designed to evaluate the efficacy and safety of zelicapavir in hospitalized and non-hospitalized children with up to 72 hours of respiratory tract infection symptoms who test positive for RSV. A total of 150 participants, 28 days to 36 months of age, received 5mg/kg (<12 months old) or 7.5mg/kg (≥12 months old) of zelicapavir or placebo once daily for 7 days and were evaluated for 28 days thereafter. The primary endpoint is the time to complete resolution of clinical signs of RSV as measured by the RESOLVE-P clinical scoring scale. Secondary endpoints evaluate additional clinical efficacy measures, antiviral activity, and safety of zelicapavir. The trial was conducted in Thailand in collaboration with the Penta Foundation, and the AMS-PHPT Research Unit at Chiang Mai University, which has deep expertise and decades of experience in conducting pediatric infectious disease trials. Topline data from LOTUS are expected in the first quarter of 2027.



Enrollment completed in 4Q 2026; Phase 2b topline data expected in 1Q 2027

*Doses are 5mg/kg for <12 months old; 7.5mg/kg for ≥12 months old
QD: Once-daily; RESOLVE-P: RESpiratory ObservabLE Reported Outcome-Pediatric; Enanta's proprietary ObsRO © 2026 Enanta Pharmaceuticals, Inc. All rights reserved.

EDP-323, Our RSV L-Protein Inhibitor:

In addition to our N-protein inhibitor, zelicapavir, our second clinical candidate for RSV is EDP-323, a novel oral, direct-acting antiviral selectively targeting the RSV L-protein, a viral RNA-dependent RNA polymerase enzyme that contains multiple enzymatic activities required for RSV replication. EDP-323 has sub-nanomolar potency against RSV-A and RSV-B *in vitro* and has protected mice in a dose-dependent manner from RSV infection as demonstrated by both virological and pathological endpoints. EDP-323 is not expected to have cross-resistance to other classes of inhibitors and has the potential to

be used alone, or in combination with other RSV mechanisms, to broaden the treatment window or addressable patient populations.

Phase 2a Study of EDP-323

In September 2024, we announced positive topline results for EDP-323 in a Phase 2a human challenge study. This study was a randomized, double-blind, placebo-controlled, human challenge study of 142 healthy adult participants inoculated with RSV. Randomized participants (n=141) received either a once-daily (QD) 600mg dose of EDP-323 for five days (high dose, n=47), a single 600mg loading dose on day one followed by a 200mg once-daily (QD) dose of EDP-323 for four days (low dose, n=47), or placebo for five days (n=47). The intent-to-treat-infected population (ITT-I) was defined as all randomized participants receiving challenge virus and at least one dose of study drug with confirmed RSV infection. EDP-323 demonstrated a rapid and sustained antiviral effect and reduced RSV symptoms.

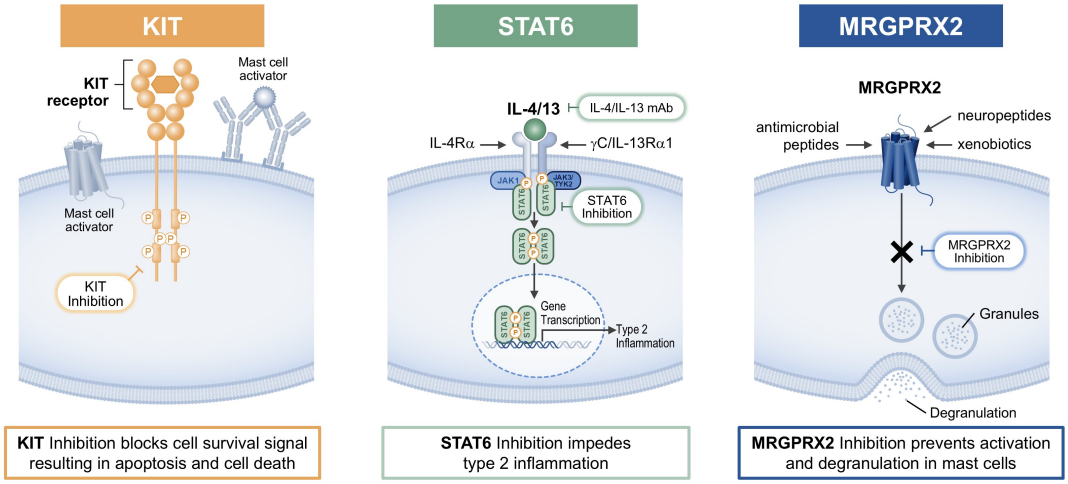
- A highly statistically significant reduction ($p<0.0001$) was observed for the primary efficacy endpoint of area under the curve, or AUC, for viral load as measured by qRT-PCR in the ITT-I population for each of the EDP-323 dosing groups as compared with placebo. Specifically, EDP-323 lowered viral load AUC by 85% in the high dose arm and 87% in the low dose arm compared to placebo. There was no statistically significant difference between the two EDP-323 dosing groups.
- A highly statistically significant reduction ($p<0.0001$) was observed for the secondary efficacy endpoint of AUC for infectious viral load as measured by quantitative culture in the ITT-I population for each of the EDP-323 dosing groups, with a reduction in viral culture AUC by 98% in the high dose arm and 97% in the low dose arm compared to placebo. There was no statistically significant difference between the two EDP-323 dosing groups.
- For the secondary efficacy endpoint of AUC for total symptom score, a highly statistically significant reduction ($p<0.0001$) was observed in the ITT-I population for each of the EDP-323 dosing groups, with a symptom reduction of 66% in the high dose arm and 78% in the low dose arm compared to placebo. There was no statistically significant difference between the two EDP-323 dosing groups.
- EDP-323 demonstrated favorable PK, supportive of once-daily dosing. Mean trough plasma concentrations were maintained at 16-fold above the protein-adjusted EC90 with the low dose, and 35-fold above the protein-adjusted EC90 with the high dose, for both RSV-A and RSV-B strains. In addition, EDP-323 demonstrated a favorable safety profile over a 5-day dosing period and through 28 days of follow-up. Adverse events, or AEs, were similar between EDP-323 dosing groups and placebo. There were no serious AEs, no severe AEs, and no AEs leading to treatment discontinuation or study withdrawal.

In addition, a post-exposure prophylaxis, or PEP, analysis was performed in subjects who were not infected by Day 5 after RSV exposure. In this population, 68 RSV-exposed, susceptible subjects were randomized to receive EDP-323 (low dose n=24, high dose n=21) or placebo (n=23). Of these subjects, 26% (6/23) of those who received placebo became infected versus 0% (0/45) of EDP-323 recipients ($p<0.001$). Evaluated separately, the two EDP-323 dosing groups' PEP effects were statistically significant (low dose $p=0.009$, high dose $p=0.022$) versus placebo.

Our Immunology Programs

In immunology, we are designing and developing highly potent and selective oral small molecule inhibitors for the treatment of type 2 inflammatory diseases by targeting key mechanisms of immune response. Type 2 immune responses are characterized by the overproduction of interleukin-4 (IL-4), interleukin-5 (IL-5), interleukin-13 (IL-13), and immunoglobulin E (IgE), through the activation of T helper 2 (Th2) cells, CD4+ T cells, B cells, and innate cellular response consisting of mast cells, ILC2s, eosinophils, basophils, and IL-4 and/or IL-13-activated macrophages. This immune response is a crucial part of the body's defense mechanism; however, an overactive response is the primary driver of a number of inflammatory diseases, including AD, urticarias, such as CSU, asthma, EoE, ARC, PN, CRSwNP, as well as some forms of COPD and other conditions.

Our first target was the receptor tyrosine kinase, known as KIT, which is critical for regulating mast cell activity. KIT inhibitors may have potential in the treatment of CSU and other mast-cell-driven diseases. We are also targeting STAT6, a transcription factor responsible for IL-4/IL-13 signaling that drives a Th2 dominant phenotype, and MRGPRX2, a non-canonical GPCR expressed on mast cells. STAT6 inhibitors may have potential in the treatment of AD and other type 2 immune-driven phenotypes. MRGPRX2 activation is implicated in the pathology of multiple diseases, including Th2 diseases and migraine.



Background and Overview of CSU

CSU is a severely debilitating, chronic inflammatory skin disease with no identified triggers. Clinical manifestations include hives, angioedema, or both. Hives are variable in size and shape and are characterized by swelling, itchiness, and/or a burning sensation. Angioedema is characterized by pronounced deep tissue swelling along with tingling, burning, tightness and sometimes pain. Patients with CSU also experience symptoms beyond skin manifestations, including sleep disturbances, fatigue, irritability, anxiety and depression, and the disease can affect performance at work or school. CSU is typically a self-limiting disorder, persisting for 2–5 years although some reports estimate that more than half of patients suffer for more than 5 years. CSU may also recur after months or years of full remission. CSU impacts twice as many women as men, with an estimated global prevalence between 0.5% and 1% of the population, which means that at any given time in the U.S. alone approximately 1.75–3.5 million people are experiencing this condition. The peak age of diagnosis is during the core years of working age, 20–40 years old. Standard of care treatment for CSU is antihistamines, however in approximately half the patients, symptom alleviation is not adequate. Only a minority of these uncontrolled cases, approximately 10%, are treated with the biologic approved over a decade ago, which does not fully relieve symptoms for most patients, likely in part due to impacting only IgE-dependent activation pathways. While there are two agents newly approved for CSU, an IL-4 and IL-13 monoclonal antibody (DUPIXENT®) and BTK inhibitor (RHAPSIDO®), there still remains substantial unmet need for an oral agent that offers efficacy against hives and itch for all patients irrespective of prior treatments and/or drugs taken concomitantly, with an acceptable safety profile.

Scientific Background

Our approach to treating CSU is to directly target mast cells, which are the root cause of pathology in CSU, and potentially multiple other diseases. Mast cells are tissue-resident immune cells (e.g., skin, lung or GI) that can be activated through various cell surface receptors, resulting in a signaling cascade that leads to degranulation and release of tryptase, histamine and other inflammatory mediators. This release of inflammatory mediators from mast cells and subsequent propagation of a type 2 inflammatory response has been implicated in multiple inflammatory diseases, including chronic urticaria. Current therapies modulate only a small subset of either mast cell stimulants or the downstream mediators of inflammation that mast cells produce (e.g., antihistamines), but do not address the underlying cause of disease, as they do not directly affect mast cells themselves.

We are targeting mast cells by inhibiting KIT, a central regulator of mast cell development and activation. KIT provides pro-survival signals critical to mast cell survival and, therefore, the inhibition of KIT signaling leads to rapid mast cell inactivation and depletion through apoptosis, thereby directly reducing the quantity of mast cells available to drive pathology. Clinical proof of concept for this approach has been demonstrated with positive Phase 3 data for an anti-KIT monoclonal antibody in CSU, suggesting best-in-disease efficacy and a reasonable safety profile.

Competitive Landscape

There are several different mechanisms being explored for the treatment of CSU, including inhibitors of IL-4R, IgE, Bruton's tyrosine kinase, or BTK, KIT and MRGPRX2. Specifically for KIT inhibitors, there are companies with monoclonal antibodies in development, including Celldex (barzolvolimab - BLA planned 2027), multiple bispecific antibodies in early development, and companies with oral small molecules in Phase 2 development (Sanofi/Blueprint, Calixis).

Our KIT program

Our lead immunology program, EDP-978, is a potent and selective once-daily oral KIT inhibitor in development for the treatment of CSU and potentially other indications by depleting mast cells, thereby addressing a primary driver of these diseases. EDP-978 demonstrates potent nanomolar activity in both binding (Kd = 0.3nM) and cellular function assays (EC_{50} = 1.6-3.4nM), sub-nanomolar activity *in vivo* (EC_{50} = 0.25nM), and high selectivity for KIT versus other kinases, and also demonstrates strong *in vitro* and *in vivo* absorption, distribution, metabolism and excretion (ADME) properties.

In April 2026, we dosed our first participant in a randomized, double-blind, placebo-controlled, first-in-human Phase 1 clinical trial. The trial is expected to enroll approximately 98 healthy adult volunteers, ranging in age from 18 to 65 years old, to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics, including serum tryptase, of EDP-978. The trial includes a SAD phase, with a two-part food-effect cohort, and a MAD phase with a 14-day treatment period. We expect to report topline data from this trial in the first quarter of 2027.

Background and Overview of AD

AD is a chronic dermatological disease characterized by dry, red, inflamed, irritated and itchy skin, and has significant quality of life impacts such as leading a limited lifestyle, avoidance of social interactions and impacted activities. The disease affects an estimated 7.3% of the U.S., adult population and approximately 40% of those have moderate to severe disease. The majority (>90%) of moderate to severe patients are treated with an IL-4 and IL-13 monoclonal antibody (e.g., DUPIXENT® (dupilumab)) despite modest efficacy, while a minority (<10%) are treated with an oral janus kinase, or JAK inhibitor (e.g., RINVOQ® (upadacitinib)) due to safety concerns (black box warning for serious infections, mortality, malignancy, major adverse cardiovascular events, or MACE, and thrombosis). Thus, there is a significant need for an efficacious and safe oral agent.

Scientific Background

Dysregulation of the Th2 immune response drives many allergic and autoimmune diseases, including AD and asthma, which is characterized by an overproduction of IL-4 and IL-13. STAT6 is a transcription factor predominantly expressed in immune and epithelial cells that is responsible for IL-4/IL-13 signaling, which results in a Th2 dominant phenotype. Evidence for STAT6 as a key driver of AD and asthma is the presence of STAT6 gain-of-function variants resulting in severe AD and STAT6 loss-of-function variants protect against type 2 high asthma. Furthermore, clinical validation of this pathway exists in a number of immunology indications from anti-IL-4 and 13 monoclonal antibodies and JAK inhibitors, which block the IL-4/IL-13 signaling pathway. Our STAT6 inhibitor program offers the potential for an "oral Dupixent", as it directly blocks IL-4/IL-13 signaling and reduces inflammation in Th2-driven preclinical models and no oral therapies selectively targeting this pathway are currently available.

Competitive Landscape

The moderate-to-severe AD treatment landscape is dominated by biologics targeting the IL-4 and/or IL-13 pathway (e.g., DUPIXENT® (dupilumab), ADBRY® (tralokinumab-ldrm), EBGLYSS™ (lebrikizumab-lbkz)), in addition to a biologic targeting the IL-33 receptor alpha (NEMLUVIO® (nemolizumab-ilto)) and oral JAK inhibitors (e.g., RINVOQ® (upadacitinib) and CIBINQO® (abrocitinib)). Multiple oral mechanisms are in development, including modulators of IRAK4, ITK, PKM2, RASP and STAT6. Oral assets being evaluated in moderate-to-severe AD patients are in Phase 2 (Corvus - ITK, Kymera - STAT6 degrader, Pfizer - STAT6 inhibitor). Companies with oral STAT6 inhibitors in Phase 1 studies include Sanofi/Recludix, J&J/Kaken and QuantX.

Our STAT6 program

We have a preclinical stage program to develop an oral STAT6 inhibitor for the treatment of type 2 immune-driven diseases, initially focusing on AD and potentially other indications by blocking the IL-4/IL-13 signaling pathway, thereby addressing a primary driver of these diseases. EDP-903 is our lead clinical candidate, which has demonstrated nanomolar potency in both binding and cellular assays, including inhibition of IL-4 induced STAT6 phosphorylation in human peripheral blood mononuclear cells, or hPBMCs (EC50 = 4nM), STAT6-mediated cellular proliferation (EC50 = 8nM) and prevention of STAT6-driven biomarkers of type 2 inflammation (including TARC EC50= 16nM and periostin EC50= 3nM). EDP-903 is highly selective for STAT6 versus other STATs with no inhibition of other STATs in hPBMCs and more than 1000-fold biochemical selectivity over other STATs.

EDP-903 results in a rapid, continuous and complete (>90%) inhibition of phosphorylated STAT6 after oral dosing in mice. Importantly, EDP-903 shows in vivo efficacy comparable to dupilumab, or an anti-mouse IL-4/IL-13 antibody, in multiple disease models of asthma (ovalbumin, house dust mite) and AD (MC903). In the house dust mite challenge asthma model, EDP-903 results in complete (>90%) inhibition of lung pSTAT6 and decreased inflammation comparable to dupilumab, including clinically relevant biomarkers of eosinophils and thymus and activation-regulated chemokine, or TARC, in the lung and serum IgE. In the MC903 atopic dermatitis model, EDP-903 demonstrates complete (>90%) inhibition of pSTAT6 in the skin and spleen, comparable to dupilumab, as well as a robust decrease in serum IgE.

EDP-903 displays favorable in vitro and in vivo ADME properties, supportive of once-daily dosing potential. While IND-enabling activities are complete, due to a delay in drug manufacturing, we are now targeting an IND filing in the second quarter of 2027.

Our MRGPRX2 program

We have a preclinical stage program to develop an oral MRGPRX2 inhibitor for the treatment of mast-cell-driven diseases, including Th2 diseases and migraine by blocking the MRGPRX2 pathway. MRGPRX2 is a non-canonical GPCR expressed on mast cells and inhibition of signaling through this receptor results in a non-depleting prevention of mast cell activation and degranulation, including IgE-independent pathways. Mast cells are involved in the pathology of multiple diseases. In Th2 diseases, like urticaria, asthma and atopic dermatitis, MRGPRX2 agonism leads to degranulation and release of inflammation-mediating components. In migraine, neurogenic inflammation is thought to be driven by crosstalk between sensory neurons and mast cells. Blocking pituitary adenylate cyclase-activating polypeptide, or PACAP, but not its receptor (i.e., PAC1 receptor), has shown efficacy in clinical studies of an anti-PACAP monoclonal antibody in migraine. Data now suggest that MRGPRX2 may be the candidate receptor for PACAP in migraine.

We have selected EPS-5336 as our lead development candidate. EPS-5336 is a potent inhibitor of MRGPRX2 signaling with subnanomolar potency (EC50 of 0.2-0.6 nM) in cellular assays via the preferred non-competitive mechanism of inhibition and has demonstrated prevention of skin mast cell activation in a mouse model. Furthermore, EPS-5336 inhibits degranulation induced by multiple ligands and is highly selective for MRGPRX2 versus other GPCRs. In addition, EPS-5336 inhibits MRGPRX2-induced degranulation in migraine-relevant meningeal mast cells. EPS-5336 exhibits favorable *in vitro* and *in vivo* ADME properties supporting once-daily dosing. We have initiated IND-enabling activities with the goal of filing an IND in the fourth quarter of 2027.

Our Out-Licensed HCV Protease Inhibitor Products

Background and Overview of HCV Market

HCV is a virus that is a common cause of viral hepatitis, an inflammation of the liver. HCV is typically contracted by contact with the blood or other body fluids of another individual infected with HCV. HCV is a leading cause of chronic liver disease, including cirrhosis, liver failure and cancer, and the leading cause of death from liver disease in the United States. HCV disease progression occurs over a period of 20 to 30 years, with the majority of HCV-infected individuals generally exhibiting no major symptoms in the early stages of the disease. Therefore, until a major symptom is diagnosed, many individuals are unaware they are infected and live undiagnosed without seeking treatment. For that reason, combined with the new availability of effective treatments for HCV, the CDC issued new guidelines in 2013 recommending screening for all Americans born between the years 1945 and 1965 so that HCV-infected individuals will be aware of their condition and can consider treatment options. Augmented CDC guidance in 2020 called for screening at least once in a lifetime and for pregnant women during each pregnancy, except in settings where prevalence is <0.1%.

The World Health Organization estimated that approximately 240,000 people died in 2024 from HCV-related liver diseases. According to the CDC, there were an estimated 5,500 new cases of acute HCV infections in 2024, the most recent year for which the CDC has published data, with an estimated total of 49,000 acute HCV infections from 2011-2024. In 2024, there were an estimated 85,000 cases of newly reported chronic HCV, with an estimated total of nearly 1.8 million chronic HCV infections from 2011-2024. We believe that both the acute and chronically infected populations remain significantly untreated, even with the introduction of several new treatment regimens beginning in 2013.

The approved treatments for HCV have provided significant benefit to HCV patients. To date, these treatments have cure rates approaching 100% in several subpopulations. Medical practice defines a “cure” as the point at which there is no quantifiable virus in a patient’s blood for a sustained period of time after cessation of therapy, which is often referred to as a sustained virologic response, or SVR. For AbbVie’s MAVYRET/MAVIRET regimen, the majority of chronic HCV patients only require 8 weeks of treatment compared to 12 weeks with other HCV regimens, including Gilead’s EPCLUSA® and HARVONI® in almost all HCV genotypes. HCV sales have declined since their peak in 2015 due to payers obtaining additional discounts, competitive market dynamics and a decline in the number of patients treated annually after the initial wave of diagnosed chronic HCV patients who had urgency for treatment. Despite the high numbers of HCV patients that have been successfully treated, there remains a large population of chronic HCV-infected patients who have yet to be treated with one of the newer “high cure” regimens. In addition, and as noted above, new HCV infections (principally in association with IV drug use) are an ongoing target population for treatment.

Our Out-Licensed Products in AbbVie’s Marketed Therapies

Glecaprevir - Our protease inhibitor, glecaprevir, which is part of the latest HCV regimen from AbbVie, was developed by AbbVie in combination with pibrentasvir, AbbVie’s second NS5A inhibitor. This co-formulated combination, marketed under the tradenames MAVYRET® (U.S.) and MAVIRET® (ex-U.S.), contains two novel DAAs, that target and inhibit proteins essential for the replication of HCV. MAVYRET/MAVIRET is approved in the U.S., EU, Japan and numerous other countries globally as an 8-week, pan-genotypic, fixed-dose combination treatment, dosed once-daily as three oral tablets, taken with food, for acute or chronic HCV patients without cirrhosis and new to treatment. MAVYRET/MAVIRET is also approved as a treatment for patients with specific treatment challenges, including those GT-1 patients not cured by prior treatment experience with either a protease inhibitor or an NS5A inhibitor (but not both), and in patients with limited treatment options, such as those with severe chronic kidney disease, or CKD, or those with genotype 3 chronic HCV. MAVYRET/MAVIRET is approved for use in patients across all stages of CKD with any of the major HCV genotypes (GT1-6). The approvals of MAVYRET/MAVIRET for the treatment of HCV in patients with CKD are supported by data from nine registrational studies in AbbVie’s clinical development program, which evaluated more than 2,300 patients in 27 countries across all major HCV genotypes (GT1-6) and special populations:

- ***8 weeks for treatment-naïve, non-cirrhotic patients:*** In November 2016, results from several Phase 3 studies of this combination demonstrated 97.5% of chronic HCV-infected patients without cirrhosis and new to treatment across all major genotypes (GT1-6) achieved sustained virologic response at 12 weeks post-treatment, referred to as SVR_{12}, with just 8 weeks of MAVYRET/MAVIRET treatment.
- ***8 weeks for GT-3:*** Data from AbbVie’s ENDURANCE-3 study were presented at the 2017 ILC, demonstrating that 95% of patients with challenging-to-treat, genotype 3, or GT3, chronic HCV infection, without cirrhosis and new to treatment, achieved SVR_{12} after 8 weeks of treatment with MAVYRET/MAVIRET.

- ***8 weeks for compensated cirrhosis:*** Data from AbbVie's EXPEDITION-8 study demonstrated that with 8 weeks of MAVYRET treatment, 100 percent (n=273/273) of genotype 1, 2, 4, 5 and 6 patients achieved a sustained virologic response 8 weeks after treatment (SVR_8) in the per protocol analysis. Based on this data and a second cohort of the study in GT3 chronic HCV-infected patients, MAVYRET is now approved for all genotypes with compensated cirrhosis in the U.S.
- ***12 weeks with chronic kidney disease:*** Results were also presented from AbbVie's EXPEDITION-4 study in chronic HCV patients with chronic kidney disease, or CKD, in which 98% of patients (n=102/104) across all major genotypes (GT1-6) achieved SVR_{12} with 12 weeks of treatment with MAVYRET/MAVIRET.

In June 2025 and June 2026, the FDA and the European Commission, respectively, approved a label expansion for MAVYRET/MAVIRET as the first and only treatment for acute HCV. The acute label expansion has also been approved in several other countries including Canada and Australia. The label expansion was supported by data from a Phase 3, multicenter, single-arm prospective study evaluating the safety and efficacy of MAVYRET/MAVIRET eight-week treatment in adults with acute HCV infection. The study results showed MAVYRET/MAVIRET to be a highly efficacious treatment for people with acute HCV. The majority of the adverse events reported were mild or moderate in severity. The most common adverse events were fatigue, asthenia, headache, and diarrhea.

Paritaprevir - The first protease inhibitor developed through our collaboration with AbbVie, paritaprevir, is part of AbbVie's 3-DAA regimen approved for the treatment of genotype 1 and 4 HCV patients. This 3-DAA combination was sold as VIEKIRA PAK® (paritaprevir/ritonavir/ombitasvir/dasabuvir) in the U.S. from December 2014 to December 2018, and as VIEKIRAX®+EXVIERA® in most other jurisdictions, for non-cirrhotic patients and those with early-stage, or compensated, cirrhosis. These regimens have been almost entirely replaced by MAVYRET/MAVIRET.

Collaboration and License Agreement with AbbVie

We entered into a Collaborative Development and License Agreement with Abbott Laboratories in November 2006 to develop and commercialize HCV NS3 and NS3/4A protease inhibitors. The agreement, which was amended in January and December 2009, was then assigned to AbbVie Inc. on January 1, 2013 in connection with Abbott's transfer of its research-based pharmaceuticals business to AbbVie. Under the agreement, we have granted AbbVie an exclusive, worldwide, royalty-bearing license, including a right to grant sublicenses, to specified intellectual property, including several issued U.S. patents, relating to protease inhibitors. We also granted AbbVie access to our drug discovery capabilities in the HCV NS3 and NS3/4A protease inhibitor field. AbbVie granted us a co-exclusive (together with AbbVie), royalty-free, fully paid license, without the right to grant sublicenses, to certain of AbbVie's intellectual property, AbbVie's interest in joint intellectual property and improvements discovered by AbbVie, for the purpose of allowing us to conduct certain development and commercialization activities in the United States relating to protease inhibitors. AbbVie is responsible for and has funded all costs associated with the development, manufacturing and commercialization of paritaprevir, glecaprevir and any other compounds under this agreement. Under the agreement, we are eligible to receive milestone payments and royalties with respect to these compounds. So long as a product candidate is being developed or commercialized under the agreement, we undertake not to conduct any activity, or grant licenses to a third party, relating to protease inhibitors.

A joint steering committee was established under the agreement with review and oversight responsibilities for all research, development and commercialization activities. The joint steering committee is comprised of three of our senior personnel and three senior personnel from AbbVie; however, AbbVie has final authority to make all decisions regarding development and commercialization activities.

The research program and the evaluation period, which was performed by both parties, ended in June 2011. The first commercialized compound was paritaprevir with the second commercialized compound, glecaprevir, approved in 2017 and marketed under the tradenames MAVYRET® (U.S.) or MAVIRET® (ex-U.S.). Under this collaboration we have received $396 million in payments from AbbVie for license payments, proceeds from a sale of preferred stock, research funding payments and milestone payments.

We also receive annually tiered, double-digit royalties per protease inhibitor product developed under the agreement, which range from ten percent up to twenty percent, or on a blended basis from ten percent up to the high teens. However, if a product is determined to be a combination product, as is the case for both glecaprevir and paritaprevir, the net sales of the combination product are adjusted on a country-by-country and product-by-product basis to reflect a good faith determination of the relative value of each pharmaceutically active ingredient, based on the estimated fair market value. This means that a portion of AbbVie's worldwide annual net sales of a combination product or regimen is first allocated to one of our protease inhibitors and then that royalty-bearing portion is multiplied by the annually tiered royalty rates to determine our actual royalty for the protease product in that regimen in a given period. Under the terms of our agreement, as amended in October 2014, 50% of AbbVie's net sales of MAVYRET/MAVIRET are allocated to glecaprevir. Beginning with each January 1, the cumulative net sales of a given royalty-bearing protease inhibitor product start at zero for purposes of calculating the tiered royalties on a product-by-product basis. Under this collaboration, we have received royalty payments from AbbVie totaling $983 million through September 30, 2026. Further details of these tiered royalties are set forth in Note 7 in Notes to Consolidated Financial Statements included in this report, which are incorporated herein by this reference.

Royalties owed to us under the agreement can be reduced by AbbVie in certain circumstances, including (i) if AbbVie exercises its right to license or otherwise acquire rights to intellectual property controlled by a third party where a product could not be legally developed or commercialized in a country without the third-party intellectual property right, (ii) where a product developed under the collaboration agreement is sold in a country and not covered by a valid patent claim in such country, or (iii) where sales of a generic product are equal to at least a specified percentage of AbbVie's market share of a product in a country.

AbbVie's obligation to pay royalties on products developed under the agreement expires on a country-by-country and product-by-product basis upon the later of (i) the date of expiration of the last of the licensed patents with a valid claim covering the product in the applicable country, and (ii) ten years after the first commercial sale of the product in the applicable country.

Our intellectual property existing as of the effective date of the agreement remains our property. Any intellectual property jointly developed is jointly owned. We will have the unilateral right to enforce our patent rights on any covered product following the first commercial sale of such product, as will AbbVie. In the event of infringement related to any of our patents, we will have the first right and option to initiate legal proceedings or take other actions. In the event of infringement related to any AbbVie patents, AbbVie will have the first right and option to initiate legal proceedings or take other actions. In the event of infringement of a joint patent right, we will discuss with AbbVie whether to initiate legal proceedings or take other actions. AbbVie will have the obligation to defend at its sole expense any actions brought against either party alleging infringement of third-party rights by reason of the activities conducted under the agreement and we will have the right to obtain separate counsel at our own expense. Additionally, AbbVie, at its sole expense, will be responsible for all trademark prosecution.

Subject to the exceptions described above, a party's rights and obligations under the agreement continue until: (i) such time as AbbVie is no longer developing a product candidate or (ii) if, as of the time AbbVie is no longer developing any product candidates, AbbVie is commercializing any other protease inhibitor product, such time as all royalty terms for all covered products and all co-development terms for all co-developed products have ended. Accordingly, the final expiration date of the agreement is currently indeterminable.

Either party may terminate the agreement for cause in the event of a material breach, subject to prior notice and the opportunity to cure, or in the event of the other party's bankruptcy. Additionally, AbbVie may terminate the agreement for any reason upon specified prior notice.

If we terminate the agreement for cause or AbbVie terminates without cause, any licenses and other rights granted to AbbVie will terminate and AbbVie will be deemed to have granted us (i) a non-exclusive, perpetual, fully paid, worldwide, royalty-free license, with the right to sublicense, under AbbVie's intellectual property used in any product candidate and (ii) an exclusive (even as to AbbVie), perpetual, fully paid, worldwide, royalty-free license, with the right to sublicense, under AbbVie's interest in joint intellectual property rights to develop product candidates resulting from covered compounds and to commercialize any products derived from such compounds. Upon our request, AbbVie will also transfer to us all rights, title and interest in any related product trademarks, regulatory filings and clinical trials.

