Risk Factors Comparison 2024-02-29 to 2023-03-01 Form: 10-K

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This Annual Report on Form 10- K contains forward- looking information based on our current expectations. Because our actual results may differ materially from any forward- looking statements that we make or that are made on our behalf, this section includes a discussion of important factors that could affect our actual future results, including, but not limited to, our ability to successfully commercialize VASCEPA and VAZKEPA, collectively referred to as VASCEPA, our capital resources, the progress and timing of our clinical programs, the safety and efficacy of our product candidates, risks associated with regulatory filings, the potential clinical benefits and market potential of our product candidates, commercial market estimates, future development efforts, patent protection, effects of healthcare reform, reliance on third parties, effects of tax reform, and other risks set forth below. Summary Risk Factors Our business is subject to numerous risks and uncertainties that you should be aware of in evaluating our business. These risks include, but are not limited to, the following: • We are substantially dependent upon VASCEPA **®** (icosapent ethyl), its commercialization in the United States and its development, launch and commercialization in Europe and other major markets. • In the United States, we **compete with, and may** face increasing competition from **,** generic drug companies **,** ~~in the near term~~ and our revenues and results ~~of operations~~ could continue to be materially and adversely affected. • In Europe, we are seeking relevant pricing approvals in various countries; however, we may not be successful in obtaining such approvals in a timely manner **,** or at all **,** and even if successfully obtained, we may not be successful in commercializing VAZKEPA in Europe **. • The commercial value of VASCEPA outside the United States may be smaller than we anticipate, particularly if we are unable to secure favorable product pricing and reimbursement levels, which vary from country to country. If we are unable to realize product reimbursement rates at reasonable price levels, or at all, patient access to VASCEPA may be limited** . • Factors outside of our control make it more difficult for VASCEPA to achieve a level of market acceptance by physicians, patients, healthcare payors and others in the medical community at levels sufficient to achieve commercial success. • Our ~~recent cost reduction and organizational~~ **Organizational** ~~restructuring~~ **Restructuring** ~~plans~~ **Program** , **or ORP, effected in July 2023** and any similar efforts we may undertake in the future, may not be successful in mitigating risks and challenges associated with our ~~Company' s~~ U. S. business and establishing a more significant international footprint. • The manufacture, supply and commercialization, including promotional activities, of VASCEPA is subject to regulatory scrutiny. • We may not be able to compete effectively against our competitors ~~' '~~ pharmaceutical product, including generic products. In addition, we face competition from omega- 3 fatty acids that are marketed by other companies as non- prescription dietary supplements, subjecting us to non- prescription competition and consumer substitution. • ~~The commercial value of VASCEPA outside the United States may be smaller than we anticipate, including if we are unable to secure favorable product reimbursement levels, which can vary from country to country. If we are unable to realize product reimbursement rates at reasonable levels, or at all, patient access to VASCEPA may be limited. •~~ Our supply of product for the commercial market and clinical trials is dependent upon relationships with third- party manufacturers and suppliers, including manufacturers and suppliers who may require us to comply with burdensome minimum purchase commitments, which may be greater than our supply needs. • Our dependence on third parties in the distribution channel from our manufacturers to patients subject us to risks that limit our profitability and could limit our ability to supply VASCEPA to large market segments. • We have limited experience commercializing VASCEPA outside the United States, and we may not be successful in building an infrastructure, including a sales force, that can navigate the regulatory and other dynamics outside of the United States. We are currently, and may continue to be, substantially dependent on third parties for our international efforts, and we may not be successful in negotiating or establishing relationships with business partners to support and maintain control over our international activities. • We are dependent on patents, proprietary rights and confidentiality obligations of our employees, agents, business partners and third parties to protect the commercial value and potential of VASCEPA. ~~•~~ Enforcing our patent rights is challenging and costly and, even if we are able to successfully enforce our patent rights, our issued patents may not prevent competitors from competing with VASCEPA. • We have pending patent applications relating to VASCEPA and its use. There can be no assurance that any of these applications will issue patents, and even if patent protection is obtained, it may be insufficient to minimize competition or support our commercialization efforts **. • Our efforts to return capital to our shareholders and increase shareholder value, including our share repurchase program (which is subject to shareholder and UK court approval), may not be implemented in a timely manner or at all, or may not have the expected results. • If we are unable to meet the listing requirements of the NASDAQ Stock Market, our stock may be delisted** . The summary risk factors described above should be read together with the text of the full risk factors below and in the other information set forth in this Annual Report on Form 10- K, including our consolidated financial statements and the related notes, as well as in other documents that we file with the SEC. If any such risks and uncertainties actually occur, our business, prospects, financial condition and results of operations could be materially and adversely affected. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not currently known to us, or that we currently deem to be immaterial may also materially adversely affect our business, prospects, financial condition and results of operations. Risks Related to the Commercialization and Development of VASCEPA We **are substantially dependent upon VASCEPA (icosapent ethyl), its commercialization in the United States and its development, launch and commercialization in Europe and other major markets. We** currently derive substantially all of our revenue from sales of VASCEPA. We may be substantially dependent on sales of VASCEPA for many years. Our financial condition and the success of our company will be materially adversely affected, we may have to further restructure our current operations, and our business prospects will be

limited , if we experience any negative developments relating to VASCEPA. In ~~For example, in~~ the first quarter of 2020, the U. S. District Court for the District of Nevada issued a ruling in favor of two generic drug companies, Dr. Reddy' s Laboratories, Inc., or Dr. Reddy' s, and Hikma Pharmaceuticals USA Inc., or Hikma, and certain of their affiliates, that declared as invalid several patents of ours protecting the first U. S. FDA- approved use of our drug, to reduce severely high triglyceride levels, or the MARINE indication , or the ANDA litigation . We were unsuccessful in our appeals and our stock price was adversely and materially impacted by the ruling, the results of the appeals process and the introduction of generic competition. If other proprietary rights protecting VASCEPA or its use are challenged, our stock price could further decline, particularly if such challenges, which are costly to defend, are successful. Although we are exploring ways to broaden our development and commercial pipeline, such efforts are likely to be time consuming, costly and may utilize resources that could otherwise be focused on commercializing VASCEPA. It ~~For example, it~~ took over a decade of preceding product development before we received marketing approval for VAZKEPA in March 2021 from the European Commission, or the EC. Likewise, if we seek to diversify our development programs or product offerings through licensing or acquisitions, such transactions are also time - consuming, may be dilutive to existing shareholdings, and may be initially disruptive to operations. These transactions may not be available on favorable terms, or at all. These dynamics can restrict our ability to respond rapidly to adverse business conditions for VASCEPA. If development of, or demand for, VASCEPA does not meet expectations, we may not have the ability to effectively shift our resources to the development of alternative products, or do so in a timely manner, without suffering material adverse effects on our business. As a result, the lack of alternative markets and products we develop could constrain our ability to generate revenues and achieve profitability. **In the United States, we compete with, and may face increasing competition from, generic drug companies and our revenues and results of operations could continue to be materially and adversely affected.** Following the ~~patent~~ ANDA litigation rulings against ~~us~~ the Company , generic versions of VASCEPA began launching in the United States in November 2020, and several generic versions are currently available , including for both the 0. 5- gram and 1- gram capsules, and we expect that VASCEPA could face more competition from generic companies in the United States. Increasing sales of generic versions of VASCEPA could continue to have a material and adverse impact on our revenues and results of operations in the United States. Generally, once a generic version of a drug is available in the market, the generic version is typically used ~~in many~~ by pharmacies across the U. S. ~~states~~ to fill ~~a prescription~~ prescriptions for any use of the drug, subject to state substitution laws. Although, we intend to vigorously defend our intellectual property rights related to VASCEPA, there can be no assurance that we will be successful in preventing use of generic versions of VASCEPA in indications for which they have not been approved by the U. S. FDA, even if such use is determined to infringe certain of our patent claims. Given the changing dynamic in the U. S. market, in 2022 we initiated cost and organizational restructuring plans which reduced our U. S. commercial team from approximately 300 sales representatives to approximately 75 sales representatives by the end of 2022 , and in July 2023 all remaining sales force positions in the U. S. were eliminated and our overall headcount was reduced by 30 % as part of our ORP . Although ~~this streamlining has~~ these initiatives are expected to ~~resulted~~ -- result in an improved expense structure, such efforts could impact employee morale and make hiring and retaining talented personnel more challenging, may not result in all of the cost -savings or other benefits we anticipate , and are costly to implement . Furthermore, such efforts may reduce our ability to expand use of VASCEPA. In Europe, we are seeking relevant pricing approvals in various countries; however, we may not be successful in obtaining such approvals in a timely manner or at all and even if successfully obtained, we may not be successful in commercializing VAZKEPA in Europe . We continue our development efforts to support commercialization of VASCEPA in major markets outside the United States, particularly in light of the level of competition, including from generic products, in the United States , and as part of our ORP, we redesigned our commercial infrastructure in Europe . This process is conducted on a country- by- country basis and is time -consuming and complex, and, even though the EC approved the marketing authorization for VAZKEPA in March 2021, and we have received positive national pricing and reimbursement decisions in various countries ~~England and Wales, Sweden and Finland~~ , there is no guarantee that we will be able to negotiate and obtain further reimbursement and pricing terms on favorable terms, or at all, in the other countries where we are pursuing commercialization. Further, successful progress or pricing terms in one country may not be indicative of our outcomes in other jurisdictions. For example, although the UK' s National Institute for Health and Care Excellence, or NICE, announced final guidance for reimbursement for VAZKEPA ® and use across the National Health Service, or NHS, in England and Wales, we decided to discontinue business operations in Germany following the conclusion of negotiations with the National Association of Statutory Health Insurance Funds during which a viable agreement on the reimbursement price of VAZKEPA could not be reached. The Arbitration Board process concluded without an agreement in November 2022 and although we plan to resubmit a pricing and reimbursement dossier with new data in Germany ~~once we have a new dossier ready~~ , we may be unable to resume commercial operations in Germany. We may not be successful in obtaining additional approvals in a timely manner with acceptable terms, or in additional countries , and if we are unable to do so, and continue to face increased competition in the United States, our financial position could be materially and adversely impacted. We have been developing VAZKEPA on our own in Europe, where we have limited experience. We are exploring possible strategic collaborations in smaller markets within Europe and in other major markets, which will increase our reliance on third parties, over whom we have limited control. We currently have multiple partners for the development and commercialization of VASCEPA in select geographies and are assessing potential partners to commercialize VASCEPA in other parts of the world. We ~~For example, we~~ have strategic collaborations for the development and commercialization of VASCEPA in Canada, the Middle East ~~and~~ , Australia, New Zealand, Greater China , South Korea and many markets in Southeast Asia, and Israel . However, we cannot make any guarantees as to the success of these efforts or that our beliefs about the value potential are accurate, or that we will be able to rely upon these third parties; if commercialization plans for VASCEPA do not meet expectations in major markets such as the United States and Europe, our business and prospects could be materially and adversely affected. **The commercial value of**

VASCEPA outside the United States may be smaller than we anticipate, including if we are unable to secure favorable product pricing and reimbursement levels, which vary from country to country. If we are unable to realize product reimbursement rates at reasonable price levels, or at all, patient access to VASCEPA may be limited. There can be no assurance as to the market for VASCEPA outside the United States ~~. For example~~ , **and we may face challenges in successfully achieving market opportunities available to us.** ~~despite~~ **Despite** having received EC approval to commercialize VAZKEPA in Europe and ~~through our partner, Edding, marketing~~ approval **elsewhere around the world** ~~for VASCEPA in Hong Kong as well as we expect to obtain through Edding, marketing approval for VASCEPA in Mainland China, Macau and Taiwan~~ , applicable regulatory agencies may impose restrictions on the product' s conditions for use, distribution or marketing **,** and in some cases may impose ongoing requirements for post- market surveillance, post- approval studies or clinical trials **, any of which could limit the market opportunity, or our ability to capitalize on such opportunity, for VASCEPA** . Further, securing adequate reimbursement is critical for commercial success of any therapeutic **,** and pricing and reimbursement levels of medications in markets outside the United States can be unpredictable and vary considerably on a country- by- country basis. In some foreign countries, including major markets in Europe, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with individual governmental authorities can take six to 12 months or longer after the receipt of regulatory marketing approval for a product, and ~~is~~ **these negotiations are** not always successful. ~~For example, after~~ **After** the conclusion of negotiations with the National Association of Statutory Health Insurance Funds, a viable agreement on the reimbursement price of VAZKEPA in Germany could not be reached. As a result of the negotiation outcome, we discontinued our German operations as of September 1, 2022. In November 2022 **,** the Arbitration Board process concluded without an agreement **and although we plan to resubmit a pricing and reimbursement dossier with new data in Germany, we may be unable to resume commercial operations in Germany** . Further, in ~~certain European~~ countries **outside the U. S.** , securing product reimbursement is a requisite to commercial launch. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a pharmacoeconomic study that compares the cost ~~–~~ effectiveness of VASCEPA to other available therapies. Such pharmacoeconomic studies can be costly and the results uncertain. The time required to secure reimbursement tends to vary from country to country and cannot be reliably predicted at this time. Our business could be harmed if reimbursement of our products is unavailable, delayed or limited in scope or amount or if pricing is set at unsatisfactory levels. If the pricing and reimbursement levels of VASCEPA are lower than we anticipate, then affordability of, and market access to, VASCEPA may be adversely affected and thus market potential in these territories would suffer. We **,** or our partners **,** may even choose to not proceed with marketing VASCEPA in a market, even after obtaining all necessary regulatory approval, due to negative commercial dynamics. Further, with regard to any indications for which we may gain approval in territories outside the United States, the number of actual patients with the condition included in such approved indication may be smaller than we anticipate. In addition, we could face competition from products similar or deemed equivalent to VASCEPA in various jurisdictions through regulatory pathways that are more lenient than in the United States or in jurisdictions in which we do not have exclusivity from regulations or intellectual property. If any of these market dynamics exist, the commercial potential in these territories for our product would suffer. We have limited experience as a company in commercializing VASCEPA outside of the United States and may be unsuccessful in developing sales internationally. We may be unsuccessful in expanding our global footprint. **We** ~~For example, we~~ are launching VAZKEPA on our own in the most commercially significant markets in Europe **, and have redesigned our commercial infrastructure in Europe** . The commercial launch of a new pharmaceutical product is a complex and resource heavy undertaking for a company to manage and **may** be impacted by decisions by and interactions with local regulators **. We** ~~, and we~~ have no prior experience as a company operating a commercial- stage pharmaceutical business in Europe. **As** ~~For example, and as~~ noted above, a viable agreement on the reimbursement price of VAZKEPA in Germany could not be reached with German regulators and we have discontinued our Germany business operations. Given the amount of time and resources, including capital, needed to support regulatory and commercial efforts aimed at international expansion, if we are unsuccessful or delayed in generating revenues overseas, our results of operations could be materially and adversely impacted. Factors that could inhibit our efforts to successfully commercialize VASCEPA include: • the impact of the expiration of regulatory exclusivities and entry into the market of additional generic versions of VASCEPA; • our inability to attract and retain adequate numbers of effective sales and marketing personnel **and senior management** , particularly in light of our recent reductions in force **, including our ORP announced in July 2023, and turnover on the management team** ; • our inability to adequately train our sales and marketing personnel and our inability to adequately monitor compliance with applicable regulatory and other legal requirements; • ~~if we have overestimated the addressable market; •~~ the inability ~~of our sales personnel~~ to obtain access to or persuade adequate numbers of physicians to prescribe or patients to use **VASCEPA; • overestimating the addressable market for** VASCEPA; • regulators may impose restrictions on VASCEPA' s conditions for use, distribution or marketing, and may impose ongoing requirements for post- market surveillance, post- approval studies or clinical trials, which may be costly or result in label or other use restrictions; • complexities and challenges in connection with pricing and reimbursement, including our ability to secure adequate reimbursement coverage, which in Europe is almost exclusively covered through public national funding, and not individual private insurance companies; • 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; • an inability by us or our partners to obtain regulatory and marketing approval or establish marketing channels in foreign jurisdictions; **and** • unforeseen costs and expenses associated with operating a new independent sales and marketing organization **outside** ~~; and • the continued or resumed impact from COVID- 19 on healthcare providers, patients and personnel which may vary considerably from jurisdiction to jurisdiction, as well as on local restrictions and practices, including the complexities~~ of ~~having to understand and navigate multiple and evolving sets of protocols and~~ the **United States** ~~accessibility and rates of vaccinations in various geographies~~ . If we experience one or more of the setbacks described above, we may not be able to pursue international

