

## Risk Factors Comparison 2024-02-27 to 2023-02-21 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text **Moved Text Section**

Except for the historical information contained herein or incorporated by reference, this **Annual report Report on Form 10-K** and the information incorporated by reference contains forward- looking statements that involve risks and uncertainties. These statements include projections about our accounting and finances, plans and objectives for the future, future operating and economic performance and other statements regarding future performance. These statements are not guarantees of future performance or events. Our actual results could differ materially from those discussed in this **Annual report Report on Form 10-K**. Factors that could cause or contribute to these differences include, but are not limited to, those discussed in the following section, as well as those discussed in Part II, Item 7 entitled “ Management’ s Discussion and Analysis of Financial Condition and Results of Operations ” and elsewhere throughout this **Annual report Report on Form 10-K** and in any documents incorporated in this **Annual report Report on Form 10-K** by reference. You should consider carefully the following risk factors, together with all of the other information included or incorporated in this **Annual report Report on Form 10-K**. If any of the following risks, either alone or taken together, or other risks not presently known to us or that we currently believe to not be significant, develop into actual events, then our business, financial condition, results of operations or prospects could be materially adversely affected. If that happens, the market price of our common stock could decline, and stockholders may lose all or part of their investment.

**Risks Related to Impact of Uncertain Capital Markets** We have in the past relied in part on sales of our common ~~shares-stock~~ through our at- the- market (ATM) offering program. Increased volatility and decreases in market prices of equity securities generally and of our common ~~shares-stock~~ in particular may have an adverse impact on our willingness and / or ability to continue to sell our common ~~shares-stock~~ through our ATM offering. Decreases in these sales would / could affect the cost or availability of equity capital, which could in turn have an adverse effect on our business, including current operations, future growth, revenues, net income and the market prices of our common ~~shares-stock~~. On ~~August~~ **April 15, 2022, we filed a new registration statement on Form S- 3 to replace**, ~~2021, we commenced an at- the- market, or our prior ATM, program to raise capital under an automatically effective registration statement on Form S- 3ASR filed on August 3, 2021~~, **which registered the offering was replaced on April 15-, issuance and sale of up to \$ 239 million of common stock from time to time in “ at- the- market ” offerings, or the New ATM Program. On February 21, 2022-2023**, **we terminated the Open Market Sales Agreement with Jefferies LLC and entered into a new registration statement on Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co., as sales agent, to provide for the issuance and sale by us of up to \$ 70 million of shares of our common stock from time to time in “ at- the- market ” offerings, or the 2023 ATM Program, pursuant to our existing Form S- 3 and the prospectus supplement filed on February 21, 2023**. ~~Under our current~~ **We may continue to use the 2023 ATM program Program**, ~~we have entered into a sales agreement to address potential short sell common shares, up to a maximum aggregate market value of \$ 70 million, through one or more at- the- term or long- market offerings term funding requirements that may arise~~. Given the volatility in the capital markets, we may not be willing or able to continue to raise equity capital through ~~our the 2023 ATM program Program~~. We may, therefore, need to turn to other sources of funding that may have terms that are not favorable to us, or reduce our business operations given capital constraints. Alternative financing arrangements, if we pursue any, could involve issuances of one or more types of securities, including common stock, preferred stock, convertible debt, warrants to acquire common stock or other securities. These securities could be issued at or below the then prevailing market price for our common ~~shares-stock~~. In addition, if we issue debt securities, the holders of the debt would have a claim to our assets that would be superior to the rights of stockholders until the principal, accrued and unpaid interest and any premium or make- whole has been paid. ~~Recent volatility~~ **Volatility** in capital markets and lower market prices for our securities may affect our ability to access new capital through sales of shares of our common stock or issuance of indebtedness, which may materially harm our liquidity, limit our ability to grow our business, pursue acquisitions or improve our operating infrastructure and restrict our ability to compete in our markets. Our operations consume substantial amounts of cash, and our future capital requirements may be significantly different from our current estimates . **Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. Our future funding requirements, both near and long- term will depend on many factors, including , but not limited to** the need to: • finance unanticipated working capital requirements; • develop or enhance our technological infrastructure and our existing solutions; and • respond to competitive pressures. Accordingly, we may need to pursue equity or debt financings to meet our capital needs. With uncertainty in the capital markets and other factors, such financing may not be available on terms favorable to us , or at all. ~~If~~ **For instance, the trading prices for our common stock and for other biopharmaceutical companies have been highly volatile. As a result, we may face difficulties raising capital through sales of our equity or debt securities or such sales may be on unfavorable terms. Similarly, adverse market or macroeconomic conditions or market volatility resulting from global economic developments, political unrest, high inflation, rising interest rates, the post- COVID environment, future public health epidemics or other factors, could materially and adversely affect our ability to consummate an equity or debt financing on favorable terms, or at all. In order to raise additional capital, we may seek a combination of private and public equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent** we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences, and privileges superior to those of holders of our common stock. Any debt financing