If AbbVie terminates the agreement for our uncured breach, the royalty payments payable by AbbVie may be reduced, the licenses granted to AbbVie will remain in place, we will be deemed to have granted AbbVie an exclusive license under our

interest in joint intellectual property, AbbVie will continue to have the right to commercialize any covered products, and all rights and licenses granted to us by AbbVie will terminate.

Royalty Sale Agreement

In April 2023, we entered into a royalty sale agreement with an affiliate of OMERS, a Canadian public employee pension fund, pursuant to which we were paid a $200.0 million cash purchase price in exchange for 54.5% of our future quarterly royalty payments on net sales of MAVYRET/MAVIRET, after June 30, 2023, through June 30, 2032, subject to a cap on aggregate payments to OMERS equal to 1.42 times the purchase price.

For accounting purposes, we will continue to record 100% of HCV royalties earned under the AbbVie agreement as royalty revenue in our consolidated statements of operations. The $200.0 million received in April 2023 was recognized on our consolidated balance sheets as a liability which will be reduced by the payments made to OMERS over the term of the royalty sale agreement. We will recognize imputed interest expense over the life of the royalty sale agreement based on our estimated future MAVYRET/MAVIRET royalties.

Other Programs for Out-Licensing in Virology

Our SARS-CoV-2 Program

Background and Overview of SARS-CoV-2

Severe acute respiratory syndrome coronavirus 2, or SARS-CoV-2, is the virus that causes COVID-19 (coronavirus disease 2019), the respiratory illness responsible for the COVID-19 pandemic. SARS-CoV-2 is the seventh known coronavirus to infect people, after 229E, NL63, OC43, HKU1, MERS-CoV, and the original SARS-CoV. Patients at higher risk for developing severe complications from COVID-19 include the elderly and those with underlying medical conditions like cardiovascular disease, diabetes, chronic respiratory disease, or cancer. As of October 2025, the World Health Organization estimated over 7 million deaths have been caused by COVID-19. There are also many patients who experience continuing effects of COVID-19, often referred to as “long COVID”. While vaccines that reduce the severity of COVID-19 are available, uptake has not been optimal. In addition, breakthrough infection occurs in many cases because the vaccines are not completely effective or their effect diminishes over time, especially against emerging variants. Thus, there remains an urgent need for effective, safe and well-tolerated, conveniently dosed, once-daily oral antiviral treatments.

Scientific Background

All coronaviruses have a single-stranded, positive-sense RNA (+ssRNA) genome, which is the largest known genome for an RNA virus. The overall structure of the SARS-CoV-2 genome is shared with other betacoronaviruses, namely MERS-CoV and SARS-CoV. The 3C-like protease, or 3CL protease (also known as 3CLpro or the main protease, or Mpro), is essential for viral replication, and is a highly attractive target for the development of direct-acting antiviral agents.

Competitive Landscape

In the United States, there are two oral antiviral treatments for non-hospitalized, high-risk patients with SARS-CoV-2 infection: PAXLOVID™, a 3CL protease inhibitor (nirmatrelvir) boosted with ritonavir (full approval), and LAGEVRIO™ (molnupiravir), a polymerase inhibitor (Emergency Use Authorization, expires June 29, 2027). The most advanced oral, DAAs for the treatment of high-risk patients with SARS-CoV-2 are in Phase 3 studies (Pfizer/ibuzatrelvir, Shionogi/secutrelvir).

EDP-235, Our Lead, Oral, 3CL Protease Inhibitor

We leveraged our expertise in developing protease inhibitors to discover compounds specifically designed to target the SARS-CoV-2 virus and potentially other coronaviruses. We selected EDP-235, an oral inhibitor of the coronavirus 3CL protease, for clinical development. In addition to nanomolar activity against all SARS-CoV-2 variants tested to date, EDP-235 has potent antiviral activity against other human coronaviruses, enabling the potential for a pan-coronavirus treatment, including possibly coronaviruses that may infect human populations in the future. Furthermore, EDP-235 has good tissue distribution, and is projected to have four times higher drug levels in lung tissue compared to plasma. In May 2023, we reported topline results from a Phase 2 clinical trial of EDP-235 in non-hospitalized, symptomatic patients with mild to moderate COVID-19 who were not at increased risk for developing severe disease. EDP-235 met the primary endpoint of the trial and was generally safe and well-tolerated. A dose-dependent improvement in total symptom score was observed with EDP-235 treatment compared to placebo, which achieved statistical significance ($p<0.05$) in the 400mg treatment group at multiple time points, starting as early as one day after the first dose. An analysis of a subset of six symptoms showed a two-day shorter time (5 days to 3 days) to improvement in patients receiving EDP-235 400mg who were enrolled within three days of symptom onset ($p<0.01$). No effect on virologic endpoints as measured in the nose was detected due to the rapid viral decline in the placebo arm of this highly immunologically-experienced, standard-risk population. However, in the subset of patients who were nucleocapsid seronegative (indicating no recent natural infection with SARS-CoV-2), a viral load decline was observed at day five in the 400mg group of 0.8 log overall and 1 log in the patients with symptom onset within three days before treatment with EDP-235. We will continue to focus on potential collaborations to progress EDP-235, as we will not advance this candidate into Phase 3 studies on our own.

Drug Discovery

We have internally discovered all of the compounds in our research and development programs. Our scientists have expertise in the areas of medicinal chemistry, molecular virology, pharmacology, and toxicology with highly developed sets of skills in compound generation, target selection, screening and pharmacology, preclinical development and lead optimization. We are utilizing these skills and capabilities in our discovery and development of small molecule drugs with an emphasis on viral infections and immunological diseases.

We focus on virology and immunology indications representing large and growing market opportunities with significant unmet medical needs. Our selection of a particular therapeutic target within those disease indications takes into consideration the experience and expertise of our scientific team and includes our ability to generate robust medicinal chemistry structure-activity relationships to assist lead optimization and secure relevant intellectual property rights. Once we have identified lead compounds, they are tested using *in vitro* and *in vivo* pharmacology studies and *in vivo* research models of antiviral or antibacterial efficacy.

Business Development

We also regularly examine opportunities to in-license compounds and technologies to complement our existing internal discovery programs. In addition, we engage in discussions with third parties to out-license intellectual property that no longer aligns with our strategic priorities for internal research and development programs. For example, in December 2022 we out-licensed one of our antibiotic compounds in exchange for a $1.0 million up-front fee and future milestone payments and royalties.

Competition

We are engaged in segments of the pharmaceutical industry that are highly competitive and rapidly changing. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations are commercializing or pursuing the development of products that target HCV, RSV, SARS-CoV-2, CSU, AD, migraine and other virology and immunology indications that we may target now or in the future.

Many of our competitors have substantially greater commercial infrastructures and financial, technical and personnel resources than we have, as well as drug candidates in late-stage clinical development. We will not be able to compete successfully unless we are able to:

- design and develop products that are superior to other products in the market;
- attract qualified scientific, medical, regulatory, sales and marketing and commercial personnel;
- obtain patent and/or other proprietary protection for our processes and product candidates;

- obtain required regulatory approvals; or
- collaborate with others in the development and commercialization of new products.

Established competitors may invest heavily to quickly discover and develop novel compounds that could make our product candidates obsolete. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety, or some combination of these factors, to overcome competition and to be commercially successful.

We expect AbbVie's MAVYRET/MAVIRET to continue to face intense competition due to existing approved products in the HCV market. AbbVie's MAVYRET/MAVIRET regimen currently competes in various geographic markets and HCV patient populations with Gilead's Epclusa® (a fixed dose combination of sofosbuvir and velpatasvir), Vosevi® (a fixed-dose combination of sofosbuvir, velpatasvir and voxilaprevir approved by the FDA for certain adults previously treated with direct-acting antivirals), Harvoni® (a fixed-dose combination of sofosbuvir and ledipasvir), and Merck's Zepatier® (a fixed-dose combination of grazoprevir and elbasvir). In December 2025, Gilead entered into a three-year agreement with the U.S. government to offer certain HCV medicines through Medicaid at prices comparable to those paid in other developed nations and to make Epclusa® available directly to patients at a discounted cash price.

Other competitive products in the form of other treatment methods or a vaccine for HCV may render MAVYRET/MAVIRET obsolete or noncompetitive. MAVYRET/MAVIRET will face competition based on its safety and effectiveness, reimbursement coverage, price, patent position, AbbVie's marketing and sales capabilities, and other factors. If MAVYRET/MAVIRET faces competition from generic products other than authorized generic versions by the manufacturer of the branded product (i.e., Gilead), our collaboration agreement provides that the royalty rate applicable to our protease product contained in the regimen is reduced significantly by a specified percentage on a product-by-product, country-by-country basis. If AbbVie is not able to compete effectively against its competitors in HCV, our business will not grow and our financial condition, operations and stock price will suffer.

RSV, COVID-19, CSU, AD and migraine represent competitive therapeutic areas. For RSV, there are currently no safe and effective therapies for already established RSV infection. Several companies are seeking to develop antiviral treatments for RSV infection in adult and pediatric patients. Ark Biosciences and Shionogi have oral compounds in late-stage clinical development. There are several prophylaxis options on the market or in development. Long-acting monoclonal antibodies from AstraZeneca/Sanofi (BEYFORTUS®) and Merck (ENFLONSIA™) are approved for prophylaxis use in infants, and Pfizer has an approved maternal vaccine (ABRYSVO®), all of which provide passive immunity to infants. There are also three approved RSV vaccines, each administered as a single dose, for high-risk adults age 18 – 59 years and for all adults age 60 years and above (Pfizer/ABRYSVO®, GSK/AREXVY® and Moderna/mRESVIA®).

In the United States, there are two oral antiviral treatments for non-hospitalized, high-risk patients with SARS-CoV-2 infection: PAXLOVID™, a 3CL protease inhibitor (nirmatrelvir) boosted with ritonavir (full approval), and LAGEVRIO™ (molnupiravir), a polymerase inhibitor (Emergency Use Authorization). The most advanced oral direct-acting antivirals for the treatment of high-risk patients with SARS-CoV-2 are in Phase 3 studies (Pfizer/ibuzatrelvir and Shionogi/secutrelvir).

For CSU, there are a number of different mechanisms being explored, including inhibitors of IL-4R, IgE, BTK, and MRGPRX2. Specifically for KIT inhibitors, companies are developing monoclonal antibodies (Celldex/barzolvolimab - BLA planned for 2027), bispecific antibodies, and oral small molecules (Sanofi/Blueprint - Phase 2, Calixis - Phase 2).

For AD, the moderate-to-severe AD treatment landscape is dominated by biologics targeting the IL-4 and/or IL-13 pathway (e.g., DUPIXENT® (dupilumab), ADBRY® (tralokinumab-ldrm), EBGLYSS™ (lebrikizumab-lbkz)) in addition to a biologic targeting the IL-33 receptor alpha (NEMLUVIO® (nemolizumab-ilto)) and oral JAK inhibitors (e.g., RINVOQ® (upadacitinib) and CIBINQO® (abrocitinib)). Multiple oral mechanisms are in development, including modulators of IRAK4, ITK, PKM2, RASP and STAT6. The latest stage oral assets being evaluated in moderate-to-severe AD patients are in Phase 2 (Corvus - ITK, Kymera - STAT6 degrader, Pfizer - STAT6 inhibitor). Companies with oral STAT6 inhibitors in Phase 1 studies include Sanofi/Recludix, J&J/Kaken and QuantX.

For migraine prevention, approved therapies target the calcitonin gene-related peptide (CGRP) pathway, including multiple monoclonal antibodies and two small molecule CGRP receptor antagonists (AbbVie/QULIPTA®, Pfizer/NURTEC ODT®/VYDURA®). Additional therapies targeting the PACAP pathway are in development (Lundbeck/bocunebart – Phase 3 planned, several earlier stage monoclonal antibody and bispecific antibody programs). Outside of oral CGRPs, there are limited other oral mechanisms in development for migraine prevention (Evommune/MRGPRX2 antagonist - Phase 2).

If we are not able to develop new products that can compete effectively against our current and future competitors, our business will not grow and our financial condition, operations and stock price will suffer.

Intellectual Property

As part of our business strategy, we actively seek patent protection for our product candidates in the United States and certain major foreign jurisdictions and file additional patent applications, when appropriate, to cover improvements to our compounds. We also rely on trade secrets, internal know-how, technological innovations and agreements with third parties to develop, maintain and protect our competitive position. Our ability to be competitive will depend on the success of this strategy.

Each of our major research and development programs for RSV as well as our out-licensed products for HCV and our SARS-CoV-2 and HBV assets, typically has several pending patent applications and issued patents in the program area containing claims to compounds, methods of use and processes for synthesis. However, only a few of the issued patents and/or pending patent applications cover the lead product candidates in a given program. We also have patent applications pending for earlier stage immunology programs.

RSV, SARS-CoV-2, HBV. Our patent portfolio directed to N- and L-protein inhibitors for RSV, protease inhibitors for SARS-CoV-2 and core inhibitors for HBV, includes issued U.S. patents or pending U.S. patent applications, or both, as well as numerous foreign patent applications. We expect that our existing patents and patent applications (assuming patents are ultimately issued), will provide patent coverage in the U.S., if and when a compound is approved by the FDA, until at least 2038 for each of our compounds currently in clinical development.

HCV NS3 Protease Inhibitor Program. The patent portfolio directed to the HCV protease inhibitor program with AbbVie includes U.S. patents and foreign patents, as well as pending applications. The issued U.S. composition-of-matter patent covering paritaprevir is expected to expire in 2031. The issued U.S. composition-of-matter patent covering glecaprevir is expected to expire in 2032. AbbVie is a joint owner of a number of patents and patent applications. AbbVie also has rights to some or all of these patents and patent applications pursuant to its collaboration agreement with us.

We may obtain patents for certain compounds many years before we obtain marketing approval for products containing such compounds. Because patents have a limited life, which usually begins to run well before the first commercial sale of the related product, the commercial value of the patent may be limited. However, we may be able to apply for patent term extensions in the United States and in a number of European and other countries, compensating in part for delays in obtaining marketing approval, but we cannot be certain we will obtain such extensions.

It is also very important that we do not infringe patents or other proprietary rights of others. If we do infringe such patents or other proprietary rights, we could be prevented from developing or selling products or from using the processes covered by those patents, could be required to pay substantial damages, or could be required to obtain a license from the third party to allow us to use their technology, which may not be available on commercially reasonable terms or at all. If we were not able to obtain a required license or develop alternative technologies, we may be unable to develop or commercialize some or all of our products, and our business could be adversely affected.

Further, the existence of issued patents does not guarantee our right to practice the patented technology or commercialize the patented product. Third parties may have already or could obtain rights to patents that could be used to prevent or attempt to prevent us from commercializing our product candidates. If these other parties are successful in obtaining valid and enforceable patents, and establishing our infringement of those patents, we could be prevented from commercializing our product candidates unless we were able to obtain a license under such patents, which may not be available on commercially reasonable terms or at all.

Much of our scientific capabilities depend upon the knowledge, experience and skills of key scientific and technical personnel. To protect our rights to our proprietary know-how and technology, we endeavor to require all employees, as well as our consultants and advisors, when feasible, to enter into confidentiality agreements that require disclosure and assignment to us of ideas, developments, discoveries and inventions made by these employees, consultants and advisors in the course of their service to us.

We may be unable to obtain, maintain and protect the intellectual property rights necessary to conduct our business, and we may be subject to claims that we infringe or otherwise violate the intellectual property rights of others, which could materially harm our business. For more information, see “Risk Factors—Risks Related to Our Intellectual Property Rights.”

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we develop. Any pharmaceutical candidate that we develop must be approved by the FDA before it may be legally marketed in the United States and by the appropriate foreign regulatory agency before it may be legally marketed in foreign countries.

United States Drug Development Process

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act, or FDCA, and implementing regulations. Drugs are also subject to other federal, state and local statutes and 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 United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA and other governmental sanctions could include refusal to approve pending applications, withdrawal of an approval, a clinical hold, enforcement 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 according to Good Laboratory Practice, or GLPs, or other applicable regulations;
- Submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- Performance of adequate and well-controlled human clinical trials according to the FDA's current Good Clinical Practice, or GCPs, to establish the safety and efficacy of the proposed drug for its intended use;
- Submission to the FDA of a New Drug Application, or an NDA, for a new drug product;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the drug is to be produced to assess compliance with the FDA's current Good Manufacturing Practice standards, or cGMP, to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- Potential FDA audit of the nonclinical and clinical trial sites that generated the data in support of the NDA; and
- FDA review and approval of the NDA.

The lengthy process of seeking required approvals, which can often take anywhere from six months from the time the NDA is filed if there is a priority review for a breakthrough therapy to at least ten months for a standard review, and the continuing need for compliance with applicable statutes and regulations, require the expenditure of substantial resources. There can be no certainty that approvals will be granted.

Before testing any compounds with potential therapeutic value in humans, the product candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with GLP and other federal regulations and requirements. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a drug at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, we cannot assure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that result in suspension or termination of such trial.

Clinical trials involve the administration of the product candidate to healthy volunteers or patients having the disease being studied under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety. Each protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted in accordance with the FDA's GCP requirements. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until it is completed.

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

- *Phase 1*. The drug is initially introduced into healthy humans and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted only in patients having the specific disease.
- *Phase 2*. The drug is evaluated 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, optimal dosage and dosing schedule for patients having the specific disease.
- *Phase 3*. Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials, which usually involve more patients than earlier trials, are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. Generally, at least two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA.

Post-approval studies, or Phase 4 clinical trials, may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and may be required by the FDA as part of the approval process.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA by the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk for human patients. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA, or the sponsor or its data safety monitoring board, may suspend a clinical trial at any time on various grounds, including a finding that the research 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.

Concurrent with clinical trials, companies usually complete additional animal studies and develop additional information about the chemistry and physical characteristics of the drug as well as 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, must include methods for testing the identity, strength, quality and purity of the final drug. Additionally, 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.

U.S. Review and Approval Processes

The results of product development, preclinical 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 by the applicant; a waiver of such fees may be obtained under certain limited circumstances.

In addition, under the Pediatric Research Equity Act, or PREA, an NDA or supplement to an NDA must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers.

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has ten months in which to complete its initial review of a standard NDA and respond to the applicant, and six months for a priority NDA. The review clock for an NDA may be extended if a major amendment is submitted during the review cycle. In addition, the FDA does not always meet its PDUFA goal dates for standard and priority NDAs.

After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. In addition to its own review, the FDA may refer applications for novel drug products or drug products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and 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. During the approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the drug. If the FDA concludes that a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without a REMS, if required.

Before approving an NDA, the FDA will inspect the facilities at which the product is to be manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to ensure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information.

The NDA review and approval process is lengthy and difficult, and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA will issue a "complete response" letter if the agency decides not to approve the NDA. The complete response letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require Phase 4 testing, which involves clinical trials designed to further assess a product's safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Expedited Development and Review Programs

The FDA has four established programs and one pilot program intended to expedite the development and review of new drugs addressing unmet medical needs or treating serious or life-threatening conditions, or drugs that align with U.S. national health priorities: fast track, breakthrough therapy, priority review, and accelerated approval, as well as the Commissioner's National Priority Voucher (CNPV) Pilot Program, or the CNPV Pilot Program, in addition to emergency use authorization, or EUA, in situations such as the COVID-19 pandemic.

The FDA "fast track" program is intended to expedite or facilitate the process for reviewing new products to treat serious or life-threatening conditions and address unmet medical needs. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. Under the fast track program, the sponsor will have more frequent interactions with the FDA during drug development, and may also submit sections of the NDA on a rolling basis to the FDA for review before submitting the complete application. Fast track does not guarantee that a product will be reviewed more quickly or receive FDA approval.

The FDA "breakthrough therapy" program is intended to expedite the development and review of drugs for serious or life-threatening conditions. Preliminary clinical evidence must show that the drug may have substantial improvement over existing therapies on one or more clinically significant endpoints. Although the drug does not have to address an unmet medical need, designation of breakthrough therapy status carries all the "fast track" program features. Additionally, the breakthrough therapy program entitles the sponsor to earlier and more frequent interaction with the FDA review team regarding development of nonclinical and clinical data, and allows the FDA to offer product development and regulatory advice necessary to shorten the time for product approval. The breakthrough therapy status does not guarantee a quicker development or review of the product, and does not ensure FDA approval.

The FDA also has a "priority review" program for products offering significant improvement in the treatment, diagnosis or prevention of a disease. The goal of the priority review program is to shorten the review period to six months from the ten months required for standard review. Any drug with breakthrough therapy, accelerated approval designation, or fast track can be granted priority review if it meets the necessary criteria.

The FDA "accelerated approval" program is intended to expedite the development and review of products with the potential to treat serious or life-threatening illnesses and provide meaningful therapeutic benefit over existing treatments. The program allows approval of a product on the basis of adequate and well-controlled clinical studies establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint that can be measured earlier than survival or irreversible morbidity. As a condition of approval, the FDA generally requires that a sponsor of the product perform adequate and well-controlled post-marketing clinical studies to establish safety and efficacy for the approved indication. Failure to conduct such studies or failure of the studies to establish required safety and efficacy may result in revocation of approval. The FDA also requires, as a condition for accelerated approval, pre-approval of promotional materials, which could adversely impact the timing of the commercial launch or subsequent marketing of the product.

The CNPV Pilot Program uses a collaborative review process to accelerate approvals for companies aligned with critical U.S. national health priorities (e.g., addressing a U.S. public health crisis, delivering more innovative cures for the American people, addressing a large unmet medical need, onshoring drug development and manufacturing to advance the health interests of Americans and strengthen U.S. supply chain resiliency, increasing affordability). Companies selected for the program are issued a voucher entitling the company to benefits including enhanced communications and rolling review to allow for a shortened review time, from 10-12 months to 1-2 months.

The FDA may also allow the use of unapproved medical products, or unapproved uses of approved medical products, under an emergency use authorization, or EUA, to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met, including that there are no adequate, approved, and available alternatives. An EUA is a mechanism to facilitate the availability and use of medical countermeasures during public health emergencies, such as the COVID-19 pandemic. Once an EUA request is submitted, the FDA will evaluate the request and determine whether the relevant statutory criteria are met, taking into account the totality of the scientific evidence about the drug that is available to the FDA. EUAs can be terminated, revoked or reissued, depending on the state of the public health emergency and new data about the drug.

Post-Approval Requirements

Any drug products for which we receive FDA approvals are subject to continuing regulation by the FDA. Certain requirements include, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information on an annual basis or more frequently for specific events, drug supply chain requirements, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA prescription drug promotion and advertising requirements. These promotion and advertising requirements include, among others, standards for direct-to-consumer advertising, prohibitions against promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use"), rules for conducting industry-sponsored scientific and educational activities and promotional activities involving the internet. Failure to comply with FDA requirements can have negative consequences, including the immediate discontinuation of noncomplying materials, adverse publicity, enforcement letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our product candidates. Manufacturers of our product candidates are required to comply with applicable FDA manufacturing requirements contained in the FDA's cGMP regulations. These regulations require, among other things, quality control and quality assurance as well as the corresponding maintenance of comprehensive records and documentation. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are also required to register their establishments and list any products they make with the FDA and to comply with related requirements in certain states. These entities are further subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in serious and extensive restrictions on a product, manufacturer or holder of an approved NDA. These restrictions may include suspension of a product until the FDA is assured that quality standards can be met, continuing oversight of manufacturing by the FDA under a "consent decree," which frequently includes the imposition of costs and continuing inspections over a period of many years, as well as possible withdrawal of the product from the market. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

The FDA also may require post-marketing testing, known as Phase 4 testing, as well as risk minimization action plans and surveillance to monitor the effects of an approved product or place conditions on an approval that could otherwise restrict the distribution or use of the product.

U.S. Patent Term Restoration and Marketing Exclusivity

Drug Price Competition and Patent Term Restoration Act of 1984

Depending upon the timing, duration and specifics of the FDA approval of the use of our product candidates, some of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as 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. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted within 60 days of approval, prior to the expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA. However, there is no guarantee that any such application will be approved.

Federal Food, Drug and Cosmetic Act, or FDCA

Market exclusivity provisions under the FDCA, which are independent of patent status and any patent-related extensions, can also delay the submission or the approval of certain applications of other companies seeking to reference another company's NDA. If the new drug is a new chemical entity subject to an NDA, 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 functional group of a molecule responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a so-called Section 505(b)(2) NDA, submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, such 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 also 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 conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. 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.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services (formerly the Health Care Financing Administration), other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the United States Department of Justice and individual United States Attorney offices within the Department of Justice, state attorneys general and state and local governments.

At such time as we market, sell and distribute any products for which we obtain marketing approval, it is possible that our business activities could be subject to scrutiny and enforcement under one or more federal or state health care fraud and abuse laws and regulations. These fraud and abuse laws include:

- The federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, in cash or in kind, to induce or reward the purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any health care items or service for which payment may be made, in whole or in part, by federal health care programs such as Medicare and Medicaid;
- The federal civil False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government;
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense, or knowingly and willfully making false statements relating to healthcare matters;
- The federal Physician Payment Sunshine Act, which is being implemented as the Open Payments Program and requires certain pharmaceutical manufacturers to engage in extensive tracking of payments and other transfers of value to physicians and teaching hospitals, and to submit such data to the Centers for Medicare & Medicaid Services, or CMS, which will then make all of this data publicly available on the CMS website; and
- Analogous state laws and regulations, including state anti-kickback and false claims laws, which may apply to items or services reimbursed under Medicaid and other state programs or, in several states, apply regardless of the payer, as well as other state laws that require pharmaceutical companies to report expenses related to the marketing and promotion of pharmaceutical products, prohibit certain gifts or payments to health care providers in the state, and/or require pharmaceutical companies to implement compliance programs or marketing codes of conduct.

Violations of fraud and abuse laws may be punishable by significant criminal and/or civil sanctions, including fines and civil monetary penalties, the possibility of exclusion from federal health care programs (including Medicare and Medicaid) and corporate integrity agreements, which impose, among other things, rigorous operational and monitoring requirements on companies. Similar sanctions and penalties also may be imposed upon executive officers and employees, including criminal sanctions against executive officers under the so-called “responsible corporate officer” doctrine, even in situations where the executive officer did not intend to violate the law and was unaware of any wrongdoing. Given the penalties that may be imposed on companies and individuals if convicted, allegations of such violations often result in settlements even if the company or individual being investigated admits no wrongdoing. Settlements often include significant civil sanctions, including fines and civil monetary penalties, and corporate integrity agreements. If the government were to allege or prove that we or our executive officers, employees or consultants had violated these laws, our business could be harmed. In addition, private individuals have the ability to bring similar actions under some of the fraud and abuse laws described above. Our activities could be subject to challenge for the reasons discussed above and due to the broad scope of these laws and extensive enforcement of them by law enforcement authorities. Further, federal and state laws that require manufacturers to make reports on pricing and marketing information could subject us to penalty provisions.

In addition, pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992, each as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Under the Veterans Health Care Act, or VHCA, drug companies are required to offer certain pharmaceutical products at a reduced price to a number of federal agencies including the United States Department of Veterans Affairs and United States Department of Defense, the Public Health Service and certain private Public Health Service—designated entities in order to participate in other federal funding programs including Medicare and Medicaid. Recent legislative changes purport to require that discounted prices be offered for certain United States Department of Defense purchases for its TRICARE program via a rebate system. Participation under the VHCA requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulation.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

Europe / Rest of World Government Regulation

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the European Union, for example, a clinical trial application, or CTA, must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trials may proceed.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with International Conference on Harmonisation (ICH) / WHO Good Clinical Practice standards and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational drug under European Union regulatory systems, we must submit a marketing authorization application to the European Medicines Agency, or the EMA. The application used to file an NDA in the United States is similar to that required in the European Union, with the exception of, among other things, country-specific document requirements.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCPs and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

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

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drug products for a particular indication. 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. In recent years, federal and state governments have increasingly considered and adopted laws that exert greater influence over the price of prescription drugs. For example, a number of states are increasingly using more aggressive price control tools such as Prescription Drug Affordability Boards that have the authority to conduct affordability reviews and establish upper payment limits. The Inflation Reduction Act passed by Congress in 2022 (discussed below), authorized the Centers for Medicare & Medicaid Services, or CMS, to begin negotiating the prices on certain drugs based on factors such as research and development costs and the health economic impact of a particular therapy. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. In certain circumstances, we may need to negotiate discounts on a drug product in order to ensure adequate formulary access for patients.

In 2003, the United States government enacted legislation providing a partial prescription drug benefit for Medicare recipients, which became effective at the beginning of 2006. Government payment for some of the costs of prescription drugs may increase demand for any products for which we receive marketing approval. However, to obtain payments under this program, we would be required to sell products to Medicare recipients through private prescription drug plans that contract with the federal government and adhere to certain minimum requirements.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively known as the Affordable Care Act, or ACA, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the pharmaceutical industry.

The ACA contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse, which since its adoption have affected existing government healthcare programs and have resulted in the development of new programs, including Medicare payment tied to performance. Additionally, 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, under which they must agree to offer 50% 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, beginning January 2011; and
- imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs.

Ten states have not implemented the provisions of the ACA that involve the expansion of Medicaid eligibility to low-income adults. While the United States Supreme Court recently rejected the latest challenge to the constitutionality of the ACA, it is possible that other legislative efforts may seek to modify it. In addition, other legislative changes have been proposed since the Affordable Care Act was enacted, and other judicial challenges to the ACA are pending in the lower courts. The One Big Beautiful Bill Act was signed into law on July 4, 2025 and makes significant changes to the Medicaid eligibility rules for low-income adults, among other changes, which the Congressional Budget Office estimates will result in a loss of coverage for approximately 7.5 million Medicaid beneficiaries.

There has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. For example, the Inflation Reduction Act of 2022, or IRA, introduces some of the most significant changes to Medicare payment for prescription drugs since the ACA. Among its many provisions, the IRA authorizes the Medicare program to negotiate pricing for certain high-cost and/or high-volume drugs, including physician-administered and self-administered drugs, that have been on the market for a minimum amount of time without generic competition. Each year, beginning with calendar year 2026, the Secretary of the Department of Health and Human Services will implement a negotiated price, known as the "Maximum Fair Price", or MFP, that will be made public and apply to the drug's Medicare utilization if the drug is among the top 10 drugs with the highest Medicare spending. Manufacturers who fail to offer the MFP, or fail to come to the table to negotiate after the Secretary has determined their drug is eligible for negotiation, will incur an excise tax of up to 95% for each sale of the drug in the United States. Depending on the share of Medicare spending each year that is attributed to MAVYRET or any other drug we may develop or out-license, and whether or not those drugs become eligible for Medicare negotiation, those drugs and our revenue may be adversely impacted by this provision.