regulatory and commercial efforts in a cost effective manner, or at all, which could cause our stock price to decline. Our ability to generate meaningful revenues outside of the United States may be limited, including due to the strict price controls and reimbursement limitations imposed by payors outside of the United States. Our ability to generate meaningful revenues of VASCEPA outside of the United States is dependent on the availability and extent of coverage and reimbursement from third-party payors. In many markets around the world, these payors, including government health systems, private health insurers and other organizations, remain focused on reducing the cost of healthcare, and their efforts have intensified as a result of rising healthcare costs and economic challenges. Drugs remain heavily scrutinized for cost containment. As a result, payors are becoming more restrictive regarding the use of biopharmaceutical products and scrutinizing the prices of these products while requiring a higher level of clinical evidence to support the benefits such products bring to patients and the broader healthcare system. These pressures are intensified where our products are subject to competition, including from ~~biosimilars~~ **generics. Refer to " Item 1. Business- Government Regulation – Pharmaceutical Pricing and Reimbursement " for further details** . In many countries outside the United States, government- sponsored healthcare systems are the primary payors for drugs. With increasing budgetary constraints and differing views on or challenges in valuing medicines, governments and payors in many countries are applying a variety of measures to exert downward price pressure. These measures can include mandatory price controls, price referencing, therapeutic- reference pricing, increases in mandates, incentives for generic substitution and biosimilar usage and government- mandated price cuts. In this regard, many countries have health technology assessment organizations that use formal economic metrics such as cost ~~–~~effectiveness to determine prices, coverage and reimbursement of new therapies; and these organizations are expanding in established and emerging markets. Many countries also limit coverage to populations narrower than the regulatory agency approved product label or impose volume caps to limit utilization. We expect that countries will continue to take aggressive actions to seek to reduce expenditures on drugs. Similarly, fiscal constraints may also affect the extent to which countries are willing to approve new and innovative therapies and / or allow access to new technologies. The dynamics and developments discussed above serve to create pressure on the pricing and potential usage of ~~our~~ products ~~and~~ **throughout** the **pharmaceutical** industry **, including VASCEPA** . Given the diverse interests in play among payors, biopharmaceutical manufacturers, policy makers, healthcare providers and independent organizations, if and whether the parties involved can achieve alignment on the matters discussed above remains unclear and the outcome of any such alignment is difficult to predict. If reimbursement of VASCEPA is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to successfully commercialize VASCEPA outside of the United States may be harmed, which could have a material and negative impact on our overall business. Government and commercial payor actions outside of the United States have affected and will continue to affect access to and sales of our products Outside of the United States, we expect countries will continue to take actions to reduce their drug expenditures. International reference pricing, or IRP, has been widely used by many countries outside ~~of~~ the United States to control costs based on an external benchmark of a product' s price in other countries. IRP policies can change quickly and frequently and may not reflect differences in the burden of disease, indications, market structures, or affordability differences across countries or regions. In addition, countries may refuse to reimburse or may restrict the reimbursed population for a product when their national health technology assessments do not consider a medicine to demonstrate sufficient clinical benefit beyond existing therapies or to meet certain cost effectiveness thresholds. Some countries also allow additional rebates or discounts to be negotiated. The outcome of such negotiations can be uncertain and could become publicly disclosed in the future. Some countries decide on reimbursement between potentially competing products through national or regional tenders that often result in one product receiving most or all of the sales in that country or region. Thus, there can be no certainty that we will negotiate satisfactory reimbursement or pricing rates in markets outside of the United States in a timely manner, or at all, or even if we are successful in obtaining satisfactory coverage and reimbursement, we may be unsuccessful in sustaining such coverage and reimbursement, or could face challenges as to the timeliness or certainty of payment by payors to physicians and other providers, which would have a material and adverse impact on our commercialization efforts outside of the United States. We as an organization have limited experience in navigating the pricing and reimbursement regimes ~~,~~outside of the United States ~~, which~~ **. The** foreign regimes are varied and complex, ~~which~~ **and this** might hinder our effectiveness in establishing satisfactory pricing, coverage and reimbursement levels in a timely manner or at all. Factors outside of our control may make it more difficult for VASCEPA to achieve market acceptance by physicians, patients, healthcare payors and others in the medical community at levels sufficient to achieve commercial success. **We** ~~In January 2013, we launched VASCEPA based on the U. S. FDA approval of our MARINE indication, for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe (TG > 500 mg / dL) hypertriglyceridemia. Guidelines for the management of very high triglyceride levels suggest that the primary goal of reducing triglyceride levels in this patient population is reduction in the risk of acute pancreatitis. A secondary goal for this patient population is to reduce cardiovascular risk. The effect of VASCEPA on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined and our U. S. FDA- approved labeling and promotional efforts state this fact. In December 2019, the U. S. FDA approved another indication and label expansion for VASCEPA as an adjunct to statin therapy to reduce the risk of MACE events in adult patients with elevated TG levels (≥ 150 mg / dL) and established cardiovascular disease or diabetes mellitus and two or more additional risk factors for cardiovascular disease, or our REDUCE- IT indication. Despite U. S. FDA approval for this indication and expanded label for VASCEPA, we~~ may ~~not meet expectations~~ **be unable to increase** ~~for~~ **or maintain** market acceptance by physicians, patients, healthcare payors and others in the medical community ~~for this approved use~~ , especially in light of generic competition. If VASCEPA does not achieve an adequate level of acceptance, we may not generate product revenues sufficient to become profitable, or, even if we do achieve profitability, we may not be able to generate consistent profitability. The degree of market acceptance of VASCEPA for its approved indications and uses or otherwise will depend on a number of factors, including: • the impact of and outcome of adjudicated, settled and pending patent litigation; • the commercialization and pricing of any current or potential generic versions of VASCEPA; • the perceived

efficacy and safety of VASCEPA by prescribing healthcare professionals and patients, as compared to no treatment and as compared to alternative treatments in various at- risk patient populations; • the prevalence and severity of any side effects and warnings in VASCEPA' s approved labeling internationally; • peer review of different elements of data supporting our REDUCE- IT indication over time; • continued review and analysis of the results of our clinical data supporting our REDUCE- IT indication by regulatory authorities internationally; • our ability to offer VASCEPA for sale at competitive prices; • convenience and ease of administration compared to alternative treatments; • the willingness of the target patient population to try ~~new~~ **our** therapies and of physicians to prescribe these therapies; • the scope, effectiveness and strength of product education, marketing and distribution support, including our sales and marketing teams; • publicity concerning VASCEPA or competing products; • our ability to continually promote VASCEPA in the United States consistent with ~~and outside of~~ U. S. FDA- approved labeling and the related perception thereof; • sufficient third- party coverage or reimbursement for VASCEPA and its prescribed uses, on- label and off- label; • natural disasters, ~~including~~ pandemics ~~such as the COVID- 19 pandemic~~, international conflicts ~~,~~ and political unrest **, all of** which could **negatively impact our supply chain or** inhibit our ability to promote VASCEPA regionally and which could negatively affect product demand by creating obstacles for patients to seek treatment and fill prescriptions; • new policies or laws affecting VASCEPA sales, such as state and federal efforts to affect drug pricing and provide or remove healthcare coverage that includes reimbursement for prescription drugs; and • the actual and perceived efficacy of the product and the prevalence and severity of any side effects and warnings in VASCEPA' s approved labeling internationally. Any one or more of the above factors could have a negative impact on our ability to successfully commercialize VASCEPA, which would in turn have a negative impact on our financial condition. Additional data or related interpretations that are generated or arise over time related to REDUCE- IT might not meet expectations, and the perception of REDUCE- IT results and VASCEPA revenue potential may suffer and our stock price may decline. ~~While the U. S. FDA approved the expanded label for VASCEPA for the REDUCE- IT indication in 2019, additional~~ **Additional** data assessment by international regulatory authorities or otherwise could yield additional information to inform greater understanding of study outcome, which information could impact the perception of VASCEPA. Such data or interpretations may not be favorable for us. Generally, trial data assessment sufficient to convey a complete picture of trial outcome can take years to complete and publish. When new data are assessed and released or presented it could exceed, match or may not meet investor expectations. In addition, the same set of data can sometimes be interpreted to reach different conclusions, as when Health Canada approved an indication based on our REDUCE- IT trial data that was different in certain respects than that approved by U. S. FDA and by the EC in Europe. It is possible the scope of subsequent regulatory approvals, if any, could likewise differ based on the same data. Conflicting interpretations of data, or new data, could impact public and medical community perception of the totality of the efficacy and safety data from REDUCE- IT. Regulatory authorities and medical guideline committees outside of the United States and Europe may consider the following additional factors, which could lead to evaluations of the totality of the efficacy and safety data from REDUCE- IT that differ from those of the U. S. FDA or the EC: • the magnitude of the treatment benefit and related risks on the primary composite endpoint, its components, secondary endpoints and the primary and secondary risk prevention cohorts; • consideration of which components of the composite or secondary endpoints have the most clinical significance; • the consistency of the primary and secondary outcomes; • the consistency of findings across cohorts and important subgroups; • safety considerations and risk / benefit considerations (such as those related to adverse events, including bleeding and atrial fibrillation generally and in different sub- populations); • consideration of REDUCE- IT results in the context of other clinical studies; • consideration of the cumulative effect of VASCEPA in studied patients; and • study conduct and data quality, integrity and consistency, including aspects such as analyses regarding the placebo used in REDUCE- IT and other studies of VASCEPA and its impact, if any, on the reliability of clinical data. If regulatory authorities and medical guideline committees outside of the United States and Europe draw conclusions that differ from those of the U. S. FDA or the EC, the U. S. FDA or the EC could reevaluate its conclusions as to the safety and efficacy of VASCEPA. Likewise, if additional data or analyses released from time to time do not meet expectations, the perception of REDUCE- IT results and the perceived and actual value of VASCEPA may suffer. In these instances our revenue and business could suffer and our stock price could significantly decline. **Any** ~~Ongoing clinical trials or~~ new clinical data **or analysis of existing data from clinical trials** involving VASCEPA and similar moderate- to- high doses of eicosapentaenoic acid or icosapent ethyl could adversely impact public perception of VASCEPA' s clinical profile and the commercial and regulatory prospects of VASCEPA. ~~Ongoing~~ **Analysis of data from** trials of moderate- to- high doses of VASCEPA and icosapent ethyl, or a similar eicosapentaenoic acid product **,** could render new or adverse information on the effects of VASCEPA and its commercial and regulatory prospects. **The** ~~For example, the~~ Randomized Trial for Evaluation in Secondary Prevention Efficacy of Combination Therapy – Statin and EPA (RESPECT- EPA; UMIN Clinical Trials Registry number, UMIN000012069) is a study examining Japanese patients with chronic coronary artery disease receiving LDL- C lowering treatment by statin therapy. Results from this study were presented during the 2022 American Heart Association Scientific Sessions in November 2022 and were consistent with the evidence from the REDUCE- IT study. In November 2020, we announced statistically significant topline results from a Phase 3 clinical trial of VASCEPA, conducted by our partner in China, Eddingpharm (Asia) Macao Commercial Offshore Limited, or Edding, which investigated VASCEPA as a treatment for patients with very high triglycerides. **China' s National Medical Products Administration, or NMPA, approved VASCEPA as an adjunct to diet to reduce the levels of triglyceride in adult patients suffering from severe hypertriglyceridemia (≥ 500mg / dL) and in October 2023 Edding submitted a regulatory filing to the NMPA which, if approved, would secure National Reimbursement Drug Listing for VASCEPA in Mainland China under the REDUCE- IT indication.** Even though such results from these trials were positive, additional clinical development efforts may be necessary in these markets to demonstrate the effectiveness of VASCEPA, which may be costly to pursue, or may not produce the desired or expected results. If the outcomes of any ~~study~~ **new studies** involving VASCEPA and icosapent ethyl **, or further analysis of existing trial data,** is unfavorable, the perception of existing clinical results of VASCEPA, such

as MARINE or REDUCE- IT, or the perceived clinical profile and commercial value of VASCEPA and its regulatory status, or perceptions about the potential for VASCEPA, including as a treatment for broader indications, may suffer. If this occurs our revenue and business could suffer and our stock price could significantly decline. **Our ORP effected in July 2023 and any similar efforts we may undertake in the future, may not be successful in mitigating risks and challenges associated with our U. S. business and establishing a more significant international footprint.** If we are not successful in our efforts to continue to market and sell VASCEPA in the United States, including following ~~the implementation of~~ our ~~cost reduction~~ **ORP announced in July 2023 which eliminated all remaining sales force positions in the United States, with the managed care** and **trade** ~~organizational --~~ **organization** ~~restructuring plan~~ **remaining to support U. S. commercial efforts, and approximately 30 % of non- sales positions** , our anticipated revenues or our expenses could be materially **adversely** ~~and negatively~~ affected, and we may not maintain profitability in the United States or obtain profitability internationally **. Further** , **we** may need to cut back on research and development activities or we may need to implement other cost- containment measures, or we may need to raise additional funding that could result in substantial dilution or impose considerable restrictions on our business ~~. Our promotional initiatives have had to adjust over the last several years, given the impact of COVID- 19 and international instability, which efforts have been costly and require considerable resources. Shifts from traditional face- to- face interactions to mostly virtual outreach, specifically, access to healthcare professionals through digital or other channels, were not as productive as in- person interactions in promoting use of VASCEPA and we have been pursuing increased face- to- face interactions with targeted health care professionals as protocols have eased and travel has resumed to more stable levels. Such efforts are costly and there can be no assurance that they will result in an increase in VASCEPA prescriptions and sales in the near future, or at all~~ . The Federal Food, Drug, and Cosmetic Act, or FDCA, has been interpreted by the U. S. FDA and the U. S. government to make it illegal for pharmaceutical companies to promote their U. S. FDA- approved products for uses that have not been approved by the U. S. FDA. Companies that market drugs for off- label uses or indications have been subject to related costly litigation, criminal penalties and civil liability under the FDCA and the FCA. However, case law over the last several years has called into question the extent to which the U. S. government, including the U. S. FDA, can, and is willing to seek to, prevent truthful and non- misleading speech related to off- label uses of U. S. FDA- approved products such as VASCEPA. As a result of a lawsuit that we and a group of independent physicians filed against the U. S. FDA in 2015, we were granted preliminary relief through the court' s declaratory judgment that confirmed we may engage in truthful and non- misleading speech promoting the off- label use of VASCEPA to healthcare professionals, i. e., to treat patients with persistently high triglycerides, and that such speech may not form the basis of a misbranding action under the FDCA. The U. S. FDA did not appeal the court' s ruling and ultimately settled this litigation under terms by which the U. S. FDA and the U. S. government agreed to be bound by the conclusions from the federal court order that we may engage in truthful and non- misleading speech promoting the off- label use of VASCEPA and that certain statements and disclosures that we proposed to make to healthcare professionals were truthful and non- misleading. As part of the settlement, given, as expressed in the court' s opinion, that the dynamic nature of science and medicine is that knowledge is ever- advancing and that a statement that is fair and balanced one day may become incomplete or otherwise misleading in the future as new studies are done and new data is acquired, we agreed that we bear the responsibility to ensure that our communications regarding off- label use of VASCEPA remain truthful and non- misleading, consistent with the federal court ruling. While we believe we are now permitted under applicable law to more broadly promote VASCEPA, the U. S. FDA- approved labeling for VASCEPA did not change as a result of this litigation and settlement, and neither government nor other third- party coverage or reimbursement to pay for the off- label use of VASCEPA promoted under the court declaration was required. Promotional activities in the biotechnology and pharmaceutical industries generally are subject to considerable regulatory scrutiny ~~and, may be subject to enhanced scrutiny to ensure that our promotion remains within the scope covered by the settlement~~ . For example, ~~under the settlement,~~ we **were recently the** ~~remain responsible for ensuring our speech is truthful and non- misleading, which is~~ subject **of** ~~to~~ **two** ~~a considerable amount of judgment. We, the U. S. FDA, the U. S. government, our competitors and other interested parties may not agree on the truthfulness and non- misleading nature of our promotional materials. Federal and state governments or agencies may also seek to find other means to prevent our promotion of unapproved truthful and non- misleading information about VASCEPA. In June 2020, we received a~~ civil investigative ~~demand~~ **demands** , or CID, from the U. S. ~~Department of Justice, or the DOJ, informing us that the DOJ is investigating whether aspects of our promotional speaker programs and copayment waiver program during the period from January 1, 2015 to the present violated the U. S. Anti- Kickback Statute and the U. S. Civil False Claims Act, or the FCA, in relation to the sale and marketing of VASCEPA by us and our previous co- marketing partner, Kowa Pharmaceuticals America, Inc., or Kowa America. Similarly, in March 2021, the United States~~ Federal Trade ~~Commission~~ **commission and** ~~, or the FTC, issued~~ a **subpoena from** ~~CID to us in connection with~~ the ~~FTC' s investigation of whether we have engaged in, or are engaging in, anticompetitive practices or unfair methods of competition relating to VASCEPA. The~~ New York ~~State attorney~~ **Attorney** ~~general~~ **General** ~~similarly issued a subpoena to us regarding the same subject matter on which the FTC CID is focused. The inquiries require us to produce documents and answer written questions~~ , or **the Investigations** ~~interrogatories, relevant to specified time periods~~ . Although we are cooperating with the government **and completed document product in mid- 2023** , we cannot predict when these investigations will be resolved, the outcome of the investigations or their potential impact on our business. **In addition** ~~Such investigations can be lengthy~~ , ~~costly and could materially affect and disrupt our business. If the government determines that~~ we **may** ~~have violated the U. S. Anti- Kickback Statute, the FCA or antitrust regulations, we could~~ be subject to ~~significant civil~~ **enhanced scrutiny to ensure that our promotion remains within the scope covered by the settlement. Under the settlement, we remain responsible for ensuring our speech is truthful** and ~~criminal fines~~ **non- misleading, which is subject to a considerable amount of judgment. We, the U. S. FDA, the U. S. government, our competitors** and **other interested** ~~penalties --~~ **parties may not agree on the truthfulness and non- misleading nature of our promotional materials. Federal and state governments or agencies may also seek to find other**

means to prevent our promotion of unapproved truthful and non- misleading information about VASCEPA . If our promotional activities or other operations are found to be in violation of any law or governmental regulation through existing or new interpretations **or as a result of the findings of the Investigations** , we may be subject to prolonged litigation, penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Also, if governmental parties or our competitors view our claims as misleading or false, we could be subject to liability based on fair competition- based statutes, such as the Lanham Act. Any allegations that our promotional activities are not truthful or misleading, even allegations without merit, could cause reputational harm and adversely affect our ability to operate our business and our results of operations. **We may not be able to compete effectively against our competitors' pharmaceutical product, including generic products. In addition, we face competition from omega- 3 fatty acids that are marketed by other companies as non- prescription dietary supplements, subjecting us to non- prescription competition and consumer substitution.** The biotechnology and pharmaceutical industries are highly competitive. There are many pharmaceutical companies, biotechnology companies, public and private universities and research organizations actively engaged in the research and development of products that may be similar to our product. We expect that the number of companies seeking to develop products and therapies similar to VASCEPA ~~will~~ **may** increase. Many of these and other existing or potential competitors may have substantially greater financial, technical and human resources than we do and may be better equipped to develop, manufacture and market products. These companies may develop and introduce products and processes competitive with, more efficient than or superior to ours. In addition, other technologies or products may be developed that have an entirely different approach or means of accomplishing the intended purposes of our products, which might render our technology and products noncompetitive or obsolete. Our competitors include large, well- established pharmaceutical and generic companies, specialty and generic pharmaceutical sales and marketing companies, and specialized cardiovascular treatment companies. With generic versions of VASCEPA launched in the U. S. by companies such as Hikma, Dr. Reddy' s, Apotex and Teva, ~~who~~ **all of which** have greater resources than us, and with the potential for further generic versions being launched **possibly in the near term** , it may not be viable for us to continue to invest in market education to grow the market and our ability to maintain current promotional efforts and attract favorable commercial terms in several aspects of our business will likely be adversely affected as we face increased generic competition, or if we launch our own generic version of VASCEPA. We also face considerable competition in the United States from branded products and generic versions of competing branded products and formulations, including Lovaza ®, Tricor, ® Trilipix ® and Niaspan ®, all of which have multiple generic competing versions. We compete with these drugs ~~,~~ in our U. S. FDA- approved indicated uses, even though such products do not have U. S. FDA approval to reduce CV risk on top of statin therapy. For a more detailed discussion of our competitors, and potential competing drugs in development, in the United States and the rest of the world, see our discussion above in Item 1. Business- Competition. Further, drugs in development that are expected to compete with VASCEPA if they are ultimately approved and commercialized, and the perceived safety and efficacy of such commercialized drugs or drug products, could have a negative impact on the perceived safety and efficacy of VASCEPA. Based on prior communications from the U. S. FDA, including communications in connection with its review of the ANCHOR indication for VASCEPA, it is our understanding that the U. S. FDA is not prepared to approve any therapy for treatment of ~~cardiovascular~~ **CV** risk based on biomarker modification without cardiovascular outcomes study data, with the potential exception of therapies which lower LDL- cholesterol, depending on the circumstances. In particular, it is our understanding that the U. S. FDA is not prepared to approve any therapy based primarily on data demonstrating lowering of triglyceride levels. In our view, this position from the U. S. FDA did not change based on the REDUCE- IT study particularly in light of significant independence of the positive benefit demonstrated in the REDUCE- IT study from triglyceride levels and benefit from the REDUCE- IT study supporting that the positive effects of VASCEPA are unique to VASCEPA and extend beyond triglyceride reduction. If the U. S. FDA were to change this position, it could potentially have a negative impact on us by making it easier for other products to achieve a ~~cardiovascular~~ **CV** risk reduction indication without the need in advance to conduct a long and expensive ~~cardiovascular~~ **CV** outcomes study. VASCEPA also faces competition from dietary supplement manufacturers marketing omega- 3 products as nutritional supplements. Such products are classified as food, not as prescription drugs or over- the- counter drugs, by the U. S. FDA ~~in~~ **and** ~~the~~ **other** ~~United States with similar regulatory~~ **regulators** ~~regimes in Europe and elsewhere~~ . Some of the promoters of such products have greater resources than us and are not restricted to the same standards as are prescription drugs with respect to promotional claims or manufacturing quality, consistency and subsequent product stability. Although we have taken successful legal action against supplement manufacturers attempting to use the REDUCE- IT results to promote their products, we cannot be sure physicians and pharmacists will view the U. S. FDA- approved, prescription- only status, and EPA- only purity and stability of VASCEPA or U. S. FDA' s stringent regulatory oversight, as significant advantages versus omega- 3 dietary supplements regardless of clinical study results and other scientific data. Consistent with the ~~U. S.~~ **competitive landscape in the United States** , our competitors **outside of the United States** include large, well- established and experienced pharmaceutical companies, specialty and generic pharmaceutical companies, marketing companies, and specialized cardiovascular treatment companies and we have ~~no~~ **limited** experience as a company self- commercializing a product outside of the United States. Recent CV outcomes trials and meta- analyses with low and high dose omega- 3 fatty acid mixtures containing DHA have not shown substantial benefit in patients receiving contemporary medical therapy, including statins. Due to failed low dose omega- 3 CV outcomes trials, the European regulatory authorities have concluded that omega- 3 fatty acid medicines (specifically Lovaza ® / Omacor ®) at a dose of 1- gram per day are not effective in preventing further events for patients who have had a heart attack. The STRENGTH trial of an omega- 3 mixture studied at 4- grams per day also failed to demonstrate cardiovascular benefit. As generic ~~company~~ competitors seek to compete with ~~copies of~~ VASCEPA in the United States and elsewhere we could face additional challenges to our patents and additional patent litigation. ~~The FDCA, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, as amended, or the Hatch- Waxman Amendments, permits the U. S. FDA to approve ANDAs for~~