secured by us in the future could involve additional restrictive covenants relating to our capital- raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. If we are unable to obtain adequate financing or financing on terms satisfactory to us, we could face significant limitations on our ability to invest in our operations and otherwise suffer harm to our business.

**Adverse developments affecting the financial services industry could have an adverse effect on our operations and financial results. Events involving limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market- wide liquidity problems. These events exposed vulnerabilities in the banking sector, including legal uncertainties, significant volatility and contagion risk, and caused market prices of regional bank stocks to plummet. In addition, investor concerns regarding the U. S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations, or fulfill our other obligations, result in breaches of our financial and / or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and / or projected business operations and financial condition and results of operations.**

Risks Related to our Business and Commercialization Risks Related to Business Development and Commercialization We depend almost entirely on the success of two products, bempedoic acid and the bempedoic acid / ezetimibe combination tablet. There is no assurance that our commercialization efforts in the U. S. and DSE' s effort in Europe with respect to either product will be successful or that we will be able to generate revenues at the levels or within the timing we expect or at the levels or within the timing necessary to support our **corporate** goals. In **2022-2023**, we generated \$ **55-78.9-3** million in **net** revenues from the sale of products in the U. S. Our ~~lead~~ products, NEXLETOL (bempedoic acid) tablet and NEXLIZET (bempedoic acid and ezetimibe) tablet, were approved by the FDA in February 2020. NEXLETOL became commercially available in the U. S. in March 2020 and NEXLIZET became commercially available in the U. S. in June 2020. On April 6, 2020, we announced that the EC approved NILEMDO (bempedoic acid) and NUSTENDI (bempedoic acid and ezetimibe) tablet for the treatment of hypercholesterolemia and mixed dyslipidemia. The decision is applicable to all 27 European Union member states plus the United Kingdom, Iceland, Norway and Liechtenstein. NILEMDO (bempedoic acid) and NUSTENDI (bempedoic acid and ezetimibe) are the branded product names for bempedoic acid and the bempedoic acid / ezetimibe combination tablet in Europe. Since 2020, Daiichi Sankyo launched NILEMDO and NUSTENDI in multiple EU countries. **Daiichi Sankyo Co. Ltd, or DS, received its first regional approval for Hong Kong and launched in late 2023 and we expect additional approvals in the DS Territory in 2024.**

There is no assurance that the commercial launches will be successful or that **the planned** additional launches will occur on the timing we anticipate **and generate the revenues we expect**. We may encounter delays or hurdles related to our launches that affect timing. Our business currently depends heavily on our ability to successfully commercialize NEXLETOL and NEXLIZET in the U. S. to treat patients as an adjunct to diet and ~~maximally tolerated~~ statin therapy for the treatment of