The IRA also requires manufacturers, beginning in 2023, to rebate the Medicare program for Medicare utilization of Part B and Part D drugs that have price increases faster than the rate of inflation. The benchmark to which price increases are compared varies depending on the drug. Although manufacturers are generally familiar with inflation rebates under the Medicaid program, where they have existed for decades, the IRA represents the first time that the Centers for Medicare and Medicaid Services, or CMS, has extended inflation rebates to the Medicare program.

The IRA also redesigns the Medicare prescription drug benefit in several important ways, beginning in calendar year 2024. First, the IRA places an annual out-of-pocket cap on Medicare beneficiary cost sharing amounts, which will take effect in calendar year 2025 before the full benefit redesign. Previously, beneficiaries' out-of-pocket costs were uncapped, even if heavily subsidized. Second, the IRA requires that manufacturers share in the cost of prescription drugs throughout the prescription drug benefit, beginning in calendar year 2025. Previously manufacturers only needed to offer discounted pricing for a single phase of the prescription drug benefit. As described above, in calendar year 2025, the IRA introduces a new $2,000 out-of-pocket maximum in the Part D program for beneficiaries. Finally, the IRA shifts the majority of liability in the "catastrophic phase"—the phase of the prescription drug benefit that only the costliest of Medicare beneficiaries enter—to the private Part D plans, thereby encouraging them to better manage costs. Previously, the federal government incurred the vast majority of liability during the catastrophic phase. Together, these changes to the Medicare prescription drug benefit will create new pricing dynamics for payers and manufacturers.

The United States Congress is also considering legislation that would dramatically reform the business model of the pharmacy benefit management, or PBM, industry. In general, the principal PBM business model relies on rebate payments from pharmaceutical manufacturers to PBMs (acting as agents of insurers) in exchange for administrative tasks such as formulary development, development of pharmacy networks, and plan benefit design. The proposed legislation would replace the rebate model with a model that relies on up-front discounts and would potentially significantly alter the relationship between manufacturers and PBMs.

As noted above, state legislatures are also increasingly considering and adopting laws that exert greater influence over the price of prescription drugs. In recent years, many states have passed cost transparency and pharmaceutical pricing laws. These laws often require manufacturers to report certain product information or other financial data to the state. States are expected to continue their focus on pharmaceutical pricing and will increasingly move to more aggressive price control tools such as Prescription Drug Affordability Boards that have the authority to conduct affordability reviews and establish upper payment limits.

Different pricing and reimbursement schemes exist in other countries. In the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any drug candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payers fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect it will continue to increase the pressure on pharmaceutical drug pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Research and Development

Our research and development expenses were $88.5 million, $106.7 million and $131.5 million for the fiscal years ended September 30, 2026, 2025, and 2024, respectively.

Manufacturing

We do not have our own manufacturing capabilities, except with respect to limited amounts of active pharmaceutical ingredients needed for preclinical development. To date, we have relied on third-party manufacturers, including manufacturers in China, for supply of active pharmaceutical ingredients and ingredients for use in clinical trials of our product candidates. We also expect that in the future we will rely on such manufacturers to produce commercial quantities of any product candidates that we commercialize ourselves. Manufacturing for glecaprevir is conducted by AbbVie. Wherever possible, we seek to identify multiple suppliers for raw materials and key intermediates to be used in our manufacturing process.

Sales and Marketing

We currently do not have any commercialization or sales and marketing capabilities, and currently have no fixed plans to invest in or build such capabilities internally. We have partnered our protease inhibitor compounds for HCV with AbbVie. We may also partner or collaborate with, or license commercial rights to, other larger pharmaceutical or biopharmaceutical companies to support the development of one or more of our wholly-owned product candidates through late-stage clinical development and, if successful, commercialization. However, we still retain all commercial rights to our independent programs and we will continue to evaluate our alternatives for commercializing them once they are more advanced in their clinical development.

Our Corporate Information

We are a Delaware corporation, incorporated in 1995. Our principal executive offices are located at 4 Kingsbury Avenue, Watertown, Massachusetts 02472, and our telephone number is (617) 607-0800. Our website address is http://www.enanta.com.

Segment Information

We provide segment information in Notes 2 and 16 to our Consolidated Financial Statements included in Item 8 of this report. We are incorporating that information into this section by this reference.

Human Capital Resources

As of September 30, 2026, we had 74 full-time employees, 36 of whom hold Ph.D. or M.D. degrees and an additional 16 of whom hold a master's degree or other post-graduate degree. In September 2026, we implemented a reduction in our workforce of approximately one-third of employees across all departments to better align our resources with our current priorities and long-term objectives. We consider the intellectual capital of our employees to be an essential driver of our business and key to our future prospects. Historically, we have had relatively low turnover of employees, but, as the number of biotechnology and pharmaceutical companies in the Boston area has increased, we have experienced an increase in the number of employees leaving for other opportunities. Given our financial resources and our track record, we continue to be able to fill the vacated positions. We also monitor our compensation programs closely and provide what we consider to be a very competitive mix of compensation and insurance benefits for all our employees, as well as participation in our equity programs. None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relations with our employees to be good.

Available Information

Our website address is http://www.enanta.com. Through our website, we make available, free of charge, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports, as well as proxy statements, and, from time to time, other documents as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission, or SEC. These SEC reports can be accessed through the "Investors" section of our website. The information found on our website is not part of this or any other report we file with or furnish to the SEC.

In addition, the SEC maintains a website that contains reports, proxy and information statements, and other information regarding Enanta Pharmaceuticals, Inc. and other issuers that file electronically with the SEC. The SEC's website address is http://www.sec.gov.

ITEM 1A. RISK FACTORS

RISK FACTORS

Our business faces significant risks and uncertainties. Certain factors may have a material adverse effect on our business prospects, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in or incorporated by reference into this Annual Report on Form 10-K and our other public filings with the SEC. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.

Risks Related to Our Business

We will require substantial additional funding to achieve our goals. A failure to obtain this funding when needed could force us to delay, limit, reduce or terminate some or all of our product development efforts.

We will continue to expend substantial resources discovering and developing our proprietary product candidates. These expenditures will exceed our royalty revenues from our AbbVie collaboration and will include costs associated with research and development, preclinical manufacturing of product candidates, conducting preclinical experiments and clinical trials and obtaining regulatory approvals, as well as commercializing any products later approved for sale. Our future capital requirements depend on many factors, including:

- the number and characteristics of our research and development programs;
- the scope, progress, results and costs of researching and developing our product candidates on our own, including conducting advanced clinical trials;
- our ability to establish new collaborations, licensing or other arrangements, if any, and the financial terms of such arrangements;
- the amount of our retained portion of royalties generated from MAVYRET/MAVIRET sales under our existing collaboration with AbbVie;
- delays and additional expenses in our clinical trials;
- the cost of manufacturing our product candidates for clinical development and any products we successfully commercialize independently;
- opportunities to in-license or otherwise acquire new technologies and therapeutic candidates;
- costs associated with any further proceedings in our patent infringement litigation in the United States and Europe regarding use of a coronavirus 3CL protease inhibitor in Paxlovid, Pfizer’s antiviral treatment for COVID-19;
- the timing of, and the costs involved in, obtaining regulatory approvals for any product candidates we develop independently;
- the cost of commercialization activities, if any, of any product candidates we develop independently that are approved for sale, including marketing, sales and distribution costs;
- the timing and amount of any sales of our product candidates, if any, or royalties thereon;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patents, including any litigation costs and the outcomes of any such litigation; and
- potential fluctuations in foreign currency exchange rates.

Accordingly, we will need to obtain additional funding to support our operations. In October 2025, we closed an underwritten public offering of our common stock, resulting in aggregate net proceeds of $69.9 million, after deducting underwriting discounts and commissions and other offering expenses. In July 2026, we entered into an Open Market Sale Agreement℠ with Jefferies LLC ("Jefferies"), as sales agent, under which we may offer and sell shares of our common stock, from time to time through Jefferies, under an at-the-market facility for aggregate gross sale proceeds of up to $75.0 million. Additional funds may not be available if and when we need them, on terms that are acceptable to us, or at all. Our ability to raise funds will depend on financial, economic and market conditions and other factors, many of which are beyond our control. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other research and development activities for one or more of our product candidates, including our Phase 2b/3 study of zelicapavir in adults at high risk of severe outcomes from RSV infection.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, including through sales under our at-the-market facility with Jefferies LLC, our existing stockholders' ownership interests will be diluted, and the terms of any such securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, could involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances, licensing arrangements or additional royalty monetization transactions, we may have to relinquish valuable rights to our product candidates, technologies or future revenue streams, including our retained portion of MAVYRET/MAVIRET royalties, or grant licenses on terms that may not be favorable to us.

We have incurred net losses in recent fiscal years and expect to continue to incur operating losses for the foreseeable future, and our results of operations may fluctuate significantly from period to period.

Although we were profitable in certain prior fiscal years as a result of milestone and royalty payments under our AbbVie collaboration, we incurred net losses of $68.2 million, $81.9 million and $116.0 million for the fiscal years ended September 30, 2026, 2025 and 2024, respectively, and as of September 30, 2026, we had an accumulated deficit of $473.2 million. We have no products approved for sale, and substantially all of our revenue consists of royalties on AbbVie's net sales of MAVYRET/MAVIRET, 54.5% of which are paid to OMERS through June 30, 2032, subject to the cap under our royalty sale agreement. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we advance zelicapavir through our RESOLVE Phase 2b/3 trial, continue clinical development of EDP-978 and advance our STAT6 and MRGPRX2 programs toward the clinic. We may never achieve or sustain profitability and, even if we do, we may not be able to sustain or increase profitability on a quarterly or annual basis.

Our operating results may fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control, including fluctuations in AbbVie's net sales of MAVYRET/MAVIRET, the timing and cost of our clinical trials and other research and development activities, and the timing of any collaboration, licensing or other strategic transaction. As a result, period-to-period comparisons of our results of operations may not be meaningful indicators of our future performance, and if our results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially.

Our revenues are dependent upon royalty revenues derived from AbbVie's net sales of its MAVYRET/MAVIRET regimen for HCV, which includes our protease inhibitor, glecaprevir. If AbbVie is unable to maintain sales of this regimen at or above current levels of sales, our royalty revenues, as well as our retained cash portion of royalties, will be adversely affected.

AbbVie's MAVYRET/MAVIRET regimen continues to be a leading HCV treatment in the U.S. and several market geographies in developed countries where it is approved. While commercialization of this regimen is exclusively in AbbVie's control without any required input from us, we believe it is possible that prices will decline further due to payors obtaining additional discounts or competitive market dynamics. For example, the states of Louisiana and Washington have negotiated a blanket price for one of the HCV drug companies to treat all patients in one or more state programs (e.g., Medicaid). Gilead has been awarded the contract in Louisiana and other states and AbbVie has been awarded the contract in Washington and other states. In addition, Gilead has been able to access the Medicaid market at a lower price point to build its market share by using an authorized generic version of its HCV regimen branded as Epclusa®. It is unknown whether these programs or other programs that states may adopt could have any further impact on MAVYRET/MAVIRET sales. There may also be fluctuations in AbbVie's market share over time due to these and other competitive actions by Gilead.

In recent years, federal and state governments have proposed or implemented Most Favored Nation, or MFN, pricing models that tie reimbursement rates for certain drugs to the lowest prices paid by other countries. In addition, in light of continued fiscal crises experienced by several countries in the European Union and Japan, governments have announced or implemented measures to manage and reduce healthcare expenditures. AbbVie may experience global pricing pressure for its MAVYRET/MAVIRET regimen from such measures, which may be reflected in larger discounts or rebates on its regimens or delayed reimbursement. Also, private and public payors may choose to exclude AbbVie's MAVYRET/MAVIRET regimen from their formulary coverage lists or limit the types of patients for whom coverage will be provided. Any such change in formulary coverage, discounts or rebates or reimbursement for MAVYRET/MAVIRET would negatively affect the demand for this regimen and our royalty revenue derived from its sales.

In addition, AbbVie has the right to make decisions regarding the commercialization of licensed products without consulting us. For example, in 2018 AbbVie entered into a royalty-free licensing agreement with the Medicines Patent Pool to accelerate access to generic versions of MAVYRET/MAVIRET in 99 low- and middle-income countries and territories. AbbVie may also make decisions with which we do not agree. If AbbVie acts in a manner that is not in our best interest, then it could adversely affect our royalty revenues.

We and AbbVie face substantial competition in the markets for HCV drugs, and there are many companies developing potential therapies for RSV and other viral infections, as well as for CSU, AD and other immunology diseases, which may result in others discovering, developing or commercializing products before we do or doing so more successfully than we do.

The pharmaceutical and biotechnology industries are intensely competitive and rapidly changing. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations are commercializing or pursuing the development of products that target viral infections, including HCV and RSV, and immunology diseases, including CSU and AD, as well as SARS-CoV-2, HBV and other viral infections or diseases that we may target in the future. Many of our competitors have substantially greater commercial infrastructure and greater financial, technical and personnel resources than we have, as well as drug candidates in late-stage clinical development.

In all the disease areas currently in the focus of our research and development efforts, there are other companies with product candidates that are more advanced than ours. Our competitors may succeed in developing these product candidates or others and obtaining regulatory approval before we can do so with any of our product candidates. If we are not "first to market" with one of our product candidates in one or more of these disease indications, our competitive position could be compromised because it may be more difficult for us to obtain marketing approval for that product candidate and market acceptance of that product candidate as a follow-on competitor. In addition, any new product that competes with an approved product typically must demonstrate compelling advantages in efficacy, convenience, tolerability or safety, or some combination of these factors, to gain regulatory approvals, overcome price competition and be commercially successful.

RSV, CSU and AD, as well as migraine, HCV and COVID, represent competitive therapeutic areas.

For RSV, there are currently no safe and effective therapies for already established RSV infection. Several companies are seeking to develop antiviral treatments for RSV infection in adult and pediatric patients. Ark Biosciences and Shionogi have compounds in late-stage clinical development.

There are several prophylaxis options on the market or in development. AstraZeneca/Sanofi (BEYFORTUS®) and Merck (ENFLONSIA™) have approved long-acting monoclonal antibodies for prophylaxis use in infants, and Pfizer has an approved maternal vaccine (ABRYSVO®), all of which provide passive immunity to infants. There are also three approved RSV vaccines, each administered as a single dose, for high-risk adults age 18 – 59 years and for all adults age 60 years and above (Pfizer/ABRYSVO®, GSK/AREXVY® and Moderna/mRESVIA®).

For CSU, there are a number of different mechanisms being explored, including inhibitors of IL-4R, IgE, BTK, KIT and MRGPRX2. Specifically for KIT inhibitors, companies are developing monoclonal antibodies (Celldex/barzolvolimab - BLA planned 2027), bispecific antibodies, and oral, small molecules (Sanofi/Blueprint - Phase 2, Calixis - Phase 2).

For AD, the moderate-to-severe atopic dermatitis treatment landscape is dominated by biologics targeting the IL-4 and/or IL-13 pathway (e.g., DUPIXENT® (dupilumab), ADBRY® (tralokinumab-ldrm), and EBGLYSS™ (lebrikizumab-lbkz)), in addition to biologics targeting the IL-33 receptor alpha (NEMLUVIO® (nemolizumab-ilto)) and oral JAK inhibitors (e.g., RINVOQ® (upadacitinib) and CIBINQO® (abrocitinib)). Multiple oral mechanisms are in development, including modulators of IRAK4, ITK, PKM2, RASP and STAT6. The latest stage oral assets being evaluated in moderate-to-severe AD patients are in Phase 2 (Corvus ITK; Kymera - STAT6 degrader, Pfizer - STAT6 inhibitor). Companies with oral STAT6 inhibitors in Phase 1 studies include Sanofi/Recludix, J&J/Kaken, and QuantX.

For migraine prevention, approved therapies target the calcitonin gene-related peptide (CGRP) pathway, including multiple monoclonal antibodies and two small molecule CGRP receptor antagonists (AbbVie/QULIPTA®, Pfizer/NURTEC ODT®/VYDURA®). Additional therapies targeting the pituitary adenylate cyclase activating peptide (PACAP) pathway are in development (Lundbeck/bocunebart – Phase 3 planned, several earlier stage monoclonal antibody and bispecific antibody programs). Outside of oral CGRPs, there are limited other oral mechanisms in development for migraine prevention (Evommune/MRGPRX2 antagonist - Phase 2).

In the HCV market, we expect AbbVie's MAVYRET/MAVIRET to continue to face intense competition due to existing approved HCV products. AbbVie's MAVYRET/MAVIRET regimen currently competes in various geographic markets and HCV patient populations with Gilead's Epclusa® (a fixed-dose combination of sofosbuvir and velpatasvir), Vosevi® (a triple combination therapy of sofosbuvir, velpatasvir and voxilaprevir approved by the FDA for certain adults previously treated with direct-acting antivirals), Harvoni® (a fixed-dose combination of sofosbuvir and ledipasvir), and Merck's Zepatier® (a fixed-dose combination of grazoprevir and elbasvir). Gilead launched authorized generic versions of Epclusa and Harvoni through its subsidiary, Asegua Therapeutics, LLC, which have had an impact on the competitive landscape. For example, in December 2025, Gilead entered into a three-year agreement with the U.S. government to offer certain HCV medicines through Medicaid at prices comparable to those paid in other developed nations and to make Epclusa® available directly to patients at a discounted cash price.

Other competitive products in the form of other treatment methods or a vaccine for HCV may render MAVYRET/MAVIRET obsolete or noncompetitive. MAVYRET/MAVIRET will face competition based on its safety and effectiveness, reimbursement coverage, price, patent position, AbbVie's marketing and sales capabilities, and other factors. If MAVYRET/MAVIRET faces competition from generic products other than authorized generic versions by the manufacturer of the branded product (e.g., Gilead), our collaboration agreement provides that the royalty rate applicable to our protease product contained in the regimen is reduced significantly by a specified percentage on a product-by-product, country-by-country basis. If AbbVie is not able to compete effectively against its competitors in HCV, including any generic products, our business will not grow and our financial condition, operations and stock price will suffer.

For COVID, there are two oral antiviral treatments for non-hospitalized, high-risk patients with SARS-CoV-2 infection: PAXLOVID™, a 3CL protease inhibitor (nirmatrelvir) boosted with ritonavir (full approval), and LAGEVRIO™ (molnupiravir), a polymerase inhibitor (Emergency Use Authorization). The most advanced direct-acting oral antivirals for the treatment of high-risk patients with SARS-CoV-2 are in Phase 3 studies (Pfizer/ibuzatrelvir, Shionogi/secutrelvir).

If we are not able to develop new products that can compete effectively against our current and future competitors, our business will not grow and our financial condition, operations and stock price will suffer.

We have not developed independently any approved products and we have limited clinical development experience, which makes it difficult to assess our ability to develop and commercialize our product candidates.

AbbVie has been responsible for all of the clinical development of our HCV protease inhibitor products. We have not yet demonstrated an ability to address successfully many of the risks and uncertainties associated with late-stage clinical development, regulatory approval and commercialization of therapeutic products such as the ones we plan to develop independently. For example, to execute our business plan for the development of our clinical-stage programs, we will need to successfully:

- execute clinical development of our product candidates and demonstrate acceptable safety and efficacy for them alone or in combination with other drugs or drug candidates;
- obtain required regulatory approvals for the development and commercialization of our product candidates;
- develop and maintain any future collaborations we may enter into for any of these programs;
- obtain and maintain patent protection for our product candidates and freedom from infringement of intellectual property of others;
- establish acceptable commercial manufacturing arrangements with third-party manufacturers;
- build and maintain robust sales, distribution and marketing capabilities, either independently or in collaboration with future collaborators;
- gain market acceptance for our product candidates among physicians, payors and patients; and
- manage our spending as costs and expenses increase due to clinical trials, regulatory approvals and commercialization.

If we are unsuccessful in accomplishing these objectives, we may not be able to successfully develop and commercialize our product candidates and expand our business or continue our operations.

If we are not successful in discovering and developing KIT, STAT6 and MRGPRX2 inhibitors, or in obtaining one or more partners to advance our RSV programs, or in discovering further product candidates, our ability to expand our business and achieve our strategic objectives will be impaired.

Much of our internal research is at preclinical stages. Research programs designed to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying additional potential product candidates, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following:

- the research methodology used may not be successful in identifying additional potential product candidates;
- competitors may develop alternatives that render our product candidates less commercially viable or obsolete;
- competitors may obtain intellectual property protection that effectively prevents us from developing a product candidate;
- a product candidate may, on further study, be shown not to be an effective treatment in humans or to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria; and
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all.

Additional drug candidates that we may develop will require significant research, preclinical and clinical studies, regulatory approvals and commitments of resources before they can be commercialized. We cannot give assurance that our research will lead to the discovery of any additional drug candidates that will generate additional revenue for us. If we are unable to identify additional compounds suitable for preclinical and clinical development, we may not be able to obtain sufficient product revenue in future periods, which likely would result in significant harm to our financial position and adversely impact our stock price.

If we fail to attract and keep senior management and key scientific personnel, or fail to successfully manage the transition of our Chief Executive Officer, we may be unable to successfully develop our product candidates, conduct our clinical trials and commercialize our product candidates.

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 senior management, particularly Jay R. Luly, Ph.D., our Chief Executive Officer and President, Tara L. Kieffer, Ph.D., our Chief Operating Officer, Yat Sun Or, Ph.D., our Chief Scientific Officer, and Scott T. Rottinghaus, M.D., our Chief Medical Officer, as well as other employees and consultants. In October 2026, Dr. Luly announced his intention to retire as President and Chief Executive Officer by February 1, 2027, and our Board of Directors has initiated a comprehensive search for his successor, considering both internal and external candidates. We expect Dr. Luly to continue to serve as a strategic advisor for the remainder of 2027. Leadership transitions can be inherently difficult to manage, and we may not be able to identify, recruit and retain a qualified successor on a timely basis, on acceptable terms or at all. Our leadership transition may result in a loss of institutional knowledge, disruption to our operations and strategy, diversion of management attention and uncertainty among our employees, collaborators, investors and other stakeholders, any of which could adversely affect our business and the price of our common stock. Although none of Drs. Or, Kieffer or Rottinghaus has informed us to date that he or she expects to retire or resign in the near future, the loss of the services of any of these individuals or one or more of our other members of senior management could delay or prevent the successful development of our product candidates.

While we have not historically experienced unique difficulties attracting and retaining qualified employees, we could experience such problems in the future. For example, competition for qualified personnel in the biotechnology and pharmaceutical fields is intense. In addition, we will need to hire additional personnel as we expand our clinical development and ultimately seek regulatory approvals and prepare for commercial activities. We may not be able to attract and retain quality personnel on acceptable terms. Further, in September 2026, we implemented a reduction in our workforce of approximately one-third of employees across all departments to better align our resources with our current priorities and long-term objectives. This workforce reduction may not result in the anticipated efficiencies or cost savings, may result in the loss of institutional knowledge and expertise, and may make it more difficult to retain and motivate our remaining employees, any of which could disrupt our operations and delay our development programs.

We may encounter difficulties expanding our operations successfully to advance our product candidates.

As we seek to advance our product candidates through clinical trials, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to obtain these capabilities. As our pipeline expands, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

Risks Related to Development, Clinical Testing and Regulatory Approval of Our Product Candidates

Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes. Any ongoing or future clinical trials of our product candidates may fail to demonstrate sufficient safety and efficacy. If clinical trials of any of our proprietary product candidates are prolonged or delayed or fail, we may be unable to commercialize our product candidates on a timely basis or ever.

Clinical testing is expensive and, depending on the stage of development, can take a substantial time period to complete. Its outcome is inherently uncertain, and failure can occur at any time during clinical development. None of our product candidates in our pipeline, other than glecaprevir, which was clinically developed by AbbVie, and zelicapavir, which is being evaluated in our ongoing Phase 2b/3 RESOLVE trial, has advanced beyond Phase 2 clinical trials. Any ongoing or future clinical trials of our product candidates may fail to demonstrate sufficient safety and efficacy. For example, the Phase 2b portion of RESOLVE may not confirm the treatment effect observed in the HR3 population in our prior Phase 2b RSVHR trial. Moreover, regulatory and administrative delays for any product candidate in our pipeline may adversely affect our or any future collaborator's clinical development plans and jeopardize our or any future collaborator's ability to attain product approval, commence product sales and compete successfully against other therapies.

Clinical trials can be delayed for a variety of reasons, including delays related to:

- reaching an agreement on acceptable terms with prospective 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;
- failure of third-party contractors, such as CROs, or investigators to comply with regulatory requirements;
- failure to obtain on a timely basis, or at all, the necessary approvals from regulators or institutional review boards, or IRBs, to commence a clinical trial at a prospective trial site, or their suspension or termination of a clinical trial once commenced;
- difficulty in recruiting suitable patients to participate in a trial;
- the broader impact of COVID-19, influenza and other viruses on the incidence of RSV;
- seasonality and variations in the incidence of infection year to year (e.g., RSV) affecting enrollment in clinical trials;
- difficulty in having patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- problems with drug product or drug substance storage and distribution;
- having to add new clinical trial sites;
- our inability to manufacture, or obtain from third parties, adequate supply of drug product sufficient to complete our preclinical studies and clinical trials;
- changes in governmental or regulatory administration;
- lack of clear guidance or changes in regulatory requirements, policy and guidelines, including guidelines specifically addressing requirements for the development of treatments for RSV infection;
- disruptions at the FDA or other regulatory authorities, including as a result of staffing reductions, leadership changes, funding shortfalls or government shutdowns;

- difficulty in obtaining and maintaining adequate insurance coverage;
- program discontinuations or clinical holds for a program of a competitor, which could increase the level of regulatory scrutiny or delay data review or other response times by regulators with respect to one of our programs in the same class as the competitor's program; or
- varying interpretations of data by the FDA, the EMA and similar foreign regulatory agencies.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trial is being conducted, by any Data Safety Monitoring Board, or DSMB, for such trial, or by the FDA, the EMA or other 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 other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, delays can occur due to safety concerns arising from trials or other clinical data regarding another company's product candidate in the same compound class as one of ours. For example, the data from the Phase 2b portion of our Phase 2b/3 study of zelicapavir in adults at high risk of severe outcomes from RSV infection may not support the Phase 3 portion. If we or any future collaborators experience delays in the completion of, or termination of, any clinical trial of one of our product candidates, the commercial prospects of the product candidate will be harmed, and our ability to commence product sales and generate product revenues from the product candidate will be delayed. In addition, any delays in completing our clinical trials will increase our costs in the long term and slow down our product candidate development and approval process. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Zelicapavir, EDP-978 or any other product candidate emerging from our current research programs, may have undesirable side effects which may delay or prevent marketing approval or, if approval is received, require our product candidate to be taken off the market, require us to include safety warnings or otherwise limit sales.

In our RSV program, we are developing inhibitors of the N-protein and L-protein. No inhibitor of the RSV N- or L-protein has completed a clinical trial beyond Phase 2, so we are not yet able to assess the potential liabilities of an N-protein or L-protein inhibitor in large scale studies or in the general population. In addition, the principal target populations in RSV, namely infants, the elderly, and the immunocompromised, represent sensitive or high-risk patient populations that could be more prone to adverse effects of therapy.

If any of our product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products:

- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- we may be required to change instructions regarding the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- the product may be subject to additional distribution restrictions under a REMS, if required by the FDA;
- sales of the product may decrease significantly;
- regulatory authorities may require us to take our approved product off the market;
- we may be subject to litigation or product liability claims; and
- our reputation and our stock price may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of any product we may develop.

If we are required to suspend or discontinue clinical trials due to side effects or other safety risks associated with our product candidates, or if we are required to conduct studies on the long-term effects associated with the use of any of those product candidates, then commercialization of any of those product candidates could be delayed or halted.

Clinical trials involving our product candidates may be suspended or terminated at any time for a number of safety-related reasons. For example, we may voluntarily suspend or terminate clinical trials if at any time one of our product candidates, or a combination therapy including any of them, presents an unacceptable safety risk to the clinical trial patients. In addition, IRBs or regulatory agencies may order the temporary discontinuation or termination of clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, including if they present an unacceptable safety risk to patients. Administering any product candidate to humans may produce undesirable side effects. The existence of undesirable side effects resulting from any of our product candidates, or a combination therapy including any of them, could cause us or regulatory authorities, such as the FDA or EMA, to interrupt, delay or halt clinical trials of our product candidates and could result in the FDA or EMA or other regulatory agencies denying further development or approval of our product candidates for any or all targeted indications. This, in turn, could prevent us from commercializing our product candidates.

Results of earlier clinical trials may not be predictive of the results of later-stage clinical trials.

To date we have only completed clinical studies of our product candidates through Phase 2. The results of preclinical studies and these early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials, if any. In addition, results of Phase 3 clinical trials in one or more ethnic groups or geographies are not necessarily indicative of results in other ethnic groups or geographies. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy results despite having progressed through preclinical studies and initial clinical trials. For example, several companies engaged in clinical development in the disease areas we are also engaged in have suffered significant setbacks in advanced clinical trials due to adverse safety profiles or lack of efficacy, notwithstanding promising results in earlier studies. Similarly, future clinical trial results may not be successful for these or other reasons. For example, in our Phase 2b RSVHR trial of zelicapavir in high-risk adults, a clinically meaningful improvement in time to complete resolution (defined as all symptoms absent) of all 13 RSV symptoms was observed for zelicapavir compared to placebo in a pre-specified high-risk population. The data from the Phase 2b portion of our RESOLVE study may not show the same benefit and support the design of the Phase 3 portion of the trial.

Product candidate development risk is heightened by any changes in the planned clinical trials compared to the completed clinical trials. As product candidates are developed through preclinical studies and early-stage and late-stage clinical trials towards approval and commercialization, it is customary that various aspects of the development program, such as manufacturing and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could make the results of planned clinical trials or other future clinical trials we may initiate less predictable and could cause our product candidates to perform differently, which could delay completion of clinical trials, delay approval of our product candidates and/or jeopardize our ability to commence product sales and generate revenues.

Interim, topline and preliminary data from our clinical trials that we 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 publicly disclose interim, topline or preliminary data from our preclinical studies and clinical trials. These data 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. 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 topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the data we previously disclosed.

Further, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses, or may interpret or weigh the importance of data differently, which could affect the value of the particular program and the approvability or commercialization of the particular product candidate. If the interim, topline or preliminary data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business and cause the price of our common stock to decline.

The regulatory approval processes of the FDA, the EMA and other comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain timely regulatory approval for our product candidates, our business will be substantially harmed.