generic versions of brand name drugs like VASCEPA. We refer to the process of generic drug applications as the " ANDA process. " The ANDA process permits competitor companies to obtain marketing approval for a drug product with the same active ingredient, dosage form, strength, route of administration, and labeling as the approved brand name drug, but without having to conduct and submit clinical studies to establish the safety and efficacy of the proposed generic product. In place of such clinical studies, an ANDA applicant needs to submit data demonstrating that its product is bioequivalent to the brand name product, usually based on pharmacokinetic studies. As an alternate path to U. S. FDA approval for modifications of products previously approved by the U. S. FDA, an applicant may submit a new drug application, or NDA, under Section 505 (b) (2) of the FDCA (enacted as part of the Hatch- Waxman Amendments). This statutory provision permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference from the owner of the data. The Hatch- Waxman Amendments permit the applicant to rely upon the U. S. FDA findings of safety and effectiveness of a drug that has obtained U. S. FDA approval based on preclinical or clinical studies conducted by others. In addition to relying on U. S. FDA prior findings of safety and effectiveness for a referenced drug product, the U. S. FDA may require companies to perform additional preclinical or clinical studies to support approval of the modification to the referenced product. If an application for a generic version of a branded product or a Section 505 (b) (2) application relies on a prior U. S. FDA finding of safety and effectiveness of a previously- approved product including an alternative strength thereof, the applicant is required to certify to the U. S. FDA concerning any patents listed for the referenced product in the U. S. FDA publication called " Approved Drug Products with Therapeutic Equivalence Evaluations, " otherwise known as the " Orange Book. " Specifically, the applicant must certify in the application that: • there is no patent information listed for the reference drug; • the listed patent has expired for the reference drug; • the listed patent for the reference drug has not expired, but will expire on a particular date and approval is sought after patent expiration; or • the listed patent for the reference drug is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of the product for which the ANDA or 505 (b) (2) NDA is submitted. The Hatch- Waxman Amendments require an applicant for a drug product that relies, in whole or in part, on the U. S. FDA' s prior approval of VASCEPA, to notify us of its application, a " paragraph IV " notice, if the applicant is seeking to market its product prior to the expiration of the patents that both claim VASCEPA and are listed in the Orange Book. A bona fide paragraph IV notice may not be given under the Hatch- Waxman Amendments until after the generic company receives from the U. S. FDA an acknowledgement letter stating that its ANDA is sufficiently complete to permit a substantive review. The paragraph IV notice is required to contain a detailed factual and legal statement explaining the basis for the applicant' s opinion that the proposed product does not infringe our patents, that the relevant patents are invalid, or both. After receipt of a valid notice, the branded product manufacturer has the option of bringing a patent infringement suit in federal district court against any generic company seeking approval for its product within 45 days from the date of receipt of each notice. If such a suit is commenced within this 45- day period, the Hatch- Waxman Amendments provide for a 30- month stay on U. S. FDA' s ability to give final approval to the proposed generic product, which period begins on the date the paragraph IV notice is received. Generally, during a period of time in which generic applications may be submitted for a branded product based on a product' s regulatory exclusivity status, if no patents are listed in the Orange Book before the date on which a complete ANDA application for a product (excluding an amendment or supplement to the application) is submitted, an ANDA application could be approved by U. S. FDA without regard to a stay. For products entitled to five- year exclusivity status, the Hatch- Waxman Amendments provide that an ANDA application may be submitted after four years following U. S. FDA approval of the branded product if it contains a certification of patent invalidity or non- infringement to a patent listed in the Orange Book. In such a case, the 30- month stay runs from the end of the five- year exclusivity period. Statutory stays may be shortened or lengthened if either party fails to cooperate in the litigation and it may be terminated if the court decides the case in less than 30 months. If the litigation is resolved in favor of the ANDA applicant before the expiration of the 30- month period, the stay will be immediately lifted and the U. S. FDA' s review of the application may be completed. Such litigation is often time- consuming and costly and may result in generic competition if such patents are not upheld or if the generic competitor is found not to infringe such patents. In addition to the ANDA patent litigation described above, we could face patent litigation related to the patents filed in the Orange Book related to the REDUCE- IT study . A **, particularly given that the** three- year period of exclusivity under the Hatch- Waxman Amendments **expired on December 13** is generally granted for a drug product that contains an active moiety that has been previously approved , **2022** such as when the application contains reports of new clinical investigations (other than bioavailability studies) conducted by the sponsor that were essential to approval of the application. Accordingly , **which** we received three- year exclusivity **would have** in connection with the approval of our sNDA for REDUCE- IT study results. Such three- year exclusivity protection precludes **precluded** , unless otherwise agreed, the U. S. FDA from approving a marketing application for an ANDA , **for** a product candidate that the U. S. FDA views **viewed** as having the same conditions of approval as VASCEPA (for example, the same indication and / or other conditions of use), or a 505 (b) (2) NDA submitted to the U. S. FDA with VASCEPA as the reference product until December 13, 2022, three years from the date of U. S. FDA approval of the REDUCE- IT sNDA. While this three- year exclusivity would generally prevent such an approval based on our REDUCE- IT indication during such time, it does not preclude tentative or final approval of an ANDA based on our MARINE indication. The U. S. FDA may accept and commence review of such REDUCE- IT- related applications during the three- year exclusivity period. Such three- year exclusivity grant does not prevent a company from challenging the validity of REDUCE- IT patents during such period. This three- year form of exclusivity may also not prevent the U. S. FDA from approving an NDA that relies only on its own data to support the change or innovation. Regulatory exclusivity is in addition to exclusivity afforded by issued patents related to VASCEPA. We may also face challenges to the validity of our patents through a procedure known as inter partes review. Inter partes review is a trial proceeding conducted through the Patent Trial and Appeal Board , of the USPTO. Such a proceeding could be introduced against us within the statutory one- year window triggered by service of a complaint for infringement related to an ANDA filing or at any time by an

entity not served with a complaint. Such proceedings may review the patentability of one or more claims in a patent on specified substantive grounds such as allegations that a claim is obvious on the basis of certain prior art. We cannot predict the outcome of the pending lawsuits, any appeals, or any subsequently filed lawsuits or inter partes review. ~~Generally, if an ANDA filer meets the approval requirements for a generic version of VASCEPA to the satisfaction of the U. S. FDA under its ANDA, U. S. FDA may grant tentative approval to the ANDA during a Hatch- Waxman 30- month stay period and during the Hatch- Waxman 36- month regulatory exclusivity period. A tentative approval is issued to an ANDA applicant when its application is approvable prior to the expiration of any exclusivities applicable to the branded, reference listed drug product. A tentative approval does not allow the applicant to market the generic drug product and postpones the final ANDA approval until applicable exclusivity protections have expired.~~ Generic versions of VASCEPA made available in the market, even if based on a MARINE indication, are often used to fill a prescription for any intended use of the drug. If any approved ANDA filers are able to supply the product in significant commercial quantities, generic companies could introduce generic versions of VASCEPA in the market, as Hikma, Dr. Reddy' s, Apotex and Teva have done. Although any such introduction of a generic version of VASCEPA would also be subject to any litigation settlement terms and patent infringement claims (including any new claims and those that may then be subject to an appeal), pursuing such litigation may be prohibitively costly or could put a substantial constraint on our resources. **The** ~~On July 9, 2021, President Biden issued an executive order directing the U. S. FDA to, among other things, continue to clarify and improve the approval framework for generic drugs and identify and address any efforts to impede generic drug competition. Any significant degree of~~ generic market ~~entry would~~ **entries beginning in 2020 have** ~~limit~~ **limited** our U. S. sales, **and had an** ~~which would have a significant~~ adverse impact on our business and results of operations ~~. In addition, even if a competitor' s effort to introduce a generic product is ultimately unsuccessful, the perception that such development is in progress and / or news related to such progress or news related to litigation outcomes could materially affect the reputation of VASCEPA or the perceived value of our company and our stock price~~ . In addition, generic market entry, whether limited to its approved indication or not, can create market disruption which leads to an overall slowing of market growth regardless of whether the net price of the generic entry is higher or lower than the net price of the branded drug. Such disruption includes potential stock shortages of the generic market entry at retail pharmacies and wholesalers which can cause filling of prescriptions for patients to be delayed or abandoned. Sponsors of generic entries typically do not fund market education initiatives to help healthcare professionals and at- risk patients learn about a new drug, which, particularly for a recently launched drug, can potentially limit overall growth. And certain ~~States~~ **states** impose restrictions on the promotion of branded drugs, particularly if the generic market entry is less expensive than the branded drug. While some companies with generic competition elect to launch an authorized generic form of the drug to counter the perception, real or imagined, that generics are less expensive, if launched, an authorized generic is typically aligned with reduction or elimination of promotion of the associated branded drug, thus limiting the extent of market growth and potentially contracting the overall size of the realized market penetration. While an authorized generic could be profitable **,** the market opportunity for growth from an authorized generic is likely less than from promotion of a branded drug, and as such we have not launched an authorized generic version of VASCEPA to date, but may elect to do so in the future. The active pharmaceutical ingredient in VASCEPA is difficult and time consuming to manufacture ~~,~~**. It** often requires considerable advanced planning and long- term financial commitments to ensure sufficient capacity is available when needed. **Certain** ~~One of our~~ generic competitors ~~has~~ filed ~~a lawsuit~~ **lawsuits** against us claiming we have engaged in anticompetitive practices related to our building of adequate supply for our needs, and government agencies are investigating our business as it relates to the supply of the active pharmaceutical ingredient in VASCEPA. Consumer lawsuits with similar allegations have also been filed. This dynamic and resulting regulatory scrutiny could be costly for us and could negatively and materially interfere with our business plans. The active pharmaceutical ingredient in VASCEPA is difficult and time consuming to manufacture, **and** often requires considerable advanced planning and necessitates long- term financial commitments to ensure sufficient capacity is available when needed. We have invested over a decade of resources and expenses to develop **active pharmaceutical ingredient, or API,** with our third- party **suppliers** , ~~active pharmaceutical ingredient,~~ **and to otherwise build** ~~or~~ **our** ~~API,~~ supply chain ~~the~~ **, improve our** technical knowhow, **establish** manufacturing processes and ~~obtained~~ -- **obtain** related regulatory approvals **to** ~~that have helped~~ -- **help** enable our suppliers to supply our clinical and commercial needs globally. Despite such efforts, the stability of the supply chain is largely out of our control and is subject to market and supply volatility and the actions of third parties. Any disruption to the supply chain, including the manufacturing processes and availability of API, would be disruptive to our business and would have a negative impact on our results of operations. In April 2021, Dr. Reddy' s filed a complaint against us in the United States District Court District of New Jersey (case no. 2: 21- cv- 10309) alleging various antitrust violations stemming from alleged anticompetitive practices related to the supply of **API** ~~active pharmaceutical ingredient~~ of VASCEPA. Damages sought include recovery for alleged economic harm to Dr. Reddy' s, payors, and consumers, treble damages and other costs and fees. Injunctive relief against the alleged violative activities is also being sought by Dr. Reddy' s. Consumer group lawsuits followed claiming similar violations and alleging ~~, for example,~~ that such alleged violations resulted in higher prices to consumers. In addition, in February 2023, Hikma filed a complaint against us in the United States District Court District of New Jersey (case no. 3: 23- cv- 01016) **making allegations consistent** with ~~consistent allegations as~~ the Dr. Reddy' s complaint. Such litigation can be lengthy, costly and could materially affect and disrupt our business ~~. In addition, as noted above, we have also received a CID from the U. S. FTC and a subpoena from the New York Attorney General with respect to practices relating to our supply of the active pharmaceutical ingredient in VASCEPA. The government inquiries require us to produce documents and answer related questions relevant to specified time periods. We are cooperating with the agencies. Such investigations can be lengthy, costly and could materially affect and disrupt our business. We cannot predict when these investigations will be resolved, the outcome of the investigations or their potential impact on our business. If a government determines that we have violated antitrust law, we could be subject to significant civil fines and penalties~~ . VASCEPA is a prescription- only omega- 3 fatty acid product. Omega- 3 fatty acids are also marketed by

other companies as non- prescription dietary supplements. As a result, in the U. S., VASCEPA is subject to non- prescription competition and consumer substitution. Our only product, VASCEPA, is a prescription- only form of EPA, an omega- 3 fatty acid in ethyl ester form. Mixtures of omega- 3 fatty acids in triglyceride form are naturally occurring substances contained in various foods, including fatty fish. Omega- 3 fatty acids are marketed by others in a number of chemical forms as non- prescription dietary supplements. We cannot be sure physicians and other providers will view the U. S. FDA approval, pharmaceutical grade purity and proven efficacy and safety of VASCEPA as having a superior therapeutic profile to ~~unproven and loosely regulated~~ omega- 3 fatty acid dietary supplements ~~. In addition~~ , **which are subject** ~~the U. S. FDA has not yet enforced~~ to **less stringent** ~~the full extent of its~~ regulatory **oversight** ~~authority what we view as illegal claims made by certain omega- 3 fatty acid product manufacturers to the extent we believe appropriate under applicable law and regulations, for example, claims that certain of such chemically altered products are dietary supplements and that certain of such products reduce triglyceride levels or could reduce cardiovascular risk~~ . Also, for over a decade, subject to certain limitations, the U. S. FDA has expressly permitted dietary supplement manufacturers that sell supplements containing the omega- 3 fatty acids EPA and / or DHA to make the following qualified health claim directly to consumers: Supportive but not conclusive research shows that consumption of EPA and DHA omega- 3 fatty acids may reduce the risk of coronary heart disease. Such companies are not, however, permitted, based on U. S. FDA enforcement activity, to make claims that suggest or imply treatment of cardiovascular disease ~~. These factors enable dietary supplements to compete with VASCEPA. We may not be successful in such efforts, or such efforts may prove too costly to be effective~~ . In addition, the net price of VASCEPA to patients even after insurance reimbursement and offered discounts could be significantly higher than the prices of commercially available omega- 3 fatty acids marketed by other companies as dietary supplements (through the lack of coverage by insurers or otherwise) ~~, . physicians~~ **Physicians** and pharmacists may recommend these ~~retail~~ **dietary supplement** alternatives instead of writing or filling prescriptions for VASCEPA or patients may elect on their own to take commercially available omega- 3 fatty acids. Also, insurance plans may increasingly impose policies that directly or indirectly favor supplement use over VASCEPA. VASCEPA pricing might not be sufficient for healthcare providers or patients to elect VASCEPA over alternative treatments that may be perceived as less expense or more convenient to access. If healthcare providers or patients favor dietary supplements over prescribing VASCEPA, we may be constrained in how we price **VASCEPA** ~~our product~~ or VASCEPA' s market acceptance may be less than expected, which would have a negative impact on our revenues and results of operations. Our products and marketing efforts are subject to extensive post- approval government regulation. Once a product candidate receives U. S. FDA marketing approval, numerous post- approval requirements apply. Among other things, the holder of an approved NDA is subject to periodic and other monitoring and reporting obligations enforced by the U. S. FDA and other regulatory bodies, including obligations to monitor and report adverse events and instances of the failure of a product to meet the specifications in the approved application. Application holders must also submit advertising and other promotional material to regulatory authorities and report on ongoing clinical trials. With respect to sales and marketing activities, advertising and promotional materials must comply with U. S. FDA rules in addition to other applicable federal and local laws in the United States and in other countries. The result of our litigation and settlement with the U. S. FDA, as discussed above, may cause the government to scrutinize our promotional efforts or otherwise monitor our business more closely. Industry- sponsored scientific and educational activities also must comply with U. S. FDA and other requirements. In the United States, the distribution of product samples to physicians must comply with the requirements of the U. S. Prescription Drug Marketing Act. Manufacturing facilities remain subject to U. S. FDA inspection and must continue to adhere to the U. S. FDA' s pharmaceutical current good manufacturing practice requirements, or cGMPs. Application holders must obtain U. S. FDA approval for product and manufacturing changes, depending on the nature of the change. ~~In addition, drug~~ **Drug** manufacturers and other entities involved in the manufacture and distribution of approved drugs are **also** subject to periodic unannounced inspections by the U. S. FDA and state agencies for compliance with cGMP requirements **. For certain commercial prescription drug products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States. In addition, under the Food and Drug Omnibus Reform Act of 2022, or FDORA, sponsors of approved drugs and biologics must provide six months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product' s ability to be marketed** . We participate in the U. S. Medicaid Drug Rebate Program, the Federal Supply Schedule, or FSS, of the U. S. Department of Veterans Affairs, or the VA, and other government drug programs, and, accordingly, are subject to complex laws and regulations regarding reporting and payment obligations. We must also comply with requirements to collect and report adverse events and product complaints associated with our products. Our activities are also subject to U. S. federal and state consumer protection and unfair competition laws, non- compliance with which could subject us to significant liability. Similar requirements exist in many of these areas in other countries. Depending on the circumstances, failure to meet post- approval requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre- marketing product approvals, or refusal to allow us to enter into supply contracts, including government contracts. We may also be held responsible for the non- compliance of our partners, **over whom** ~~such as our former co- promotion partner Kowa America. As discussed above, in June 2020, we received a CID from the DOJ informing us that the DOJ is investigating whether aspects of our promotional speaker programs and copayment waiver programs during the period from January 1, 2015 to the present violated the U. S. Anti- Kickback Statute and the U. S. FCA in relation to the sale and marketing of VASCEPA by us and our previous co- marketing partner, Kowa America. The New York State attorney general similarly issued a subpoena to us regarding the same subject matter on which the FTC CID is focused. The inquiries require us to produce documents and answer~~