**primary hyperlipidemia in** adults with HeFH or ~~established~~ ASCVD who require additional lowering of LDL- C. We **also expect approval decisions on the expanded indications for NEXLETOL and NEXLIZET in the first quarter of 2024. We**

may never be able to successfully commercialize the products **even with their expanded indications** or meet our expectations with respect to revenues. Prior to our launch in March 2020, we had never marketed, sold or distributed for commercial use any pharmaceutical product. There is no guarantee that the infrastructure, systems, processes, personnel, relationships and materials we have built and may alter to commercialize these products in the U. S. will be sufficient for us to achieve success at the levels we expect. Additionally, healthcare providers may not accept a new treatment paradigm for patients with HeFH or ~~established~~ ASCVD who require additional lowering of LDL- C **or wish to reduce their cardiovascular risk**. We may also

encounter challenges related to reimbursement of bempedoic acid and the bempedoic acid / ezetimibe combination tablet, even if we have positive early indications from payors, including potential limitations in the scope, breadth, availability, or amount of reimbursement covering each product. Additionally, coverage by a third- party payor does not guarantee reimbursement. For example, the terms of certain agreements require or may require practitioners to seek prior authorization from the third- party payor. Payors have implemented prior authorization requirements for our products which has impacted utilization and, thus, our ability to generate revenue from commercial sales of NEXLIZET and NEXLETOL in the United States. The Company implemented a prior authorization support program to support patients and physician practices in facilitating prior authorizations. In addition, we have created a bridge program for patients who have been prescribed our product but are experiencing delays in obtaining insurance coverage. If patients continue to experience difficulty in obtaining prior authorization for our products and / or our programs on a timely basis **following approval of the expanded product indications**, this may adversely impact ongoing sales of our products. We have obtained regulatory approval from the FDA, the EC, and Swissmedic

for both of our leading product candidates as an adjunct to diet and ~~maximally tolerated~~ statin therapy for the treatment of **primary hyperlipidemia in** adults with HeFH or ~~established~~ ASCVD who require additional lowering of LDL- C, but we cannot be certain that we will be able to obtain approval from regulatory authorities in other territories we decide to pursue, or successfully commercialize our products and any future product candidates. Additionally, we cannot be certain that we will be able to obtain approval either of our candidates for any other indication or approval of any future product candidates. Bempedoic acid and the bempedoic acid / ezetimibe combination tablet may require substantial additional clinical development, testing, and regulatory approvals before we are permitted to commence their commercialization in markets outside of the U. S. and Europe