The regulatory approval process is expensive and, while the time required to gain FDA and foreign regulatory approval is uncertain, it may take years. Regulatory approvals are unpredictable and depend upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of preclinical and clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We may be required to undertake and complete certain additional preclinical studies to generate toxicity and other data required to support the submission of a New Drug Application, or NDA, to the FDA or comparable application to other regulatory authorities. AbbVie obtained all regulatory approvals for its paritaprevir-containing regimens and for MAVYRET/MAVIRET, which contains glecaprevir. We have not obtained regulatory approval by ourselves for any of our wholly-owned product candidates and it is possible that none of our existing product candidates or any of our future product candidates will ever obtain regulatory approval. Furthermore, approval in the United States by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, the EMA or other comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, the EMA or other comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, the EMA or other comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA, the EMA or other comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submissions or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies of any of our product candidates; and
- the approval policies or regulations of the FDA, the EMA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

We cannot be assured that, after spending substantial time and resources, we will obtain regulatory approvals in any desired jurisdiction. Even if we were to obtain approval, regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Significant clinical trial delays could allow our competitors to obtain marketing approval before we do or could in effect shorten the patent protection period during which we may have the exclusive right to commercialize our product candidates. In addition, it may ultimately not be possible to achieve the prices intended for our product candidates. In many foreign countries, including those in the European Union, a product candidate must be approved for reimbursement before it can be approved for sale in that country. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates and our business.

Disruptions at the FDA and other government agencies, including as a result of staffing reductions, leadership changes, funding shortfalls or government shutdowns, could delay the review of our regulatory submissions, hinder the agencies' ability to perform routine functions and otherwise negatively impact our business.

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

If another prolonged government shutdown occurs, or if funding shortages, staffing limitations or further global health concerns emerge, such events could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

The regulatory pathway for approval of a therapeutic treatment for COVID-19 such as EDP-235 is continually evolving and may result in unexpected or unforeseen challenges and longer timelines than seen for earlier COVID-19 vaccines and therapeutics.

Initial COVID-19 vaccines, therapeutic antibodies and other therapeutics that demonstrated positive results in clinical trials have moved rapidly through the FDA regulatory review and emergency use authorization, or EUA, process, as well as the review and authorization process in a number of other jurisdictions, including the EU when there were no adequate, approved, and available alternatives. The speed at which all parties acted to create and test many therapeutics for COVID-19 was unusual. The end of the pandemic, however, may have changed those dynamics. Evolving priorities within the FDA or the regulatory authorities in other jurisdictions, including changes based on new data regarding potential therapeutics of others, and new variants of the virus, may significantly affect the regulatory timeline for further authorizations or approvals for therapeutics such as EDP-235. Accordingly, it is still uncertain what the timelines or regulatory processes will be for the authorization or approval of new treatments for COVID-19, including EDP-235.

Even if we receive regulatory approval for any of our product candidates we develop independently, we will be subject to ongoing FDA obligations and continued regulatory review in other jurisdictions, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we or our collaborators fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals that we receive for our product candidates we develop independently may be subject to limitations on the approved indicated uses for which the product may be marketed or subject to certain conditions of approval, or may contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate.

In addition, if the FDA approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, as well as continued compliance with current good manufacturing practices, or cGMP, and good clinical practices, or GCP, for any clinical trials that we or our collaborators conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with 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 the product, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on any post-approval clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we, or AbbVie in the case of any licensed HCV product, are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or AbbVie are not able to maintain regulatory compliance, our product candidates or AbbVie's licensed HCV products may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

We may delay or terminate the development of a product candidate at any time if we believe the perceived market or commercial opportunity does not justify further investment, which could materially harm our business and adversely affect our stock price.

Even though the results of preclinical studies and clinical trials that we have conducted or may conduct in the future may support further development of one or more of our product candidates, we may delay, suspend or terminate the future development of a product candidate at any time for strategic, business, financial or other reasons, including the determination or belief that the emerging profile of the product candidate is such that it may not receive regulatory approvals in key markets, gain meaningful market acceptance, otherwise provide any competitive advantages in its intended indication or market or generate a significant return to stockholders. Such a delay, suspension or termination could materially harm our business, results of operations or financial condition.

Risks Related to Commercialization of Our Product Candidates

Unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives in the United States could harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. In the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively referred to as the ACA, has significantly changed the way healthcare is financed by both governmental and private insurers. While we cannot predict what impact on federal reimbursement policies this law or any amendment to it will continue to have in general or specifically on MAVYRET/MAVIRET or any product or regimen that we may commercialize, the ACA or any such amendment may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of new products. In addition, several states have not implemented the provisions of the ACA that involve the expansion of Medicaid eligibility for low-income adults. While the United States Supreme Court rejected the most recent challenge to the constitutionality of the ACA, it is possible that other legislative efforts may seek to modify it. We cannot predict what effect any legislation may have on us or on AbbVie's sales of MAVYRET/MAVIRET. In addition, other legislative changes have been proposed since the Affordable Care Act was enacted. There has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Most recently, the Inflation Reduction Act of 2022, or IRA, among other provisions, included several measures intended to lower the cost of prescription drugs and related healthcare reforms. Specifically, the Act authorizes and directs the Department of Health and Human Services, or DHHS, to set drug price caps for certain high-cost Medicare Part B and Part D qualified drugs, with the initial list of drugs selected in August 2023, and the first year of maximum price applicability to begin in calendar year 2026. The IRA further authorizes the DHHS to penalize pharmaceutical manufacturers that increase the price of certain Medicare Part B and Part D drugs faster than the rate of inflation. Finally, the IRA creates significant changes to the Medicare Part D benefit design by capping Part D beneficiaries' annual out-of-pocket spending beginning in calendar year 2025. We cannot be sure whether additional or related legislation or rulemaking will be issued or enacted, or what impact, if any, such changes will have on the royalty revenue we receive from MAVYRET/MAVIRET or revenue from any of our drug candidates, if approved for commercial use, in the future. If any further healthcare reform measures adopted in the future result in additional downward pressure on the price that AbbVie receives for MAVYRET/MAVIRET, this would adversely affect our future revenues, and the price of our common stock could be materially adversely affected.

Our ability to commercialize any product candidate successfully, as well as AbbVie's continued commercialization of MAVYRET/MAVIRET, will also depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. In the case of HCV, limitations of coverage have recently been used to limit access to HCV treatments for only those patients with more advanced fibrosis. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and, in many cases involving HCV drugs, seeking discounts in exchange for greater patient access to a particular HCV drug. In addition, there are private and public payors challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product that we may commercialize and, if reimbursement is available, the level of reimbursement. In addition, reimbursement may impact the demand for, or the price of, MAVYRET/MAVIRET or any product candidate for which we may obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we may seek marketing approval.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable authorities in other jurisdictions. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also be insufficient to cover our and any collaborator's costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. AbbVie's inability to continue to obtain coverage and profitable payment rates from both government-funded and private payors for MAVYRET/MAVIRET, or our inability to obtain the same for any product candidate that we develop, could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

In general, the United States and several other jurisdictions are considering a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in recent years, federal and state governments have proposed or implemented MFN pricing models that tie reimbursement rates for certain drugs to the lowest prices paid by other countries. We expect to experience pricing pressures in connection with the sale of any products that we develop or that are being commercialized under our collaboration with AbbVie. The implementation of cost containment measures or other healthcare reforms may limit our ability to generate revenue, maintain profitability or commercialize our product candidates.

Foreign governments tend to impose strict price controls, which may adversely affect our future profitability.

In most foreign countries, particularly in the European Union and Japan, prescription drug pricing and/or reimbursement is subject to governmental control. In those countries that impose price controls, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies.

Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we (or AbbVie in the case of MAVYRET/MAVIRET) might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay the commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues that are generated from the sale of the product in that country. If reimbursement of MAVYRET/MAVIRET or of any of our product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, or if there is competition from lower priced cross-border sales, our results of operations will be negatively affected.

If, in the future, we are unable to establish our own sales, marketing and distribution capabilities or enter into licensing or collaboration agreements for these purposes, we may not be successful in commercializing any product candidates.

We do not have a sales or marketing infrastructure and have no sales, marketing or distribution experience. We will seek to either build our own commercial infrastructure to commercialize any products if and when they are approved, or enter into licensing or collaboration agreements where our collaborator is responsible for commercialization, as in the case of our collaboration with AbbVie, or where we have the right to assist in the future development and commercialization of such products.

To develop internal sales, distribution and marketing capabilities, we will have to invest significant amounts of financial and management resources, some of which will be committed prior to any confirmation that any of our proprietary product candidates will be approved. For product candidates for which we decide to perform sales, marketing and distribution functions ourselves, we could face a number of additional risks, including:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

Where and when appropriate, we may elect to utilize contract sales forces or distribution partners to assist in the commercialization of our product candidates. If we enter into arrangements with third parties to perform sales, marketing and distribution services for our products, the resulting revenues or the profitability from these revenues to us are likely to be lower than if we had sold, marketed and distributed our products ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of these third parties may fail to devote the necessary resources and attention to sell, market and distribute our products effectively.

If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

Commercial success of our product candidates depends upon significant market acceptance among physicians, patients and healthcare payors of any resulting approved drug.

Zelicapavir, EDP-323, and any other product candidate that we may develop in the future, whether as part of a combination therapy or as a monotherapy, are subject to market acceptance among physicians, healthcare payors, patients and the medical community. The degree of market acceptance of any product candidate for which we obtain approval for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of treatment regimens containing one of our product candidates, as demonstrated in clinical trials, and the degree to which these regimens represent a clinically meaningful improvement in care as compared with other available therapies;
- the clinical indications for which any treatment regimen containing one of our product candidates become approved;
- acceptance among physicians, major operators of clinics, payors and patients of any treatment regimen containing one of our product candidates;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the potential and perceived advantages of treatment regimens containing one of our product candidates over alternative treatments;
- the cost of treatment of regimens containing one of our product candidates in relation to the cost of alternative treatments;
- the availability of adequate reimbursement and pricing by third parties and government authorities and successful negotiation of favorable agreements with payors by us or any collaborator of ours, as well as the impact of any agreements among any of the foregoing and one or more of our competitors limiting access to our product in favor of one or more competitive products;

- the continued longevity of any market for which we develop a drug;
- the levels of funding provided by government-funded healthcare for treatment of any disease for which we develop a drug;
- the relative convenience and ease of administration of any treatment regimen containing one of our product candidates compared to competitive regimens;
- the prevalence and severity of adverse side effects, whether involving the use of treatment regimens containing one of our product candidates or similar, competitive treatment regimens; and
- the effectiveness of our sales and marketing efforts.

If treatment regimens containing one of our product candidates are approved and then fail to achieve market acceptance, we may not be able to generate significant additional revenue. Further, if new, more favorably received therapies are introduced after any such regimen achieves market acceptance, then we may not be able to maintain that market acceptance over time.

Risks Related to Our Dependence on Third Parties

We may not be successful in establishing new product collaborations, which could adversely affect our ability to develop and commercialize one or more of our product candidates. If we are unsuccessful in maintaining or forming alliances on favorable terms, our business may not succeed.

We may seek to enter into additional product collaborations in the future, including alliances with other biotechnology or pharmaceutical companies, to enhance and accelerate the development and commercialization of one or more of our product candidates. For example, our continued development of EDP-235 is dependent on establishing collaborations. We are also evaluating potential partnership opportunities to advance our RSV programs. We face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish other product collaborations or other alternative arrangements for any product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort and/or third parties may not view our product candidates and programs as having the requisite potential to demonstrate safety and efficacy. Even if we are successful in our efforts to establish product collaborations, the terms that we agree upon may not be favorable to us and we may not be able to maintain such product collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing.

If our existing collaboration agreement with AbbVie is terminated, or if we determine that entering into other product collaborations is in our best interest but we either fail to enter into, experience a delay in entering into, or fail to maintain, such collaborations:

- the development of certain of our product candidates may be terminated or delayed;
- our cash expenditures related to the development of certain of our product candidates would increase significantly and we may need to seek additional financing;
- we may be required to hire additional employees or otherwise develop expertise, such as clinical, regulatory, sales and marketing expertise, which we do not currently have;
- we will bear all of the risk related to the development of any such product candidates; and
- the competitiveness of any product candidate that is commercialized could be reduced.

We intend to rely on third-party manufacturers to produce our development-stage product candidate supplies and any commercial supplies of any approved product candidates. Any failure by a third-party manufacturer to produce acceptable supplies for us may delay or impair our ability to initiate or complete our clinical trials or sell any resulting product.

We do not currently own or operate any manufacturing facilities. We plan to continue to work with third-party contract manufacturers to produce sufficient quantities of any product candidates for preclinical testing, clinical trials and commercialization. If we are unable to arrange for such a third-party manufacturing source for any of our product candidates, or fail to do so on commercially reasonable terms, we may not be able to successfully produce, develop and market one or more of our product candidates, or we may be delayed in doing so.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including reliance on the third party for regulatory compliance and quality control and assurance, volume production, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to synthesize and manufacture our product candidates in accordance with our product specifications), shutdowns of manufacturing sites or other supply chain constraints, and the possibility of termination or nonrenewal of the agreement by the third party at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates be manufactured according to cGMP and similar foreign standards. Pharmaceutical manufacturers and their subcontractors are required to register their facilities and/or products manufactured at the time of submission of the marketing application and then annually thereafter with the FDA and certain state and foreign agencies. They are also subject to periodic unannounced inspections by the FDA, state and other foreign authorities. Any subsequent discovery of problems with a product, or a manufacturing or laboratory facility used by us or our collaborators, may result in restrictions on the product or on the manufacturing or laboratory facility, including marketed product recall, suspension of manufacturing, product seizure, or a voluntary withdrawal of the drug from the market. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates.

We plan to rely on third-party manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical studies. There are a small number of suppliers for certain capital equipment and materials that we plan to use to manufacture our drugs. Such suppliers may not sell these materials to our manufacturers at the times we need them or on commercially reasonable terms. Moreover, we currently do not have any agreements for the production of these materials. Although we do not intend to begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the clinical trial, any significant delay in the supply of a product candidate or the material components thereof for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenue from the sale of our product candidates.

Contract manufacturers may not be able to manufacture our product candidates at a cost or in quantities or in a timely manner necessary to develop and commercialize them. If we successfully commercialize any of our product candidates, to meet our projected needs we may need to find third parties that will increase their scale of production, or we may have to establish or access large-scale commercial manufacturing capabilities. We may require additional funds, personnel and other resources to build, lease or operate any manufacturing facility.

A portion of our research and a portion of our manufacturing of certain key intermediates used in the manufacture of the active pharmaceutical ingredients for our product candidates take place in China through third-party researchers and manufacturers. A significant disruption in the operation of those researchers or manufacturers, or a trade war, geopolitical unrest, legislation (such as the BIOSECURE Act), sanctions or other regulatory requirements, or an epidemic in China, such as the COVID-19 pandemic, could materially adversely affect our business, financial condition and results of operations.

Although manufacturing for MAVYRET/MAVIRET is being conducted by AbbVie, we have relied on third parties located in China to manufacture and supply certain key intermediates used in the manufacture of our active pharmaceutical ingredients, or API, for our current product candidates, and we expect to continue to use such third-party manufacturers for such intermediates for any product candidates we develop independently. Any disruption in production or inability of our manufacturers in China to produce adequate quantities to meet our needs, whether as a result of a natural disaster, pandemic or other cause, could impair our ability to operate our business on a day-to-day basis and to continue our research and development of our product candidates. We also use contract researchers in China to conduct a portion of our research for our early-stage programs. Any disruption in the team conducting that research could cause delays in one or more of our research programs and could require us to curtail one or more programs, at least until we could contract for that research to be done elsewhere. For example, either of these risks could be triggered by an epidemic such as the outbreak of COVID-19 in China or the series of so-called “lock-downs” in China when strict quarantine requirements were imposed on large population areas in response to new incidents of COVID infection. Our contract manufacturers in China managed to avoid any material delays in their ability to deliver API and other services through extraordinary efforts, including temporarily housing staff in the manufacturing facility. Furthermore, since these researchers and manufacturers are located in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the United States or Chinese governments, geopolitical unrest or unstable economic conditions in China. For example, a trade war could lead to tariffs on the chemical intermediates we use that are manufactured in China. In addition, our contract manufacturers and researchers in China may be subject to U.S. legislation, sanctions, tariffs, trade restrictions and other foreign regulatory

requirements, which could increase the cost or reduce the supply of material available to us or delay or prevent the procurement or supply of such material. Any of these matters could materially and adversely affect our business and results of operations despite our ongoing efforts to mitigate these risks. For example, the BIOSECURE Act enacted in December 2025 targets U.S. government contracts, grants, and loans for entities that use equipment and services from certain named Chinese biotech companies, and authorizes the U.S. government to name additional Chinese biotechnology companies of concern, which has the potential to severely restrict the ability of companies to work with certain Chinese biotechnology companies of concern without losing the ability to contract with, or otherwise receive funding from, the U.S. government.

Any recall of the manufacturing lots or similar action regarding our API used in clinical trials could delay the trials or detract from the integrity of the trial data and its potential use in future regulatory filings. In addition, manufacturing interruptions or failure to comply with regulatory requirements by any of these manufacturers could significantly delay clinical development of potential products and reduce third-party or clinical researcher interest and support of proposed trials. These interruptions or failures could also impede commercialization of our product candidates and impair our competitive position. Further, we may be exposed to fluctuations in the value of the local currency in China. Future appreciation of the local currency could increase our costs. In addition, our labor costs could continue to rise as wage rates increase due to increased demand for skilled laborers and the availability of skilled labor declines in China.

We rely on third parties to monitor, support, conduct and/or oversee clinical trials of our product candidates that we develop independently and, in some cases, to maintain regulatory files for those product candidates. If we are not able to maintain or secure agreements with such third parties on acceptable terms, if these third parties do not perform their services as required, if geopolitical unrest disrupts activity at a number of our clinical trial sites, or if these third parties fail to timely transfer any regulatory information held by them to us, we may not be able to conduct our clinical trials in a timely manner, obtain regulatory approval for, or commercialize, our product candidates.

We rely on CROs, hospitals, clinics, academic institutions and other third-party collaborators who are outside our control to monitor, support, conduct and/or oversee preclinical and clinical studies of our product candidates. We also rely on third parties to perform clinical trials of our product candidates if and when they reach that stage. As a result, we have less control over the timing and cost of these studies and the ability to recruit trial subjects than if we conducted these trials wholly by ourselves. If we are unable to maintain or enter into agreements with these third parties on acceptable terms or engagement is terminated, we may be unable to enroll patients on a timely basis or otherwise conduct our trials in the manner we anticipate. Additionally, although no situations to date have caused a significant disruption in our clinical trial operations, geopolitical unrest or a pandemic could disrupt a number of our clinical trial sites and cause one or more of our clinical trials to be delayed. For example, our LOTUS trial is being conducted in Thailand in collaboration with the Penta Foundation and the AMS-PHPT Research Unit at Chiang Mai University, and our RESOLVE trial is being conducted at sites globally. Political instability, armed conflict, trade disputes or changes in local regulatory requirements in any of the countries in which our trial sites are located could disrupt or delay these trials. In addition, there is no guarantee that these third parties will devote adequate time and resources to our studies or perform as required by a contract or in accordance with regulatory requirements, including maintenance of clinical trial information regarding our product candidates. If these third parties fail to meet expected deadlines, fail to timely transfer to us any regulatory information, fail to adhere to protocols or fail to act in accordance with regulatory requirements or our agreements with them, or if they otherwise perform in a substandard manner or in a way that compromises the quality or accuracy of their activities or the data they obtain, then clinical trials of our product candidates may be extended, delayed or terminated, or our data may be rejected by the FDA or other regulatory agencies.

To the extent we elect to enter into additional licensing or collaboration agreements to partner our product candidates, our dependence on such relationships may adversely affect our business.

Our commercialization strategy for some of our product candidates may depend on our ability to enter into collaboration agreements with other companies to obtain access to other compounds for use in combination with any of our product candidates or for assistance and funding for the development and potential commercialization of any of these product candidates, similar to what we have done with AbbVie. Supporting diligence activities conducted by potential collaborators and negotiating the financial and other terms of a collaboration agreement are long and complex processes with uncertain results. Even if we are successful in entering into one or more additional collaboration agreements, collaborations can involve greater uncertainty for us, as we may have limited or no control over certain aspects of our collaborative programs. We may determine that continuing a collaboration under the terms provided is not in our best interest, and we may terminate the collaboration. Our collaborators could delay or terminate their agreements with us, and our product candidates subject to collaborative arrangements may never be successfully commercialized.

Further, our collaborators may develop alternative products or pursue alternative technologies either on their own or in collaboration with others, including our competitors, and the priorities or focus of our collaborators may shift such that our programs receive less attention or resources than we would like, or they may be terminated altogether. Any such actions by our collaborators may adversely affect our business prospects and ability to earn revenue. In addition, we could have disputes with our collaborators, such as the interpretation of terms in our agreements. Any such disagreements could lead to delays in the development or commercialization of any potential products or could result in time-consuming and expensive litigation or arbitration, which may not be resolved in our favor.

Even with respect to programs that we intend to commercialize ourselves, we may enter into agreements with collaborators to share in the burden of conducting clinical trials, manufacturing and marketing our product candidates or products. In addition, our ability to apply our proprietary technologies to develop proprietary compounds will depend on our ability to establish and maintain licensing arrangements or other collaborative arrangements with the holders of proprietary rights to such compounds. We may not be able to establish such arrangements on favorable terms or at all, and our collaborative arrangements may not be successful.

Risks Related to Our Intellectual Property Rights

We are competing to develop intellectual property in areas of small-molecule drug development that are highly competitive. We could be unsuccessful in obtaining or maintaining adequate patent protection for one or more of our product candidates.

Our commercial success will depend, in large part, on our ability to obtain and maintain patent and other intellectual property protection with respect to our product candidates. We cannot be certain that patents will be issued or granted with respect to our patent applications that are currently pending, or that issued or granted patents will not later be found to be invalid and/or unenforceable, be interpreted in a manner that does not adequately protect our products, or otherwise provide us with any competitive advantage. The patent position of biotechnology and pharmaceutical companies is generally uncertain because it involves complex legal and factual considerations. The standards applied by the United States Patent and Trademark Office and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology and pharmaceutical patents. Consequently, patents may not issue from our pending patent applications. As such, we do not know the degree of future protection that we will have on our proprietary products and technology, if any, and a failure to obtain adequate intellectual property protection with respect to our product candidates and proprietary technology could have a material adverse impact on our business.

In addition, certain of our activities in the past have been funded, and others may in the future be funded, by the United States federal government. For example, the preclinical and early clinical development of the lead antibiotic product candidate in our former antibiotic program, which we are no longer developing, was funded under a contract with NIAID, an entity of the United States federal government. When new technologies are developed with United States federal government funding, the government obtains certain rights in any resulting patents, including a nonexclusive license authorizing the government to use the invention for non-commercial purposes. These rights may permit the government to disclose our confidential information to third parties and to exercise “march-in” rights to use or allow third parties to use our patented technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the United States government-funded technology, or because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to United States industry. In addition, United States government-funded inventions must be reported to the government and United States government funding must be disclosed in any resulting patent applications. Further, our rights in such inventions are subject to certain requirements to manufacture products in the United States.

Claims that our product candidates or the sale or use of our products infringe the patent or other intellectual property rights of third parties could result in costly litigation or could require substantial time and money to resolve, even if litigation is avoided.

Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidates and use our proprietary technology without infringing the intellectual property rights of others. We cannot guarantee that our product candidates or any uses of our product candidates do not and will not in the future infringe third-party patents or other intellectual property rights. Third parties might allege that we or our collaborators are infringing their patent rights or that we have misappropriated their trade secrets, or that we are otherwise violating their intellectual property rights, whether with respect to the manner in which we have conducted our research or to the composition, use or manufacture of the compounds we have developed or are developing with our collaborators. Such third parties might resort to litigation against us or other parties we have agreed to indemnify, which litigation could be based on either existing intellectual property or intellectual property that arises in the future.

It is also possible that we failed to identify, or may in the future fail to identify, relevant patents or patent applications held by third parties that cover our product candidates. Other patent applications in the United States and several other jurisdictions are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Furthermore, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we or our collaborators were the first to invent, or the first to file patent applications on, our product candidates or for their uses, or that our product candidates will not infringe patents that are currently issued or that are issued in the future. In the event that a third party has also filed a patent application covering one of our product candidates or a similar invention, we may have to participate in an adversarial proceeding, known as an interference, declared by the U.S. Patent and Trademark Office or its foreign counterpart to determine priority of invention. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our products or their use.

In order to avoid or settle potential claims with respect to any patent or other intellectual property rights of third parties, we may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both, which could be substantial. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced, by court order or otherwise, to cease some or all aspects of our business operations, if, as a result of actual or threatened patent or other intellectual property claims, we are unable to enter into licenses on acceptable terms. Further, we could be found liable for significant monetary damages as a result of claims of intellectual property infringement. For example, we have received, and may in the future receive, offers to license and demands to license from third parties claiming that we are infringing their intellectual property or owe license fees and, even if such claims are without merit, there can be no assurance that we will successfully avoid or settle such claims.

In addition, if AbbVie licenses or otherwise acquires rights to intellectual property controlled by a third party in various circumstances, for example, where a product could not be legally developed or commercialized in a country without the third-party intellectual property right, it is entitled under our collaboration agreement to decrease payments payable to us on a product-by-product basis and, in certain cases, on a country-by-country basis. Any of the foregoing events could harm our business significantly.

Defending against claims of patent infringement, misappropriation of trade secrets or other violations of intellectual property rights could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. Claims that our product candidates or the sale or use of our future products infringe, misappropriate or otherwise violate third-party intellectual property rights could therefore have a material adverse impact on our business.

Issued patents covering one or more of our product candidates could be found invalid or unenforceable if challenged in court, including as a result of counterclaims filed against us in connection with our efforts to enforce our intellectual property rights against third parties.

Despite measures we take to obtain patent and other intellectual property protection with respect to our product candidates and proprietary technology, any of our intellectual property rights could be challenged or invalidated. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable, as Pfizer asserted in our patent infringement suit in the United States and Europe regarding Paxlovid, Pfizer's antiviral treatment for COVID-19. In the United States, the United States District Court for the District of Massachusetts granted summary judgment that the asserted claims of our U.S. Patent No. 11,358,953 were invalid, the U.S. Court of Appeals for the Federal Circuit affirmed that decision in June 2026, and in September 2026 the Federal Circuit denied our combined petition for panel rehearing and rehearing en banc. In Europe, in October 2026, the Unified Patent Court concluded that the European counterpart patent, European Patent No. EP 4 051 265, is invalid and that our infringement action was unfounded in light of its decision on validity, and Pfizer has also filed an opposition against that patent with the European Patent Office.

In patent litigation in the United States, Europe and in other jurisdictions, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the United States Patent and Trademark Office, or the applicable foreign counterpart, or made a misleading statement, during prosecution. Although we believe that we have conducted our patent prosecution in accordance with the duty of candor and in good faith, the outcome following legal assertions of invalidity and unenforceability during patent litigation is

unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, other than in litigation like the Pfizer case, which did not cover EDP-235, we would lose at least part, and perhaps all, of the patent protection on a product candidate. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others. Any loss of patent protection could have a material adverse impact on one or more of our product candidates and our business.

Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend and could require us to pay substantial damages, cease the sale of certain products or enter into a license agreement and pay royalties (which may not be possible on commercially reasonable terms or at all). Any efforts to enforce our intellectual property rights are also likely to be costly and may divert the efforts of our scientific and management personnel.

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

During the course of any intellectual property litigation, there could be public announcements of the 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 products, programs or intellectual property could be diminished. Accordingly, the market price 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.

Intellectual property rights do not necessarily protect us from 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. The following examples are illustrative:

- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or may in the future exclusively license, which could result in the patent applications not issuing or being invalidated after issuing;
- we might not have been the first to file patent applications covering certain of our inventions, which could result in the patent applications not issuing or being invalidated after issuing;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- we may obtain patents for certain compounds many years before we obtain marketing approval for products containing such compounds, and because patents have a limited life, which may begin to run prior to the commercial sale of the related product, the commercial value of our patents may be limited;
- 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 fail to develop additional proprietary technologies that are patentable;
- the laws of certain foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States (e.g., in March 2022, the Russian government adopted a decree allowing Russian local entities and individuals to use inventions, utility models and industrial designs held by owners from “unfriendly states” without the consent of the owner and without liability for compensation), or we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate; and
- the patents of others may have an adverse effect on our business, for example, by preventing us from marketing one or more of our product candidates for one or more indications.

Any of the aforementioned threats to our competitive advantage could have a material adverse effect on our business.

Unfavorable outcomes in intellectual property litigation could limit our research and development activities and/or our ability to commercialize certain products.

If third parties successfully assert their intellectual property rights against us, we might be barred from using certain aspects of our technology or barred from developing and commercializing certain products. Prohibitions against using certain technologies, or prohibitions against commercializing certain products, could be imposed by a court or by a settlement agreement between us and a plaintiff. In addition, if we are unsuccessful in defending against allegations that we have infringed, misappropriated or otherwise violated patent or other intellectual property rights of others, we may be forced to pay substantial damage awards to the plaintiff. There is inevitable uncertainty in any litigation, including intellectual property litigation. There can be no assurance that we would prevail in any intellectual property litigation, even if the case against us is weak or flawed. If litigation leads to an outcome unfavorable to us, we may be required to obtain a license from the intellectual property owner to continue our research and development programs or to market any resulting product. It is possible that the necessary license will not be available to us on commercially acceptable terms, or at all. Alternatively, we may be required to modify or redesign our products to avoid infringing or otherwise violating third-party intellectual property rights. This may not be technically or commercially feasible, may render our products less competitive, or may delay or prevent the entry of our products to the market. Any of the foregoing could limit our research and development activities, our ability to commercialize one or more product candidates, or both.

Most of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex intellectual property litigation longer than we could. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to conduct our clinical trials, continue our internal research programs, in-license needed technology, or enter into strategic partnerships that would help us bring our product candidates to market.

In addition, any future intellectual property litigation, interference or other administrative proceedings will result in additional expense and distraction of our personnel. An adverse outcome in such litigation or proceedings may expose us or any future strategic partners to loss of our proprietary position, expose us to significant liabilities, or require us to seek licenses that may not be available on commercially acceptable terms, if at all, each of which could have a material adverse effect on our business.

Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.