~~written questions, or interrogatories, relevant to specified time periods. We cannot predict when these investigations will be resolved, the outcome of the investigations or their potential impact on our business. If the government determines that~~ we have **limited** ~~violated the U. S. Anti- Kickback Statute, the FCA or antitrust regulations, we could be subject to significant civil and criminal fines and penalties, and our~~ **or no control** ~~reputation may be harmed. In addition, even if we comply with U. S. FDA and other requirements, new information regarding the safety or effectiveness of a product could lead the U. S. FDA to modify or withdraw a product approval~~. Newly discovered or developed safety or effectiveness data may require changes to a drug' s approved labeling and marketing, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Adverse regulatory action, whether pre- or post- approval, can potentially lead to product liability claims and increase our product liability exposure. We must also compete against other products in qualifying for coverage and reimbursement under applicable third- party payment and insurance programs. In addition, all of the above factors may also apply to any regulatory approval for VASCEPA obtained in territories outside the United States. In Europe, for example, restrictions regarding off- label promotion are in some ways more stringent than in the United States, including restrictions covering certain communications with shareholders. Given our inexperience with marketing and commercializing products outside the United States, in certain territories we may need to rely on third parties, such as our partners in Canada, China and the Middle East, to assist us in dealing with any such issues and we will have limited or no control over such partners. ~~Legislative~~ **The success of** ~~or~~ **our** ~~regulatory reform of~~ **product candidates, if approved, depends on** the **availability of coverage** ~~healthcare system in the United States~~ and ~~foreign jurisdictions~~ **adequate reimbursement from third- party payors. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we** may **develop** ~~affect our ability to profitably sell VASCEPA~~. Our ability to commercialize VASCEPA or any future products successfully, alone or with collaborators, will depend in part on the extent to which coverage and reimbursement for the products will be available from government and health administration authorities, private health insurers and other third- party payors. The continuing efforts of the U. S. and foreign governments, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce healthcare costs may adversely affect our ability to set prices for our products which we believe are fair, and our ability to generate revenues and achieve and maintain profitability **. For example, the IRA recently was enacted in the United States in an effort to manage certain drug prices, which includes provisions such as a $ 2, 000 out- of- pocket cap for Medicare Part D beneficiaries, the imposition of new manufacturer financial liability on most drugs in Medicare Part D, permitting the U. S. government to negotiate Medicare Part B and Part D pricing for certain high- cost drugs and biologics without generic or biosimilar competition, requiring companies to pay rebates to Medicare for drug prices that increase faster than inflation, and delay until January 1, 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. This could have an adverse impact on our future revenues** . Refer to Item 1. Business- United States Healthcare Reform and Legislation and Item 1. Business- Pharmaceutical Pricing and Reimbursement for further details. In addition, it is time-consuming and expensive for us to go through the process of seeking coverage and reimbursement from Medicare and private payors. Our products may not be considered cost effective, and government and third- party private health insurance coverage and reimbursement may not be available to patients for any of our future products or sufficient to allow us to sell our products on a competitive and profitable basis. Our results of operations could be adversely affected by ACA and by other healthcare reforms that may be enacted or adopted in the future. In addition, increasing emphasis on managed care in the United States will continue to put pressure on the pricing of pharmaceutical products. ~~For example, proposals~~ **Proposals** are being considered to expand the use of dietary supplements in addition to or in place of drugs in government and private payor plans. In addition, cost control initiatives could decrease the price that we or any potential collaborators could receive for any of our future products and could adversely affect our profitability. These and similar regulatory dynamics, including the entry of generic versions of VASCEPA into the market, and the potential for additional generic versions in the near term, can affect our ability to commercialize VASCEPA on commercially reasonable terms and limit the commercial value of VASCEPA. If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects. We participate in the Medicaid Drug Rebate program, the 340B drug pricing program, and the VA' s FSS pricing program. Under the Medicaid Drug Rebate program, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part ~~B~~ **D** . Those rebates are based on pricing data reported by us on a monthly and quarterly basis to CMS, the federal agency that administers the Medicaid Drug Rebate program. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug which, in general, represents the lowest price available from the manufacturer to any commercial entity in the U. S. in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions. Our failure to comply with these price reporting and rebate payment obligations could negatively impact our financial results. The **Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the** ACA **,** made significant changes to the Medicaid Drug Rebate program. CMS issued a final regulation, which became effective in 2016, to implement the changes to the Medicaid Drug Rebate program under the ACA. The issuance of the final regulation has increased and will continue to increase our costs and the complexity of compliance, has been and will continue to be time-consuming to implement, and could have a material adverse effect on our results of operations, particularly if CMS challenges the approach we take in our implementation of the final regulation. Federal law requires that any company that participates in the Medicaid Drug Rebate program also participate in the Public Health Service' s 340B drug pricing program in order for

federal funds to be available for the manufacturer' s drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B " ceiling price " for the manufacturer' s covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low- income patients. The 340B ceiling price is calculated using a statutory formula based on the average manufacturer price and Medicaid rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program, and in general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price calculation and discount requirement. Any additional future changes to the definition of average manufacturer price and the Medicaid rebate amount under the ACA, other legislation, or in regulation could affect our 340B ceiling price calculations and negatively impact our results of operations. The Health Resources and Services Administration, or HRSA, which administers the 340B program, issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, which became effective on January 1, 2019. We also are required to report our 340B ceiling prices to HRSA on a quarterly basis. Implementation of the civil monetary penalties regulation and the issuance of any other final regulations and guidance could affect our obligations under the 340B program in ways we cannot anticipate. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting. Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies and the courts. In the case of our Medicaid pricing data, if we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate program and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we are required to offer our products under the 340B program or could require us to issue refunds to 340B covered entities. Significant civil monetary penalties can be applied if we are found to have knowingly submitted any false pricing information to CMS, or if we fail to submit the required price data on a timely basis. Such conduct also could be grounds for CMS to terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part ~~B~~ **D** for our covered outpatient drugs. Significant civil monetary penalties also can be applied if we are found to have knowingly and intentionally charged 340B covered entities more than the statutorily mandated ceiling price. We cannot assure you that our submissions will not be found by CMS or HRSA to be incomplete or incorrect. In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part ~~B~~ **D** programs and purchased by certain federal agencies and grantees, as noted above, we participate in the VA' s FSS pricing program. As part of this program, we are obligated to make our products available for procurement on an FSS contract under which we must comply with standard government terms and conditions and charge a price that is no higher than the statutory Federal Ceiling Price, or FCP, to four federal agencies (the VA, U. S. Department of Defense, or DOD, Public Health Service, and the U. S. Coast Guard). The FCP is based on the Non- Federal Average Manufacturer Price, or Non- FAMP, which we calculate and report to the VA on a quarterly and annual basis. Pursuant to applicable law, knowing provision of false information in connection with a Non- FAMP filing can subject a manufacturer to significant penalties for each item of false information. These obligations also contain extensive disclosure and certification requirements. We also participate in the Tricare Retail Pharmacy program, under which we pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non- FAMP and FCP. We are required to list our covered products on a Tricare Agreement in order for these products to be eligible for DOD formulary inclusion. If we overcharge the government in connection with our FSS contract or Tricare Agreement, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and / or to identify contract overcharges can result in allegations against us under the FCA and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time- consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects. Changes in reimbursement procedures by government and other third- party payors may limit our ability to market and sell our approved drugs. These changes could have a material adverse effect on our business and financial condition. In the U. S., Europe and other regions globally, sales of pharmaceutical drugs are dependent, in part, on the availability of reimbursement to the consumer from third- party payors, such as government and private insurance plans. Third- party payors decide which products and services they will cover and the conditions for such coverage. Third **-** party payors also establish reimbursement rates for those products and services. Increasingly, third- party payors are challenging the prices charged for medical products and services. Some third- party payor benefit packages restrict reimbursement, charge copayments to patients, or do not provide coverage for specific drugs **, uses,** or drug classes. In addition, certain U. S. **-** based healthcare providers are moving toward a managed care system in which such providers contract to provide comprehensive healthcare services, including prescription drugs, for a fixed cost per person. We are unable to predict the reimbursement policies employed by third- party healthcare payors **which** may not be favorable to us. We expect to experience pricing and reimbursement pressures in connection with the sale of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative and executive proposals, as well as the availability of generic versions of VASCEPA. In addition, we may confront limitations in, or exclusions from, insurance coverage for our products, particularly as generic competition intensifies. If we fail to successfully secure and maintain reimbursement coverage for our approved drugs or are significantly delayed in doing so, we may have difficulty achieving market acceptance of our approved drugs and investigational drug candidates for which we obtain approval, and our business may be harmed. Congress has enacted healthcare reform and may

enact further reform, which could adversely affect the pharmaceutical industry as a whole, and therefore could have a material adverse effect on our business. Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations. In the U. S. and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post- approval activities and affect our ability to profitably sell any products for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record- keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. Refer to Item 1. Business- Current and Future Legislation and Item 1. Business- United States Healthcare Reform and Legislation **. There has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U. S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs. The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may adversely affect: • the demand for any of our product candidates, if approved; • the ability to set a price that we believe is fair for any of our product candidates, if approved; • our ability to generate revenues and achieve or maintain profitability; • the level of taxes that we are required to pay; and • the availability of capital** . There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The enactment and implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates. Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and / or adverse publicity and could negatively affect our operating results and business. We and any potential collaborators may be subject to federal, state, and foreign data protection laws and regulations (i. e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e. g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health- related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA. Although we are not directly subject to HIPAA – other than with respect to providing certain employee benefits – we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA- covered entity in a manner that is not authorized or permitted by HIPAA. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Compliance with U. S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation, and / or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects, employees and other individuals about whom we or our potential collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time- consuming to defend and could result in adverse publicity that could harm our operating results and business. European data collection is governed by restrictive regulations governing the use, processing and cross- border transfer of personal information. **We** ~~The REDUCE- IT cardiovascular outcomes trial was conducted in part through clinical sites in the EEA. As a result, we~~ are subject to **European data protection regulations, where we collect and use personal data relating to Europe, including in relation to our personnel in the European Economic Area, or the EEA, or in the United Kingdom, or the UK. This regulatory regime includes the GDPR, as well as other** ~~additional~~ --- **national** ~~privacy restrictions. The~~ **data protection legislation in force in relevant EU and EEA member states and the UK (including the UK Data Protection Act 2018 in the UK), which govern the** collection ~~and~~ **, use , storage, disclosure, transfer, or other processing** of personal **data (including** health data **processed in the context of clinical trials): (i) regarding individuals** in the EU ~~is governed by~~ **, EEA and UK; and / or (ii) carried out in** the ~~provisions~~ **context** of the **activities of our establishment in any EU and EEA member state or the UK. Currently, the EU** GDPR **and UK GDPR remain largely aligned** . The GDPR imposes several requirements **on companies that process personal data, including requirements** relating to the **processing of health and other sensitive data,** legal basis for processing personal data which may include **obtaining** the consent of the individuals to whom the personal data relates, ~~the~~ **providing detailed** information ~~provided~~ to ~~the~~ individuals **about how their personal data is used, notification of personal data breaches to data protection authorities** and **individuals, and implementing safeguards to protect** the security and

confidentiality of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the EEA **and UK** to third countries, including the United States **in certain circumstances, unless a derogation exists or a valid GDPR transfer mechanism (e** . **g.,** ~~A decision by the Court of Justice of~~ the European **Commission approved** ~~Union, or CJEU, in 2020 invalidated the EU- U. S. Privacy Shield Framework, which was one of the primary mechanisms used by U. S. companies to import personal information from Europe in compliance with the GDPR' s cross- border data transfer restrictions, and raised questions about whether the EC' s~~ Standard Contractual Clauses, or SCCs, ~~one of the primary alternatives to the Privacy Shield, can lawfully be used for personal information transfers from Europe to the United States or most other countries. Furthermore, on June 4, 2021, the EC issued new forms of standard contractual clauses for data transfers from controllers or processors in the EEA, or otherwise subject to the GDPR, to controllers or processors established outside the EEA,~~ and ~~not subject to the GDPR. The new forms of standard contractual clauses have replaced the standard contractual clauses that were adopted previously under the Data Protection Directive. They require a case- by- case assessment of the law in the recipient country to ensure it provides " essentially equivalent " protections to safeguard the transferred personal data as the EEA, and require businesses to adopt supplementary measures if such standard is not met The new SCCs do not apply to~~ the UK ~~, but the UK Information Commissioner' s Office has published its own transfer mechanism, the~~ International Data Transfer Agreement **/ Addendum** , or UK IDTA ~~, which entered into force~~ **) have been put in place. Where relying** on **the SCCs / UK IDTA for** ~~March 21, 2022, and enables~~ data transfers **, we may also** ~~originating from the UK. It requires a similar assessment of the data protection provided in the importer' s country. We will~~ be required to **carry out** ~~transition to the new forms of transfer mechanisms and doing so will require significant effort and cost. The new transfer mechanisms may also impact our business as companies based in Europe may be reluctant to utilize the new clauses to legitimize transfers of personal information to third countries given the burdensome requirements of~~ transfer impact assessments ~~and~~ **to assess whether** the ~~substantial obligations that~~ **recipient is subject to local laws which allow public authority access to personal data. Any inability to transfer personal data from** the ~~new standard contractual clauses impose upon exporters~~ **EEA and UK to the United States in compliance with data protection laws may impede our business operations and may adversely affect our business and financial position. The UK Government has introduced a Data Protection and Digital Information Bill, or Data Reform Bill, into the UK legislative process to reform the UK' s data protection regime, and if passed, the final version of the Data Reform Bill may have the effect of further altering the similarities between the UK and EEA data protection regimes and threaten the UK international transfers adequacy decision from the European Commission, which may lead to additional compliance costs for us and could increase our overall risk. It is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the UK will be regulated in the long term** . Failure to comply with the requirements of the GDPR ~~or the UK GDPR,~~ and ~~the~~ related national data protection laws of the EEA Member States or the UK may result in substantial fines **of up to € 20 million or 4 % of a company' s global annual revenues for the preceding financial year, whichever is higher. Moreover, the GDPR grants data subjects and consumer associations the right to claim material and non- material damages resulting from infringement of the GDPR** . The GDPR ~~may impose~~ **imposes** additional responsibility and liability in relation to personal data that we process **, where such processing is subject to the GDPR** and we may be required to put in place additional mechanisms ensuring compliance with these and / or new data protection rules. This may be costly, onerous and adversely affect our business, financial condition, prospects and results of operations **. Although the EU GDPR and the UK GDPR currently impose substantially similar obligations, it is possible that over time the UK GDPR could become less aligned with the EU GDPR. In addition, EEA Member States have adopted national laws to supplement the EU GDPR, which may partially deviate from the EU GDPR, and the competent authorities in the EEA Member States may interpret EU GDPR obligations slightly differently from country to country, such that we do not expect to operate in a uniform legal landscape in the EEA and UK with respect to data protection regulations. The potential of the respective provisions and enforcement of the EU GDPR and UK GDPR further diverging in the future creates additional regulatory challenges and uncertainties for us. The lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations could add legal risk, uncertainty, complexity and compliance cost to the handling of European personal data and our privacy and data security compliance programs could require us to amend our processes and procedures to implement different compliance measures for the UK and the EEA** . The U. S. FDA, other regulatory agencies and industry organizations strictly regulate the promotional claims that may be made about prescription products and promotional efforts such as speaker programs. If we or our partners are found to have improperly promoted uses, efficacy or safety of VASCEPA or otherwise are found to have violated the law or applicable regulations, we may become subject to significant fines and other liability. The government may seek to find means to prevent our promotion of truthful and non- misleading information beyond the current court ruling and litigation settlement or seek to find violations of other laws or regulations in connection with the promotional efforts we undertake on our own or through third parties. The U. S. FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. In particular, in general, the U. S. government' s position has been that a product may not be promoted for uses that are not approved by the U. S. FDA as reflected in the product' s approved labeling. The Federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off- label promotion. The U. S. FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. Even though we received U. S. FDA marketing approval for VASCEPA for the MARINE indication and for the REDUCE- IT indication, and our settlement with the U. S. FDA affords us a degree of protection for other promotional efforts, physicians may still prescribe VASCEPA to their patients for use in the treatment of conditions that are not included as part of the indication statement in our U. S. FDA- approved VASCEPA label or our settlement. If we are found to have promoted VASCEPA outside the terms of the litigation settlement or in violation of what federal or state government may determine to be