for an LDL- C lowering **or cardiovascular risk reduction** indication. The clinical studies, manufacturing and marketing of our products and any future product candidates are subject to extensive and rigorous review and regulation by numerous government authorities in the U. S. and in other countries where we intend to test and, if approved, market any product candidate. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through preclinical testing and clinical studies that the product candidate is safe and effective for use in each target indication. This process can take many years and require the expenditure of substantial resources, and may include post- marketing studies and surveillance. Of the large number of drugs in development in the U. S., only a small percentage successfully complete the approval process at the FDA, EMA or any other foreign regulatory agency, and are commercialized. Accordingly, we cannot assure you that bempedoic acid and the bempedoic acid / ezetimibe combination tablet or any other of our product candidates we may develop will be successfully developed or commercialized **in any other territory**. We are not permitted to market our product candidates in the U. S. or in Europe for any other indication until we receive approval of an NDA supplement from the FDA, Marketing Authorisation Application, or MAA, from the EC, or in any other foreign countries until we receive the requisite approval from such countries. Additionally, we may decide to submit a supplemental NDA or MAA in the future for bempedoic acid and the bempedoic acid / ezetimibe combination tablet for other indications, such as our ~~planned~~ **submissions in 2023** for a CVD risk reduction indication in the U. S. and Europe. As a condition to submitting an NDA supplement or MAA for bempedoic acid to treat patients with hypercholesterolemia for a CVD risk reduction indication, we ~~have~~ **completed the CLEAR Outcomes CVOT, and we have intend to use used** the data from this trial to support ~~future~~ **future further** regulatory submissions **and may use it to support additional regulatory submissions in the future**. Obtaining approval of an NDA or MAA is a complex, lengthy, expensive and uncertain process, and the FDA or EMA may delay, limit or deny approval of bempedoic acid and the bempedoic acid / ezetimibe combination tablet for many reasons, including, among others: • the FDA, EMA or any other regulatory authorities may change their approval policies or adopt new regulations; • the FDA, EMA or any other regulatory authorities may change their approval policies for an LDL- C lowering indication for bempedoic acid and the bempedoic acid / ezetimibe combination tablet if there is a shift in the future standard- of- care for statin intolerant patients with hypercholesterolemia; • the FDA, EMA, or any other regulatory authorities may change their approval policies with regard to a CVD risk reduction indication; • ~~we may not be able to demonstrate that bempedoic acid and the bempedoic acid / ezetimibe combination tablet are safe and effective in reducing cardiovascular risk or in treating patients with hypercholesterolemia to the satisfaction of the FDA, EMA or any other regulatory agency;~~ • the results of our clinical studies may not meet the level of statistical or clinical significance required by the FDA or EMA for marketing approval; • the magnitude of the treatment effect must also be clinically meaningful along with the drug’ s safety for a favorable benefit / risk assessment by the FDA, EMA or any other regulatory agency; • the FDA, EMA or any other regulatory agency may change in the future the number, design, size, duration, patient enrollment criteria, exposure of patients, or conduct or implementation of our clinical studies; • the FDA, EMA or any other regulatory agency may require that we conduct additional clinical studies; • the FDA, EMA or any other regulatory agency may not approve the formulation, specifications or labeling of bempedoic acid and the bempedoic acid / ezetimibe combination tablet; • the clinical research organizations, or CROs, that we retain to conduct our clinical studies may take actions outside of our control that materially adversely impact our clinical studies; • the FDA, EMA or any other regulatory agency may find the data from preclinical studies and clinical studies insufficient to demonstrate that the clinical and other benefits of bempedoic acid and the bempedoic acid / ezetimibe combination tablet outweigh the safety risks; • the FDA, EMA or any other regulatory agency may disagree with our interpretation of data from our preclinical studies and clinical studies; • the FDA, EMA or any other regulatory agency may not accept data generated at our clinical study sites; • if our NDAs are reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our applications or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical studies, limitations in approved labeling or distribution and use restrictions; • the FDA, EMA or any other regulatory agency may require the development of a REMS as a condition of approval or post- approval; or • the FDA, EMA or any other regulatory agency may not approve the manufacturing processes or facilities of third- party manufacturers with which we contract. Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully market bempedoic acid and the bempedoic acid / ezetimibe combination tablet. Moreover, because our business is almost entirely dependent upon these product candidates, any setback in our pursuit of initial or additional regulatory approvals would have a material adverse effect on our business and prospects. The development and approvals required for the approval of the bempedoic acid / ezetimibe combination tablet are substantially identical to those for bempedoic acid, and the risks relating to the clinical development and approval of bempedoic acid apply equally to the bempedoic acid / ezetimibe combination tablet. Any failure in our development of bempedoic acid would materially and adversely affect our ability to develop, seek approval for and commercialize the bempedoic acid / ezetimibe combination tablet for the planned indications. In addition, even if bempedoic acid succeeds in its clinical development and is approved for one or more indications, there can be no assurance that the bempedoic acid / ezetimibe combination tablet would be developed successfully and approved for the same indications or at all, and vice versa. We have limited experience as a commercial company and the marketing and sale of bempedoic acid and the bempedoic acid / ezetimibe combination tablet or any future approved drugs may be unsuccessful or less successful than anticipated. While we have commercially launched our approved drugs in the U. S. and DSE has commercially launched in multiple countries in the EU, we have limited experience as a commercial company and there is limited information about our ability to successfully overcome many of the risks and uncertainties encountered by companies commercializing drugs in the biopharmaceutical industry. To execute our business plan, in addition to successfully marketing and selling bempedoic acid and the bempedoic acid / ezetimibe combination tablet **in their current and planned future indications**, we will need to successfully: • establish and maintain our relationships with healthcare providers who will be treating the patients who may receive our drugs and any future drugs; •