In addition to patents, we rely on trade secrets, technical know-how and proprietary information concerning our business strategy and product candidates to protect our competitive position in the field of each of our virology and immunology product candidates. In the course of our research and development activities and our business activities, we often rely on confidentiality agreements to protect our proprietary information. Such confidentiality agreements are used, for example, when we talk to vendors of laboratory or clinical development services or potential strategic partners. In addition, each of our employees is required to sign a confidentiality agreement and invention assignment agreement upon joining our company. We take steps to protect our proprietary information, and our confidentiality agreements and invention assignment agreements are carefully drafted to protect our proprietary interests. Nevertheless, there can be no guarantee that an employee or an outside party will not make an unauthorized disclosure of our proprietary confidential information. This might happen intentionally or inadvertently. It is possible that a competitor will make use of such information, and that our competitive position will be compromised, in spite of any legal action we might take against persons making such unauthorized disclosures. In addition, to the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, business partners or outside scientific collaborators might intentionally or inadvertently disclose our trade secret information to competitors or our trade secrets may otherwise be misappropriated. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States sometimes are less willing than United States courts to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

Our collaborators may have rights to publish data and other information to which we have rights. In addition, we sometimes engage individuals or entities to conduct research relevant to our business. The ability of these individuals or entities to publish or otherwise publicly disclose data and other information generated during the course of their research is subject to certain contractual limitations. These contractual provisions may be insufficient or inadequate to protect our confidential information. If we do not apply for patent protection prior to such publication, or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized, which could adversely affect our business.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with many other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining, maintaining and enforcing patents in the biopharmaceutical industry involves both technological complexity and legal complexity. Therefore, the process of obtaining, maintaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. In addition, recent legislative and judicial developments in the United States and elsewhere have in some cases narrowed the protection afforded to patent owners, made patents more difficult to obtain, or increased the uncertainty regarding the ability to obtain, maintain and enforce patents. For example, Congress recently passed patent reform legislation, and may pass patent reform legislation in the future. The United States Supreme Court has ruled on several patent cases in recent years, and in certain circumstances has narrowed the scope of patent protection available or otherwise weakened the rights of patent owners. 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 and actions by the United States Congress, the federal courts, the United States Patent and Trademark Office, and their respective foreign counterparts, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to maintain and enforce our existing patents and patents that we might obtain in the future.

Risks Related to Our Industry

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

We face an inherent risk of product liability as a result of the clinical testing of our product candidates, and we will face an even greater risk if we commercialize any product candidates. For example, we may be sued if any of our product candidates, including any that are developed in combination therapies, is alleged to cause injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. There is also risk that third parties we have agreed to indemnify could incur liability.

Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates or any resulting products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize our product candidates; and
- a decline in our stock price.

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 products we develop. We currently carry product liability insurance covering our clinical studies. Although we 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 also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Our internal computer systems, or those of our collaborator, CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of development programs for our product candidates.

Despite the implementation of security measures, our internal computer systems and those of our collaborators, CROs, and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, pandemics, terrorism, war and telecommunication and electrical failures. Information security risks have significantly increased in recent years in part due to the proliferation of new technologies, the increased sophistication and activities of organized crime, hackers, terrorists and other external parties, including foreign state actors as well as remote working for many businesses. As cyber threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any information security breaches.

While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our independent drug development programs. For example, the loss of clinical trial data from ongoing or future clinical trials for any of our product candidates could result in delays in regulatory approval efforts and significantly increase costs to recover or reproduce the data. Our information security systems are also subject to laws and regulations requiring that we take measures to protect the privacy and security of certain information we gather and use in our business. For example, HIPAA and its implementing regulations impose, among other requirements, certain regulatory and contractual requirements regarding the privacy and security of personal health information. In the European Union, the General Data Protection Regulation, or GDPR, is even more restrictive with respect to all personal information, including information masked by a coding system. In addition to HIPAA and GDPR, numerous other federal and state laws, including, without limitation, state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, disclosure and storage of personal information. To the extent that any disruption or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of confidential or proprietary information or personal health information, we could incur substantial liability, our reputation would be damaged, and the further development of our product candidates could be delayed.

Our relationships with customers and third-party payors in the United States and elsewhere will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal, state and foreign healthcare laws and regulations include the following:

- the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or *qui tam* actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or 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, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal false statements statute prohibits 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;
- the federal transparency requirements under the Patient Protection and Affordable Care Act of 2010 require manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests;
- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures; and
- analogous anti-kickback, fraud and abuse and healthcare laws and regulations in other states, as well as in foreign countries.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other providers or entities with whom we expect to do business, including our collaborators, are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which could also materially affect our business.

Risks Related to Our Common Stock

Our stock price has been, and is likely to continue to be, volatile, and thus our stockholders could incur substantial losses.

Our stock price has been volatile and could be subject to wide fluctuations in response to various factors, many of which are beyond our control. From October 1, 2021 through September 30, 2026, the daily closing price of our common stock on the Nasdaq Global Select Market has ranged from $4.26 to $97.37. The stock market in general and the market for biopharmaceutical companies, and for those developing potential therapies for viral infections in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your holdings of our common stock at or above your purchase price, if at all. The market price for our common stock may be influenced by many factors, including:

- results from or delays of clinical trials of our product candidates, as well as results of regulatory reviews relating to the approval of our product candidates;
- the results of our efforts to discover or develop additional product candidates;
- new products, product candidates or new uses for existing products or technologies introduced or announced by our competitors and the timing of these introductions or announcements;
- market expectations about and response to the levels of sales or scripts achieved by, or the announced prices or discounts for, AbbVie's MAVYRET/MAVIRET regimen or competitive HCV drugs;
- failure of AbbVie's MAVYRET/MAVIRET regimen to maintain its sales levels;
- our dependence on third parties, including our collaborators, CROs, manufacturers, clinical trial sponsors and clinical investigators;
- regulatory, political or legal developments in the United States or other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key scientific or management personnel;
- our ability to commercialize our product candidates we develop independently, if approved;

- the level of expenses related to any of our product candidates or clinical development programs;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- period-to-period variations in our financial results or those of companies that are perceived to be similar to us;
- market conditions in the pharmaceutical and biotechnology sectors;
- sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock;
- changes in the structure of healthcare payment systems or other actions that affect the effective reimbursement rates for treatment regimens containing our products or for competitive regimens;
- general economic, industry and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies; and
- the other factors described in this "Risk Factors" section.

A sale of a substantial number of shares of our common stock in the public market could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of September 30, 2026 we had 29.1 million shares of common stock outstanding. In addition, as of September 30, 2026, we had 6.3 million and 0.5 million shares of common stock that are subject to outstanding options and restricted stock unit awards (including performance share units and relative total stockholder return units), respectively, under our outstanding equity plans eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, and Rule 144 under the Securities Act. If these additional shares of common stock are sold, or it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research about our business, our stock price and trading volume would likely 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 or our business. For example, when those analysts are unable to predict accurately the demand and net sales of AbbVie's HCV regimens, our reported revenues have often been lower than the so-called "market consensus" of our projected revenues, which has at times negatively affected our stock price. When one or more of the analysts who cover us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price has declined. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline. In addition, if too few securities or industry analysts cover our company, the trading price for our stock would likely be negatively impacted.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which they might otherwise receive a premium for their shares.

These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified or staggered board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;

- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- provide that the state courts or, in certain circumstances, the federal courts, in Delaware shall be the sole and exclusive forum for certain actions involving us, our directors, officers, employees and stockholders;
- provide our board of directors with the authority to designate the terms of and issue a new series of preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 66 2/3% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibit a person who owns 15% or more of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Any provision in our corporate charter or our bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

Our employment agreements with our executive officers may require us to pay severance benefits to any of those persons who are terminated in connection with a change of control of us, which could harm our financial condition or results.

Our executive officers are parties to employment agreements that provide for aggregate cash payments of up to approximately $6.6 million for severance and other non-equity-based benefits in the event of a termination of employment in connection with a change of control of our company. The payment of these severance benefits could harm our company's financial condition and results. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with us.

Because we do not anticipate paying cash dividends on our common stock for the foreseeable future, investors in our common stock may never receive a return on their investment.

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any cash dividends to holders of our common stock for the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our existing operations.

Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not invest in our common stock.

Our ability to use future net operating loss carryforwards, research and development tax credit carryforwards, and certain other tax attributes may be limited.

Our ability to utilize future net operating loss carryforwards ("NOLs") generated as well as research and development tax credit carryforwards may be limited under Section 382 of the Internal Revenue Code ("IRC") or applicable state tax law. The Section 382 limitations apply if an "ownership change" occurs. Generally, an ownership change results from transactions that increase the ownership of 5% stockholders in the stock of a corporation by more than 50% in the aggregate over a three-year period. We have evaluated whether one or more ownership changes under Section 382 have occurred since our inception and have determined that there have been such changes through September 30, 2022. Although we believe that these ownership changes have not resulted in material limitations on our ability to utilize existing NOL carryforwards and research and development tax credit carryforwards, our ability to utilize future NOLs and research and development tax credit carryforwards may be limited due to future ownership changes or for other reasons. As a result, we may not be able to take full advantage of NOL carryforwards and research and development tax credit carryforwards for U.S. federal and state income tax purposes.

We are a smaller reporting company, and any decision on our part to comply only with reduced reporting and disclosure requirements applicable to such companies could make our common stock less attractive to investors.

Since March 31, 2024, we have qualified as a "smaller reporting company," as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act. For as long as we continue to be a smaller reporting company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies that are not smaller reporting companies, including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and only being required to provide two years of audited financial statements in annual reports.

We will remain a smaller reporting company so long as, as of March 31 of the preceding year, (i) the market value of our common stock held by non-affiliates, or our public float, is less than $250.0 million; or (ii) we have annual revenues less than $100.0 million and either we have no public float or our public float is less than $700.0 million.

If we take advantage of some or all of the reduced disclosure requirements available to smaller reporting companies, investors may find our common stock less attractive, which may result in a less active trading market for our common stock and greater stock price volatility. For so long as we are a smaller reporting company and are not classified as an "accelerated filer" or "large accelerated filer" pursuant to SEC rules, we will be exempt from the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act.

General Risk Factors

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials or our or third parties' disposal of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

We may incur substantial costs to comply with current or future environmental, health and safety laws and regulations. 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.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials. This insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of hazardous or radioactive materials.

Our insurance policies are expensive and only protect us from specified business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, employment practices liability, property, auto, workers' compensation, cybersecurity, products liability and directors' and officers' insurance. We do not know, however, if we have adequate levels of coverage for any liability we may incur, or whether we will always be able to continue to maintain such insurance. Any significant uninsured liability may require us to make substantial payments, which would adversely affect our financial position and results of operations. Furthermore, any increase in the volatility of our stock price, or changes in the insurance market generally, may result in us being required to pay substantially higher premiums for our directors' and officers' liability insurance than those to which we were previously subject and may even cause one or more of our underwriters to be unwilling to insure us.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement newly required or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act of 2002, or

any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

Our information technology systems, or those used by our CROs or other contractors or consultants, may fail or suffer other breakdowns, cyber-attacks, or information security breaches, which could adversely affect our business.

We are increasingly dependent upon information technology systems, infrastructure, and data to operate our business. We also rely on third-party vendors and their information technology systems. Despite the implementation of security measures, our recovery systems, security protocols, network protection mechanisms, and other security measures and those of our current or future CROs or other contractors and consultants are vulnerable to system failure, interruption, compromise, or damage from data corruption, breakdown, computer hacking, malicious code (such as computer viruses or worms), fraudulent activity, employee misconduct, theft, or error, denial-of-service attacks, telecommunication, and electrical failures, natural disasters, public health epidemics, such as the COVID-19 pandemic, cyber-attacks by sophisticated nation-state and nation-state supported actors, or other system attacks, disruption, or accidents. We receive, generate and store significant and increasing volumes of personal health data and other confidential and proprietary information. There can be no assurance that we, or our collaborators, CROs, third-party vendors, contractors and consultants, will be successful in efforts to detect, prevent, protect against or fully recover systems or data from all breakdowns, service interruptions, attacks or breaches.

The costs to respond to a security breach and/or to mitigate any security vulnerabilities that may be identified could be significant, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service, negative publicity, and other harm to our business and our competitive position. Remediation of any potential security breach may involve significant time, resources, and expenses. Despite our best efforts, our network security and data recovery measures and those of our vendors may still not be adequate to protect against such security breaches and disruptions, which could cause harm to our business, financial condition and results of operations.

Any cybersecurity incident could adversely affect our business, by leading to, for example, the loss of confidential information or other intellectual property, demands for ransom or other forms of blackmail or the unauthorized disclosure of personal, confidential or proprietary information of our employees, clinical trial participants, customers and others. We could be subject to regulatory actions taken by governmental authorities, litigation under laws that protect the privacy and security of personal information, or other forms of legal proceedings, which could result in significant investigations, liabilities or penalties.

We may not have adequate insurance coverage for security incidents or breaches. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

Use of social media could give rise to liability or reputational harm.

We and our employees use social media to communicate externally. There is risk that the use of social media by us or our employees to communicate about our product candidates or business may give rise to liability, lead to the loss of trade secrets or other intellectual property or result in public exposure of personal information of our employees, clinical trial patients, customers, and others. Furthermore, negative posts or comments about us or our product candidates in social media could seriously damage our reputation, brand image, and goodwill. Any of these events could have a material adverse effect on our business, prospects, operating results, and financial condition and could adversely affect the price of our common stock.

We maintain our cash at financial institutions, often in balances that exceed federally insured limits.

The majority of our cash is held in accounts at U.S. banking institutions. Cash held in depository accounts may exceed the Federal Deposit Insurance Corporation ("FDIC") standard deposit insurance limit of $250,000. If such banking institutions were to fail, such as Silicon Valley Bank when the FDIC took control in March 2023, we could lose all or a portion of those amounts held in excess of such insured amounts. In the future, access to our cash in amounts adequate to finance our operations could be significantly impaired if the financial institutions with which we have arrangements encounter liquidity constraints or failures. Any future limitation on timely access to our funds or any material loss that we may experience in the future could have a material adverse effect on our financial condition and could materially impact our ability to pay our operating expenses or make other payments.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Cybersecurity Risk Management and Strategy

We have continued to invest in an evolving cybersecurity framework of tools, processes, training, and people designed to assess, identify, and remediate material risks from cybersecurity threats that could affect business operations, financials, or public reputation. Our multi-layered approach to cybersecurity involves regular network monitoring, vulnerability scanning, advanced threat detection, and incident response capabilities against recognized cyber threats to our business and stakeholders, including ransomware, data breaches and insider threats. We regularly update our security measures, as necessary, in an effort to address new threats and technologies, using the National Institute of Standards and Technology ("NIST") Framework as a guide, when appropriate and relevant to our business.

As further protections, we utilize encryption, access control mechanisms and secure cloud infrastructures, and we invest in extensive user training. All users regularly undergo updated cybersecurity awareness training in an ongoing effort to reduce the risk of human error contributing to any potential security incidents. All users are also subject to simulated phishing emails with real time feedback for a more continuous layer of training.

We have retained an industry expert to be our virtual Information Security Officer ("vISO") to assist and guide our IT organization in maintaining and evolving our cybersecurity environment. Monthly meetings review all facets of our current status against appropriate NIST standards, review any incidents, and review the results of ongoing simulated phishing exercises to identify certain users who may need extended training. In addition, as part of our annual security review, we hire a third-party network penetration testing firm to provide simulated probing and subsequent reporting. We use the results of these annual tests to improve the strength and flexibility of our network's security. We also maintain processes to oversee and identify cybersecurity risks associated with our use of third-party service providers, including security assessments and questionnaires as part of vendor onboarding, contractual security and incident-notification requirements, and periodic review of vendor security practices.

Our Incident Response Plan ("IRP") has evolved with our cyber environment and consists of a set of tools capable of monitoring, reporting and alerting, as well as regular reviews. The IRP also sets forth guidelines on how to triage, assess the severity and materiality of findings, and remediate and escalate findings to upper management in a timely manner, as necessary. In addition, as part of our overall risk mitigation strategy, we also maintain cyber insurance coverage. However, such insurance may not be sufficient to cover us against all possible claims related to security breaches, cyber-attacks and other related breaches. As of the date of this report, we have not identified any risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations or financial condition. However, cybersecurity risk is dynamic, and future incidents could materially affect our operations, financial condition, or reputation. See "Risk Factors—Our information technology systems, or those used by our CROs or other contractors or consultants, may fail or suffer other breakdowns, cyber-attacks, or information security breaches, which could adversely affect our business."

Cybersecurity Governance and Oversight

The Board of Directors has assigned the Audit Committee to be responsible for reviewing our cybersecurity risk management and strategy program and is presented by management, at least annually, with a review of our environment and reported incidents. Part of our IRP also calls for the elevation of any material incidents to upper management in a timely manner whenever they occur.

Our cybersecurity program is managed by our head of information technology, who has over 25 years of experience in information technology and information security. We have also formed a steering committee, composed of IT staff and relevant business leaders responsible for our material information, including commercially sensitive data. The goals of this steering committee include overseeing our annual material risk assessment and documenting and reporting to senior management. The steering committee also reviews changes to procedural and other controls. We have also formed a risk register subcommittee to review and formally discuss any critical risks identified during our vISO annual assessment of our cyber environment.

ITEM 2. PROPERTIES

Our corporate headquarters is located in Watertown, Massachusetts, where we lease approximately 73,000 square feet of office and laboratory space at 4 Kingsbury Avenue. We also lease approximately 38,000 square feet of additional office space located at 400 Talcott Avenue in Watertown, Massachusetts. Both property leases expire in September 2034.

ITEM 3. LEGAL PROCEEDINGS

Information with respect to legal proceedings is included in Note 13 of the Notes to Consolidated Financial Statements contained in Part II, Item 8 of this Annual Report on Form 10-K, which is incorporated herein by reference.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR THE COMPANY'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock has been listed on The Nasdaq Global Select Market under the symbol “ENTA” since March 21, 2013.

Holders of Record

We had 14 stockholders of record as of October 30, 2026. This number does not include stockholders for whom shares are held in “nominee” or “street” name.

Dividends

We have never declared or paid cash dividends on our common stock, and we do not expect to declare or pay any cash dividends for the foreseeable future.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Neither we nor any affiliated purchaser or anyone acting on behalf of us or an affiliated purchaser made any purchases of shares of our common stock during the fourth quarter of fiscal 2026.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of financial condition and results of operations together with our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion and other parts of this Annual Report on Form 10-K contain forward-looking statements that involve risks and uncertainties, such as statements regarding our plans, objectives, expectations, intentions, and projections. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in Item 1A, "Risk Factors," of this Annual Report on Form 10-K.

Overview

We are a biotechnology company that uses our robust, chemistry-driven approach and drug discovery capabilities to discover and develop small molecule drugs with an emphasis on viral infections and immunological diseases.

Virology

We discovered glecaprevir, the second of two antiviral protease inhibitors developed through our collaboration with AbbVie for the treatment of acute or chronic infection with hepatitis C virus, or HCV. Glecaprevir is co-formulated as part of AbbVie's leading brand of direct-acting antiviral, or DAA, combination treatment for HCV, which has been marketed under the tradenames MAVYRET® (U.S.) and MAVIRET® (ex-U.S.) (glecaprevir/pibrentasvir) since 2017 for the treatment of chronic HCV. MAVYRET®/MAVIRET® were also approved as the first and only treatments for acute HCV infection in the United States and the European Union in June 2025 and June 2026, respectively, as well as several other countries including Canada and Australia.

Our active development programs in virology are focused on respiratory syncytial virus, or RSV, the most common cause of bronchiolitis and pneumonia and a leading cause of U.S. hospitalization in young children and a significant cause of respiratory illness in older adults. Populations at high risk for severe RSV infection include infants and young children, adults older than 65 years of age, and those with comorbidities such as chronic heart or lung disease, diabetes, kidney disease, immunodeficiency and others. Estimates from the CDC for the 2024-2025 RSV season indicate that RSV led to up to 6.8 million outpatient visits, approximately 370,000 hospitalizations, and up to 24,000 deaths, in the United States. We estimate a global market opportunity of between $2.5 billion and $3.5 billion for an oral RSV antiviral for children and all high-risk adults, with a potential total addressable population of up to 4 million patients in the United States. Additionally, we believe that the recent FDA approval of at-home combination self-tests capable of detecting RSV, influenza A and B, and COVID-19 will further drive RSV diagnosis and potentially enable a test-to-treat model for zelicapavir.

We also have a clinical-stage program in virology for SARS-CoV-2, the virus that causes COVID-19.

Immunology

In immunology, we are designing and developing highly potent and selective oral small molecule inhibitors for the treatment of type 2 inflammatory diseases by targeting key mechanisms of the immune response. An overactive response is a primary driver of a number of inflammatory diseases for which there is an enduring unmet need including atopic dermatitis, or AD, urticaria, asthma, prurigo nodularis, or PN, chronic rhinosinusitis with nasal polyps, or CRSwNP, as well as some forms of chronic obstructive pulmonary disease, or COPD, eosinophilic esophagitis, or EoE, allergic rhinoconjunctivitis, or ARC, and other conditions. Based on industry reports, by 2032 the market is projected to be approximately $37 billion for urticaria and AD, approximately $47 billion for the combined market of asthma, COPD, CRSwNP, EoE, ARC and PN and could include an additional $40 billion or greater taking into account potential expansion into gastrointestinal and neurology indications thought to be associated with mast cells.

Our initial immunology targets involve the following mechanisms:

- KIT, a receptor tyrosine kinase, critical for regulating mast cell survival and activation, including release of potent inflammatory mediators such as histamine, which is a primary driver of inflammation and implicated in multiple allergic diseases;
- STAT6, a transcription factor uniquely responsible for interleukin-4, or IL-4, and interleukin-13, or IL-13, cell signaling, which drives a type 2 dominant phenotype and downstream inflammation; and
- MRGPRX2, a non-canonical G-protein-coupled-receptor, or GPCR, expressed predominantly on mast cells, which upon activation triggers degranulation and release of inflammation-mediating components, leading to an inflammatory response that is a driver in multiple allergic diseases, and potentially implicated in migraine.

These mechanisms are implicated, along with others, in several diseases, and it is not uncommon for an efficacious treatment for one disease to be tested and approved for other immunology indications. In addition, these mechanisms are orthogonal approaches that may provide additive or complementary benefit if used in combination. We currently plan to focus our initial immunology drug development proof-of-concept efforts on the following disease indications:

- Urticaria, including chronic spontaneous urticaria, or CSU, a severely debilitating, chronic inflammatory skin disease manifested by hives, angioedema, which is swelling of soft tissues, or both, but with no identified triggers, which has an estimated global prevalence of between 0.5% – 1% of the population, resulting in approximately 1.75 – 3.5 million people with this condition at any given time in the U.S. alone and chronic inducible urticaria (CIndU) of various forms with a variety of known triggers; and
- Atopic dermatitis, or AD, a chronic dermatological disease characterized by dry, red, inflamed, irritated and itchy skin with significant quality of life impacts such as leading a limited lifestyle, avoidance of social interactions and a reduced range of activities, with AD affecting 7.3% of the U.S. adult population, of whom approximately 40% have moderate to severe disease.

As of September 30, 2026, we had $194.5 million in cash, cash equivalents and marketable securities. Based on our operating plan, we believe that our existing cash, cash equivalents and marketable securities as of September 30, 2026, as well as our retained portion of future HCV royalties, will enable us to fund our operating expenses and capital expenditure requirements into fiscal 2029.

Our Royalty Revenue Collaboration and Royalty Sale Agreement

Our royalty revenue is generated through our Collaborative Development and License Agreement with AbbVie (the "AbbVie Agreement"), under which we have discovered and out-licensed to AbbVie two protease inhibitor compounds that have been clinically tested, manufactured, and commercialized by AbbVie as part of its combination regimens for HCV.

Glecaprevir is the HCV protease inhibitor we discovered that was developed by AbbVie in a fixed-dose combination with its NS5A inhibitor, pibrentasvir, for the treatment of chronic HCV. This product was also approved by the FDA and European Commission as the first and only treatment for acute HCV infection in June 2025 and June 2026, respectively, and has also been approved in several other countries including Canada and Australia. This patented combination, currently marketed under the brand names MAVYRET® (U.S.) and MAVIRET® (ex-U.S.), is referred to in this report as MAVYRET/MAVIRET. The first protease inhibitor developed through this collaboration, paritaprevir, is part of AbbVie's initial HCV regimens, which have been almost entirely replaced by MAVYRET/MAVIRET. Since August 2017, substantially all of our royalty revenue has been derived from AbbVie's net sales of MAVYRET/MAVIRET. Our ongoing royalty revenues from this regimen consist of annually tiered, double-digit, per-product royalties on 50% of the calendar year net sales of the glecaprevir/pibrentasvir combination in MAVYRET/MAVIRET. The annual royalty tiers return to the lowest tier for sales on and after each January 1.

In April 2023, we entered into a royalty sale agreement with an affiliate of OMERS, a Canadian public employee pension fund, pursuant to which we were paid a $200.0 million cash purchase price in exchange for 54.5% of our future quarterly royalty payments on net sales of MAVYRET/MAVIRET, after June 30, 2023, through June 30, 2032, subject to a cap on aggregate payments to OMERS equal to 1.42 times the purchase price.

For accounting purposes, we continue to record 100% of HCV royalties earned under the AbbVie Agreement as royalty revenue in our consolidated statements of operations. The $200.0 million received in April 2023 was recognized on our consolidated balance sheets as a liability, which will be reduced by the payments made to OMERS over the term of the Agreement. We recognize imputed interest expense over the life of the royalty sale agreement based on our estimated future MAVYRET/MAVIRET royalties.

Financial Operations Overview

We are currently funding all research and development for our wholly-owned programs, which are targeted toward the discovery and development of novel compounds. In October 2026, we dosed the first patient in the RESOLVE study, a global registrational Phase 2b/3, clinical trial of zelicapavir in adults at high risk of severe outcomes from RSV infection. In addition, in the fourth quarter of 2026, we completed enrollment in the LOTUS study, a Phase 2b clinical trial of zelicapavir in pediatric patients with RSV, and we are conducting a Phase 1 clinical trial of EDP-978, our lead clinical candidate in our immunology programs, including EDP-903, our STAT6 clinical candidate, for which we are targeting an IND filing in the second quarter of 2027, and EPS-5336, our MRGPRX2 development candidate, for which we are conducting IND-enabling activities with the goal of filing an IND in the fourth quarter of 2027.

As a result of the timing of our clinical and preclinical development programs, we expect our research and development expenses will fluctuate from period to period. In the next 12 months, we expect an increase in our external research and development expenses, primarily driven by the timing of clinical trials in our RSV programs.

To date, we have funded our operations primarily through royalty payments received under our collaboration agreement with AbbVie, a $200.0 million payment received in April 2023 from our royalty sale agreement, proceeds from our public offering in October 2025 and our existing cash, cash equivalents, and marketable securities. Based on our operating plan, we believe that our existing cash, cash equivalents, and marketable securities, as well as our retained portion of future HCV royalties, will enable us to fund our operating expenses and capital expenditure requirements into fiscal 2029.

Revenue

Our revenue is primarily derived from our collaboration agreement with AbbVie and AbbVie's sales of MAVYRET/MAVIRET, an 8-week treatment regimen for acute or chronic HCV.

The following table is a summary of revenue recognized for the years ended September 30, 2026, 2025, and 2024:

	Years Ended September 30,		
	2026	2025	2024
		(in thousands)	
Revenue			
Royalty revenue	$ 63,001	$ 65,324	$ 67,635
Total revenue	$ 63,001	$ 65,324	$ 67,635

As disclosed above regarding our OMERS royalty sale agreement, we only retain 45.5% of the cash payments from royalties on net sales of MAVYRET/MAVIRET occurring after June 30, 2023 through June 30, 2032, subject to a cap on aggregate payments to OMERS equal to 1.42 times OMERS' purchase price.

Internal Programs

As our internal product candidates are currently in preclinical or clinical development, we have not generated any revenue from our own product sales. We do not expect to generate any revenue from product sales derived from these product candidates for at least the next several years.

Operating Expenses

Our operating expenses are comprised of research and development expenses and general and administrative expenses.

Research and Development Expenses

Research and development expenses consist of costs incurred to conduct basic research, such as the discovery and development of novel small molecules as therapeutics, as well as any external expenses of preclinical and clinical development activities. We expense all costs of research and development as incurred. These expenses consist primarily of:

- third-party contract costs relating to research, formulation, manufacturing, preclinical study, and clinical trial activities;
- personnel costs, including salaries, related benefits, and stock-based compensation for employees engaged in scientific research and development functions;
- allocated facility-related costs;
- laboratory consumables; and
- third-party license fees.

At any given time, we have later-stage programs in clinical development as well as several active early-stage research and drug discovery projects. Our internal resources, employees and infrastructure are utilized across multiple projects, including our early-stage discovery projects. As such, we report information regarding costs incurred based on our programs (i.e., disease area) rather than on a project specific basis. All indirect costs are allocated to programs based on headcount and square footage of our facilities. Certain prior year program amounts have been reclassified for consistency with the current year presentation. We expect that our research and development expenses will fluctuate from period to period as we advance our research and development programs. However, in the next 12 months, we expect an increase in our external research and development expenses, primarily driven by the timing of clinical trials in our RSV programs. To date, we have not identified any significant impact of inflation on spending in research and development, but it is uncertain whether there will be inflationary impacts in future periods.

Our research and drug discovery and development programs are in early stages; therefore, the successful development of our product candidates is highly uncertain and may not result in approved products. Completion dates and completion costs can vary significantly for each product candidate and are difficult to predict. Given the uncertainty associated with clinical trial enrollments and the risks inherent in the development process, we are unable to determine the duration and completion costs of the current or future clinical trials of our product candidates or if, or to what extent, we will generate revenue from the commercialization and sale of any of our product candidates. We anticipate that we will make determinations as to which development programs to pursue and how much funding to direct to each program on an ongoing basis in response to the preclinical and clinical success and prospects of each product candidate, as well as ongoing assessments of the commercial potential of each product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs, which include salaries, related benefits and stock-based compensation, of our executive, finance, business and corporate development and other administrative functions. General and administrative expenses also include allocated facility-related costs not otherwise included in research and development expenses, directors' and officers' liability insurance premiums, professional fees for auditing, tax, and legal services, patent expenses and litigation expenses associated with prosecuting our patent infringement litigation.

We expect that general and administrative expenses may increase in the long term. To date we have not experienced a significant impact of inflation on general and administrative expenses.

Other Income (Expense)

Other income (expense) consists of interest expense, interest and investment income, net and the change in fair value of Series 1 nonconvertible preferred stock. Interest expense consists of the interest expense and amortization of debt issuance costs associated with the royalty sale agreement with an affiliate of OMERS. Interest income consists of interest earned on our cash equivalents and marketable securities balances. Investment income consists of the net amortization and accretion of any purchased premiums and discounts, respectively, on our marketable securities. The change in fair value of Series 1 nonconvertible preferred stock relates to the remeasurement of these financial instruments from period to period as these instruments may require a transfer of assets because of the liquidation preference features of the underlying instrument.

