

Risk Factors Comparison 2024-11-27 to 2023-11-22 Form: 10-K

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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 prosecuting our patent infringement suit 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, ~~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. 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. 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 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, RSV and immunology diseases, including CSU and AD, as well as SARS-CoV-2 and HBV assets 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 HCV, RSV, SARS-CoV-2 and 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 COVID-19 and HBV, 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, Pfizer / ReViral (acquired in June 2022) and Shionogi Merck all have compounds in clinical development. Synagis, a There are several prophylactic prophylaxis options on, monoclonal antibody-based treatment from AstraZeneca, which is commercialized by AbbVie outside the market U.S., is approved for or in development infants considered at high risk for RSV infection; however, studies have found that most young children with RSV infection were previously healthy, and thus would not normally be prescribed prophylactic treatment. AstraZeneca / Sanofi (BEYFORTUS®) and Merck (Clesrovimab – Phase 3 complete) are developing long-acting versions of the monoclonal antibody antibodies for prophylaxis use in infants. In addition, a number and Pfizer has an approved maternal vaccine (ABRYSVO®), all of companies have which provide passive immunity to infants. Sanofi is also evaluating a vaccine in infants and toddlers (RSVt vaccine – Phase 3). There are also two approved RSV vaccines for adults over 60 years in development, primarily directed at prevention of age (Pfizer / ABRYSVO® and Moderna / Mresvia®) and one approved RSV infection, and some companies are also evaluating vaccines vaccine in a therapeutic mode for treatment adults over 50 years of established RSV infection age (GSK / AREXVY®). Currently For CSU, there are a number two Emergency Use Authorizations of oral antiviral treatments for non-different mechanisms being explored, including inhibitors of IL-6 hospitalized 4R, high IgE, BTK, SIGLEC-6 risk patients with SARS-CoV-2 infection: PAXLOVID™, a 3CL protease and MRGPRX2. Specifically for KIT inhibitor inhibitors (nirmatrelvir) boosted with ritonavir, and LAGEVRIO™ (molnupiravir), a polymerase inhibitor. Additionally, there are companies with antibodies in developing development, including Celldex (barzolvolimab oral direct acting antivirals for SARS-CoV-2 that are currently in global Phase 3) studies include Shionogi, Atea, and Gilead Jasper (an oral formulation of remdesivir briquillimab- Phase 1b / 2a), as well as additional compounds companies with oral, small molecules in early clinical or preclinical development, including Third Harmonic, Blueprint, Arcus, and Alivexis. For AD, the moderate-severe atopic dermatitis treatment landscape is dominated by biologics targeting the IL-4 and / or IL-13 pathway (e. g., DUPIXENT® (dupilumab) and ADBRY® (tralokinumab-ldrm)), with JAK inhibitors (e. g., RINVOQ® (upadacitinib) and CIBINQO® (abrocitinib)) as the only oral option. Multiple oral mechanisms are in development, including inhibitors of MRGPRX2, IRAK4, STAT6, RASP and PKM2. The latest stage oral assets are in Ph2 (Incyte MRGPRX2 – Ph2a; Sanofi / Kymera IRAK4 – Ph2). For STAT6 inhibitors specifically, companies with oral assets in development include Kymera (KT-621 – Phase 1) studies. While there are antiviral medications prescribed for HBV that can suppress HBV DNA, they generally have low cure rates, resulting in the need for lifelong treatment. Many companies are seeking to develop new HBV drugs that alone or in combination with other mechanisms could lead to a functional cure for HBV. Vir, GSK, Arbutus, and Sanofi / Recludix (Roche have multiple combination regimens under investigation in later stage clinical preclinical) studies. In addition, a number of companies have Phase 1 or earlier stage HBV programs. In the chronic 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 faces competition in various world markets and subpopulations of HCV from 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 specified sofosbuvir treatment failures and NS5A-inhibitor treatment failures) and Harvoni® (a fixed-dose combination of sofosbuvir and ledipasvir); and to a lesser extent 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, the state of Louisiana selected Asegua as their HCV subscription model pharmaceutical partner to provide the state with unrestricted access to its direct-acting antiviral medication. 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. g., Gilead and Asegua Therapeutics), 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). There are no oral direct acting antivirals for the treatment of SARS- CoV- 2 in late stage global clinical trials. While there are antiviral medications prescribed for HBV that can suppress HBV DNA, they generally have low cure rates, resulting in the need for lifelong treatment. Many companies are seeking to develop new HBV drugs that alone or in combination with other mechanisms could lead to a functional cure for HBV. Vir, GSK, Arbutus, and Roche have multiple combination regimens under investigation in later stage clinical studies. In addition, a number of companies have Phase 1 or earlier stage HBV programs**. 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 independent RSV ~~and HBV~~ 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 developing **zelicapavir or EDP- 938, EDP- 323**, **or discovering and developing KIT and STAT6 inhibitors**, or in obtaining a partner to advance **EDP- 235 or EDP- 514**, 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, 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, Yat Sun Or, Ph. D., our Senior Vice President, Research and Development and Chief Scientific Officer, and Scott T. Rottinghaus, M. D., our Senior Vice President and Chief Medical Officer ~~whom we hired in August 2022~~, as well as other employees and consultants. Although none of Drs. Luly, Or, or Rottinghaus has informed us to date that he 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. 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, has yet to advance beyond Phase 2 clinical trials. Any ongoing or future clinical trials of our product candidates may fail to demonstrate sufficient safety and efficacy. Moreover, regulatory and administrative delays, including those caused by the COVID-19 pandemic, 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 and on the incidence of other viruses on the incidence of (e.g., RSV), and the political and socio-economic stability affecting our clinical trial sites generally;
- 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, COVID-19 or HBV infection;
- 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. 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-938 or EDP-323, 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 progressed beyond a Phase 2 clinical trial, 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 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 tested our product candidates through initial Phase 2 studies. 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 are not necessarily indicative of results in other ethnic groups. 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. 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. 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 ~~products~~ **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. 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 will be the timelines or regulatory processes required 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 Affordability 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 recently rejected the latest 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, which, 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 to be selected **in August** by ~~September 1,~~ 2023, and the first year of maximum price applicability to begin in calendar year 2026. The Act 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