obtain adequate pricing and reimbursement for bempedoic acid and the bempedoic acid / ezetimibe combination tablet and any future drugs; • develop and maintain successful strategic alliances; and • manage our spending for clinical trials, marketing approvals, and commercialization. If we are unsuccessful in accomplishing these objectives, we may not be able to successfully commercialize bempedoic acid and the bempedoic acid / ezetimibe combination tablet or any future drug candidates, raise capital, expand our business, or continue our operations. The commercialization of the bempedoic acid / ezetimibe combination tablet in the U. S. and Europe, and, ~~if approved~~ in other territories, depends on the continued availability of ezetimibe. The bempedoic acid / ezetimibe combination tablet is dependent on the continued availability of ezetimibe in the marketplace, and there can be no assurance that the current availability of ezetimibe will continue. The producers of ezetimibe are under no obligation to continue producing, commercializing or making ezetimibe available to patients, or to continue producing ezetimibe in any particular quantity, which could prevent our ability to obtain ezetimibe. For example, such producers may encounter manufacturing or other production issues and fail to produce enough ezetimibe, and this could cause our commercialization efforts to fail or be significantly delayed. Our reliance on sole source third- party suppliers could harm our ability to commercialize bempedoic acid and the bempedoic acid / ezetimibe combination tablet or any drug candidates that may be approved in the future. We have scaled up our manufacturing process for bempedoic acid and the bempedoic acid / ezetimibe combination tablet in order to meet our estimated commercial requirements. We do not currently own or operate manufacturing facilities for the production of bempedoic acid and the bempedoic acid / ezetimibe combination tablet or any future drug candidates that may be approved in the future. We rely on sole source third- party suppliers to manufacture and supply bempedoic acid and the bempedoic acid / ezetimibe combination tablet which may not be able to produce sufficient inventory to meet commercial demand in a cost- efficient, timely manner, or at all. Our third- party suppliers may not be required to, or may be unable to, provide us with any guaranteed minimum production levels or have sufficient dedicated capacity for our drugs. As a result, there can be no assurances that we will be able to obtain sufficient quantities of bempedoic acid and the bempedoic acid / ezetimibe combination tablet or any drug candidates that may be approved in the future, which could have a material adverse effect on our business as a whole. Even though we have received marketing approval for bempedoic acid and the bempedoic acid / ezetimibe combination tablet in the U. S. and Europe, and even if we receive such approval in other markets, we may still face future development, ongoing regulatory oversight and regulatory difficulties. Even though we have received marketing approval for bempedoic acid and the bempedoic acid / ezetimibe combination tablet in the U. S. and Europe, and even if we receive such approval in other markets, regulatory authorities may still impose significant restrictions on bempedoic acid or the bempedoic acid / ezetimibe combination tablet' s indicated uses or marketing or impose ongoing requirements for potentially costly post- approval studies. Bempedoic acid and the bempedoic acid / ezetimibe combination tablet will also be subject to ongoing FDA requirements governing the packaging, storage, labeling, advertising and promotion of the product, recordkeeping and submission of safety updates and other post- marketing information. The FDA has significant post- marketing authority, including, for example, the authority to require labeling changes based on new safety information and to require post- marketing studies or clinical studies to evaluate serious safety risks related to the use of a drug product. For example, as part of our NEXLETOL and NEXLIZET approval, the FDA has required both a PK / PD and Phase 3 study evaluating bempedoic acid in patients with HeFH aged 10 years to less than 18 years, a worldwide descriptive study that collects prospective and retrospective data in women exposed to NEXLETOL and NEXLIZET during pregnancy to assess the risk of pregnancy and maternal complications, adverse effects on the developing fetus and neonate, and adverse effects on the infant through the first year of life, and a lactation study to analyze milk in lactating women who have received therapeutic doses of NEXLETOL and NEXLIZET. The EMA and other foreign regulatory authorities may impose similar requirements on bempedoic acid or the bempedoic acid / ezetimibe combination tablet as those described above with respect to the FDA. Manufacturers of drug products and their facilities are subject to continual review and periodic unannounced inspections by the FDA and other regulatory authorities for compliance with current Good Manufacturing Practices and other regulations. 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. Additionally, if we or a regulatory agency discover problems with bempedoic acid or the bempedoic acid / ezetimibe combination tablet, such as adverse events of unanticipated severity or frequency, or problems with the facility where bempedoic acid or the bempedoic acid / ezetimibe combination tablet is manufactured, a regulatory agency may impose restrictions on bempedoic acid or the bempedoic acid / ezetimibe combination tablet, the manufacturer or us, including requiring withdrawal of bempedoic acid or the bempedoic acid / ezetimibe combination tablet from the market or suspension of manufacturing. Additionally, under the Food and Drug Omnibus Reform Act of 2020, or FDORA, sponsors of approved drugs must provide 6 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. If we, bempedoic acid or the bempedoic acid / ezetimibe combination tablet or the manufacturing facilities for bempedoic acid or the bempedoic acid / ezetimibe combination tablet fail to comply with applicable regulatory requirements, a regulatory agency may, among other things: • issue warning letters or untitled letters; • seek an injunction or impose civil or criminal penalties or monetary fines; • suspend or withdraw marketing approval; • suspend any ongoing clinical studies; • refuse to approve pending applications or supplements to applications submitted by us; • suspend or impose restrictions on operations, including costly new manufacturing requirements; or • seize or detain products, refuse to permit the import or export of products, or request that we initiate a product recall. If the FDA, EMA or other comparable foreign regulatory authorities approve generic or other versions of bempedoic acid or the bempedoic acid / ezetimibe combination tablet, the sales of our approved products could be adversely affected. Once a new drug application, or NDA, is approved, the product covered thereby becomes a “ reference listed drug ” in the FDA’ s publication, “ Approved Drug Products with Therapeutic Equivalence