Income Tax Benefit (Expense)

Income tax benefit (expense) is based on our best estimate of taxable net income (loss), applicable income tax rates, net research and development tax credits and carryforwards, net operating loss carrybacks and interest earned on such refunds, changes in valuation allowance estimates and deferred income taxes.

On July 4, 2025, the U.S. government enacted the One Big Beautiful Bill Act ("OBBBA"), which includes several changes to U.S. federal income tax law, including the temporary and permanent extension of expiring provisions of the Tax Cuts and Jobs Act of 2017. We determined that the tax provisions of the legislation do not have a material impact on our 2025 and 2026 consolidated financial statements, and we continue to assess the impact on future years.

Critical Accounting Policies

Our consolidated financial statements are prepared in accordance with accounting principles generally accepted in the U.S. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amount of assets, liabilities, equity, revenue, costs and expenses, and related disclosures. We believe that the estimates and assumptions involved in the accounting policies described below may have the greatest potential impact on our consolidated financial statements and, therefore, consider these to be our critical accounting policies. We evaluate our estimates and assumptions on an ongoing basis. Actual results may differ from these estimates under different assumptions and conditions. See also Note 2 to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for information about these critical accounting policies as well as a description of our other significant accounting policies.

Research and Development and Pharmaceutical Drug Manufacturing Accruals

We have entered into various contracts with third parties to perform research and development and pharmaceutical drug manufacturing. These include contracts with contract research organizations, or CROs, clinical manufacturing organizations, or CMOs, testing laboratories, research hospitals and not-for-profit organizations and other entities to support our research and development activities. We expense the cost of each contract as the work is performed. When billing terms under these contracts do not coincide with the timing of when the work is performed, we are required to make estimates of our outstanding obligations to those third parties as of period-end. Our accrual estimates are based on a number of factors, including our knowledge of the research and development programs and pharmaceutical drug manufacturing activities and associated timelines, invoicing to date, and the provisions in the contract. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from our estimates.

Liability Related to the Sale of Future Royalties

We accounted for the $200.0 million payment from OMERS as a liability on our consolidated balance sheets because (1) under the royalty sale agreement, OMERS will receive a portion of our royalty payments up to a capped amount of 1.42 times the original payment to us, and (2) we have significant continuing involvement in the generation of cash flows under the AbbVie Agreement. Interest expense for the liability related to the sale of future royalties will be recognized using the effective interest rate method over the term of the royalty sale agreement.

The liability related to the sale of future royalties and the related interest expense are based on our current estimates of future royalties, which we determine by using third-party forecasts of MAVYRET/MAVIRET sales. Third-party forecasts are updated periodically based on the latest pricing, market share, and patient data. Changes in the amount or timing of estimated royalties will affect the interest rate utilized in calculating the liability related to the sale of future royalties.

Results of Operations

	Years Ended September 30,		
	2026	2025	2024
	(in thousands)		
Revenue	$ 63,001	$ 65,324	$ 67,635
Operating expenses:			
Research and development	88,546	106,740	131,476
General and administrative	36,835	43,933	57,850
Total operating expenses	125,381	150,673	189,326
Loss from operations	(62,380)	(85,349)	(121,691)
Other income (expense)			
Interest expense	(14,074)	(7,681)	(10,940)
Interest and investment income, net	8,225	9,442	14,770
Change in fair value of Series 1 nonconvertible preferred stock	21	39	73
Total other income (expense), net	(5,828)	1,800	3,903
Loss before income taxes	(68,208)	(83,549)	(117,788)
Income tax benefit (expense)	(40)	1,660	1,743
Net loss	$ (68,248)	$ (81,889)	$ (116,045)

Comparison of the Years Ended September 30, 2026 and 2025

Revenue

We recognized revenue of $63.0 million and $65.3 million during the years ended September 30, 2026 and 2025, respectively. The $2.3 million decrease in revenue year-over-year was primarily due to AbbVie's lower reported HCV sales as compared to the same period in fiscal 2025.

Our royalty revenues eligible to be earned in the future will depend on AbbVie's HCV market share, the pricing of the MAVYRET/MAVIRET regimen, the number of patients treated and the effect of the label expansion for MAVYRET/MAVIRET for the treatment of patients with acute HCV infection. In addition, at the beginning of each calendar year (the second quarter of our fiscal year), our royalty rate resets to the lowest tier for each of our royalty-bearing products licensed to AbbVie.

Beginning with the three months ended September 30, 2023, 54.5% of our quarterly royalty payments on net sales of MAVYRET/MAVIRET that are included in our total revenue are paid to OMERS through June 30, 2032, subject to a cap on aggregate payments equal to 1.42 times the purchase price. The $200.0 million received in April 2023 was recognized on our consolidated balance sheets as a liability which will be reduced by the payments made to OMERS over the term of the royalty sale agreement. We will continue to record 100% of HCV royalties earned under the AbbVie Agreement as royalty revenue in our consolidated statements of operations since the AbbVie Agreement has not been amended and is independent of our agreement with OMERS.

Research and development expenses

	Years Ended September 30,		
	2026	2025	2024
		(in thousands)	
R&D programs:			
Virology			
RSV	$ 25,898	$ 59,808	$ 86,367
Total Virology	25,898	59,808	86,367
Immunology			
KIT	17,067	18,052	19,822
STAT6	25,543	16,614	4,691
MRGPRX2	12,393	9,114	6,525
Total Immunology	55,003	43,780	31,038
Other Programs			
Early discovery	6,869	2,214	8,471
Other pipeline programs	776	938	5,600
Total Other Programs	7,645	3,152	14,071
Total research and development expenses	$ 88,546	$ 106,740	$ 131,476

Research and development expenses for the year ended September 30, 2026 decreased by $18.2 million compared to the same period in 2025.

Virology

The costs in our virology program decreased by $33.9 million primarily due to the timing of clinical trials in our RSV programs, including the cost associated with our LOTUS and RESOLVE trials, partially offset by the completion of our Phase 2b RSVHR trial in fiscal 2025.

Immunology

The costs in our immunology programs increased by $11.2 million primarily due to scale-up and IND-enabling activities for our STAT6 and MRGPRX2 programs.

Other Programs

Other program costs increased by $4.5 million as we advanced early-stage drug discovery efforts.

General and administrative expenses

General and administrative expenses decreased by $7.1 million for the year ended September 30, 2026, compared to the same period in 2025. The decrease was primarily due to lower stock-based compensation expenses and a decrease in legal expenses related to our patent infringement suits against Pfizer.

Other income (expense)

Changes in components of other income (expense) were as follows:

Interest expense

Interest expense increased by $6.4 million for the year ended September 30, 2026, as compared to the same period in 2025. The increase is due to an increase in forecasted royalties arising from AbbVie's product sales under the AbbVie Agreement during the first half of our 2026 fiscal year and the corresponding royalty payment to OMERS arising from such sales pursuant to our royalty sale agreement.

Interest and investment income, net

Interest and investment income, net, decreased by $1.2 million for the year ended September 30, 2026, as compared to the same period in 2025. The decrease was due to lower interest rates year over year.

Income tax benefit (expense)

During the years ended September 30, 2026 and 2025, we recorded an income tax expense of less than $0.1 million and an income tax benefit of $1.7 million, respectively. The income tax expense recorded in 2026 was primarily due to state income taxes. The income tax benefit recorded in 2025 was primarily due to interest earned on a federal income tax refund of $33.8 million (inclusive of interest) received in April 2025.

Comparison of the Years Ended September 30, 2025 and 2024

For a discussion of our results of operations for the year ended September 30, 2025, as compared to the year ended September 30, 2024, see Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations—Comparison of the Years Ended September 30, 2025 and 2024 included in our Annual Report on Form 10-K for the fiscal year ended September 30, 2025.

Liquidity and Capital Resources

We fund our operations with cash flows from our retained portion of our royalty revenue and our existing financial resources. At September 30, 2026, our principal sources of liquidity were cash, cash equivalents and marketable securities of $194.5 million.

The following table shows a summary of our cash flows:

	Years Ended September 30,		
	2026	2025	2024
		(in thousands)	
Cash provided by (used in):			
Operating activities	$ (42,560)	$ (19,272)	$ (78,764)
Investing activities	(17,185)	40,347	58,235
Financing activities	47,719	(26,618)	(27,626)
Net decrease in cash, cash equivalents and restricted cash	$ (12,026)	$ (5,543)	$ (48,155)

Net cash used in operating activities

Cash used in operating activities was $42.6 million for the year ended September 30, 2026 as compared to cash used in operating activities of $19.3 million for the same period in 2025. The increase in cash used in operating activities of $23.3 million was primarily due to the receipt of a $33.8 million federal income tax refund in April 2025, partially offset by lower research and development payments in 2026.

Net cash provided by (used in) investing activities

Cash used in investing activities was $17.2 million for the year ended September 30, 2026 as compared to cash provided by investing activities of $40.3 million for the same period in 2025. The change in cash from investing activities of $57.5 million was driven by the timing of purchases, sales and maturities of marketable securities in 2026 compared to 2025. This change was partially offset by a reduction in capital expenditures in fiscal 2026 as we completed the buildout of our new office and laboratory space at 4 Kingsbury Avenue in 2025.

Net cash provided by (used in) financing activities

Cash provided by financing activities was $47.7 million for the year ended September 30, 2026 as compared to cash used in financing activities of $26.6 million for the same period in 2025. Our cash provided by financing activities increased $74.3 million, driven primarily by the proceeds received from our October 2025 public offering.

Year Ended September 30, 2025

For a discussion of our cash flows for the year ended September 30, 2025, see Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Cash Flows included in our Annual Report on Form 10-K for the fiscal year ended September 30, 2025.

Funding Requirements

As of September 30, 2026, we had $194.5 million in cash, cash equivalents and marketable securities. Based on our operating plan, we believe that our existing cash, cash equivalents and marketable securities as of September 30, 2026, as well as our retained portion of future HCV royalties, will enable us to fund our operating expenses and capital expenditure requirements into fiscal 2029. Additionally, in July 2026, we entered into an Open Market Sale Agreement℠ with Jefferies LLC ("Jefferies"), as sales agent, under which we may offer and sell shares of our common stock, from time to time through Jefferies, under an at-the-market facility for aggregate gross sale proceeds of up to $75.0 million (the "ATM Facility"). As of September 30, 2026, we have not issued any shares of common stock under the ATM Facility. This may be used to further support our operating expenses and capital expenditure requirements. However, our projection 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.

Our future capital requirements are difficult to forecast and will depend on many factors, including:

- the number and characteristics of our research and development programs;
- the scope, progress, results and costs of researching and developing our product candidates on our own, including conducting advanced clinical trials;
- our ability to establish new collaborations, licensing or other arrangements, if any, and the financial terms of such arrangements;
- the amount of our retained portion of royalties generated from MAVYRET/MAVIRET sales under our existing collaboration with AbbVie;

- delays and additional expenses in our clinical trials;
- the cost of manufacturing our product candidates for clinical development and any products we successfully commercialize independently;
- opportunities to in-license or otherwise acquire new technologies and therapeutic candidates;
- costs associated with any further proceedings in our patent infringement litigation in the United States and Europe regarding use of a coronavirus 3CL protease inhibitor in Paxlovid, Pfizer's antiviral treatment for COVID-19;
- the timing of, and the costs involved in, obtaining regulatory approvals for any product candidates we develop independently;
- the cost of commercialization activities, if any, of any product candidates we develop independently that are approved for sale, including marketing, sales and distribution costs;
- the timing and amount of any sales of our product candidates, if any, or royalties thereon;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patents, including any litigation costs and the outcomes of any such litigation; and
- potential fluctuations in foreign currency exchange rates.

Off-Balance Sheet Arrangements

We do not engage in any off-balance sheet financing activities. We do not have any interest in entities referred to as variable interest entities, which include special purpose entities and other structured finance entities.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is set forth in Note 2 to the consolidated financial statements included in this Annual Report on Form 10-K.

Contractual Obligations and Commitments

Facility Leases

As of the date of this report, we lease space in Watertown, Massachusetts, under two separate lease agreements with one landlord.

In May 2022, we entered into a ten-year lease for new laboratory and office space in Watertown, Massachusetts, adjacent to our 400 Talcott Avenue premises at Arsenal on the Charles at 4 Kingsbury Avenue since our lease for office and laboratory space at 500 Arsenal Street was to expire on September 1, 2027. The construction of the facility shell was completed and we gained access to the building to construct tenant improvements in 2024. Upon gaining access to the 4 Kingsbury Avenue building, we capitalized a right-of-use asset of $32.5 million and a lease liability of $31.9 million on our consolidated balance sheets, which reflects our fixed base rent payments, net of $15.2 million of a tenant improvement allowance provided by the landlord, over the 10-year term of the lease. The 4 Kingsbury Avenue lease ends September 30, 2034.

The second lease for office space located at 400 Talcott Avenue commenced on September 24, 2018 for a term of six years. In May 2022, we amended this lease to expand the rented space and extend the lease term through June 1, 2034. We spent approximately $6.3 million in capital expenditures for the additional space and received a tenant improvement allowance from the landlord of $2.5 million. In July 2024, we amended our lease agreement to confirm alignment with the lease end date of our 4 Kingsbury Avenue lease of September 30, 2034.

Total estimated minimum lease payments for the next 5 years and thereafter under our existing facility and leased equipment agreements are $8.7 million in 2027, $9.0 million in 2028, $9.3 million in 2029, $9.5 million in 2030, $9.8 million in 2031 and $31.2 million thereafter.

Preferred Stock

As of September 30, 2026, we had 1.9 million outstanding shares of Series 1 nonconvertible preferred stock, all of which we classified as a long-term liability on our consolidated balance sheet and recorded at fair value of $1.3 million. The fair value of the preferred stock was measured based on significant inputs not observable in the market, which represented a Level 3 measurement within the fair value hierarchy. The fair value of these instruments represents less than 10% of liabilities as of September 30, 2026. The Series 1 nonconvertible preferred stock issued would require the payment of approximately $2.0 million in the event of a qualifying merger or sale of the company.

OMERS Agreement

In April 2023, we entered into a royalty sale agreement with an affiliate of OMERS, pursuant to which we were paid a $200.0 million cash purchase price in exchange for 54.5% of our future quarterly royalty payments on net sales of MAVYRET/MAVIRET after June 30, 2023, through June 30, 2032, subject to a cap on aggregate payments equal to 1.42 times the purchase price.

The $200.0 million received in April 2023 was recognized on our consolidated balance sheets as a liability which will be reduced by the payments made to OMERS over the term of the royalty sale agreement.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

We had cash, cash equivalents and marketable securities of $194.5 million and $188.9 million at September 30, 2026 and 2025, respectively, which consisted of cash, money market funds, and treasury notes. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of these investments, a change in market interest rates of 1% would not be expected to have a material impact on our financial condition or results of operations for either period.

Foreign Exchange Risk

As we continue to progress our wholly-owned programs into clinical development, we will conduct clinical trials and clinical manufacturing outside of the U.S. and thus will face exposure to movements in foreign currency exchange rates, primarily the British Pound and Euro, against the U.S. Dollar, arising from our accounts payable and accrued expenses. During fiscal 2026 and 2025, the impact of foreign currency exposure was immaterial and thus did not have a significant impact on our consolidated financial statements. Our operations may become subject to more significant fluctuations in foreign currency exchange rates in the future if we continue to contract with vendors outside of the U.S.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated financial statements, together with the report of our independent registered public accounting firm, appear on pages F-1 through F-28 of this Annual Report on Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures and Internal Control over Financial Reporting

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to management, including our Chief Executive Officer (Principal Executive Officer, or "PEO") and Vice President, Finance (Principal Financial Officer or "PFO"), as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily was required to apply its judgment in evaluating the risk related to controls and procedures.

In connection with the preparation of this Form 10-K, as of September 30, 2026, an evaluation was performed under the supervision and with the participation of our management, including the PEO and PFO, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on that evaluation, our PEO and PFO concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of September 30, 2026. These conclusions were communicated to the Audit Committee.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) and Rule 15d-15(f) under the Exchange Act. Our internal control system is designed to provide reasonable assurance to our management and Board of Directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Our management has assessed the effectiveness of our internal control over financial reporting as of September 30, 2026. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in its 2013 *Internal Control—Integrated Framework.* Based on this assessment, our management has concluded that as of September 30, 2026, our internal control over financial reporting is effective.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2026 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Rule 10b5-1 Trading Arrangements. During the three months ended September 30, 2026, our officers (as defined in Rule 16a-1(f) under the Exchange Act) set forth below adopted or terminated a "Rule 10b5-1 trading arrangement" as that term is defined in Item 408(a) of Regulation S-K, all of which were entered into during an open trading window in accordance with our Securities Trading Policy and all of which were intended to satisfy Rule 10b5-1(c).

- On August 12, 2026, Jay R. Luly, Ph.D., our President, Chief Executive Officer and Director, adopted a Rule 10b5-1 trading plan providing for the sale of up to 96,005 shares of our common stock, including shares vested under performance stock units and restricted stock units, as well as shares vesting under outstanding stock options which expire in November 2027, so long as the market price of our common stock is higher than certain minimum threshold prices specified in the plan in various periods between November 19, 2026 (subject to the applicable cooling-off period) and April 30, 2027, or such earlier date as all authorized sales under the plan are completed.
- On August 13, 2026, Tara L. Kieffer, Ph.D., our Chief Operating Officer, adopted a Rule 10b5-1 trading plan providing for the sale of up to 83,419 shares of our common stock, including shares vested under performance stock units and restricted stock units, as well as shares vesting under outstanding stock options, so long as the market price of our common stock is higher than certain minimum threshold prices specified in the plan in various periods between November 19, 2026 (subject to the applicable cooling-off period) and November 24, 2027, or such earlier date as all authorized sales under the plan are completed.
- On September 9, 2026, Scott Rottinghaus, M.D., our Chief Medical Officer, adopted a Rule 10b5-1 trading plan providing for the sale of up to 22,037 shares of our common stock, including shares vested under performance stock units and restricted stock units, so long as the market price of our common stock is higher than certain minimum threshold prices specified in the plan in various periods between April 1, 2027 and August 2, 2027, or such earlier date as all authorized sales under the plan are completed.

Except as set forth above, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-rule 10b5-1 trading arrangement," as each term is defined in item 408(a) of Regulation S-K.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Portions of the response to this item are incorporated herein by reference to the discussion responsive thereto in the Company's Definitive Proxy Statement relating to the 2027 Annual Meeting of Stockholders, also referred to as the 2027 Proxy Statement, which will be filed within 120 days after September 30, 2026.

We have adopted a Code of Business Conduct and Ethics (the code of ethics) that applies to all of our employees, officers and directors. The code of ethics is available on our website at http://www.enanta.com. In addition, if we make any substantive amendments to the code of ethics or grant any waiver, including any implicit waiver, from a provision of the code to any of our executive officers or directors, we will disclose the nature of such amendment or waiver as required by applicable law on our website or on a Form 8-K.

ITEM 11. EXECUTIVE COMPENSATION

The response to this item is incorporated herein by reference from the discussion responsive thereto in the 2027 Proxy Statement, which will be filed within 120 days after September 30, 2026.

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

The response to this item is incorporated herein by reference from the discussion responsive thereto in the 2027 Proxy Statement, which will be filed within 120 days after September 30, 2026.

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

The response to this item is incorporated herein by reference from the discussion responsive thereto in the 2027 Proxy Statement, which will be filed within 120 days after September 30, 2026.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The response to this item is incorporated herein by reference from the discussion responsive thereto in the 2027 Proxy Statement, which will be filed within 120 days after September 30, 2026.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) 1. FINANCIAL STATEMENTS

The financial statements are included under Part II, Item 8 of this Report.

2. FINANCIAL STATEMENTS SCHEDULE

Schedules are omitted because they are not applicable, or are not required, or because the information is included in the consolidated financial statements and notes thereto.

3. EXHIBITS –

The exhibits are listed below under Part IV, Item 15(b) of this Report.

(b) EXHIBITS

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	Date	Exhibit Number	File Number	
3.1	Restated Certificate of Incorporation of Enanta Pharmaceuticals, Inc.	8-K	03/28/2013	3.1	001-35839	
3.2	Amended and Restated Bylaws of Enanta Pharmaceuticals, Inc. (as amended and restated in August 2015).	8-K	08/18/2015	3.2	001-35839	
4.1	Specimen certificate evidencing shares of common stock.	S-1/A	02/05/2013	4.1	333-184779	
4.2	Specimen certificate evidencing shares of Series 1 Non-Convertible Preferred Stock	10-K	12/11/2017	4.3	001-35839	
4.3	Description of securities registered pursuant to Section 12 of the Securities Exchange Act of 1934	10-K	11/27/2019	4.3	001-35839	
10.1#	Form of Indemnification Agreement for directors and officers.	S-1/A	02/05/2013	10.7	333-184779	
10.2#	Amended and Restated Employment Agreement between the Company and Jay R. Luly, Ph.D., dated as of March 4, 2013.	S-1/A	03/05/2013	10.5	333-184779	
10.3#	Form of Amended and Restated Employment Agreement for Executive Officers other than the Chief Executive Officer.	S-1/A	03/05/2013	10.17	333-184779	
10.4†	Collaborative Development and License Agreement between the Company and Abbott Laboratories, dated November 27, 2006; as amended by a First Amendment to Collaborative Development and License Agreement dated January 27, 2009 and a Second Amendment to Collaborative Development and License Agreement dated December 9, 2009 (assigned to AbbVie Inc. as of January 1, 2013).	8-K	02/05/2021	10.1	001-35839	
10.5†	Third Amendment to Collaborative Development and License Agreement between the Company and AbbVie dated October 20, 2014.	8-K	02/05/2021	10.2	001-35839	
10.6	Fourth Amendment to Collaborative Development and License Agreement between the Company and AbbVie dated as of March 3, 2015.	10-Q	05/08/2015	10.1	001-35839	

10.7	Royalty Purchase Agreement between Enanta Pharmaceuticals, Inc. and OCM Life Sciences Portfolio LP dated as of April 25, 2023	8-K	04/27/2023	10.1	001-35839
10.8	Lease Agreement between Company and Athena Arsenal, LLC, dated as of September 24, 2018.	10-K	11/29/2018	10.10	001-35839
10.9	First Amendment to Lease Agreement made as of May 12, 2022 by and between ARE-MA Region No. 75, LLC and the Company.	8-K	05/17/2022	10.2	001-35839
10.10	Lease Agreement made as of May 12, 2022 by and between ARE-MA Region No. 75, LLC and the Company.	8-K	05/17/2022	10.3	001-35839
10.11#	2012 Equity Incentive Plan (As adjusted to reflect the application of the 1-for-4.31 reverse stock split of the Company's common stock effected on March 1, 2013).	10-K/A	01/06/2017	10.14	001-35839
10.12#	Form of Incentive Stock Option Agreement under 2012 Equity Incentive Plan.	S-1/A	03/05/2013	10.13	333-184779
10.13#	Form of Non-Statutory Stock Option Agreement under 2012 Equity Incentive Plan.	S-1/A	03/05/2013	10.14	333-184779
10.14#	Form of Non-Statutory Stock Option Certificate for directors under 2012 Equity Incentive Plan.	S-1/A	03/05/2013	10.15	333-184779
10.15#	Form of Performance Share Unit Certificate under 2012 Equity Incentive Plan.	10-K	12/11/2017	10.18	001-35839
10.16#	Form of Relative Total Stockholder Return Unit Certificate under 2012 Equity Incentive Plan.	10-K	12/11/2017	10.19	001-35839
10.17#	Employee Stock Purchase Plan.	S-1/A	02/05/2013	10.16	333-184779
10.18#	2019 Equity Incentive Plan (As amended March 2026)	8-K	03/12/2026	10.1	001-35839
10.19#	Form of Notice of Grant of Non-Statutory Stock Option under 2019 Equity Incentive Plan.	10-Q	05/10/2019	10.2	001-35839
10.20#	Form of Notice of Grant of Non-Statutory Stock Option for Directors under 2019 Equity Incentive Plan.	10-Q	05/10/2019	10.3	001-35839
10.21#	Form of Relative Total Stockholder Return Unit Certificate under 2019 Equity Incentive Plan.	10-Q	05/10/2019	10.4	001-35839
10.22#	Form of Performance Share Unit Certificate under 2019 Equity Incentive Plan.	10-Q	05/10/2019	10.5	001-35839
10.23#	Form of Notice of Restricted Stock Unit Award under 2019 Equity Incentive Plan.	10-K	11/25/2020	10.27	001-35839
10.24#	2024 Inducement Stock Incentive Plan	S-8	05/08/2024	99.2	333-279217
10.25#	Form of Notice of Grant of Non-Statutory Stock Option under 2024 Inducement Stock Incentive Plan	10-K	11/27/2024	10.26	001-35839
10.26#	Form of Notice of Grant of Restricted Stock Unit Award under 2024 Inducement Stock Incentive Plan	10-K	11/27/2024	10.27	001-35839
10.27#	Form of Performance Share Unit Certificate under 2024 Inducement Stock Incentive Plan	10-K	11/27/2024	10.28	001-35839
10.28#	Form of Relative Total Stockholder Return Unit Certificate under 2024 Inducement Stock Incentive Plan	10-K	11/27/2024	10.29	001-35839

10.29#	Form of Incentive Stock Option Grant Notice and Option Agreement under 2019 Equity Incentive Plan	10-Q	02/11/2026	10.1	001-35839	
10.30	Second Amendment to Lease Agreement, dated as of July 26, 2024, between ARE-MA REGION NO. 75, LLC and the Company	10-K	11/27/2024	10.30	001-35839	
10.31	Third Amendment to Lease Agreement, dated as of September 13, 2024, between ARE-MA REGION NO. 75, LLC and the Company	10-K	11/27/2024	10.31	001-35839	
19.1	Amended and Restated Securities Trading Policy	10-K	11/27/2024	19.1	001-35839	
21.1	Subsidiaries of the Company.					X
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.					X
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.					X
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.					X
32.1	Certification of the Chief Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
97.1	Amended and Restated Compensation Clawback Policy	10-K	11/27/2024	97.1	001-35839	
101.INS	XBRL Instance Document - The instance document does not appear in the interactive data file because its XBRL tags are embedded within the inline XBRL document					X
101.SCH	Inline XBRL Taxonomy Extension Schema with embedded Linkbases document					
104	Cover Page Interactive Data File (formatted as Inline XBRL with applicable Taxonomy Extension information contained in Exhibit 101)					

Management contract or compensatory plan, contract or agreement.

† Confidential treatment granted as to portions of this Exhibit. The confidential portions of this Exhibit have been omitted and are marked by asterisks.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, this 18th day of November, 2026.

ENANTA PHARMACEUTICALS, INC.

By: /s/ Jay R. Luly, Ph.D.
Jay R. Luly, Ph.D.
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Company in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Jay R. Luly, Ph.D. Jay R. Luly, Ph.D.	President and Chief Executive Officer and Director (Principal Executive Officer)	November 18, 2026
/s/ Harry R. Trout, III, MBA Harry R. Trout, III, MBA	Vice President, Finance (Principal Financial Officer)	November 18, 2026
/s/ Kathleen S. Capps Kathleen S. Capps, CPA	Executive Director of Accounting, Controller (Principal Accounting Officer)	November 18, 2026
/s/ Bruce L.A. Carter, Ph.D. Bruce L.A. Carter, Ph.D.	Director	November 18, 2026
/s/ Mark G. Foletta Mark G. Foletta	Director	November 18, 2026
/s/ Yujiro S. Hata Yujiro S. Hata	Director	November 18, 2026
/s/ Kristine Peterson Kristine Peterson	Director	November 18, 2026
/s/ Lesley Russell, MB. Ch.B., MRCP Lesley Russell, MB. Ch.B., MRCP	Director	November 18, 2026
/s/ Terry Vance Terry Vance	Director	November 18, 2026

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

ENANTA PHARMACEUTICALS, INC.

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Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Enanta Pharmaceuticals, Inc. and its subsidiary (the "Company") as of September 30, 2026 and 2025, and the related consolidated statements of operations, of comprehensive loss, of stockholders' equity and of cash flows for each of the three years in the period ended September 30, 2026, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of September 30, 2026 and 2025, and the results of its operations and its cash flows for each of the three years in the period ended September 30, 2026 in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

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

Research and Development and Pharmaceutical Drug Manufacturing Accruals

As described in Notes 2 and 6 to the consolidated financial statements, the Company has entered into various contracts with third parties to perform research and development and pharmaceutical drug manufacturing. When billing terms under these contracts do not coincide with the timing of when the work is performed, management is required to make estimates of outstanding obligations to those third parties as of period end. Within accrued expenses and other current liabilities, total accrued research and development expenses and accrued pharmaceutical drug manufacturing amounted to $4.4 million and $1.7 million as of September 30, 2026, respectively. The accrual estimates are based on a number of factors, including management's knowledge of the research and development programs and pharmaceutical drug manufacturing activities and associated timelines, invoicing to date, and the provisions in the contract. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period.

The principal considerations for our determination that performing procedures relating to research and development and pharmaceutical drug manufacturing accruals is a critical audit matter are the significant judgment by management in developing the accrual estimates, as the estimates are based on a number of factors, including management's knowledge of the research and development programs and pharmaceutical drug manufacturing activities and associated timelines, invoicing to date, and the provisions in the contracts, which in turn led to a high degree of auditor judgment, subjectivity and effort in performing procedures and evaluating management's significant assumptions related to progress towards completion of the research and development programs and pharmaceutical drug manufacturing activities.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included, among others (i) testing management's process for developing estimates based upon the progress of the research and development programs and pharmaceutical drug manufacturing activities; (ii) evaluating the appropriateness of the method used by management to develop the estimates; (iii) reading research and development and pharmaceutical drug manufacturing contracts on a test basis; (iv) evaluating the completeness and accuracy of data used by management; and (v) evaluating the reasonableness of significant assumptions related to the progress towards completion. Evaluating management's assumptions related to progress towards completion of the research and development programs and pharmaceutical drug manufacturing activities included evaluating whether the assumptions were reasonable considering the associated timelines, invoicing to date and the provisions in the contracts.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
November 18, 2026

We have served as the Company's auditor since 1999.