acceptable, we may become subject to significant government fines and other related liability, such as under the FDCA, the FCA, or other theories of liability. Government may also seek to hold us responsible for the non- compliance of our former co-promotion partner, Kowa America, or our commercialization partners outside the United States or other third- parties that we retain to help us implement our business plan. In addition, incentives exist under applicable laws that encourage competitors, employees and physicians to report violations of rules governing promotional activities for pharmaceutical products. These incentives could lead to so- called " whistleblower lawsuits " as part of which such persons seek to collect a portion of moneys allegedly overbilled to government agencies due to, for example, promotion of pharmaceutical products beyond labeled claims. These incentives could also lead to suits that we have mischaracterized a competitor' s product in the marketplace and we may, as a result, be sued for alleged damages to our competitors. Such lawsuits, whether with or without merit, are typically time - consuming and costly to defend. Such suits may also result in related shareholder lawsuits, which are also costly to defend. ~~For example, the June 2020, CIDs from the DOJ informing us that the DOJ is investigating whether aspects of our promotional speaker programs and copayment waiver program violated the U. S. Anti- Kickback Statute and from the FCA relating to the sale and marketing of VASCEPA by us and our previous co- marketing partner, Kowa America, as well as the March 2021, CID from the FTC in connection with the FTC' s investigation of whether we have engaged in, or are engaging in, anticompetitive practices or unfair methods of competition relating to VASCEPA require us to produce documents and answer written questions, or interrogatories, relevant to specified time periods. As does the subpoena from the New York State attorney general regarding the same subject matter on which the FTC CID is focused. Such investigations can be lengthy, costly and could materially affect and disrupt our business. If the government determines that we have violated the U. S. Anti- Kickback Statute, the FCA or antitrust regulations we could be subject to significant civil and criminal fines and penalties.~~ We may not be successful in developing and receiving regulatory approval for VASCEPA in other jurisdictions or marketing future products if we cannot meet the extensive regulatory requirements of regulatory agencies ~~,~~ such as for quality, safety, efficacy and data privacy. The success of our research and development efforts is dependent in part upon our ability, and the ability of our partners or potential partners, to meet regulatory requirements in the jurisdictions where we or our partners or potential partners ultimately intend to sell such products once approved. The development, manufacture and marketing of pharmaceutical products are subject to extensive regulation by governmental authorities in the United States and elsewhere. In the United States, the U. S. FDA generally requires preclinical testing and clinical trials of each drug to establish its safety and efficacy and extensive pharmaceutical development to ensure its quality before its introduction into the market. Regulatory authorities in other jurisdictions impose similar requirements. The process of obtaining regulatory approvals is lengthy and expensive and the issuance of such approvals is uncertain. The commencement and rate of completion of clinical trials and the timing of obtaining marketing approval from regulatory authorities may be delayed by many factors, including, among others: • the lack of efficacy during clinical trials; • the inability to manufacture sufficient quantities of qualified materials under cGMPs for use in clinical trials; • slower than expected rates of patient recruitment; • the inability to observe patients adequately after treatment; • changes in regulatory requirements for clinical trials or preclinical studies; • the emergence of unforeseen safety issues in clinical trials or preclinical studies; • delay, suspension, or termination of a trial by the institutional review board responsible for overseeing the study at a particular study site; • unanticipated changes to the requirements imposed by regulatory authorities on the extent, nature or timing of studies to be conducted on quality, safety and efficacy; • compliance with laws and regulations related to patient data privacy; • government or regulatory delays or " clinical holds " requiring suspension or termination of a trial; and • political instability or other social or government protocols affecting our clinical trial sites. Even if we obtain positive results from our efforts to seek regulatory approvals, from early stage preclinical studies or clinical trials, we may not achieve the same success in future efforts. Clinical trials that we or potential partners conduct may not provide sufficient safety and efficacy data to obtain the requisite regulatory approvals for product candidates. The failure of clinical trials to demonstrate safety and efficacy for our desired indications could harm the development of that product candidate as well as other product candidates, and our business and results of operations would suffer. **In** ~~For example, in~~ connection with U. S. FDA' s review of REDUCE-IT data and sNDA in 2019, the agency determined that an interaction between mineral oil and statins leading to decreased absorption of statins cannot be excluded when the two are co- administered as could have been the case in some patients in REDUCE- IT and that, in the agency' s view, indirect evidence suggested the presence of a potential inhibitory effect on statin absorption by mineral oil. However, U. S. FDA' s exploratory analysis indicated that the effect of LDL cholesterol values on the time to the primary endpoint was numerically small and unlikely to change the overall conclusion of treatment benefit. U. S. FDA then relied on this assessment and all data available to it to approve a new indication statement and labeling based on REDUCE- IT results. This matter illustrates that concerns such as this may arise in the future that could affect our product development, regulatory reviews or the public perception of our products and our future prospects, including REDUCE- IT results. Any approvals that are obtained may be limited in scope, may require additional post- approval studies or may require the addition of labeling statements, including boxed warnings, focusing on product safety that could affect the commercial potential for our product candidates. Any of these or similar circumstances could adversely affect our ability to gain approval for new indications and affect revenues from the sale of our products. Even in circumstances where products are approved by a regulatory body for commercialization, the regulatory or legal requirements may change over time, or new safety or efficacy information may be identified concerning a product, which may lead to the withdrawal of a product from the market or similar use restrictions. The discovery of previously unknown problems with a clinical trial or product, or in connection with the manufacturer of products, may result in regulatory issues that prevent proposed future approvals of a product and / or restrictions on that product or manufacturer, including withdrawal of an indication or the product from the market, which would have a negative impact on our potential revenue stream. As we continue to scale our infrastructure for commercializing VASCEPA based on market dynamics for VASCEPA in the United States and commercial initiatives and plans for VAZKEPA in Europe and other parts of the world, we may encounter difficulties in managing the size and adaptability of our operations successfully.

The process of establishing, maintaining, expanding and streamlining a commercial infrastructure is difficult, expensive and time ~~-~~consuming, particularly when such efforts need to adapt to changing market and business dynamics. ~~We~~ **In 2022 we** implemented cost and organizational restructuring plans, which included a reduction to our U. S. commercial team to approximately 75 sales representatives by the end of 2022 **, and in July 2023 all remaining sales force positions in the U** . ~~Our~~ **S. were eliminated and our overall headcount was reduced by 30 % as part of our ORP. As a result, we do not have a** sales team **to** ~~promotes~~ **promote** VASCEPA to ~~a targeted group of~~ physicians and other healthcare professionals in ~~select geographies in~~ the United States ~~who recognize the potential benefit to patients~~ , and ~~this team is not large enough~~ **will rely on only our managed care and trade organization** to **support sales** ~~call upon a sufficient number~~ of ~~physicians~~ **VASCEPA in the United States** . In addition to **the elimination of our** sales force ~~reductions~~ in the United States, we continue to work on our own and with our international partners to support regulatory efforts outside the United States based on REDUCE- IT results. If we are successful in obtaining sufficient approvals and adequate pricing and reimbursement levels in major markets in Europe and elsewhere, we will need to ensure that our operations are adequate to support a commercial launch and continued promotion. **We redesigned our commercial infrastructure** ~~Although we are preparing for growth~~ in Europe **to better align with pricing** and ~~elsewhere by expanding our infrastructure, we are~~ **reimbursement status and commercial potential. We will be** operating with streamlined teams **in Europe** and **elsewhere outside the United States; however, we** will **anticipate the** need to expand internally and ~~we~~ expect that we will need to manage additional relationships with various collaborative partners, suppliers and other third parties **as we progress in Europe and outside the United States** . Future growth and streamlining efforts will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate the right number of employees. **In** ~~For example, in~~ Europe we have built out our team subsequent to EC approval of the marketing authorization acceptance in 2021, with plans to continue to expand our European staff as deemed appropriate on a country **-** by **-** country basis. The time required to secure reimbursement tends to vary from country to country and cannot be reliably predicted at this time. While we believe that we have strong arguments regarding the cost effectiveness of VAZKEPA, the success of such reimbursement negotiations could have a significant impact on our ability to hire and retain personnel and realize the commercial opportunity of VAZKEPA in Europe. Our future financial performance and our ability to commercialize VASCEPA and to compete effectively will depend, in part, on our ability to manage our future growth effectively ~~, and such efforts may be disrupted by ongoing or reinstated COVID- 19 protocols~~ . To that end, we must be able to manage our development efforts effectively, and hire, train, integrate and retain an appropriate level of management, administrative and sales and marketing personnel and have limited experience managing a commercial organization. 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. Our **business is depending on successful** life- cycle management **efforts** ~~, in large part, currently depends on our ability to develop, obtain regulatory approval and commercialize a fixed- dose combination of VASCEPA and yet to be disclosed statins~~ . Our **drug** ~~life- cycle management is substantially dependent on our ability to develop~~ **development efforts are subject** ~~, obtain regulatory approval and commercialize a fixed- dose combination of VASCEPA and yet~~ to ~~be disclosed statins~~ **the risks and uncertainties inherent in any drug development program** . Due to the risks and uncertainties involved in progressing through development and bioequivalence or even potential additional trials (as may be required by specific regulatory agencies), and the time and cost involved in obtaining regulatory approvals, we cannot reasonably estimate the timing, completion dates and costs, or range of costs, of our drug development program, or of the successful development of any particular **derivative,** ~~fixed- dose~~ combination **or next generation product candidate** . The potential success of any **derivative,** ~~fixed- dose~~ combination **or next generation product candidate** will depend on a number of factors, including the **scope of and our success with** ~~following: • Our ability to successfully manufacture~~ **manufacturing ,** ~~a combination of VASCEPA and a statin; • Our ability to maintain a supply of necessary statin for use in the fixed- dose combination; • Our ability to obtain~~ **obtaining** regulatory approvals **and achieving sufficient (** ~~for~~ **or** any **) levels** ~~and all markets in which we intend to commercialize a fixed- dose combination~~ of ~~VASCEPA and a statin; • Our ability to obtain payor acceptance and market access for a fixed- dose combination product of VASCEPA and a statin; and • Our ability to achieve~~ market acceptance ~~of a fixed- dose combination of VASCEPA and a statin. The continued scale, scope and duration of business interruptions caused by the COVID- 19 pandemic and related recovery efforts remain uncertain. Despite recent improvements, the ongoing presence of COVID- 19 has created significant volatility, uncertainty and disruption in healthcare, social, supply and economic infrastructures. The extent to which the coronavirus pandemic will continue to impact our business, operations and financial results will depend on numerous evolving factors that we may not be able to accurately predict or plan around, including: • the duration, volatility and scope of the pandemic, including resurgences, and the efficacy of recovery efforts; • governmental, business and individuals' actions that have been and continue to be taken in response to the pandemic; • the impact of the pandemic on economic and political activity and actions taken in response; • the effect on patients, healthcare providers and business partners, including patients' ability to access supplies of VASCEPA and the willingness of patients to visit doctors for non- urgent medical examination or to visit labs for blood tests to assess biomarkers such as lipid levels; • our ability to commercialize VASCEPA, including~~ if **approved** ~~travel restrictions, social distancing and other containment measures are resumed or intensified; • the enrollment or monitoring of patients in clinical trials, particularly at clinical trial sites located in highly impacted jurisdictions and jurisdictions where vaccination rates are low; • the ability to access, secure and otherwise obtain and deliver sufficient and timely commercial or clinical supplies of VASCEPA at reasonable prices and sufficient to meet demand if the production capabilities of suppliers is disrupted; • disruptions in regulatory oversight and actions if regulators and industry professionals continue to expend significant and unexpected resources addressing COVID- 19; • the availability of coverage and reimbursement from government and health administration authorities, private health insurers and other third- party payors if the system continues to be overly strained; • the ability of regulators to complete inspections and reviews of operations and applications, respectively, in a timely manner; and • any further, prolonged or reinstated closures of our and our~~

~~partners' offices, operations and facilities impeding our ability to work together as a company and with our business and healthcare partners. Even as the impacts of the pandemic appear to subside, additional variants may emerge and as vaccine usage and protocols evolve, face- to- face interactions may continue to be challenging for us to predict. The circumstances surrounding COVID- 19 vary geographically and vary over time, with continued risk of potential resurgences in COVID- 19 cases, and the possibility of reinstitution of protocols, in various geographies as the efficacy of the vaccine on various strains remains uncertain. While we have supplemented our face- to- face interactions with virtual outreach, these efforts may not be as impactful as traditional, in- person interactions. Specifically, access to healthcare professionals through the internet or other channels, may not be as productive as in- person interactions. The disruptions associated with the coronavirus pandemic could delay the potential timing of subsequent steps for the launch of commercialization of VAZKEPA in Europe. Additionally, COVID- 19 has already and could continue to limit our ability to have access with healthcare professionals to help educate them regarding VAZKEPA so that they are more likely to prescribe it to their at- risk patients. And, similar to our experience in the United States, the effects of COVID- 19 and related preventative measures may reduce the frequency at which at- risk patients seek non- urgent preventative medical care~~ . Risks Related to Our Reliance on Third Parties We have no in- house manufacturing capacity and rely entirely on contract manufacturers for our clinical and commercial product supply. We cannot provide assurance that we will successfully manufacture any product we may develop, either independently or under manufacturing arrangements, if any, with our third- party manufacturers. Moreover, if our manufacturers should cease doing business with us or experience delays, shortages of supply or excessive demands on their capacity, or if they insist on burdensome terms, such as excessive minimum supply commitments, we may not be able to obtain adequate quantities of product in a timely manner, at cost efficient levels or at all. If we are not able to continue to operate our business relationships in a manner that is sufficiently profitable for us and our suppliers, certain members of our supply chain could compete with us through supply to competitors, such as generic drug companies, through breach of our agreements or otherwise. Any manufacturing problem, natural or manmade disaster affecting manufacturing facilities, government action, or the loss of a contract manufacturer could potentially be disruptive to our operations and result in lost sales. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to future contract manufacture caused by problems at suppliers could delay shipment of products, increase our cost of goods sold and / or result in lost sales. If our suppliers were unable to supply us with adequate volumes of ~~active pharmaceutical ingredient, or~~ API ~~,~~ (drug substance) or encapsulated bulk product (drug product), it would have a material adverse effect on our ability to continue to commercialize VASCEPA. We have contractual freedom to source the API for VASCEPA and to procure other services supporting our supply chain. We have entered into supply agreements with multiple suppliers who also rely on other third- party suppliers to manufacture the API and other elements necessary for the sale of VASCEPA. We continue to take steps to negotiate our contract supply agreements to align supply arrangements with current and future global market demand. Expanding manufacturing capacity and qualifying such capacity is complex and subject to numerous regulations and other operational challenges. We require supply capacity to support our direct and indirect commercialization of VASCEPA. We are also committed to providing supply to our commercial partners and distributors in **Australia and New Zealand,** Canada, China, the Middle East and North Africa **, South Korea and Southeast Asia, and Israel** , and we anticipate potential additional supply requirements as we pursue commercial opportunities in other countries. The resources of our suppliers vary and are limited; costs associated with projected expansion and qualification can be significant, and lead- times for supply purchases and capacity expansion are long requiring certain supply related decisions and commitment to be made in advance of commercial launch, including in China and various European countries. Our aggregate capacity to produce API is dependent upon the continued qualification of our API suppliers and, depending on the ability of existing suppliers to meet our supply demands, ~~and~~ the ability to qualify any new suppliers. If no additional API supplier is approved by the U. S. FDA as part of an sNDA, our API supply will be limited to the API we purchase from previously approved suppliers. For example, the EMA has not yet approved use of each of our suppliers used for VASCEPA in the United States for supply of VAZKEPA in the EU. Further, there can be no guarantee that current suppliers and future suppliers with which we have contracted to encapsulate API will be continually qualified to manufacture the product to our specifications or that current and any future suppliers will have the manufacturing capacity to meet anticipated demand for VASCEPA. If our third- party manufacturing capacity is not appropriately qualified and / or compliant with applicable regulatory requirements, we may not be able to supply sufficient quantities of VASCEPA to meet anticipated demand. We cannot guarantee that we can contract with any future manufacturer on acceptable terms or that any such alternative supplier will not require capital investment from us in order for them to meet our requirements. Alternatively, our purchase of supply, or any minimum purchase requirements, may exceed actual demand for VASCEPA. ~~For example, certain~~ **Certain** of our agreements with our suppliers include minimum purchase obligations and limited exclusivity provisions. These purchases are generally made on the basis of rolling 12- month forecasts which in part are binding on us and the balance of which are subject to adjustment by us subject to certain limitations. Certain of our agreements also include contractual minimum purchase commitments regardless of the rolling 12- month forecasts. We may not purchase sufficient quantities of VASCEPA to meet actual demand or we may be required to purchase more supply than needed to meet actual demand. If our minimum purchase commitments exceed our supply needs for VASCEPA, we may have to renegotiate with partners in our supply chain who may not be incentivized to renegotiate terms that are favorable to us, or at all. If we are unable to secure adequate levels of supply to meet demand, our financial condition could be negatively and materially impacted. We sell VASCEPA principally to a limited number of major wholesalers, as well as selected regional wholesalers and mail order pharmacy providers, or collectively, our distributors or our customers, that in turn resell VASCEPA to retail pharmacies for subsequent resale to patients and healthcare providers. These parties exercise a substantial amount of bargaining power over us given their control over large segments of the market for VASCEPA. This bargaining power has ~~led~~ **required** us to bear increasingly higher discounts in the sale of

VASCEPA. In addition, payors have broad latitude to change individual products' formulary position or to implement other barriers that inhibit patients from receiving therapies prescribed by their healthcare professionals. These payor barriers include requirements that patients try another drug before VASCEPA, known as step edits, and the requirement that prior authorization be obtained by a healthcare provider after a prescription is written before a patient will be reimbursed by their health plan for the cost of a VASCEPA prescription. Further, pharmacy benefit managers implement plans that act as disincentives for VASCEPA use, such as increasingly higher deductibles. One practical impact of higher deductibles is that they may cause patients to delay filling prescriptions for asymptomatic, chronic care medications such as hypertriglyceridemia earlier in the year, until patients meet their deductible and the cost of VASCEPA is then borne more by their insurance carrier. Collectively, these dynamics ~~negatively~~ **adversely** affect our profitability for the sale of VASCEPA and could increase over time further impacting our operating results. Consolidation among these industry participants could increase the pressure on us from these market dynamics. The manufacture, packaging and distribution of pharmaceutical products such as VASCEPA are subject to U. S. FDA regulations and those of similar foreign regulatory bodies. If we or our third- party manufacturers fail to satisfy these requirements, our product development and commercialization efforts may be materially harmed. The manufacture, packaging and distribution of pharmaceutical products, such as VASCEPA, are regulated by the U. S. FDA and similar foreign regulatory bodies and must be conducted in accordance with the U. S. FDA' s cGMPs and comparable requirements of foreign regulatory bodies. There are a limited number of manufacturers that operate under these cGMPs as well as the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, or ICH, regulations and guidelines, that are both capable of manufacturing VASCEPA and willing to do so. Failure by us or our third- party manufacturers to comply with applicable regulations, requirements, or guidelines could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals, license revocation, seizures or voluntary recalls of product, operating restrictions and criminal prosecutions and penalties, any of which could significantly and adversely affect our business. If we are not able to manufacture VASCEPA to required specifications through our current and potential API suppliers, we may be delayed in successfully supplying the product to meet anticipated demand and our anticipated future revenues and financial results may be materially adversely affected. Changes in the manufacturing process or procedure, including a change in the location where the product is manufactured or a change of a third- party manufacturer, may require prior U. S. FDA review and pre- approval of the manufacturing process and procedures in accordance with the U. S. FDA' s cGMPs. Any new facility may be subject to a pre- approval inspection by the U. S. FDA and would again require us to demonstrate product comparability to the U. S. FDA. If any third- party manufacturer with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different third- party manufacturer, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials or commercial distribution could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original third- party manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back- up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change **a** third- party manufacturer for any reason, we will be required to verify that the new third- party manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product according to the specifications previously submitted to or approved by the U. S. FDA or another regulatory authority. The delays associated with the verification of a new third- party manufacturer could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a third- party manufacturer may possess technology related to the manufacture of our product candidate that such third- party manufacturer owns independently. This would increase our reliance on such third- party manufacturer or require us to obtain a license from such third- party manufacturer in order to have another third- party manufacturer manufacture our products or product candidates. In addition, in the case of the third- party manufacturers that supply **our** ~~any future~~ product candidates, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials. There are comparable foreign requirements under ICH guidelines. ~~In addition, certain past COVID- 19 restrictions have affected Regulatory Agencies' ability to conduct facility inspections and may affect the timing of further approvals. This review may be costly and time consuming and could delay or prevent the launch of a product.~~ Furthermore, the U. S. FDA and foreign regulatory agencies require that we be able to consistently produce the API and the finished product in commercial quantities and of specified quality on a repeated basis, including demonstrated product stability, and document our ability to do so. This requirement is referred to as process validation. Process validation includes stability testing, measurement of impurities and testing of other product specifications by validated test methods. If the U. S. FDA does not consider the result of the process validation or required testing to be satisfactory, the commercial supply of VASCEPA may be delayed, or we may not be able to supply sufficient quantities of VASCEPA to meet anticipated demand ~~. On March 27, 2020, former President Trump signed into law the CARES Act in response to the COVID- 19 pandemic. Throughout the COVID- 19 pandemic, there has been public concern over the availability and accessibility of critical medical products, and the CARES Act enhances U. S. FDA' s existing authority with respect to drug shortage measures. Under the CARES Act, we must have in place a risk management plan that identifies and evaluates the risks to the supply of approved drugs for certain serious diseases or conditions for each establishment where the drug or API is manufactured. The risk management plan will be subject to U. S. FDA review during an inspection. If we experience shortages in the supply of our marketed products, our results could be materially impacted~~ . The U. S. FDA and