Evaluations,” commonly known as the Orange Book. Under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch- Waxman Act to the Federal Food, Drug, and Cosmetic Act, or FDCA, a company may seek approval of generic versions of reference listed drugs through submission of abbreviated new drug applications, or ANDAs, in the United States. In support of an ANDA, a generic manufacturer need not conduct clinical trials to assess safety and efficacy. Rather, the applicant generally must show that its product has the same active ingredient (s), dosage form, strength, route of administration and conditions of use or labelling as the reference listed drug and that the generic version is bioequivalent to the reference listed drug, meaning it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the reference listed drug and companies that produce generic products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference listed drug is typically lost to the generic product. Under the Hatch- Waxman Act, a company may also submit an NDA under Section 505 (b) (2) of the FDCA that references the FDA’s prior approval of the innovator product. A 505 (b) (2) NDA product may be for a new or improved version of the original innovator product. The Hatch- Waxman Act also provide for certain periods of regulatory exclusivity, which preclude FDA approval (or in some circumstances, FDA filing and review) of an ANDA or 505 (b) (2) NDA until any applicable period of non- patent exclusivity for the reference listed drug has expired. For example, a new drug containing a new chemical entity, or NCE, may be eligible for five years of marketing exclusivity in the United States following regulatory approval if that drug is classified as a new chemical entity, or NCE. A drug can be classified as a NCE if the FDA has not previously approved any other drug containing the same active moiety. In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, product formulation or an approved use of the drug, which would be listed in the Orange Book. If there are patents listed in the Orange Book for a product, an ANDA or 505 (b) (2) applicant that seeks to market its product before expiration of the innovator drug patents must include in their applications what is known as a “ Paragraph IV ” certification, challenging the validity or enforceability, or claiming non- infringement, of the listed patent or patents. Notice of the certification must be given to the patent owner and NDA holder and if, within 45 days of receiving notice, either the patent owner or NDA holder sues for patent infringement, approval of the ANDA or 505 (b) (2) NDA is stayed for up to 30 months, or as lengthened or shortened by a court. Accordingly, competitors could file ANDAs for generic versions or 505 (b) (2) NDAs that reference our NEXLETOL and NEXLIZET products, which were granted marketing approval by the FDA on February 21, 2020 and February 26, 2020, respectively. For example, given that NEXLETOL was granted market exclusivity by the FDA on February 21, 2020, an ANDA or 505 (b) (2) NDA referencing our NEXLETOL NDA may not be submitted to the FDA until the expiration of five years, e. g., February 21, 2025, unless the submission is accompanied by a Paragraph IV certification that a patent covering the reference listed drug is either invalid or will not be infringed by the generic or 505 (b) (2) product, in which case the applicant may submit its application four years following approval of the reference listed drug, e. g., February 21, 2024, for NEXLETOL. Competitors may seek to launch generic or 505 (b) (2) versions of NEXLETOL following the expiration of the applicable exclusivity period for NEXLETOL, even if we still have regulatory exclusivity and / or patent protection for NEXLETOL, and the same could happen for any of our other drug products upon approval. Competition that NEXLETOL could face from an approved generic and other versions of NEXLETOL could materially and adversely affect our future revenue, profitability, and cash flows and substantially limit our ability to obtain a return on the investments we have made in developing NEXLETOL. The same could happen for NEXLIZET. 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 U. S. 