ENANTA PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS
(in thousands, except per share data)

	September 30, 2026	September 30, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 20,272	$ 32,298
Short-term marketable securities	174,241	156,566
Accounts receivable	5,855	6,882
Prepaid expenses and other current assets	5,626	8,590
Total current assets	205,994	204,336
Property and equipment, net	30,858	35,395
Operating lease, right-of-use assets	35,249	37,549
Long-term restricted cash	3,360	3,360
Other long-term assets	116	92
Total assets	$ 275,577	$ 280,732
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,750	$ 1,948
Accrued expenses and other current liabilities	14,685	12,751
Liability related to the sale of future royalties	32,968	30,710
Operating lease liabilities	4,057	3,146
Total current liabilities	54,460	48,555
Liability related to the sale of future royalties, net of current portion	88,637	111,132
Operating lease liabilities, net of current portion	50,700	54,757
Series 1 nonconvertible preferred stock	1,290	1,311
Other long-term liabilities	295	260
Total liabilities	195,382	216,015
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Common stock; $0.01 par value per share, 100,000 shares authorized; 29,142 and 21,387 shares issued and outstanding at September 30, 2026 and September 30, 2025, respectively	291	214
Additional paid-in capital	554,064	469,771
Accumulated other comprehensive loss	(983)	(339)
Accumulated deficit	(473,177)	(404,929)
Total stockholders' equity	80,195	64,717
Total liabilities and stockholders' equity	$ 275,577	$ 280,732

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

ENANTA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	Years Ended September 30,		
	2026	2025	2024
Revenue			
Royalty revenue	$ 63,001	$ 65,324	$ 67,635
Total revenue	63,001	65,324	67,635
Operating expenses:			
Research and development	88,546	106,740	131,476
General and administrative	36,835	43,933	57,850
Total operating expenses	125,381	150,673	189,326
Loss from operations	(62,380)	(85,349)	(121,691)
Other income (expense):			
Interest expense	(14,074)	(7,681)	(10,940)
Interest and investment income, net	8,225	9,442	14,770
Change in fair value of Series 1 nonconvertible preferred stock	21	39	73
Total other income (expense), net	(5,828)	1,800	3,903
Loss before income taxes	(68,208)	(83,549)	(117,788)
Income tax benefit (expense)	(40)	1,660	1,743
Net loss	$ (68,248)	$ (81,889)	$ (116,045)
Net loss per share, basic and diluted	$ (2.35)	$ (3.84)	$ (5.48)
Weighted average common shares outstanding, basic and diluted	29,001	21,336	21,157

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

ENANTA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands)

	Years Ended September 30,		
	2026	2025	2024
Net loss	$ (68,248)	$ (81,889)	$ (116,045)
Other comprehensive income (loss):			
Net unrealized gains (losses) on marketable securities	(644)	(641)	1,476
Total other comprehensive income (loss)	(644)	(641)	1,476
Comprehensive loss	$ (68,892)	$ (82,530)	$ (114,569)

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

ENANTA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at September 30, 2023	21,059	$ 211	$ 424,693	$ (1,174)	$ (206,995)	$ 216,735
Exercise of stock options	16	—	147	—	—	147
Vesting of restricted stock units, net of withholding	119	1	(295)	—	—	(294)
Stock-based compensation expense	—	—	26,795	—	—	26,795
Other comprehensive income	—	—	—	1,476	—	1,476
Net loss	—	—	—	—	(116,045)	(116,045)
Balances at September 30, 2024	21,194	212	451,340	302	(323,040)	128,814
Exercise of stock options	16	—	145	—	—	145
Vesting of restricted stock units, net of withholding	177	2	(279)	—	—	(277)
Stock-based compensation expense	—	—	18,565	—	—	18,565
Other comprehensive loss	—	—	—	(641)	—	(641)
Net loss	—	—	—	—	(81,889)	(81,889)
Balances at September 30, 2025	21,387	214	469,771	(339)	(404,929)	64,717
Issuance of common stock from October 2025 public offering, net of issuance costs of $4,802	7,475	75	69,873	—	—	69,948
Exercise of stock options	91	1	818	—	—	819
Vesting of restricted stock units, net of withholding	189	1	(424)	—	—	(423)
Stock-based compensation expense	—	—	14,026	—	—	14,026
Other comprehensive loss	—	—	—	(644)	—	(644)
Net loss	—	—	—	—	(68,248)	(68,248)
Balances at September 30, 2026	29,142	$ 291	$ 554,064	$ (983)	$ (473,177)	$ 80,195

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

ENANTA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Years Ended September 30,		
	2026	2025	2024
Cash flows from operating activities			
Net loss	$ (68,248)	$ (81,889)	$ (116,045)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	14,026	18,565	26,795
Depreciation and amortization expense	4,782	4,586	2,336
Non-cash interest expense associated with the sale of future royalties	1,158	(630)	(135)
Non-cash royalty revenue	1,230	(283)	2,350
Premium paid on marketable securities	(1,240)	—	—
Amortization (accretion) of premiums (discounts) on marketable securities	(100)	503	(1,138)
Loss on disposal of property and equipment	—	6	16
Change in fair value of Series 1 nonconvertible preferred stock	(21)	(39)	(73)
Change in operating assets and liabilities:			
Accounts receivable	1,027	(236)	1,968
Prepaid expenses and other current assets	2,964	3,823	850
Income tax receivable	—	31,999	(995)
Operating lease, right-of-use assets	2,300	4,308	6,096
Other long-term assets	(24)	2	709
Accounts payable	763	(1,311)	(414)
Accrued expenses	1,934	58	(5,646)
Operating lease liabilities	(3,146)	1,237	4,994
Other long-term liabilities	35	29	(432)
Net cash used in operating activities	(42,560)	(19,272)	(78,764)
Cash flows from investing activities			
Purchase of marketable securities	(231,877)	(209,629)	(307,282)
Proceeds from maturities and sale of marketable securities	214,898	262,872	383,465
Purchase of property and equipment	(206)	(12,896)	(17,948)
Net cash provided by (used in) investing activities	(17,185)	40,347	58,235
Cash flows from financing activities			
Proceeds from October 2025 public offering, net of issuance costs of $4,802	69,948	—	—
Payments on royalty sale liability, net of imputed interest	(22,625)	(26,486)	(27,479)
Proceeds from the exercise of stock options	819	145	147
Payments for settlement of share-based awards	(423)	(277)	(294)
Net cash provided by (used in) financing activities	47,719	(26,618)	(27,626)
Net decrease in cash, cash equivalents and restricted cash	(12,026)	(5,543)	(48,155)
Cash, cash equivalents and restricted cash at beginning of period	35,658	41,201	89,356
Cash, cash equivalents and restricted cash at end of period	$ 23,632	$ 35,658	$ 41,201
Supplemental disclosure of cash flow information			
Cash received from federal tax refund	$ —	$ 33,785	$ —
Cash received from state tax refund	$ 8	$ —	$ —
Cash paid for state taxes	$ —	$ 109	$ 241
Cash paid for interest	$ 12,916	$ 8,794	$ 11,710
Cash received from tenant improvement allowances	$ 330	$ 5,881	$ 9,358
Supplemental disclosure of non-cash information:			
Purchases of fixed assets included in accounts payable and accrued expenses	$ 39	$ —	$ 5,597
Operating lease liabilities arising from obtaining right-of-use assets	$ —	$ 1,199	$ 23,960

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

1. Nature of the Business

Enanta Pharmaceuticals, Inc. (collectively with its subsidiary, the "Company"), incorporated in Delaware in 1995, is a biotechnology company that uses its robust, chemistry-driven approach and drug discovery capabilities to discover and develop small molecule drugs with an emphasis on viral infections and immunological diseases. The Company discovered glecaprevir, the second of two antiviral protease inhibitors discovered and developed through its collaboration with AbbVie, Inc. ("AbbVie") for the treatment of acute or chronic infection with hepatitis C virus, or HCV. Glecaprevir is co-formulated as part of AbbVie's leading brand of direct-acting antiviral combination treatment for HCV, which has been marketed under the tradenames MAVYRET® (U.S.) and MAVIRET® (ex-U.S.) (glecaprevir/pibrentasvir) since 2017 for the treatment of chronic HCV. MAVYRET®/MAVIRET® were also approved as the first and only treatments for acute HCV infection in the United States and the European Union in June 2025 and June 2026, respectively, as well as several other countries including Canada and Australia.

The Company is subject to many of the risks common to companies in the biotechnology industry, including but not limited to, the uncertainties of research and development, competition from technological innovations of others, dependence on collaborative arrangements, protection of proprietary technology, dependence on key personnel and compliance with government regulation. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approvals, prior to commercialization. These efforts require significant amounts of capital, adequate personnel and infrastructure, and extensive compliance reporting capabilities.

Liquidity

In October 2025, the Company closed an underwritten public offering of its common stock. The Company issued and sold 7,475 shares of its common stock at a public offering price of $10.00 per share. The aggregate net proceeds of the offering were $69,948, after deducting underwriting discounts and commissions and other offering expenses.

In July 2026, the Company entered into an Open Market Sale Agreement℠ with Jefferies LLC ("Jefferies"), as sales agent, under which the Company may offer and sell shares of its common stock, from time to time through Jefferies, under an at-the-market facility for aggregate gross sale proceeds of up to $75.0 million (the "ATM Facility"). As of September 30, 2026, the Company has not issued any shares of common stock under the ATM Facility.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements include those of the Company and its subsidiary, Enanta Pharmaceuticals Security Corporation, after elimination of all intercompany accounts and transactions. The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, management's judgments with respect to its revenue arrangements; liability related to the sale of future royalties; valuation of stock-based awards and the accrual of research and development expenses. Estimates are periodically reviewed in light of changes in circumstances, facts and experience.

Cash Equivalents and Marketable Securities

The Company considers all short-term, highly liquid investments with original maturities of ninety days or less at acquisition date to be cash equivalents. Marketable securities with original maturities of greater than ninety days and remaining maturities of less than one year from the balance sheet date are classified as short-term marketable securities. Marketable securities with remaining maturities of greater than one year from the balance sheet date are classified as long-term marketable securities.

The Company classifies all of its marketable securities as available-for-sale. The Company continually evaluates the credit ratings of its investment portfolio and underlying securities. The Company invests in accordance with its investment policy and invests at the date of purchase in securities with a rating of A3/A- or higher according to Moody's or S&P or A- by Fitch. The cost of securities sold is determined on a specific identification basis and realized gains and losses are included in other income (expense) within the consolidated statements of operations. Any premium or discount arising at purchase is amortized to interest income or accreted to interest expense, respectively, over the life of the underlying security.

The Company reports available-for-sale investments at fair value as of each balance sheet date and records any unrealized gains or losses as a component of stockholders' equity. If the fair value is below the amortized cost of a marketable security, an estimate of expected credit losses is made. The Company's estimate considers issuer specific credit ratings and historical losses as well as current economic conditions and the Company's expectations for future economic conditions. The credit-related impairment amount, if any, is recognized in the consolidated statements of operations. Credit losses are recognized through the use of an allowance for credit losses account in the consolidated balance sheet and subsequent improvements in expected credit losses are recognized as a reversal of an amount in the allowance account. If the Company has the intent to sell the security or it is more likely than not that the Company will be required to sell the security prior to recovery of its amortized cost basis, then the allowance for the credit loss is written-off and the excess of the amortized cost basis of the asset over its fair value is recorded in the consolidated statements of operations. There were no credit losses recorded during the years ended September 30, 2026, 2025, and 2024, and the Company did not have an allowance for credit losses as of September 30, 2026 and 2025.

Restricted Cash

As of September 30, 2026 and 2025, the Company had an outstanding letter of credit collateralized by a money market account totaling $3,360 to the benefit of the landlord of the Company's building lease, which was classified as long-term restricted cash.

Concentration of Credit Risk and of Significant Customers and Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents, short-term marketable securities and accounts receivable. The Company has all cash and investment balances at one accredited financial institution, including cash in amounts that exceed federally insured limits. The Company does not believe it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company has historically generated the majority of its revenue from its collaborative research and license agreements. For the years ended September 30, 2026, 2025, and 2024, the Company's royalty revenue consisted of amounts earned under the Collaborative Development and License Agreement (as amended, the "AbbVie Agreement"), with AbbVie. As of September 30, 2026 and 2025, accounts receivable consisted of amounts due from the Company's principal collaborator.

The Company is completely dependent on third-party manufacturers for product supply for preclinical and clinical research activities. The Company relies and expects to continue to rely exclusively on several manufacturers to supply the Company with its drug supply requirements related to these activities. These research programs would be adversely affected by a significant interruption in the supply from these third-party manufacturers.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. A fair value hierarchy is based on three levels of inputs that are used to measure fair value, of which the first two levels are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices) such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company’s instruments that are carried at fair value are cash equivalents, short-term marketable securities and the Series 1 nonconvertible preferred stock. The carrying values of accounts receivable, prepaid expenses and other current assets, accounts payable, and accrued expenses and other current liabilities approximate their fair value due to the short-term nature of these assets and liabilities.

Accounts Receivable

The Company's receivable relates to the retained portion of HCV royalties under its collaboration agreement with AbbVie. The Company believes that credit risk associated with its collaboration partner is not significant. To estimate the allowance for credit losses, the Company determines the allowance based on ongoing credit evaluation, historical experience, and the aging of such receivables, among other factors. To date, the Company has not had any write-offs and did not have an allowance for credit losses related to its accounts receivable as of September 30, 2026 and 2025.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation expense is recognized using the straight-line method over the following estimated useful lives:

	Estimated Useful Life
Laboratory and office equipment	5 years
Leasehold improvements	Shorter of life of lease or estimated useful life
Purchased software	3 years
Computer equipment	3 years
Furniture	7 years

Expenditures for repairs and maintenance of assets are charged to expense as incurred. Costs of major additions and betterments are capitalized and depreciated on a straight-line basis over their useful lives. Upon retirement or sale, the cost and related accumulated depreciation of assets disposed are removed from the accounts and any resulting gain or loss is included in other income (expense) in the consolidated statements of operations.

Leases

The Company accounts for a contract as a lease when it has the right to control the asset for a period of time while obtaining substantially all of the asset’s economic benefits. The Company determines if an arrangement is a lease or contains an embedded lease at inception. For arrangements that meet the definition of a lease, the Company determines the initial classification and measurement of its right-of-use asset and lease liability at the lease commencement date and thereafter if modified. The lease term includes any renewal options that the Company is reasonably assured to exercise. The present value of lease payments is determined by using the interest rate implicit in the lease, if that rate is readily determinable; otherwise, the Company uses its estimated secured incremental borrowing rate for that lease term. The Company’s policy is to not record leases with an original term of 12 months or less on its consolidated balance sheets and recognizes those lease payments in the consolidated statements of operations on a straight-line basis over the lease term.

In addition to rent, the leases may require the Company to pay additional costs, such as utilities, maintenance and other operating costs, which are generally referred to as non-lease components. The Company has elected to not separate lease and non-lease components. Only the fixed costs for lease components and their associated non-lease components are accounted for as a single lease component and recognized as part of a right-of-use asset and lease liability. Rent expense for operating leases is recognized on a straight-line basis over the reasonably assured lease term based on the total lease payments and is included in operating expense in the consolidated statements of operations.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, primarily property and equipment and right-of-use assets, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value, determined based on discounted cash flows. To date, the Company has not recorded any impairment losses on long-lived assets.

Liability Related to the Sale of Future Royalties

In April 2023, the Company entered into a royalty sale agreement with an affiliate of OMERS, pursuant to which the Company was paid a $200,000 cash purchase price in exchange for 54.5% of the Company's future quarterly royalty payments on net sales of MAVYRET/MAVIRET. The Company recognized the $200,000 received from OMERS as a liability on its consolidated balance sheets because the $200,000 will be paid back to OMERS up to 1.42 times the purchase price and the Company has significant continuing involvement under the AbbVie Agreement. Interest expense for the liability related to the sale of future royalties is recognized using the effective interest rate method over the term of the royalty sale agreement.

The liability related to the sale of future royalties and related interest expense are based on current estimates of future royalties, which the Company determines by using third-party forecasts of MAVYRET/MAVIRET sales. The Company periodically assesses the forecasted sales and to the extent the amount or timing of future estimated royalty payments is materially different than previous estimates, the Company will account for any such change by adjusting the liability related to the sale of future royalties and prospectively recognizing the related non-cash interest expense.

Revenue Recognition

The Company's revenue has been generated primarily through collaborative research and license agreements. The terms of these agreements contain multiple deliverables, which may include (i) licenses, (ii) research and development activities, and (iii) participation in joint research and development steering committees. The terms of these agreements may include nonrefundable upfront license fees, payments for research and development activities, payments based upon the achievement of certain milestones, and royalty payments based on product sales derived from the collaboration.

The Company recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. The Company receives sales-based royalties for which the license is deemed to be the predominant item to which the royalties relate and thus the Company recognizes sales-based royalties as the underlying sales are earned.

Research and Development Costs

Included in research and development costs are wages, stock-based compensation and benefits of employees performing research and development, third-party license fees and other operational costs related to the Company's research and development activities, including facility-related expenses and external costs of outside contractors engaged to conduct both preclinical and clinical studies and manufacture quantities of product for preclinical and clinical studies. The Company expenses the cost of each contract as the work is performed.

Upfront payments and milestone payments made for the licensing of technology are expensed as research and development in the period in which they are incurred. Advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

Research and Development and Pharmaceutical Drug Manufacturing Accruals

The Company has entered into various contracts with third parties to perform research and development and pharmaceutical drug manufacturing. This includes contracts with contract research organizations, clinical manufacturing organizations, testing laboratories, research hospitals and not for profit organizations and other entities to support the Company's research and development activities. When billing terms under these contracts do not coincide with the timing of when the work is performed, the Company is required to make estimates of outstanding obligations to those third parties as of period end. The accrual estimates are based on a number of factors, including the Company's knowledge of the research and development programs and pharmaceutical drug manufacturing activities and associated timelines, invoicing to date, and the provisions in the contract. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are recorded as general and administrative expenses as incurred.

Stock-Based Compensation

The Company measures all stock options and other stock-based awards granted to employees at fair value on the date of grant. The Company uses the Black-Scholes option-pricing model in the valuation of its stock options. The fair value of restricted stock units with service-based and performance-based vesting is based on the fair value of the stock on the date of grant. The Company uses the Monte-Carlo model to calculate the fair value on the date of grant of market-based awards. The fair value of service-based awards is recognized as stock-based compensation expense over the requisite service period, which is generally the vesting period of the respective award. For awards with graded vesting, the straight-line method of expense recognition is applied to all awards with service-only based conditions. The Company uses the graded-vesting method to record the expense of awards with both service-based and performance-based vesting conditions, commencing once achievement of the performance condition becomes probable. The Company classifies stock-based compensation expense in the consolidated statements of operations in the same manner in which the award recipient's payroll costs are classified. The Company accounts for stock-based compensation expense related to forfeitures as the forfeitures occur.

Income Taxes

The Company accounts for income taxes using 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 recognized in the financial statements or in the Company's tax returns. Deferred taxes are determined based on the difference between the financial reporting and tax basis of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in income tax expense.

The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes based upon the weight of available evidence, that it is more likely than not that all or a portion of deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. The realization of deferred tax assets is dependent upon the Company's ability to generate future taxable income during the periods in which those temporary differences become deductible. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

Uncertain tax positions represent tax positions for which reserves have been established. The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more likely than not to be sustained, the tax position is then assessed to determine the amount of benefit to be recognized in the financial statements. The amount that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. Income tax expense includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Net Income (Loss) per Share

Basic net income (loss) per common share is computed by dividing the net income (loss) by the weighted average number of shares of common stock outstanding for the period. Diluted net income (loss) per common share is computed by dividing net income (loss) by the weighted average number of common shares outstanding for the period, including potential dilutive common shares assuming the dilutive effect of outstanding stock options and unvested restricted stock units. For periods in which the Company reported a net loss, diluted net loss per common share is the same as basic net loss per common share, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

The Company reported net losses for each of the years ended September 30, 2026, 2025, and 2024. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect:

	Years Ended September 30,		
	2026	2025	2024
		(in thousands)	
Options to purchase common stock	6,272	5,759	5,184
Unvested rTSRUs	104	93	92
Unvested PSUs	104	93	92
Unvested restricted stock units	278	408	428

Segment Data

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company is a biotechnology company focused on discovering and developing small molecule drugs, with an emphasis on viral infections and immunological diseases. Revenue is generated exclusively from transactions occurring with partners located in the United States, and all assets are held in the United States.

Comprehensive Income (Loss)

Comprehensive income (loss) includes net income (loss) as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders. The Company's only element of other comprehensive income (loss) is unrealized gains and losses on available-for-sale marketable securities, net of tax.

Going Concern

ASU 2014-15, *Presentation of Financial Statements - Going Concern (Subtopic 205-40)* requires the Company to assess its ability to continue as a going concern within one year after the date that the Company's consolidated financial statements are issued and, in certain circumstances, provide additional footnote disclosures. Based on a detailed cash forecast incorporating current research and development activities and related spending plans, the Company believes that its current cash, cash equivalents and marketable securities on hand at September 30, 2026 will enable it to fund its operating expenses and capital expenditure requirements for at least the next twelve months beyond the date of issuance of these consolidated financial statements. The amount of capital available will depend on the Company's management of its existing cash, cash equivalents and marketable securities, as well as its retained portion of future HCV royalties. The Company may seek additional funding through equity offerings, non-dilutive financings, collaborations, strategic alliances or licensing agreements. The Company may not be able to obtain sufficient financing on acceptable terms, or at all, and the Company may not be able to enter into collaborations or other arrangements. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. If the Company is unable to obtain funding, the Company could be forced to delay, reduce or eliminate some or all of its research and development programs, product expansion or commercialization efforts, or the Company may be unable to continue operations.

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740)* ("ASU 2023-09"), which requires (i) enhanced disclosures in connection with an entity's effective tax rate reconciliation and (ii) income taxes paid disaggregated by jurisdiction. ASU 2023-09 applies to disclosure requirements only. The Company retrospectively adopted ASU 2023-09 during the fiscal year ended September 30, 2026 and provided the required annual disclosures in its consolidated financial statements for the periods ending September 30, 2026, 2025, and 2024.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-03, *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40)* ("ASU 2024-03"), which requires public entities to provide disaggregated disclosure of income statement expenses. Public entities are required to disaggregate, in a tabular presentation, each relevant expense caption on the face of the consolidated statements of operations such as the following expenses: purchases of inventory, employee compensation, intangible asset amortization, and depreciation. ASU 2024-03 is effective for the Company in the fiscal year beginning October 1, 2027, with early adoption permitted. The Company is currently evaluating the potential impact that ASU 2024-03 may have on its financial statement disclosures.

3. Fair Value of Financial Assets and Liabilities

The following tables present information about the Company's financial assets and liabilities that were subject to fair value measurement on a recurring basis as of September 30, 2026 and 2025 and indicate the fair value hierarchy of the valuation inputs utilized to determine such fair value:

	Fair Value Measurements at September 30, 2026 Using:			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
Cash equivalents:				
Money market funds	$ 10,390	$ —	$ —	$ 10,390
Marketable securities:				
U.S. Treasury notes	174,241	—	—	174,241
	184,631	—	—	184,631
Liabilities:				
Series 1 nonconvertible preferred stock	—	—	1,290	1,290
	$ —	$ —	$ 1,290	$ 1,290

	Fair Value Measurements at September 30, 2025 Using:			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
Cash equivalents:				
Money market funds	$ 11,580	$ —	$ —	$ 11,580
Marketable securities:				
U.S. Treasury notes	156,566	—	—	156,566
	168,146	—	—	168,146
Liabilities:				
Series 1 nonconvertible preferred stock	—	—	1,311	1,311
	$ —	$ —	$ 1,311	$ 1,311

Cash equivalents as of September 30, 2026 and 2025 consist of money market funds that are readily convertible to cash with less than 90 days until maturity.

During the years ended September 30, 2026, 2025, and 2024, there were no transfers between Level 1, Level 2 and Level 3.

The fair value of Level 1 instruments are valued using quoted prices in active markets.

The outstanding shares of Series 1 nonconvertible preferred stock as of September 30, 2026 and 2025 are measured at fair value. These outstanding shares are financial instruments that might require a transfer of assets because of the liquidation features in the contract and are therefore recorded as liabilities and measured at fair value. The fair value of the outstanding shares is based on significant inputs not observable in the market, which represent a Level 3 measurement within the fair value hierarchy. The Company utilizes a probability-weighted valuation model, which takes into consideration various outcomes that may require the Company to transfer assets upon liquidation. Changes in the fair values of the Series 1 nonconvertible preferred stock are recognized in other income (expense) in the consolidated statements of operations.

The recurring Level 3 fair value measurements of the Company's outstanding Series 1 nonconvertible preferred stock using probability-weighted discounted cash flow include the following significant unobservable inputs:

Series 1 nonconvertible preferred stock	Range September 30,	
Unobservable Input	**2026**	**2025**
Probabilities of payout	0%-65%	0%-65%
Discount rate	8.00%	8.25%

The following table provides a rollforward of the aggregate fair value of the Company's outstanding Series 1 nonconvertible preferred stock for which fair value is determined by Level 3 inputs:

	Series 1 Nonconvertible Preferred Stock
	(in thousands)
Balance, September 30, 2023	$ 1,423
Change in fair value	(73)
Balance, September 30, 2024	1,350
Change in fair value	(39)
Balance, September 30, 2025	1,311
Change in fair value	(21)
Balance, September 30, 2026	$ 1,290

In April 2023, the Company entered into a royalty sale agreement with an affiliate of OMERS, pursuant to which the Company was paid a $200,000 cash purchase price in exchange for 54.5% of future quarterly royalty payments on net sales of MAVYRET/MAVIRET, after June 30, 2023, through June 30, 2032, subject to a cap on aggregate payments equal to 1.42 times the purchase price. The Company accounted for the upfront payment as a liability related to the sale of future royalties. The carrying value of the liability related to the sale of future royalties approximates fair value as of September 30, 2026 and 2025 and is based on current estimates of future royalties expected to be paid to OMERS over the remaining term, which are considered Level 3 inputs.

4. Marketable Securities

As of September 30, 2026 and 2025, the fair value of available-for-sale marketable securities, by type of security, was as follows:

	September 30, 2026				
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Credit Losses	Fair Value
	(in thousands)				
U.S. Treasury notes	$ 174,840	$ —	$ (599)	$ —	$ 174,241
	$ 174,840	$ —	$ (599)	$ —	$ 174,241

	September 30, 2025				
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Credit Losses	Fair Value
	(in thousands)				
U.S. Treasury notes	$ 156,521	$ 47	$ (2)	$ —	$ 156,566
	$ 156,521	$ 47	$ (2)	$ —	$ 156,566

As of September 30, 2026 and 2025 marketable securities consisted of investments that mature within one year.

5. Property and Equipment, Net

Property and equipment, net consisted of the following as of September 30, 2026 and 2025:

	September 30,	
	2026	2025
	(in thousands)	
Leasehold improvements	$ 38,214	$ 38,200
Laboratory and office equipment	16,236	16,092
Furniture	3,404	3,404
Computer equipment	889	889
Purchased software	615	615
Construction in progress	79	—
	59,437	59,200
Less: Accumulated depreciation and amortization	(28,579)	(23,805)
	$ 30,858	$ 35,395

Depreciation and amortization expense for property and equipment, was $4,782, $4,586 and $2,336 for the years ended September 30, 2026, 2025, and 2024, respectively.

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following as of September 30, 2026 and 2025:

	September 30,	
	2026	2025
	(in thousands)	
Accrued payroll and related expenses	$ 7,373	$ 6,469
Accrued research and development expenses	4,412	1,800
Accrued pharmaceutical drug manufacturing	1,722	2,691
Accrued professional fees	950	1,386
Accrued other	228	405
	$ 14,685	$ 12,751

7. Collaboration Agreements

AbbVie Collaboration

Under the AbbVie Agreement to identify, develop and commercialize HCV NS3 and NS3/4A protease inhibitor compounds, including paritaprevir and glecaprevir, the Company has received license payments, proceeds from a sale of preferred stock, research funding payments, milestone payments and royalties totaling approximately $1,379,000 through September 30, 2026. Since the Company satisfied all of its performance obligations under the AbbVie Agreement by the end of fiscal 2011, all milestone payments received since then have been recognized as revenue when the milestones were achieved by AbbVie.

The Company is receiving annually tiered royalties per Company protease product ranging from ten percent up to twenty percent, or on a blended basis from ten percent up to the high teens, on the portion of AbbVie's calendar year net sales of each HCV regimen that is allocated to the protease inhibitor in the regimen. Beginning with each January 1, the cumulative net sales of a given royalty-bearing protease inhibitor product start at zero for purposes of calculating the tiered royalties on a product-by-product basis. The following table details the royalty tiers associated with cumulative calendar year net sales allocated to each royalty-bearing product as provided in the AbbVie Agreement:

Calendar Year Net Sales (in thousands)	Royalty Tier (%)
up to $500,000	10%
from $500,000 up to $750,000	12%
from $750,000 up to $1,000,000	14%
from $1,000,000 up to $2,500,000	17%
greater than or equal to $2,500,000	20%

Royalties owed to the Company under the agreement can be reduced by AbbVie in certain circumstances, including (i) if AbbVie exercises its right to license or otherwise acquire rights to intellectual property controlled by a third party where a product could not be legally developed or commercialized in a country without the third-party intellectual property right, (ii) where a product developed under the collaboration agreement is sold in a country and not covered by a valid patent claim in such country, and (iii) where sales of a generic product are equal to at least a specified percentage of AbbVie's market share of its product in a country.

AbbVie's obligation to pay royalties on a product developed under the agreement expires on a country-by-country basis upon the later of (i) the date of expiration of the last of the licensed patents with a valid claim covering the product in the applicable country, or (ii) ten years after the first commercial sale of the product in the applicable country.

Subject to certain exceptions, a party's rights and obligations under the agreement continue until (i) such time as AbbVie is no longer developing a product candidate or (ii) if, as of the time AbbVie is no longer developing any product candidates, AbbVie is commercializing any other protease inhibitor product, such time as all royalty terms for all covered products have ended. Accordingly, the final expiration date of the agreement is currently indeterminable.

Either party may terminate the agreement for cause in the event of a material breach, subject to prior notice and the opportunity to cure, or in the event of the other party's bankruptcy. Additionally, AbbVie may terminate the agreement for any reason upon specified prior notice.

If the Company terminates the agreement for cause or AbbVie terminates without cause, any licenses and other rights granted to AbbVie will terminate and AbbVie will be deemed to have granted the Company (i) a non-exclusive, perpetual, fully-paid, worldwide, royalty-free license, with the right to sublicense, under AbbVie's intellectual property used in any product candidate, and (ii) an exclusive (even as to AbbVie), perpetual, fully-paid, worldwide, royalty-free license, with the right to sublicense, under AbbVie's interest in any joint intellectual property rights to develop product candidates resulting from covered compounds and to commercialize any products derived from such compounds. Upon the Company's request, AbbVie will also transfer to the Company all right, title and interest in any related product trademarks, regulatory filings and clinical trials.

If AbbVie terminates the agreement for the Company's uncured breach, the milestone and royalty payments payable by AbbVie may be reduced, the licenses granted to AbbVie will remain in place, the Company will be deemed to have granted AbbVie an exclusive license under the Company's interest in joint intellectual property, AbbVie will continue to have the right to commercialize any covered products, and all rights and licenses granted to the Company by AbbVie will terminate.