similar foreign regulatory bodies may also implement new requirements, or change their interpretation and enforcement of existing requirements, for manufacture, packaging or testing of products at any time. If we or our approved suppliers are unable to comply, we may be subject to regulatory, civil actions or penalties, or we may be prevented from manufacturing or selling VASCEPA, all of which could significantly and adversely affect our business. Furthermore, reductions in government operations due to pandemic mitigation efforts, or other factors, may delay timely regulatory review by U. S. FDA or similar foreign regulatory bodies. ~~For example, since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the U. S. FDA has been working to resume pre- pandemic levels of inspection activities, including routine surveillance, bioresearch monitoring and pre- approval inspections. Should the U. S. FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the U. S. FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. During the COVID- 19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA' s inability to complete required inspections for their applications. Regulatory authorities outside the U. S. may adopt similar restrictions or other policy measures in response to the ongoing COVID- 19 pandemic and may experience delays in their regulatory activities. We have limited experience commercializing VASCEPA outside the United States, and we may not be successful in building an infrastructure, including a sales force, that can navigate the regulatory and other dynamics outside of the United States. We are currently, and may continue to be, substantially dependent on third parties for our international efforts, and we may not be~~ We have expanded our VASCEPA commercialization activities outside of the United States through several contractual arrangements in territories including China, the Middle East, North Africa ~~and ,~~ Canada **and, most recently, Australia, New Zealand, South Korea and Southeast Asia, and Israel** . We continue to assess other opportunities to develop VASCEPA commercialization outside of the United States through similar arrangements. ~~For example,~~ Edding is responsible for development and commercialization activities in the China Territory and associated expenses under our development, commercialization and supply agreement with them. Additionally, Edding is required to conduct clinical trials in the China Territory to secure regulatory approval in certain territories. ~~Although~~ Edding has successfully undertaken clinical trials and approval initiatives under our arrangement with them, including the announcement of statistically significant positive topline results from Edding' s Phase 3 clinical trial of VASCEPA and has obtained approval for VASCEPA **in Hong Kong** under the REDUCE- IT indication **and** ~~in Hong Kong, with anticipated approval~~ in Mainland China ~~expected by mid~~ **under the MARINE indication. In October 2023, Edding submitted for the approval of the REDUCE** - ~~year of 2023~~ **IT indication in Mainland China. However** , Edding may be required to undertake **pre- or post- approval** clinical development efforts in these markets, or Edding may face challenges or be unsuccessful in ~~pursuing~~ commercial launch. Further, any development and regulatory efforts in the China Territory may be negatively impacted ~~if the coronavirus pandemic worsens, continues or spreads, and if resources~~ by ~~regulators and industry professionals continue to be diverted to address~~ the ~~prolonged~~ **lingering effects of the** coronavirus pandemic. Any development and regulatory efforts in the China Territory may be negatively impacted by heightened political tension between China and the United States, including ~~in connection with COVID- 19 and other~~ issues expressed between the countries regarding trade practices, tariffs and honoring intellectual property rights. If Edding is not able to effectively ~~develop and~~ commercialize VASCEPA in the China Territory, we may not be able to generate revenue from **our** ~~the DCS Agreement~~ **agreement with Edding** resulting from the sale of VASCEPA in the China Territory. We are party to arrangements with Biologix FZCo, or Biologix, to register and commercialize VASCEPA in several Middle Eastern and North African countries ~~and ,~~ with HLS Therapeutics Inc., or HLS, to register, commercialize and distribute VASCEPA in Canada **, with CSL Seqirus, or CSL, to commercialize and distribute VASCEPA in Australia and New Zealand, Lotus Pharmaceuticals, or Lotus, to commercialize and distribute VASCEPA in several countries in Southeast Asia and Neopharm (Israel) 1996 Ltd., or Neopharm, to distribute VASCEPA in Israel** . Although Biologix is currently actively commercializing VASCEPA in the United Arab Emirates ~~and ,~~ Lebanon **, Kuwait and Saudi Arabia** , and HLS is currently commercializing VASCEPA in Canada, we are completely reliant on these third parties to ~~secure approval and~~ successfully commercialize the product in those markets, which markets can be complex and challenging. ~~Further, development and commercialization across the Middle East and North Africa is subject to similar risks as in the China Territory, and has been negatively impacted by COVID- 19 and the destabilized local economies in the region.~~ If Edding, Biologix ~~or ,~~ HLS **, CSL, Lotus or Neopharm** , or other third parties who we rely on for development and commercialization of VASCEPA, do not successfully carry out their contractual obligations or meet expected deadlines, our recourse and remedies against these parties is limited **.** Our efforts to launch and support commercialization of VAZKEPA on our own in Europe is a complex undertaking for a company that, other than ~~our launch of VAZKEPA in Germany in September 2021 (where operations were subsequently discontinued) and~~ the launch of VAZKEPA in certain countries in the **last two years** ~~fourth quarter of 2022, including the UK in October 2022~~ , has not launched or otherwise commercialized a product in Europe and could be subject to significant risks of execution to our successful development and revenue generation of VAZKEPA in Europe. We have limited experience working with partners outside the United States to develop and market our products in non- U. S. jurisdictions. In order for our partners to market and sell VASCEPA in any country outside of the United States for any indication, it will be necessary to obtain regulatory approval from the appropriate regulatory authorities. The requirements and timing for regulatory approval, which may include conducting clinical trials, vary widely from country to country and may in some cases be different than or more rigorous than requirements in the United States. Any failure by us or our partners to obtain approval for VASCEPA in non- U. S. jurisdictions in a timely manner may limit the commercial success of VASCEPA and our ability to grow our revenues. Our relationships with healthcare providers and physicians and third- party payors are 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 pharmaceutical products. Arrangements with third- party payors and customers can expose pharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute pharmaceutical products. In particular, the promotion, sales and marketing of healthcare items and services, as well as a wide range of pricing, discounting, marketing and promotion, structuring and commission (s), certain customer incentive programs and other business arrangements, are subject to extensive laws designed to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission (s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. Refer to " Item 1. Business- Government Regulation- Fraud and Abuse Laws and Data Regulation" for further details. The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record- keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products. In addition, manufacturers and other parties involved in the drug supply chain for prescription drug products must also comply with product tracking and tracing requirements and for notifying U. S. FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies continue to give regular and close scrutiny to interactions between healthcare companies and healthcare providers, and such scrutiny often leads to investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource- consuming and can divert a company' s attention from the business ~~. For example~~ , **including** the ~~June 2020 CIDs from the DOJ informing us that the DOJ is investigating whether aspects of our promotional speaker programs and copayment waiver program violated the U. S. Anti- Kickback Statute, and from the FCA relating to the sale and marketing of VASCEPA by us and our previous co- marketing partner, Kowa America as well as the March 2021 CID from the FTC in connection with the FTC' s investigation~~ **Investigation referenced above** ~~of whether we have engaged in, or are engaging in, anticompetitive practices or unfair methods of competition relating to VASCEPA require us to produce documents and answer written questions, or interrogatories, relevant to specified time periods. As does the subpoena from the New York State attorney general regarding the same subject matter on which the FTC CID is focused. As noted, we are cooperating with the government, but we cannot predict when these investigations will be resolved, the outcome of the investigations or their potential impact on our business~~ . Such investigations can be lengthy, costly and could materially affect and disrupt our business. If the government determines that we have violated the U. S. Anti- Kickback Statute, the FCA or antitrust regulations, we could be subject to significant civil and criminal fines and penalties. The failure to comply with any of these laws or regulatory requirements subjects entities to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in federal and state funded healthcare programs (such as Medicare and Medicaid), contractual damages and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical manufacturer to incur significant legal expenses and divert management' s attention from the operation of the business. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way. **In the U. S., to help patients afford our approved product, we utilize programs to assist them, including patient assistance programs and co- pay coupon programs for eligible patients. Government enforcement agencies have shown increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. It is possible that changes in insurer policies regarding co- pay coupons and / or the introduction and enactment of new legislation or regulatory action could restrict or otherwise negatively affect these patient support programs, which could result in fewer patients using affected products, and therefore could have a material adverse effect on our sales, business, and financial condition.** It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations ~~. Third party patient assistance programs that receive financial support from companies have become the subject of enhanced government and regulatory scrutiny. Government enforcement agencies have shown increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. The U. S. government has established guidelines that suggest that it is lawful for pharmaceutical manufacturers to make donations to charitable organizations who provide co- pay assistance to Medicare patients, provided that such organizations, among other things, are bona fide charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a first- come basis according to consistent financial criteria and do not link aid to use of a donor' s product. However, donations to patient assistance programs have received some negative publicity and have been the subject of multiple government enforcement actions, related to allegations regarding their use to promote branded pharmaceutical products over other less costly alternatives.~~

~~Specifically, in recent years there have been multiple settlements resulting out of government claims challenging the legality of their patient assistance programs under a variety of federal and state laws. It is possible that we may make grants to independent charitable foundations that help financially needy patients with their premium, co- pay, and co- insurance obligations. If we choose to do so, and if we or our vendors or donation recipients are deemed to fail to comply with relevant laws, regulations or evolving government guidance in the operation of these programs, we could be subject to damages, fines, penalties, or other criminal, civil, or administrative sanctions or enforcement actions. We cannot ensure that our compliance controls, policies, and procedures will be sufficient to protect against acts of our employees, business partners, or vendors that may violate the laws or regulations of the jurisdictions in which we operate. Regardless of whether we have complied with the law, a government investigation could impact our business practices, harm our reputation, divert the attention of management, increase our expenses, and reduce the availability of foundation support for our patients who need assistance. Further, it is possible that changes in insurer policies regarding co- pay coupons and / or the introduction and enactment of new legislation or regulatory measures impacting patients using affected products could have a material adverse effect on our sales, business and financial condition. For example, on December 31, 2020, CMS published a new rule, effective January 1, 2023, requiring manufacturers to ensure the full value of co- pay assistance is passed on to the patient or these dollars will count toward the Average Manufacturer Price and Best Price calculation of the drug. On May 17, 2022, the U. S. District Court for the District of Columbia granted the Pharmaceutical Research and Manufacturers of America' s, or PhRMA, motion for summary judgment invalidating the accumulator adjustment rule. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the current U. S. presidential administration may reverse or otherwise change these measures, both the current U. S. presidential administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs. We cannot predict how the implementation of and any further changes to this rule will affect our business~~ . In addition, with the approval and commercialization of any of our products outside the United States, we will also likely be subject to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. We rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet established deadlines for the completion of such clinical trials. Our reliance on third parties for clinical development activities reduces our control over these activities. However, if we sponsor clinical trials, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trials. Moreover, the U. S. FDA requires us to comply with requirements, commonly referred to as good clinical practices, for conducting, recording, and reporting the results of clinical trials to ensure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be delayed in obtaining regulatory approvals for our product candidates and may be delayed in our efforts to successfully commercialize our product candidates for targeted diseases. **In addition, investigator initiated trials, or IITs, which are scientific research that is initiated, sponsored, and conducted by an independent investigator (s) and / or institution (s) not affiliated with us, are being, and additional IITs, may be conducted involving potential product candidates. The investigator, sponsor, and / or investigator / sponsor remains responsible for conception, design, data analysis, publication, and compliance with applicable law. Investigator initiated trials can contribute towards enhancing the understanding of products (such as mechanism of action) and sparking new ideas for further research; however, IITs are generally not supported by pharmaceutical companies for the purposes of generating data that can lead to product labelling changes. Even if an IIT has positive results, additional studies, along with regulatory agency guidance and approval, would be required to advance a pharmaceutical product to the next stage of development and new potential labelling changes or indications. If we are unable to confirm or replicate the results from an IIT or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development. Further, if the data proves to be inadequate compared to the firsthand knowledge we might have gained had the IIT been sponsored and conducted by us, then our ability to design and conduct any future clinical trials ourselves may be adversely affected. Negative results in IITs could have a material adverse effect on our efforts to obtain regulatory approval for such product candidates and the public perception of such product candidates. In addition, third parties that are investigating product candidates which have not been provided by us may seek and obtain regulatory approval of product candidates before we do, which may adversely affect our development strategy and eligibility for certain exclusivities for which we may otherwise be eligible.** Risks Related to Our Intellectual Property **We are dependent on patents, proprietary rights and confidentiality obligations of our employees, agents, business partners and third parties to protect the commercial value and potential of VASCEPA. Enforcing our patent rights is challenging and costly** Our success depends in part on our ability to obtain and maintain intellectual property protection for our drug candidates, technology and know- how, and to operate without infringing the proprietary rights of others. Refer to " Item 1. Business- Patents, Proprietary Technology, Trade Secrets for further details. We plan to vigorously defend our rights under issued patents, however such defense activities can be costly to pursue and may not have the desired results. **On** ~~For example, on~~ November 30, 2020 **,** we filed a patent infringement lawsuit against Hikma for making, selling, offering to sell and importing generic icosapent ethyl capsules in and into the United States in a manner that we allege has induced the infringement of patents covering the use of VASCEPA to reduce specified ~~cardiovascular~~ **CV** risk. On January 25, 2021, we expanded the scope of this patent infringement lawsuit to include a ~~health~~ **healthcare** ~~care~~ insurance provider, Health Net, LLC. On January 4, 2022, the district court hearing the case granted Hikma' s motion to dismiss. On October 13, 2022, the district court granted final judgement and ~~we have appealed this~~ **the Company is appealing (Fed. Cir. No. 23- 1169 filed November 21, 2022) the** decision **of the district court** but cannot predict the outcome or the impact on ~~our~~ **its** business. We entered into a settlement agreement with Health Net, LLC

on December 26, 2022. ~~We likewise plan~~ **The Company intends** to **continue to vigorously enforce its** ~~engage in similar patent litigation should other competitors arise with products that infringe our~~ intellectual property rights **relating to VASCEPA, but cannot predict the outcome of these lawsuits or any subsequently filed lawsuits** . Patent litigation is a time- consuming and costly process. There can be no assurance that we will be successful in enforcing ~~this~~ **any** patent or that it will not be successfully challenged and invalidated. Even if we are successful in enforcing this patent, the process could take years to reach conclusion. Other drug companies may challenge the validity, enforceability, or both of our patents and seek to design its products around our issued patent claims and gain marketing approval for generic versions of VASCEPA or branded competitive products based on new clinical studies. The pharmaceutical industry is highly competitive and many of our competitors have greater experience and resources than we have. Any such competition could undermine sales, marketing and collaboration efforts for VASCEPA, and thus reduce, perhaps materially, the revenue potential for VASCEPA. Even if we are successful in enforcing our issued patents, we may incur substantial costs and divert management' s time and attention in pursuing these proceedings, which could have a material adverse effect on us. Patent litigation is costly and time consuming, and we may not have sufficient resources to bring these actions to a successful conclusion. We have filed and are prosecuting numerous families of patent applications in the United States and internationally with claims designed to protect the proprietary position of VASCEPA **/ VAZKEPA** . For certain of these patent families, we have filed multiple patent applications. Collectively **,** the patent applications include numerous independent claims and dependent claims. Several of our patent applications contain claims that are based upon what we believe are unexpected and favorable findings from our clinical trials. However, our pending patent applications may not be granted or, if they **are** ~~grant~~ **granted** , **there is no certainty** that they will prevent competitors from competing with VASCEPA. Securing patent protection for a product is a complex process involving many legal and factual questions. The patent applications we have filed in the United States and internationally are at varying stages of examination, the timing of which is outside our control. The process to getting a patent granted can be lengthy and claims initially submitted are often modified in order to satisfy the requirements of the patent office. This process includes written and public communication with the patent office. The process can also include direct discussions with the patent examiner. There can be no assurance that the patent office will accept our arguments with respect to any patent application or with respect to any claim therein. We cannot predict the timing or results of any patent application. In addition, we may elect to submit, or the patent office may require, additional evidence to support certain of the claims we are pursuing. Furthermore, third parties may attempt to submit publications for consideration by the patent office during examination of our patent applications. Providing such additional evidence and publications could prolong the patent office' s review of our applications and result in us incurring additional costs. We cannot be certain what commercial value any granted patent in our patent estate will provide to us. Despite the use of confidentiality agreements and / or proprietary rights agreements, which themselves may be of limited effectiveness, it may be difficult for us to protect our trade secrets. In addition to our patent portfolio and strategy, we will also rely upon trade secrets and know- how to help protect our competitive position. We rely on trade secrets to protect technology in cases when we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. While we require certain of our academic collaborators, contractors and consultants to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary information. Risks Related to Our Business If the estimates we make, or the assumptions on which we rely, in preparing our projected guidance prove inaccurate, our actual results may vary from those reflected in our projections and accruals. In January ~~2023~~ **2024** , we ~~disclosed~~ **reiterated** our **belief that current cash** ~~2023 financial outlook. Such outlook~~ and ~~estimates~~ **investments and other assets are adequate to support continued operations, including the share repurchase program. This and similar statements** are based on estimates, assumptions and the judgment of management **at such time** . Because of the inherent nature of estimates, including during the uncertainty of our European launch and the impact from U. S. generic competition, we have suspended providing net revenue guidance, as there could be significant differences between our estimates and the actual amount of product demand. If we fail to realize or if we change or update any element of our publicly disclosed financial guidance as we have done in the past or other expectations about our business and initiative change, our stock price could decline in value. The loss of key personnel could have an adverse effect on our business, particularly in light of **recent senior** ~~our announcement of~~ management **changes** ~~succession plan~~ . We are highly dependent upon the efforts of our senior management. The loss of the services of one or more members of senior management could have a material adverse effect on us. Given our rapidly expanding enterprise coupled with a streamlined management structure and sales force **and the changes to our Board and senior management team during 2023** , the departure of any key person could have a significant impact and would be potentially disruptive to our business until such time as a suitable replacement is hired. Furthermore, because of the specialized nature of our business, as our business plan progresses, we will be highly dependent upon our ability to attract and retain qualified scientific, technical and key management personnel. As we continue to expand our commercialization efforts ~~, particularly on a global~~ **globally** ~~scale,~~ we may experience continued or increased turnover among members of our senior management team. We may have difficulty identifying, attracting and integrating new executives to replace any such losses. As we ~~expand~~ **pursue** commercialization efforts in Europe, we need to rapidly hire employees and ensure that they are well trained and working cohesively with core values which are consistent with our existing operations and which, we believe, help improve our position for success. In the United States, **where we have recently eliminated all sales force positions,** employees are increasingly being recruited by other companies. **The** ~~While our business remains focused on continued promotion of VASCEPA in the United States, and expansion in Europe, the~~ current and potential threat of generic competition and our recent reductions in force **, including as part of our Organizational Restructuring Program announced in July 2023,** can create employee uncertainty which could lead to increased employee turnover. There is intense competition for qualified personnel in the areas of our activities. In this environment, we may not be able to attract or retain the personnel necessary for the development of our business, particularly if we do not achieve profitability. The failure to recruit key scientific, technical and management personnel would be detrimental to our ability to