Act 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. 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-938 and 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 products 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, **we plan to out our continued development of EDP-235 license our FXR agonist candidates for combination therapy for NASH and EDP-514 are dependent on establishing collaborations seeking potential partners for this program.** 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 takes 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 proposed 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, ~~pandemics~~ **pandemic** or other ~~causes~~ **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 the Wuhan region of 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, which are not located in the Wuhan region, 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, 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 recently proposed BIOSECURE Act that was passed by the U. S. House of Representatives in September 2024, as well as a substantially similar bill in the U. S. Senate, target U. S. government contracts, grants, and loans for entities that use equipment and services from certain named Chinese biotech companies, and authorize the U. S. government to name additional Chinese biotechnology companies of concern. If these bills become law, or similar laws are passed, they would have 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 ~~will~~ 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 ~~will~~ 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 ~~will~~ 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. In the case of **zelicapavir EDP-938**, we paused recruitment and dosing as a result of the COVID- 19 pandemic in March 2020, but we were able to resume the studies in July 2020. The pause in these studies, as well as the absence of RSV in the population generally, delayed enrollment of these studies, and it is uncertain whether any of our other ongoing studies may be subject to further disruptions. 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 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. In addition, 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. ~~For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue.~~ 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. ~~The same could occur~~, **as has been asserted by Pfizer** in our patent infringement suit ~~recently brought against Pfizer~~ regarding Paxlovid, ~~its Pfizer's~~ **antiviral treatment for COVID- 19**, ~~even though our '953 patent at issue does not cover EDP- 235~~. In patent litigation in the United States and in some 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, we would lose at least part, and perhaps all, of the patent protection on a product candidate. If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, other than in litigation like the Pfizer case, **which does 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. Any efforts to enforce our intellectual property rights are also likely to be costly~~, as **has been and may well continue to** be the case with the Pfizer suit, 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 from the owner and 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 antiviral product candidates and our NASH compounds. 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 allegedly~~ **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 ~~in the amount of \$ 15.0 million in the aggregate~~ and during the COVID-19 pandemic. 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 and during the COVID-19 pandemic 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 **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, **2018-2019** through September 30, **2023-2024**, the daily closing price of our common stock on the NASDAQ Global Select Market has ranged from \$ **11-8. 09-18** to \$ **105-97. 66-37**. 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, **2023-2024** we had **21. 1-2** million shares of common stock outstanding. In addition, as of September 30, **2023-2024**, we had **4-5. 4-2** million and 0. 6 million shares of common stock that are subject to outstanding options and restricted stock unit awards, 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. 2-4 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. As of March 31, 2024, we qualified as a “smaller reporting company,” as defined in the 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 ~~failure to maintain effective internal control as a result of shutdowns during the global COVID-19 pandemic could result in deficiencies in internal control. 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.