8. Liability Related to the Sale of Future Royalties

In April 2023, the Company entered into a royalty sale agreement with an affiliate of OMERS, pursuant to which the Company was paid a $200,000 cash purchase price in exchange for 54.5% of future quarterly royalty payments on net sales of MAVYRET/MAVIRET, after June 30, 2023, through June 30, 2032, subject to a cap on aggregate payments equal to 1.42 times the purchase price.

Because the royalty sale agreement will be paid back to OMERS up to a capped amount as well as the Company's significant continuing involvement in the generation of future cash flows under its AbbVie Agreement, the Company recorded the proceeds from the transaction as a liability on its consolidated balance sheets which will be amortized as interest expense in the consolidated statements of operations under the effective interest rate method over the life of the royalty sale agreement. The Company will continue to record the full amount of royalties earned on MAVYRET/MAVIRET sales as royalty revenue in the consolidated statements of operations.

The Company's liability related to the sale of future royalties is estimated based on forecasted worldwide MAVYRET/MAVIRET royalties to be paid to OMERS over the course of the royalty sale agreement. This estimate requires significant judgment, including the amount and timing of royalty payments up until the end of the royalty sale agreement, which is estimated to be the stated term of June 30, 2032. As royalties are earned by OMERS, the liability is reduced on the Company's consolidated balance sheets.

At September 30, 2026, the estimated future cash flows resulted in an effective annual imputed interest rate of approximately 11.22%.

The following table summarizes the activity of the liability related to the sale of future royalties:

	Liability related to the sale of future royalties (in thousands)
Balance - September 30, 2023	$ 194,505
Royalty payable to royalty purchaser	(7,960)
Payments on royalty sale liability	(28,916)
Interest expense, including capitalized interest of $672	11,612
Balance - September 30, 2024	$ 169,241
Royalty payable to purchaser	(8,243)
Payments on royalty sale liability	(27,356)
Interest expense, including capitalized interest of $520	8,200
Balance - September 30, 2025	$ 141,842
Royalty payable to purchaser	(7,014)
Payments on royalty sale liability	(27,297)
Interest expense, including capitalized interest of $0	14,074
Balance - September 30, 2026	$ 121,605

9. Stockholders' Equity

The Company is authorized to issue 100,000 shares of common stock at a par value of $0.01 per share. Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive such dividends as may be declared by the board of directors, if any.

The Company also is authorized to issue 5,000 shares of preferred stock at a par value of $0.01 per share, of which 2,000 shares are designated as Series 1 Nonconvertible preferred stock and 3,000 shares are undesignated and unissued.

In October 2025, the Company closed an underwritten public offering of its common stock. The Company issued and sold 7,475 shares of its common stock at a public offering price of $10.00 per share. The aggregate net proceeds of the offering were $69,948, after deducting underwriting discounts and commissions and other offering expenses.

In July 2026, the Company entered into an Open Market Sale Agreement℠ with Jefferies LLC ("Jefferies"), as sales agent, under which the Company may offer and sell shares of its common stock, from time to time through Jefferies, under an at-the-market facility for aggregate gross sale proceeds of up to $75.0 million (the "ATM Facility"). As of September 30, 2026, the Company has not issued any shares of common stock under the ATM Facility.

10. Series 1 Nonconvertible Preferred Stock

The Company's Certificate of Incorporation authorized the issuance of up to 2,000 shares of Series 1 nonconvertible preferred stock at a par value of $0.01 per share. Holders of Series 1 nonconvertible preferred stock are not entitled to receive dividends. In the event of any liquidation, deemed liquidation, dissolution or winding up of the Company, the Series 1 nonconvertible preferred stockholders are entitled to receive in preference to all other stockholders, an amount equal to $1.00 per share, adjusted for any stock dividends, stock splits or reclassifications. Series 1 nonconvertible preferred stockholders are not entitled to vote unless required by the Company pursuant to the laws of the State of Delaware. The Company may redeem the Series 1 nonconvertible preferred stock with the approval of the holders of a majority of the outstanding shares of Series 1 nonconvertible preferred stock at a redemption price of $1.00 per share. The Company must redeem the stock within 60 days of such election. Shares that are redeemed will be retired or canceled and not reissued by the Company. As these shares qualify as a derivative, they are classified as a liability on the Company's consolidated balance sheet.

As of September 30, 2026 and 2025, 1,930 shares of Series 1 nonconvertible preferred stock were issued and outstanding. For the years ended September 30, 2026, 2025, and 2024, the remeasurement of the Series 1 nonconvertible preferred stock resulted in a non-cash gain of $21, $39, and $73, respectively, which was recorded in other income (expense) in the consolidated statements of operations. The total fair value of the Series 1 nonconvertible preferred stock was $1,290 and $1,311 as of September 30, 2026 and 2025, respectively.

11. Stock-Based Awards

The Company grants stock-based awards, including stock options, restricted stock units and other unit awards under its 2019 Equity Incentive Plan (the "2019 Plan"), which was approved by its stockholders on February 28, 2019 and amended in March 2021, March 2022, March 2023, March 2024, December 2024, March 2025, and March 2026 and its 2024 Inducement Stock Incentive Plan ("2024 Inducement Plan"). The Company also has outstanding stock option awards under its 2012 Equity Incentive Plan (the "2012 Plan") but is no longer granting awards under this plan. The Company's 2019 Plan permits the Company to sell or issue awards of common stock or restricted common stock or to grant awards of incentive stock options or nonqualified stock options for the purchase of common stock, restricted stock units, performance units, stock appreciation rights or other cash incentive awards, to employees, members of the board of directors and consultants of the Company. The number of shares of common stock that may be issued under the 2019 Plan is subject to increase by the number of shares forfeited under any options forfeited and not exercised under the 2019 Plan or any predecessor plans such as the 2012 Plan. Pursuant to the Company's 2024 Inducement Plan, the Company may grant non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards to persons who (i) were not previously an employee or director of the Company or (ii) are commencing employment with the Company following a bona fide period of non-employment, in either case as an inducement material to the individual's entering into employment with the Company and in accordance with the requirements of Nasdaq Stock Market Rule 5635(c)(4). As of September 30, 2026, 2,861 shares remained available for future awards under the 2019 Plan and 2024 Inducement Plan. Under the Company's Employee Stock Purchase Plan ("ESPP") a total of 186 shares of common stock are reserved for issuance. As of September 30, 2026, the Company had not commenced any offering under the ESPP and no ESPP shares have been issued.

Options granted to employees under the 2019 Plan and the 2024 Inducement Plan generally vest over four years and to non-employee directors over one year and expire after ten years. As required under the equity plans, the exercise price for awards granted is not to be less than the fair value of common shares on the date of grant. Restricted stock units with service-based vesting conditions generally vest over four years.

Stock Option Valuation

The fair value of each stock option award is determined on the date of grant using the Black-Scholes option-pricing model. The volatility has been determined using the Company's traded stock price to estimate expected volatility. The Company utilized historical data to determine the expected term of stock options granted. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The expected dividend yield is zero due to the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future. The relevant data used to determine the value of the stock option awards are as follows, presented on a weighted average basis:

	Years Ended September 30,		
	2026	2025	2024
Risk-free interest rate	3.72%	4.14%	4.45%
Expected term (in years)	6.29	6.22	6.01
Expected volatility	64%	53%	52%
Expected dividends	0%	0%	0%
Weighted average grant date fair value	$ 8.56	$ 4.80	$ 5.43

The following table summarizes stock option activity, including aggregate intrinsic value for the year ended September 30, 2026:

	Shares Issuable Under Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in years	Aggregate Intrinsic Value
	(in thousands)			(in thousands)
Outstanding as of September 30, 2025	5,759	$ 36.31	6.0	$ 6,457
Granted	1,293	13.72		
Exercised	(91)	8.96		
Forfeited	(233)	12.84		
Expired	(456)	43.85		
Outstanding as of September 30, 2026	6,272	$ 32.37	5.8	$ 7,995
Options vested and expected to vest as of September 30, 2026	6,272	$ 32.37	5.8	$ 7,995
Options exercisable as of September 30, 2026	4,520	$ 40.20	4.7	$ 4,819

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the options and the fair value of the Company's common stock. The following tables summarize additional exercise and grant date information:

	Years Ended September 30,		
	2026	2025	2024
		(in thousands)	
Aggregate intrinsic value of stock options exercised	$ 471	$ 17	$ 93
Proceeds to Company from stock options exercised	$ 819	$ 145	$ 147

Market and Performance-Based Stock Unit Awards

The Company awards both performance share units ("PSUs") and relative total stockholder return units ("rTSRUs") to its executive officers.

The PSUs vest and result in issuance, or settlement, of common shares for each recipient, based upon the recipient's continued employment with the Company through the settlement date of the award and the Company's achievement of specified research and development milestones. The requisite service period of the PSUs is generally two years. The fair value of PSUs is based on the fair value of the stock on the date of grant, which is determined to be the closing price of the Company's common stock. Stock-based compensation expense for PSUs is recorded in the statements of operations over the service period, commencing when it is probable that the specified research and development milestone is achieved.

The rTSRUs vest and result in the issuance of common stock based upon the recipient's continuing employment with the Company through the settlement date of the award and the relative ranking of the total stockholder return, or TSR, of the Company's common stock in relation to the TSR of the component companies in the Nasdaq Biotech Index over two specified periods that are two years apart, based on a comparison of average closing stock prices in specified periods noted in the award agreement. The number of market-based rTSRUs awarded represents the target number of shares of common stock that may be earned; however, the actual number of shares that may be earned ranges from 0% to 150% of the target number, depending on the award agreement and the year of the award. The Company used a Monte Carlo model to estimate the grant-date fair value of the rTSRUs. Stock-based compensation expense for rTSRUs is recorded in the statements of operations over the service period regardless of whether the market condition is achieved.

Assumptions and estimates utilized in the calculation of the fair value of the rTSRUs include the risk-free interest rate, dividend yield, expected volatility based on the historical volatility of publicly traded peer companies and the remaining performance period of the award. The table below sets forth the weighted average grant date fair value assumptions used to value the rTSRUs:

	Years Ended September 30,		
	2026	2025	2024
Risk-free interest rate	3.45%	3.94%	4.40%
Dividend yield	0%	0%	0%
Expected volatility	71%	70%	74%
Performance period (years)	2.03	1.83	2.00

The following table summarizes PSU and rTSRU activity (at target) for the year ended September 30, 2026:

	PSUs		rTSRUs	
	Shares	Weighted Average Grant Date Fair Value per Share	Shares	Weighted Average Grant Date Fair Value per Share
	(in thousands, except per share data)			
Unvested at September 30, 2025	93	$ 8.47	93	$ 9.57
Granted	58	15.39	58	18.33
Vested	(14)	9.59	(44)	10.56
Cancelled	(33)	9.58	(3)	10.38
Unvested at September 30, 2026	104	$ 11.83	104	$ 14.01

The total fair value of PSUs and rTSRUs vested during the years ended September 30, 2026, 2025, and 2024 were $824, $396, and $307, respectively.

Restricted Stock Units

The following table summarizes the restricted stock unit activity for the year ending September 30, 2026:

	Restricted Stock Units	Weighted Average Grant Date Fair Value per Share
	(in thousands, except per share data)	
Unvested at September 30, 2025	408	$ 24.15
Granted	182	13.70
Vested	(161)	34.04
Cancelled	(151)	14.03
Unvested at September 30, 2026	278	$ 17.15

The total fair value of restricted stock units vested during the years ended September 30, 2026, 2025, and 2024 were $2,265, $1,290, and $1,228, respectively.

Stock-Based Compensation Expense

The Company recorded the following stock-based compensation expense for the years ended September 30, 2026, 2025, and 2024:

	Years Ended September 30,		
	2026	2025	2024
		(in thousands)	
Research and development	$ 5,768	$ 6,306	$ 7,389
General and administrative	8,258	12,259	19,406
	$ 14,026	$ 18,565	$ 26,795

	Years Ended September 30,		
	2026	2025	2024
		(in thousands)	
Stock options	$ 9,715	$ 11,860	$ 15,342
Restricted stock units	3,285	5,224	6,123
rTSRUs	650	667	1,243
PSUs	376	814	4,087
	$ 14,026	$ 18,565	$ 26,795

As of September 30, 2026, the Company had an aggregate of $14,832 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 2.3 years.

12. Leases

The Company has two real estate leases for properties located in Watertown, Massachusetts. The first lease is for office and laboratory space at 4 Kingsbury Avenue and the second lease is for office space located at 400 Talcott Avenue.

Lease payments for the Company's real estate leases include fixed lease payments that escalate over the terms of the leases and require the Company to pay certain operating expenses based on actual costs incurred. Operating expenses that are not fixed in nature are expensed in the period incurred and included in variable lease costs. The leases do not include any restrictions or covenants that had to be accounted for under the lease guidance.

In May 2022, the Company entered into its lease agreement for 4 Kingsbury Avenue with its existing landlord, adjacent to its 400 Talcott Avenue premises. Construction of the facility shell was completed by the landlord and the Company gained access to the building to construct tenant improvements in 2024. The estimated minimum lease payments for the 4 Kingsbury Avenue facility total $76,470 over the ten-year term. The lease also contained a tenant improvement allowance of $15,205, which was fully received as of September 30, 2026. The Company recorded a right-of-use asset of $32,499 and lease liability of $31,939 upon commencement of the lease during the year ended September 30, 2024. The Company moved its lab operations into the newly constructed 4 Kingsbury Avenue facility in November 2024.

During the years ended September 30, 2025 and 2024, the Company leased units of equipment over an eighteen-month lease period commencing upon shipment of each unit. The lease agreements contained options to terminate the leases early or to extend the leases for successive six-month periods, however these options were not included in the right-of-use assets and lease liability as they were not reasonably certain of being exercised. The equipment leases required the Company to pay for certain consumable and peripheral equipment supplies based on actual costs incurred. As these costs are not fixed in nature, they were expensed in the period incurred and included in variable lease costs.

The components of lease expense for the Company's real estate and equipment leases were as follows:

	Years Ended September 30,		
	2026	2025	2024
		(in thousands)	
Operating lease cost	$ 7,138	$ 9,572	$ 10,574
Variable lease cost	4,144	6,044	4,720
	$ 11,282	$ 15,616	$ 15,294

Supplemental disclosure of cash flow information related to the Company's operating leases included in cash flows used in operating activities in the consolidated statements of cash flows were as follows:

	Years Ended September 30,		
	2026	2025	2024
		(in thousands)	
Cash paid for amounts included in the measurement of operating lease liabilities	$ 8,467	$ 9,856	$ 8,283
Tenant improvement allowance received	$ 330	$ 5,881	$ 9,358
Operating lease liabilities arising from obtaining right-of-use assets	$ —	$ 1,199	$ 23,960

The weighted-average remaining lease term and discount rate were as follows:

	September 30,	
	2026	2025
Weighted-average remaining lease term - operating leases (in years)	8.0	9.0
Weighted-average discount rate - operating leases	8.8%	8.8%

As the Company's leases do not provide an implicit rate, the Company utilized its incremental borrowing rate based on information available at the lease commencement date, which represents an internally developed rate that would be incurred to borrow, on a collateralized basis, over a similar term, an amount equal to the lease payments in a similar economic environment.

Future annual minimum lease payments relating to the Company's lease liabilities as of September 30, 2026 were as follows:

Years ended September 30,	(in thousands)
2027	$ 8,721
2028	8,983
2029	9,252
2030	9,530
2031	9,816
Thereafter	31,249
Total future minimum lease payments	77,551
Less: imputed interest	(22,794)
Less: tenant improvement allowance	—
Total operating lease liabilities	$ 54,757

The Company is required to maintain security deposits of $92 in connection with the real estate lease of 400 Talcott Avenue, which is included in other long-term assets on the Company's consolidated balance sheets. In addition, the Company is required to maintain a letter of credit in connection with the real estate lease of 4 Kingsbury Avenue, collateralized by money market accounts of $3,360, which amounts are classified as long-term restricted cash on the consolidated balance sheets.

13. Commitments and Contingencies

Litigation and Contingencies Related to Use of Intellectual Property

From time to time, the Company may become subject to legal proceedings, claims and litigation arising in the ordinary course of business. Except as described below, the Company currently is not a party to any threatened or pending litigation. However, third parties might allege that the Company or its collaborators are infringing their patent rights or that the Company is otherwise violating their intellectual property rights. Such third parties may resort to litigation against the Company or its collaborators, which the Company has agreed to indemnify. With respect to some of these patents, the Company expects that it will be required to obtain licenses and could be required to pay license fees or royalties, or both. These licenses may not be available on acceptable terms, or at all. A costly license, or inability to obtain a necessary license, would have a material adverse effect on the Company's financial condition, results of operations or cash flows. The Company accrues contingent liabilities when it is probable that future expenditures will be made, and such expenditures can be reasonably estimated.

In June 2022, the Company announced that it filed suit in the United States District Court for the District of Massachusetts on June 21, 2022 against Pfizer Inc. seeking damages for infringement of U.S. Patent No. 11,358,953 (the "'953 Patent") in the manufacture, use, and sale of Pfizer's COVID-19 antiviral, Paxlovid™ (nirmatrelvir tablets; ritonavir tablets). The United States Patent and Trademark Office awarded the '953 Patent to the Company in June 2022 based on the Company's July 2020 patent application describing coronavirus protease inhibitors invented by the Company. In December 2024, the District Court issued a summary judgment decision ruling that the asserted claims of the '953 Patent were invalid. The Company filed a notice of appeal with the United States Court of Appeals for the Federal Circuit and, in June 2026, the Federal Circuit affirmed the decision of the District Court and ruled that the claims of the '953 Patent were invalid. In July 2026, the Company filed a combined petition for panel or en banc rehearing of the Federal Circuit's decision, which was denied in September 2026.

In the European litigation, the Company filed a patent infringement action in the Unified Patent Court (the "UPC") of the European Union against Pfizer Inc. and certain of its subsidiaries in August 2025. The suit sought a determination of liability for infringement of European Patent No. EP 4 051 265 (the "'265 Patent") in connection with Pfizer's manufacture, use, and sale of Paxlovid™ (nirmatrelvir tablets; ritonavir tablets) in the 18 EU member states participating in the UPC. The '265 Patent is the European counterpart to the '953 Patent. A hearing on the infringement action and counterclaim for revocation was held on September 29, 2026 and, on October 29, 2026, the UPC released its decision concluding that the '265 Patent is invalid. The UPC also determined that the infringement action was unfounded in light of its decision on validity. In May 2026, Pfizer also filed an opposition against the '265 Patent with the European Patent Office (the "EPO"). The EPO has set a hearing date in April 2027. All decisions remain subject to potential rights of appeal and other customary proceedings.

The Company records all legal expenses associated with the patent infringement suit as incurred in the consolidated statements of operations.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnifications of varying scope and terms to customers, vendors, lessors, business partners, and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from services to be provided to the Company, or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and its executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. In addition, the Company maintains directors' and officers' insurance coverage. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and has not accrued any liabilities related to such obligations in its consolidated financial statements as of September 30, 2026 and 2025.

14. Income Taxes

Income before income taxes for all periods presented is from domestic operations, which are the Company's only operations. During the years ended September 30, 2026, 2025, and 2024, the Company recorded income tax benefit (expense) as follows:

	Years Ended September 30,		
	2026	2025	2024
		(in thousands)	
Current income tax (expense) benefit:			
Federal	$ —	$ 1,772	$ 1,936
State	(40)	(112)	(193)
Deferred income tax (expense) benefit:			
Federal	—	—	—
State	—	—	—
Income tax (expense) benefit	$ (40)	$ 1,660	$ 1,743

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective tax rate is as follows:

	Years Ended September 30,					
	2026		2025		2024	
	Amount	Percent	Amount	Percent	Amount	Percent
	(in thousands, except percentages)					
U.S. federal statutory income tax rate	$ 14,324	(21.0) %	$ 17,545	(21.0) %	$ 24,736	(21.0) %
State and local income taxes, net of federal income tax effect	(262)	0.4	(88)	0.1	(37)	—
Tax credits						
Research and development tax credits	3,069	(4.5)	4,135	(4.9)	2,611	(2.2)
Changes in valuation allowance	(15,939)	23.4	(14,407)	17.2	(20,961)	17.8
Nontaxable or nondeductible items						
Stock-based compensation	(1,169)	1.7	(7,031)	8.4	(5,880)	5.0
Other	(46)	0.1	(63)	0.1	(70)	0.1
Changes in unrecognized tax benefits	(12)	—	(12)	—	(6)	—
Interest on net operating loss carryback claim	—	—	1,594	(1.9)	1,450	(1.3)
Other adjustments	(5)	—	(13)	—	(100)	0.1
Effective income tax rate	$ (40)	0.1 %	$ 1,660	(2.0) %	$ 1,743	(1.5) %

The effective tax rates during the years ended September 30, 2026 and 2025 differ from the U.S. federal statutory rate primarily due to the full valuation allowance maintained on the Company's net deferred tax assets. The state and local income tax component of the effective tax rate reconciliation was primarily attributable to Massachusetts.

Changes in the valuation allowance for deferred tax assets during the years ended September 30, 2026, 2025, and 2024 are as follows:

	Years Ended September 30,		
	2026	2025	2024
		(in thousands)	
Valuation allowance, beginning of year	$ (142,233)	$ (127,244)	$ (115,120)
Increase recorded to valuation allowance	(17,272)	(14,989)	(12,124)
Valuation allowance, end of year	$ (159,505)	$ (142,233)	$ (127,244)

Net deferred tax assets as of September 30, 2026 and 2025 consisted of the following:

	September 30,	
	2026	2025
	(in thousands)	
Deferred tax assets:		
Capitalized research and development	$ 47,919	$ 58,675
Liability related to the sale of future royalties	25,537	29,787
Tax credit carryforwards	28,122	24,196
Share-based compensation	12,112	12,911
Operating lease liability	11,499	12,229
Net operating loss carryforward	43,971	14,782
Accrued compensation	925	1,209
Accrued expenses	114	288
Other temporary differences	124	140
Total deferred tax assets	170,323	154,217
Valuation allowance	(159,505)	(142,233)
Net deferred tax assets	10,818	11,984
Deferred tax liabilities:		
Operating lease, right-of-use assets	(7,402)	(7,885)
Depreciation	(3,389)	(3,920)
Prepaid expenses	(152)	(170)
Unrealized loss (gain)	125	(9)
Total deferred tax liabilities	(10,818)	(11,984)
Net deferred income tax assets (liabilities)	$ —	$ —

As of September 30, 2026, the Company had federal net operating loss carryforwards of $196,293, which do not expire, and state net operating loss carryforwards of $43,550, which may be available to offset future taxable income and expire at various dates beginning in 2032. As of September 30, 2026, the Company also had federal and state research and development tax credit carryforwards of $21,111 and $9,053, respectively, which may be available to reduce future tax liabilities and expire at various dates beginning in 2042 and 2035, respectively.

Utilization of the federal and state net operating loss carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, and corresponding provisions of state law, due to ownership changes that may have occurred previously or that could occur in the future. These ownership changes may limit the amount of net operating loss and research and development tax credit carryforwards that can be utilized annually to offset future tax liabilities. In general, an ownership change, as defined by Section 382, results from transactions that increase the ownership of 5% stockholders in the stock of a corporation by more than 50% in the aggregate over a three-year period. The Company completed a review of the changes in ownership through September 30, 2022 and determined that the transactions have not resulted in an ownership change during the year ended September 30, 2022, as defined by Section 382. The impact of historical ownership changes has been reflected within the Company's deferred tax assets shown in the table above. Although the Company believes that these ownership changes have not resulted in material limitations on its ability to use these net operating losses and credit carryforwards, its ability to utilize these and future net operating losses and credit carryforwards may be limited due to future ownership changes or for other reasons. As a result, the Company may not be able to take full advantage of its carryforwards for U.S. federal and state tax purposes.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets, which are comprised primarily of capitalized research and development costs, net operating loss carryforwards and research and development tax credit carryforwards. The Company considers it more likely than not that it will not have sufficient taxable income in the future that will allow it to realize all of its existing deferred tax assets. This is due to the fact the Company continues to progress its wholly-owned research and development programs and its declining royalty revenues from the AbbVie Agreement. As a result, the Company continued to record a valuation allowance as of September 30, 2026 against its deferred tax assets to reduce a portion of the Company’s deferred tax assets for which the Company does not believe it is more likely than not these will be realized.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. The Company's tax years in the U.S. are still open under statute from 2022 to the present. Earlier years may be examined to the extent that tax credit or net operating loss carryforwards are used in future periods. During the year ended September 30, 2024, the Company received notice of examination by the Internal Revenue Service ("IRS") for the years ending September 30, 2018 and September 30, 2019. The Company received and agreed to a notice of proposed adjustment from the IRS in October 2024, resulting in an additional refund of $871 related to the year ended September 30, 2019. The Company has not received notice of examination by any other jurisdictions for any other tax year open under statute.

Uncertain tax positions represent tax positions for which reserves have been established. The Company's policy is to record interest and penalties related to uncertain tax positions as part of income tax expense. Total interest related to uncertain tax positions recorded as a liability on the Company's consolidated balance sheets were $41 and $26 as of September 30, 2026 and 2025, respectively. A reconciliation of the beginning and ending amount of uncertain tax positions is summarized as follows:

	September 30,	
	2026	2025
	(in thousands)	
Beginning Balance	$ 892	$ 905
Additions based on tax positions for the current period	—	—
Reductions for tax positions due to lapse of statute of limitations	(10)	(13)
Additions (reductions) for tax positions of prior periods	—	—
Ending Balance	$ 882	$ 892

The Company does not expect that its uncertain tax position will materially change within the next twelve months.

On July 4, 2025, the U.S. government enacted the One Big Beautiful Bill Act, which includes several changes to U.S. federal income tax law, including the temporary and permanent extension of expiring provisions of the Tax Cuts and Jobs Act of 2017, such as 100% bonus depreciation and immediate expensing of domestic research and development costs. The new legislation has multiple effective dates, with certain provisions effective in 2025 and others in the future. The Company determined that the tax provisions of the legislation do not have a material impact on its 2026 and 2025 consolidated financial statements and continues to assess the impact on future years.

15. 401(k) Plan

The Company has a 401(k) plan. This plan covers substantially all employees who meet minimum age and service requirements. During the years ended September 30, 2026, 2025, and 2024, the Company recognized $1,569, $1,684, and $1,697, respectively, of expense related to its contributions to this plan.

16. Segment Information

The Company manages its operations as a single operating segment for the purposes of assessing performance and making operating decisions. The Company's singular focus is on discovering and developing small molecule drugs with an emphasis on viral infections and immunological diseases. The Company's Chief Operating Decision Maker ("CODM") is the Company's Chief Executive Officer. The CODM reviews consolidated operating results and utilizes net loss from the Statement of Operations against budget forecasts as the primary measure of segment profit or loss in making decisions surrounding allocating resources and assessing performance of the Company. The CODM is regularly provided detailed expense information, including expenses by expense category and program. The CODM makes decisions surrounding capital and personnel allocation using this information on a consolidated basis. Certain prior year program amounts have been reclassified for consistency with the current year presentation provided to the CODM. Asset information on a reportable segment basis is not disclosed as this information is not separately identified and internally reported to the Company's CODM. The CODM is regularly provided information on total cash, which is inclusive of cash, cash equivalents and marketable securities, as a measure of segment assets. As of September 30, 2026, the Company's cash, cash equivalents and marketable securities were $194,513.

The following table presents selected financial information with respect to the Company's single operating segment for the years ended September 30, 2026, 2025, and 2024 (in thousands):

	Years Ended September 30,		
	2026	2025	2024
Revenue			
Royalty revenue	$ 63,001	$ 65,324	$ 67,635
Total revenue	63,001	65,324	67,635
Operating expenses:			
RSV	25,898	59,808	86,367
Total virology	25,898	59,808	86,367
KIT	17,067	18,052	19,822
STAT6	25,543	16,614	4,691
MRGPRX2	12,393	9,114	6,525
Total immunology	55,003	43,780	31,038
Early discovery	6,869	2,214	8,471
Other pipeline programs	776	938	5,600
Total other programs	7,645	3,152	14,071
General and administrative	36,835	43,933	57,850
Total operating expenses	125,381	150,673	189,326
Loss from operations	(62,380)	(85,349)	(121,691)
Other income (expense):			
Interest expense	(14,074)	(7,681)	(10,940)
Interest and investment income, net	8,225	9,442	14,770
Change in fair value of Series 1 nonconvertible preferred stock	21	39	73
Total other income (expense), net	(5,828)	1,800	3,903
Loss before income taxes	(68,208)	(83,549)	(117,788)
Income tax benefit (expense)	(40)	1,660	1,743
Net loss	$ (68,248)	$ (81,889)	$ (116,045)

Exhibit 21.1

Enanta Pharmaceuticals, Inc.

Subsidiaries of the Company

NAME	PARENT	STATE OR COUNTRY OF INCORPORATION
Enanta Pharmaceuticals Security Corporation	Enanta Pharmaceuticals, Inc.	Massachusetts

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-293390) and Form S-8 (Nos. 333-189217, 333-192935, 333-202257, 333-209542, 333-215011, 333-221988, 333-231375, 333-231384, 333-255957, 333-264794, 333-273800, 333-279217, 333-287274, and 333-295821) of Enanta Pharmaceuticals, Inc. of our report dated November 18, 2026 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
November 18, 2026

Exhibit 31.1

Certification Pursuant to Section 240.13a-14 or 240.15d-14
of the Securities Exchange Act of 1934, as amended

I, Jay R. Luly, certify that:

1. I have reviewed this annual report on Form 10-K of Enanta Pharmaceuticals, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: November 18, 2026

/s/ Jay R. Luly, Ph.D.
Jay R. Luly, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification Pursuant to Section 240.13a-14 or 240.15d-14
of the Securities Exchange Act of 1934, as amended

I, Harry R. Trout III, certify that:

1. I have reviewed this annual report on Form 10-K of Enanta Pharmaceuticals, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: November 18, 2026

/s/ Harry R. Trout III, MBA
Harry R. Trout III, MBA
Vice President, Finance
(Principal Financial Officer)

Exhibit 32.1

Certification of Periodic Financial Report
Pursuant to 18 U.S.C. Section 1350
as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Each of the undersigned officers of Enanta Pharmaceuticals, Inc. (the "Company") certifies, to his knowledge and solely for the purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report on Form 10-K of the Company for the year ended September 30, 2026 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 18, 2026

/s/ Jay R. Luly, Ph.D.
Jay R. Luly, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Dated: November 18, 2026

/s/ Harry R. Trout III, MBA
Harry R. Trout III, MBA
Vice President, Finance
(Principal Financial Officer)