implement our business plan. Our internal computer systems, or those of our third - party clinical research organizations or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our commercial, research and development and other programs. Despite the implementation of security measures, our internal computer systems and those of our third - party clinical research organizations and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. Any such incident could cause interruptions in our operations or a material disruption of our programs. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or products candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and our research and development program could be delayed. We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company and our vendors, including personal information of our employees and patients, and company and vendor confidential data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and / or systems. We may experience threats to our data and systems, including malicious codes and viruses, phishing and other cyber- attacks. The number and complexity of these threats continue to increase over time. For example, in June 2019, a report published by security researchers claimed that a database belonging to one of our vendors containing information about individuals who use or have expressed interest in VASCEPA was accessible to unauthorized users. Although we were informed that such breach did not include social security numbers or credit card information, a more material breach could occur in the future. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks and to repair reputational costs. In addition, we could be subject to regulatory actions and / or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. We may incur significant costs or divert significant internal resources as a result of any regulatory actions or private litigation. Any of the foregoing consequences may adversely affect our business and financial condition. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients, and rely more on cloud- based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems. In addition, there can be no assurance that our internal information technology systems or those of our third- party contractors, or our consultants' efforts to implement adequate security and control measures, will be sufficient to protect us against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyberattack, security breach, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm. We are subject to potential product liability. We are subject to the potential risk of product liability claims relating to the manufacturing and marketing of VASCEPA. Any person who is injured as a result of using VASCEPA may have a product liability claim against us without having to prove that we were at fault. In addition, we could be subject to product liability claims by persons who took part in clinical trials involving our current or former development stage products. A successful claim brought against us could have a material adverse effect on our business. We cannot guarantee that a product liability claim will not be asserted against us in the future. A change in our tax residence and / or tax laws could have a negative effect on our future profitability. We expect that our tax jurisdiction will remain in Ireland. Under current UK legislation, a company incorporated in England and Wales, or which is centrally managed and controlled in the UK, is regarded as resident in the UK for taxation purposes. Under current Irish legislation, a company is regarded as resident for tax purposes in Ireland if it is centrally managed and controlled in Ireland, or, in certain circumstances, if it is incorporated in Ireland. Up to December 31, 2019, where a company was treated as tax resident under the domestic laws of both the UK and Ireland, then the provisions of article 4 (3) of the Double Tax Agreement, or DTA, between the UK and Ireland provided that such enterprise would be treated as resident only in the jurisdiction in which its place of effective management is situated. We ~~had~~ **have** at all times sought to conduct our affairs in such a way so as to be solely resident in Ireland for tax purposes by virtue of having our place of effective management situated in Ireland. These rules regarding determination of tax residence changed effective January 1, 2020, when a modified Ireland- UK DTA came into effect pursuant to the OECD' s Multilateral Instrument, or MLI. Under the modified Ireland- UK DTA, from January 1, 2020, we would be solely tax resident in Ireland and not tax resident in the UK if we continued to be centrally managed and controlled in Ireland and if it were mutually agreed between the Irish and UK tax authorities under the MLI " tie- breaker rule " that we are solely tax resident in Ireland. Having made the relevant submission under the amended provisions, we received confirmation effective January 1, 2020 of the mutual agreement of Irish and UK tax authorities that we are solely tax resident in Ireland for the purposes of the modified DTA. However, we cannot assure you that we are or will continue to be solely resident in Ireland for tax purposes. It is possible that in the future, whether as a result of a change in law or the practice of any relevant tax authority or as a result of any change in the conduct of our affairs, we could become, or be regarded as having become resident in a jurisdiction other than Ireland. Should we cease to be an Irish tax resident, we may be subject to a charge to Irish capital gains tax on our assets and the basis on which our income is taxed may also change. Similarly, if the tax residency of our Irish or UK subsidiaries were to change from their current jurisdiction, they may be subject to a charge to local capital gains tax on their assets and the basis on which their income is

taxed may also change. Our and our subsidiaries' income tax returns are periodically examined by various tax authorities, including the Internal Revenue Service, or the IRS, and ~~states~~ **state tax authorities** . For example, the IRS began an examination of our 2018 U. S. income tax return in the first quarter of 2020. Although the outcome of tax audits is always uncertain and could result in significant cash tax payments, we do not believe the outcome of any ongoing or future audits will have a material adverse effect on our consolidated financial position or results of operations. We could be adversely affected by our exposure to customer concentration risk. A significant portion of our sales are to wholesalers in the pharmaceutical industry. Three customers individually accounted for 10 % or more of our U. S. gross product sales. Customers A, B, and C accounted for ~~35~~ **36** %, ~~31~~ **28** %, and ~~27~~ **29** %, respectively, of gross product sales for the year ended December 31, ~~2022~~ **2023** and represented ~~35~~ **36** %, ~~21~~ **18** %, and ~~39~~ **38** %, respectively, of the gross accounts receivable balance as of December 31, ~~2022~~ **2023** . Customers A, B, and C accounted for ~~37~~ **35** %, ~~28~~ **31** %, and 27 %, respectively, of gross product sales for the year ended December 31, ~~2021~~ **2022** and represented **35 %, 21 %, and** 39 ~~%, 22 %, and 35~~ %, respectively, of the gross accounts receivable balance as of December 31, ~~2021~~ **2022** . We expect that we may have customer concentration risk as we enter additional countries. There can be no guarantee that we will be able to sustain our accounts receivable or gross sales levels from our key customers. If, for any reason, we were to lose, or experience a decrease in the amount of business with our largest customers, whether directly or through our distributor relationships, our financial condition and results of operations could be negatively affected. Risks Related to Our Financial Position and Capital Requirements We have a history of operating losses and anticipate that we will incur continued losses for an indefinite period of time. We have not yet reached sustained profitability. For the fiscal year ended December 31, **2023 and** 2022 ~~and 2020~~ , we reported net losses of approximately $ **59. 1 million and $** 105. 8 ~~million and $ 18. 0~~ million, respectively. For the fiscal year ended December 31, 2021, we reported net income of approximately $ 7. 7 million. We had an accumulated deficit as of December 31, ~~2022~~ **2023** of $ 1. ~~5~~ **6** billion. Substantially all of our operating losses resulted from costs incurred in connection with our research and development programs, from general and administrative costs associated with our operations, and costs related to the commercialization of VASCEPA. Additionally, as a result of our significant expenses relating to commercialization and research and development, we expect to continue to incur significant operating losses for an indefinite period. Because of the numerous risks and uncertainties associated with developing and commercializing pharmaceutical products, we are unable to predict the magnitude of these future losses. Our historic losses, combined with expected future losses, have had and will continue to have an adverse effect on our cash resources, shareholders' deficit and working capital. We may never generate sufficient revenue to achieve a steady state of profitability. Our ability to become profitable on a sustained basis depends upon our ability to generate revenue. We have been generating product revenue from sales of VASCEPA since January 2013, but we may not be able to generate sufficient revenue to achieve a steady state of profitability. Our ability to generate profits on sales of VASCEPA is subject to the market acceptance and commercial success of VASCEPA and our ability to manufacture commercial quantities of VASCEPA through third parties at acceptable cost levels, and may also depend upon our ability to effectively market and sell VASCEPA through our strategic collaborations. Even though VASCEPA has been approved by the U. S. FDA for marketing in the United States for two important indications, received marketing authorization in Europe ~~,~~ and is approved in smaller jurisdictions, it may not gain enough market acceptance to support consistent profitability. We anticipate continuing to incur significant costs associated with expanding the commercialization of VASCEPA. We may not achieve profitability on a sustained basis in the near term due to high costs associated with, for example, our ~~expanded~~ commercialization efforts in the United States and ~~our expected commercialization efforts in~~ Europe. If we are unable to consistently generate robust product revenues, we will not become profitable on a sustained basis in the near term, if ever, and may be unable to continue operations without continued funding. Our operating results are unpredictable and may fluctuate. If our operating results are below the expectations of securities analysts or investors, the trading price of our stock could decline. Our operating results are difficult to predict and will likely fluctuate from quarter to quarter and year to year, and VASCEPA prescription figures will likely fluctuate from month to month. VASCEPA sales are difficult to predict from period to period and as a result, you should not rely on VASCEPA sales results in any period as being indicative of future performance ~~, and sales of VASCEPA may be below the expectation of securities analysts or investors in the future~~ . We believe that our quarterly and annual results of operations may be affected by a variety of factors, including those risks and uncertainties described in this Part II, Item 1A and the following: • the recent and future potential launches of additional generic versions of VASCEPA; • ~~continued and prolonged disruption to our business, or delays in resuming normal business activities, or reinstating restrictions after protocols have been lifted, from~~ the ~~COVID- 19 pandemic~~ **timing and ability of efforts outside the United States, to develop, register and commercialize VASCEPA in Europe, the China Territory, several Middle Eastern and North African countries, and Canada, including obtaining necessary regulatory approvals, favorable pricing and establishing marketing channels** ; • the continuing evolution of the medical community' s and the public' s perception of the REDUCE- IT study results; • the level of demand for VASCEPA, due to changes in prescriber sentiment, quarterly changes in distributor purchases, and other factors; • the extent to which coverage and reimbursement for VASCEPA is available from government and health administration authorities, private health insurers, managed care programs and other third- party payors and the timing and extent to which such coverage and reimbursement changes; • the timing, cost and level of investment in our sales and marketing efforts to support VASCEPA sales, and our cost and reorganization efforts, including our ~~recent cost reduction plan~~ **ORP announced in July 2023** , and the resulting effectiveness of those efforts; • disruptions or delays in our or our partners' commercial or development activities, including as a result of political instability, civil unrest, terrorism, pandemics or other natural disasters, such as the coronavirus pandemic ~~; • the timing and ability of efforts outside the United States, to develop, register and commercialize VASCEPA in Europe, the China Territory, several Middle Eastern and North African countries, and Canada, for example, including obtaining necessary regulatory approvals, favorable pricing and establishing marketing channels~~ ; • additional developments regarding our intellectual property portfolio and regulatory exclusivity protections, if any; • outcomes of litigation and other legal proceedings;

and • our ongoing regulatory dialogue. We may require substantial additional resources to fund our operations. If we cannot find additional capital resources, we will have difficulty in operating as a going concern and growing our business. We currently operate with limited resources. We believe that our cash and cash equivalents balance of $ ~~217~~ **199** . ~~7~~ **3** million and short- term investment balance of $ ~~91~~ **121** . ~~7~~ **4** million as of December 31, ~~2022~~ **2023** , will be sufficient to fund our projected operations **, including the share repurchase program,** for at least 12 months from the issuance date of consolidated financial statements included elsewhere in this Annual Report on Form 10- K. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect or fail to achieve positive cash flow. Depending on the level of cash generated from operations, and depending in part on the rate of prescription growth for VASCEPA, additional capital may be required to support planned VASCEPA promotion and potential VASCEPA promotion beyond which we are currently executing and for commercialization of VAZKEPA in Europe. If additional capital is required and we are unable to obtain additional capital on satisfactory terms, or at all, we may be forced to delay, limit or eliminate certain promotional activities. We anticipate that quarterly net cash outflows in future periods will be variable as a result of the timing of certain items, including our purchases of API and VASCEPA promotional and educational activities, including launch activities in Europe, on our operations and those of our customers and any current or potential generic competition. In order to fully realize the market potential of VASCEPA, we may need to enter into a new strategic collaboration or raise additional capital. Our future capital requirements will depend on many factors, including: • the timing, amount and consistency of revenue generated from the commercial sale of VASCEPA; • the costs associated with commercializing VASCEPA in the United States ~~and sales force sizing~~ , and for commercializing VAZKEPA in Europe, including hiring experienced professionals, and for additional regulatory approvals internationally, if any, the cost and timing of securing commercial supply of VASCEPA and the timing of entering into any new strategic collaboration with others relating to the commercialization of VASCEPA, if at all, and the terms of any such collaboration; • continued costs associated with litigation and other legal proceedings and governmental inquiries; • the time and costs involved in obtaining additional regulatory approvals for VASCEPA based on REDUCE- IT results internationally; • the extent to which we continue to develop internally, acquire or in- license new products, technologies or businesses; and • the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights. If we require additional funds and adequate funds are not available to us in amounts or on terms acceptable to us or on a timely basis, or at all, our commercialization efforts for VASCEPA, and our business generally, may suffer materially. Changes in tax laws could have a material adverse effect on our business, financial condition and results of operations. Tax law and policies in the United States and Ireland are unsettled and may be subject to significant change, including based on adjustments in political perspectives and administration shifts. In the United States and internationally, how to tax entities with international operations, like us, has been subject to significant re- evaluation. We believe we developed VASCEPA in and from Ireland based on understanding of applicable requirements. In recent years, particularly since 2013 when commercial sale of VASCEPA commenced in the United States, the majority of our consolidated operations have been in the United States. Ownership of VASCEPA continues to reside with our wholly- owned Ireland- based subsidiary, Amarin Pharmaceuticals Ireland Ltd., and oversight and operations of that entity are structured to be maintained in Ireland. In order to effectively utilize our accumulated net operating loss carryforwards for tax purposes in Ireland, our operations, particularly for this subsidiary, need to be active in Ireland under applicable requirements. In addition, utilization of these accumulated net operating loss carryforwards assumes that tax treaties between Ireland and other countries, particularly the United States, do not change in a manner that limit our future ability to offset earnings with these operating loss carryforwards for tax purposes. Similarly, a change in our Irish tax residence could materially affect our ability to obtain and maintain profitability, if otherwise achievable. Changes in tax law and tax rates, particularly in the United States and Ireland, could also impact our assessment of deferred taxes. Any change in our assessment of the realizability or the timing for realizing deferred taxes could have a negative impact our future profitability. Changes in tax laws ~~(including in response to the COVID- 19 pandemic)~~ or tax rulings, or changes in interpretations of existing laws, could cause us to be subject to additional income- based taxes and non- income taxes (such as payroll, sales, use, value-added, digital tax, net worth, property, and goods and services taxes), which in turn could materially affect our financial position and results of operations. In particular, there have been a number of significant changes to the U. S. federal income tax rules in recent years and additional tax reform proposed by the Biden administration may be enacted. The effect of any such tax reform is uncertain. As we continue to expand internationally, we will be subject to varied and complex tax regimes, and the tax laws of one jurisdiction may impact our expansion to or operations in other jurisdictions. Additionally, new, changed, modified, or newly interpreted or applied tax laws could increase our partners' and our compliance, operating and other costs, as well as the costs of our products. As we expand the scale of our business activities, any changes in the taxation of such activities may increase our effective tax rate and harm our business, financial condition, and results of operations. The IRA was enacted into law on August 16, 2022. Included in the IRA was a provision to implement a 15 % corporate alternative minimum tax on corporations whose average annual adjusted financial statement income during the most recently completed three- year period exceeds $ 1. 0 billion. This provision is effective for tax years beginning after December 31, 2022. We **do not expect** ~~are in the process of evaluating~~ the provisions of the IRA **to have a material impact** . Risks Related to Ownership of our ADSs and Common Shares **The implementation of our announced share repurchase agreement is conditional upon shareholder and UK court approval, as required under UK company law. Although we intend to accelerate our annual general meeting of shareholders to April 2024 to seek such shareholder approval, we will thereafter need to proceed with the requisite court process to undertake a reduction of capital in order to create the necessary distributable profits for the funding of the repurchases, which process could be completed by the end of the second quarter of 2024, with share repurchases commencing shortly thereafter; however, we cannot guarantee that the share repurchase program will receive shareholder or court approval in a timely manner or at all. Further, the share repurchase program and other efforts to return capital to shareholders may not have the anticipated effect or increase shareholder value in the long term. If we**

are no longer able to meet the listing requirements of the NASDAQ Stock Market, our stock may be delisted. The NASDAQ Stock Market, or NASDAQ, on which our ADSs are listed and traded, has listing requirements that include a $ 1. 00 minimum closing bid price requirement. NASDAQ will issue a deficiency notice if an issuer is in violation of a listing standard for a period of 30 business consecutive days. Such deficiency letter does not result in the immediate delisting of an issuer as there is a period of 180 calendar days from the deficiency notice to regain compliance with NASDAQ' s minimum bid price requirement. If an issuer is unable to comply with NASDAQ' s minimum bid price requirement after this 180 day calendar period, NASDAQ may elect, subject to any potential additional cure periods, to initiate a process that could delist the issuer from trading on the NASDAQ. We received a deficiency letter from NASDAQ in October 2023, as our ADSs had traded below $ 1. 00 for 30 consecutive business days. In January 2024 we regained compliance with the NASDAQ listing requirements as our ADSs had traded above $ 1. 00 for 10 consecutive business days. Should such a delisting occur, it would adversely impact the liquidity and price of our ADSs and would impede our ability to raise capital. The price of our ADSs and common shares may be volatile. The stock market has from time to time experienced significant price and volume fluctuations that may be unrelated to the operating performance of particular companies. In addition, the market prices of the securities of many pharmaceutical and medical technology companies have been especially volatile in the past, and this trend is expected to continue in the future. As of February ~~24~~ **23** , ~~2023~~ **2024** , we had ~~406~~ **410** , ~~115~~ **671** , ~~721~~ **800** common shares outstanding including ~~385~~ **401** , ~~785~~ **870** , ~~809~~ **067** shares held as ADSs and ~~20~~ **8** , ~~329~~ **801** , ~~912~~ **733** held as ordinary shares (which are not held in the form of ADSs). There is a risk that there may not be sufficient liquidity in the market to accommodate significant increases in selling activity or the sale of a large block of our securities. Our ADSs have historically had limited trading volume, which may also result in volatility **. Our planned share repurchase program, which is subject to requisite shareholder and UK High Court approval under UK law, would, if implemented, reduce the number of shares outstanding and could result in reduced trading volumes** . If any of our large investors seek to sell substantial amounts of our ADSs, particularly if these sales are in a rapid or disorderly manner, or other investors perceive that these sales could occur, the market price of our ADSs could decrease significantly. The market price of our ADSs and common shares may also be affected by factors such as: • developments or disputes concerning ongoing patent prosecution efforts and any future patent or proprietary rights; • litigation and regulatory developments in the United States affecting our VASCEPA promotional rights, and regulatory developments in other countries; • actual or potential medical results relating to our products or our competitors' products; • interim failures or setbacks in product development; • innovation by us or our competitors; • currency exchange rate fluctuations; and • period- to- period variations in our results of operations. ~~Further, the effects of Brexit are uncertain and may have a negative effect on global economic conditions, financial markets and our business, which could reduce the price of our ADSs and common shares. In particular, Brexit could lead to a period of considerable uncertainty in relation to the UK financial and banking markets, as well as on the regulatory process in Europe, which could cause the broader global financial markets to experience significant volatility. Asset valuations, currency exchange rates and credit ratings may also be subject to increased market volatility due to the ongoing uncertainty. Lack of clarity about future UK laws and regulations as the United Kingdom determines which EU rules and regulations to replace or replicate could decrease foreign direct investment in the UK, increase costs, disrupt our business, depress economic activity and restrict our access to capital, any of which could negatively impact the price of our ADSs and common shares. Actual or potential sales of our common shares by our employees, including members of our senior management team, pursuant to pre- arranged stock trading plans could cause our stock price to fall or prevent it from increasing for numerous reasons, and actual or potential sales by such persons could be viewed negatively by other investors. In accordance with the guidelines specified under Rule 10b5- 1 under the Exchange Act and our policies regarding stock transactions, a number of our directors and employees, including members of our senior management team, have adopted and may continue to adopt pre- arranged stock trading plans to sell a portion of our common stock that they beneficially own. Generally, sales under such plans by members of our senior management team and directors require public filings. Actual or potential sales of our ADSs by such persons could cause the price of our ADSs to fall or prevent it from increasing for numerous reasons. For example, a substantial amount of our ADSs becoming available (or being perceived to become available) for sale in the public market could cause the market price of our ADSs to fall or prevent it from increasing. Also, actual or potential sales by such persons could be viewed negatively by other investors.** If we were to be characterized as a passive foreign investment company there could be adverse consequences to U. S. investors. A non- U. S. corporation will be classified as a passive foreign investment company, or PFIC, for U. S. federal income tax purposes for any taxable year, if either (i) 75 % or more of its gross income for such year consists of certain types of " passive " income or (ii) 50 % or more of the value of its assets (determined on the basis of a quarterly average) during such year produce or are held for the production of passive income. Passive income generally includes dividends, interest, royalties, rents, annuities, net gains from the sale or exchange of property producing such income and net foreign currency gains. In addition, a non- U. S. corporation will be treated as owning its proportionate share of the assets and earning its proportionate share of the income of any other corporation in which it owns, directly or indirectly, no more than 25 % (by value) of the stock. Based on certain estimates of our gross income and gross assets, the latter determined by reference to the expected value of our ADSs and **ordinary** shares, we believe that we will not be classified as a PFIC for the taxable year ended December 31, ~~2022~~ **2023** , and we do not expect to be treated as a PFIC in any future taxable year for the foreseeable future. However, because PFIC status is based on our income, assets and activities for the entire taxable year, which we expect may vary substantially over time, it is not possible to determine whether we will be characterized as a PFIC for any taxable year until after the close of the taxable year. Moreover, we must determine our PFIC status annually based on tests that are factual in nature, and our status in future years will depend on our income, assets and activities in each of those years. There can be no assurance that we will not be considered a PFIC for any taxable year. We do not intend to pay cash dividends on the ordinary shares in the foreseeable future. We have never paid dividends on ordinary shares and do not anticipate paying any cash dividends on the ordinary shares

in the foreseeable future. Under English law, any payment of dividends would be subject to relevant legislation and our Articles of Association, which requires that all dividends must be approved by our board of directors and, in some cases, our shareholders, and may only be paid from our distributable profits available for the purpose, determined on an unconsolidated basis. The rights of our shareholders may differ from the rights typically offered to shareholders of a U. S. corporation. We are incorporated under English law. The rights of holders of ordinary shares and, therefore, certain of the rights of holders of ADSs, are governed by English law, including the provisions of the Companies Act 2006, and by our Articles of Association. These rights differ in certain respects from the rights of shareholders in typical U. S. corporations. The principal differences include the following: • Under English law and our Articles of Association, each shareholder present at a meeting has only one vote unless demand is made for a vote on a poll, in which case each holder gets one vote per share owned. Under U. S. law, each shareholder typically is entitled to one vote per share at all meetings. • Under English law, it is only on a poll that the number of shares determines the number of votes a holder may cast. You should be aware, however, that the voting rights of ADSs are also governed by the provisions of a deposit agreement with our depositary bank. • Under English law, subject to certain exceptions and disapplications, each shareholder generally has preemptive rights to subscribe on a proportionate basis to any issuance of ordinary shares or rights to subscribe for, or to convert securities into, ordinary shares for cash. Under U. S. law, shareholders generally do not have preemptive rights unless specifically granted in the certificate of incorporation or otherwise. • Under English law and our Articles of Association, certain matters require the approval of 75 % of the shareholders who vote (in person or by proxy) on the relevant resolution (or on a poll of shareholders representing 75 % of the ordinary shares voting (in person or by proxy)), including amendments to the Articles of Association. This may make it more difficult for us to complete corporate transactions deemed advisable by our board of directors. Under U. S. law, generally only majority shareholder approval is required to amend the certificate of incorporation or to approve other significant transactions. • In the **UK** ~~United Kingdom~~ , takeovers may be structured as takeover offers or as schemes of arrangement. Under English law, a bidder seeking to acquire us by means of a takeover offer would need to make an offer for all of our outstanding ordinary shares / ADSs. If acceptances are not received for 90 % or more of the ordinary shares / ADSs under the offer, under English law, the bidder cannot complete a " squeeze out " to obtain 100 % control of us. Accordingly, acceptances of 90 % of our outstanding ordinary shares / ADSs will likely be a condition in any takeover offer to acquire us, not 50 % as is more common in tender offers for corporations organized under Delaware law. By contrast, a scheme of arrangement, the successful completion of which would result in a bidder obtaining 100 % control of us, requires the approval of a majority of shareholders voting at the meeting and representing 75 % of the ordinary shares voting for approval. • Under English law and our Articles of Association, shareholders and other persons whom we know or have reasonable cause to believe are, or have been, interested in our shares may be required to disclose information regarding their interests in our shares upon our request, and the failure to provide the required information could result in the loss or restriction of rights attaching to the shares, including prohibitions on certain transfers of the shares, withholding of dividends and loss of voting rights. Comparable provisions generally do not exist under U. S. law. • The quorum requirement for a shareholders' meeting is a minimum of two shareholders entitled to vote at the meeting and present in person or by proxy or, in the case of a shareholder which is a corporation, represented by a duly authorized officer (although the marketplace rules of the Nasdaq Stock Market require that shareholders holding at least one- third of our outstanding shares of voting stock are present at the meeting or by proxy). Under U. S. law, a majority of the shares eligible to vote must generally be present (in person or by proxy) at a shareholders' meeting in order to constitute a quorum. The minimum number of shares required for a quorum can be reduced pursuant to a provision in a company' s certificate of incorporation or bylaws, but typically not below one- third of the shares entitled to vote at the meeting. Shareholder protections found in provisions under the UK City Code on Takeovers and Mergers, or the Takeover Code, do not apply to us. **We believe that our place of central management and control is not currently in the UK (or the Channel Islands or the Isle of Man) for the purposes of the jurisdictional criteria of the Takeover Code. Accordingly, we believe that we are not currently subject to the Takeover Code and, as a result, our shareholders are not currently entitled to the benefit of certain takeover offer protections provided under the Takeover Code, including the rules regarding mandatory takeover bids. In the event that this changes, or if the interpretation and application of the Takeover Code by the Panel on Takeovers and Mergers, or Takeover Panel, changes (including changes to the way in which the Takeover Panel assesses the application of the Takeover Code to English companies whose shares are listed outside of the UK), the Takeover Code may apply to us in the future.** The Takeover Code provides a framework within which takeovers of certain companies organized in the United Kingdom are regulated and conducted. However, because our place of central management and control is currently outside of the United Kingdom, we are not subject to the Takeover Code. As a result, our shareholders are not entitled to the benefit of certain takeover offer protections provided under the Takeover Code. The following is a brief summary of some of the most important rules of the Takeover Code which, as noted, does not apply to us: • In connection with a potential offer, if following an approach by or on behalf of a potential bidder, the company is " the subject of rumor or speculation " or there is an " untoward movement " in the company' s share price, there is a requirement for the potential bidder to make a public announcement about a potential offer for the company, or for the company to make a public announcement about the potential offer. • When ~~a~~ **any** person ~~or group~~ **acquires, whether by a series** of **transactions over a period of time or not, an interest in shares which (taken together with shares already held by that person and an interest in shares held or acquired by** persons ~~who are treated as "~~ acting in concert ~~"~~ with ~~each~~ **him or** ~~other~~ -- **her** ~~(a~~) ~~acquires interests in shares carrying~~ --- **carry** 30 % or more of the voting rights of a company **that** ~~(which percentage~~ is ~~treated by~~ **subject to** the Takeover Code **, that person** ~~as the level at which effective control~~ is ~~obtained)~~ **generally required to make a mandatory offer to all the holders of any class of equity share capital** or ~~(b) increases the~~ **other** ~~aggregate percentage~~ **class of transferable securities carrying voting rights in that company to acquire the balance of their** ~~interest~~ **interests in** ~~they~~ -- **the** ~~have~~ **company. •** ~~when~~ **When** ~~they are already~~ **any person who, together with persons acting in concert with him or her, is** interested in **shares**

representing not less than 30 % ~~and~~ **but does** not **hold** more than 50 % ~~,~~ **of** ~~they~~ **the voting rights of a company that is subject to the Takeover Code, and such person, or any person acting in concert with him or her, acquires an additional interest in shares which increases the percentage of shares carrying voting rights in which he or she is interested, then such person is generally required to make a mandatory offer to all the holders of any class of equity share capital or other class of transferable securities carrying voting rights of that company to acquire the balance of their interests in the company. • A mandatory offer triggered in the circumstances described in the two paragraphs above** must ~~make a~~ **be in** cash ~~offer to all other shareholders~~ **(or be accompanied by a cash alternative) and** at **not less than** the highest price paid ~~by~~ **within** ~~them~~ **the preceding** ~~in the~~ 12 months ~~before~~ **to acquire any interest in shares in the company by the person required to make** the offer ~~was announced~~ **or any person acting in concert with him or her** . • **In relation to a voluntary offer (i. e., any offer which is not a mandatory offer),** ~~When~~ **when** interests in shares of any class representing 10 % of shares of that class have been acquired for cash by an offeror (i. e., a bidder) **and any person acting in concert with it** during the offer period (i. e., broadly speaking, the period after the potential offer has been made public) and within 12 months prior to commencement of the offer period, the offer must be in cash or be accompanied by a cash alternative for all shareholders of that class at **not less than** the highest price paid **for any interest in shares of that class** by the offeror in that period. Further, if an offeror acquires any interest in shares for cash during the offer period, the offer for the shares must be in cash or accompanied by a cash alternative at a price at ~~least equal to~~ **not less than** the **highest** price paid for such shares during the offer period. • If after an announcement is made, the offeror **or any person acting in concert with them** acquires an interest in shares in an offeree company (i. e., a target) at a price higher than the value of the offer, the offer must be increased ~~accordingly~~ **to not less than the highest price paid for the interest in shares so acquired** . • The offeree company must appoint a competent independent adviser whose advice on the financial terms of the offer must be made known to all the shareholders, together with the opinion of the board of directors of the offeree company. • **Special or** ~~Favorable~~ **favorable** deals for selected shareholders are not permitted, except in certain circumstances where independent shareholder approval is given and the arrangements are regarded as fair and reasonable in the opinion of the financial adviser to the offeree. • All shareholders must be given the same information. • ~~The~~ **Each document published in connection with an offer by or on behalf of the offeror or offeree must state that the** directors of ~~those~~ -- **the** ~~parties issuing takeover circulars must include statements taking~~ **offeror or the offeree, as the case may be, accept** responsibility for the ~~contents thereof~~ **information contained therein** . • Profit forecasts, quantified financial benefits statements and asset valuations must be made to specified standards and must be reported on by professional advisers. • Misleading, inaccurate or unsubstantiated statements made in documents or to the media must be publicly corrected immediately. • Actions during the course of an offer (or even before if the board of the offeree company is aware that an offer is imminent) by the offeree company, which might frustrate the offer are generally prohibited unless shareholders approve these plans (or the bidder consents to the proposed course of action). Frustrating actions would include, for example, issuing new shares, lengthening the notice period for directors under their service contract or agreeing to sell off material parts of the target group. • Stringent requirements are laid down for the disclosure of dealings in relevant securities during an offer, including the prompt disclosure of positions and dealing in relevant securities by the parties to an offer and any person who is interested (directly or indirectly) in 1 % or more of any class of relevant securities. • Employees of both the offeror and the offeree company and the trustees of the offeree company' s pension scheme must be informed about an offer. In addition, the offeree company' s employee representatives and pension scheme trustees have the right to have a separate opinion on the effects of the offer on employment and pension schemes appended to the offeree board of directors' circular or published on a website. U. S. shareholders may not be able to enforce civil liabilities against us. We are incorporated under the laws of England and Wales, and our subsidiaries are incorporated in various jurisdictions, including foreign jurisdictions. A number of the officers and directors of each of our subsidiaries are non- residents of the United States, and all or a substantial portion of the assets of such persons are located outside the United States. As a result, it may not be possible for investors to affect service of process within the United States upon such persons or to enforce against them judgments obtained in U. S. courts predicated upon the civil liability provisions of the federal securities laws of the United States. We have been advised by our English solicitors that there is doubt as to the enforceability in England in original actions, or in actions for enforcement of judgments of U. S. courts, of civil liabilities to the extent predicated upon the federal securities laws of the United States. U. S. holders of the ADSs or ordinary shares may be subject to U. S. federal income taxation at ordinary income tax rates on undistributed earnings and profits. There is a risk that we will be classified as a controlled foreign corporation, or CFC, for U. S. federal income tax purposes. If we are classified as a CFC, any ADS holder or shareholder that is a U. S. person that owns directly, indirectly or by attribution, 10 % or more of the voting power of our outstanding shares may be subject to U. S. income taxation at ordinary income tax rates on all or a portion of our undistributed earnings and profits attributable to " subpart F income. " Such 10 % holder may also be taxable at ordinary income tax rates on any gain realized on a sale of ordinary shares or ADS, to the extent of our current and accumulated earnings and profits attributable to such shares. The CFC rules are complex and U. S. holders of the ordinary shares or ADSs are urged to consult their own tax advisors regarding the possible application of the CFC rules to them in their particular circumstances. General Risk Factors Potential technological changes in our field of business create considerable uncertainty. The pharmaceutical industry in which we operate is characterized by extensive research efforts and rapid technological progress. New developments in research are expected to continue at a rapid pace in both industry and academia. We cannot assure you that research and discoveries by others will not render some or all of our programs or product candidates uncompetitive or obsolete. Our business strategy is based in part upon new and unproven technologies to the development of therapeutics to improve cardiovascular health. We cannot assure you that unforeseen problems will not develop with these technologies or applications or that any commercially feasible products will ultimately be developed by us. ~~Legal, political and economic uncertainty surrounding the exit of the UK from the EU may be a source of instability in international markets, create significant currency fluctuations, adversely affect our operations in the UK and pose additional risks to our business, revenue,~~

~~financial condition, and results of operations. The continued uncertainty concerning the UK' s legal, political and economic relationship with the EU after Brexit may be a source of instability in the international markets, create significant currency fluctuations, and / or otherwise adversely affect trading agreements or similar cross- border co- operation arrangements whether economic, tax, fiscal, legal, regulatory or otherwise. These developments, or the perception that any of them could occur, may have a significant adverse effect on global economic conditions and the stability of global financial markets, and could significantly reduce global market liquidity and limit the ability of key market participants to operate in certain financial markets. In particular, it could also lead to a period of considerable uncertainty in relation to the UK financial and banking markets, as well as on the regulatory process in Europe. Asset valuations, currency exchange rates and credit ratings may also be subject to increased market volatility. If the UK and the EU are unable to implement acceptable agreements or if other EU member states pursue withdrawal, barrier- free access between the UK and other EU member states or among the European Economic Area, or EEA, overall could be diminished or eliminated. The long- term effects of Brexit will depend on any agreements (or lack thereof) between the UK and the EU. Such a withdrawal from the EU is unprecedented, and it is unclear how the UK' s access to the European single market for goods, capital, services and labor within the EU, or single market, and the wider commercial, legal and regulatory environment, will impact our current and future operations (including business activities conducted by third parties and contract manufacturers on our behalf) and clinical activities in the UK. In addition to the foregoing, our UK operations support our current and future operations and clinical activities in other countries in the EU and EEA and these operations and clinical activities could be disrupted by the ongoing effects of Brexit. We may also face new regulatory costs and challenges that could have an adverse effect on our operations. The impact of the terms of the recent trade deal between the UK and EU are uncertain. Since the regulatory framework in the UK covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from EU directives and regulations, Brexit could materially impact the future regulatory regime with respect to the commercialization of our products in the UK. Any delay in commercializing our products in the UK and / or the EU could restrict our ability to generate revenue and achieve and sustain profitability. The uncertainty around the UK' s future relationship with the EU continues to cause economic uncertainty which could adversely impact customer confidence resulting in customers reducing their spending budgets on our solutions, which could adversely affect our business, revenue, financial condition, results of operations and could adversely affect the market price of our ADSs.~~ Negative economic conditions would likely have a negative effect on our ability to obtain financing on acceptable terms. While we may seek additional funding through public or private financings, we may not be able to obtain financing on acceptable terms, or at all. There can be no assurance that we will be able to access equity or credit markets in order to finance our current operations or expand development programs for VASCEPA, or that there will not be deterioration in financial markets and confidence in economies ~~, particularly in light of the continued volatility attributed to COVID- 19 and other global instability~~ . We may also have to scale back or further restructure our operations. If we are unable to obtain additional funding when needed, we may be required to curtail or terminate some or all of our research or development programs or our commercialization strategies. Raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish rights. We may seek additional capital through a combination of private and public equity offerings, debt financings and collaboration, strategic and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing, if available, may involve agreements that include burdensome covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration, strategic alliance and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, VASCEPA or product candidates beyond the rights we have already relinquished, or grant licenses on terms that are not favorable to us. Potential business combinations or other strategic transactions may disrupt our business or divert management' s attention. On a regular basis, we explore potential business combination transactions, including an acquisition of us by a third party, exclusive licenses of VASCEPA or other strategic transactions or collaborations with third parties. The consummation and performance of any such future transactions or collaborations will involve risks, such as: • diversion of managerial resources from day- to- day operations; • exposure to litigation from the counterparties to any such transaction, other third parties or our shareholders; • misjudgment with respect to the value; • higher than expected transaction costs; or • an inability to successfully consummate any such transaction or collaboration. As a result of these risks, we may not be able to achieve the expected benefits of any such transaction or collaboration or deliver the value thereof to our shareholders. If we are unsuccessful in consummating any such transaction or collaboration, we may be required to **re-** ~~reevaluate~~ -- **evaluate** our business only after we have incurred substantial expenses and devoted significant management time and resources. We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability, including in Europe, and record inflation. Our business, financial condition and results of operations could be materially and adversely affected by any negative impact on the global economy and capital markets resulting from these global economic conditions, particularly if such conditions are prolonged or worsen. Economic uncertainty in various global markets, including the U. S. ~~and~~ **,** Europe **and the Middle East** , caused by political instability and conflict, such as Russia' s invasion of Ukraine **and current armed conflict in Israel and the Gaza Strip** , and economic challenges caused by **pandemics or** ~~the~~ **other health crises, such as the recent** COVID- 19 pandemic, have led to market disruptions, including significant volatility in commodity prices, credit and capital market instability and supply chain interruptions, which have caused record inflation globally. Although, to date, our business has not been materially impacted by these global economic and geopolitical conditions, it is impossible to predict the extent to which our operations will be impacted in the short and long term, or the ways in which such instability could impact our business and results of operations. The extent and duration of these market disruptions, whether as a result of the military conflict between Russia and Ukraine, **the current armed conflict in**

Israel and the Gaza Strip, geopolitical tensions, record inflation or otherwise, are impossible to predict, but could be substantial. Any such disruptions may also magnify the impact of other risks described in this report.