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, including, without limitation, the federal Anti- Kickback Statute, the False Claims Act, laws and regulations related to the reporting of payments to physicians and teaching hospitals, and HIPAA, 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 certain business arrangements in the healthcare industry, 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. Additionally, we are subject to state and foreign equivalents of each of the healthcare laws described in the section entitled “ Business – Other Healthcare Laws ”, among others, some of which may be broader in scope and may apply regardless of the payor. For instance, state anti- kickback and false claims laws may apply to items or services reimbursed by any third- party payor, including commercial insurers or patients. Laws related to insurance fraud may provide claims involving private insurers. Further data privacy and security laws and regulations in foreign jurisdictions that may be more stringent than those in the U. S. (such as the European Union, which adopted the GDPR, which became effective in May 2018). Analogous state laws may additionally govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect. 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 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. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden 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 these rules will affect our business. 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 often scrutinize interactions between healthcare companies and healthcare providers, which has led to a number of 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. 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 civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting 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. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way. We have adopted a code of business conduct and ethics, but 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. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations, guidance or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the U. S. will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. Formulary Coverage, Pricing, and Reimbursement policies could limit our ability to sell bempedoic acid or the bempedoic acid / ezetimibe combination tablet. Sales of our products will depend, in part, on the extent to which our products will be covered and reimbursed by third- party payors-payers, such as government health programs, commercial insurance and managed healthcare organizations. Adequate coverage and reimbursement from third party payors-payers are critical to new product acceptance. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U. S. Department of Health and Human Services. CMS decides whether and to what extent our products will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Market acceptance and sales of bempedoic acid and the bempedoic acid / ezetimibe combination tablet will depend, in part, on the extent to which our products in the U. S. will be covered and reimbursed by third- party payors, such as government health care programs, commercial insurance, and managed healthcare organizations and may be affected by healthcare reform measures. See the section entitled “ Business – Coverage, Reimbursement and Healthcare Reform. ” Cost containment is a primary concern in the U. S. healthcare industry and elsewhere. Government authorities and these third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. The U. S. federal government, state legislatures and foreign governments have shown significant interest in implementing cost- containment programs, including price controls,

restrictions on reimbursement, utilization management and requirements for substitution of generic products. Adoption of price controls and cost- containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third- party reimbursement for bempedoic acid and the bempedoic acid / ezetimibe combination tablet or a decision by a third- party payor to not cover bempedoic acid and the bempedoic acid / ezetimibe combination tablet could reduce physician usage of the products and could have a material adverse effect on our sales, results of operations and financial condition. We cannot be sure that reimbursement will be available for bempedoic acid or the bempedoic acid / ezetimibe combination tablet and, if reimbursement is available, the level of such reimbursement. Reimbursement may impact the demand for, or the price of, bempedoic acid or the bempedoic acid / ezetimibe combination tablet. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize bempedoic acid or the bempedoic acid / ezetimibe combination tablet. There may also be delays in obtaining coverage and reimbursement for newly approved drugs **(of new indications for previously approved drugs)**, and coverage may be more limited than the indications for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Reimbursement rates may vary, by way of example, according to the use of the product and the clinical setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost drugs or may be incorporated into existing payments for other services. In addition, increasingly, third- party payors are requiring higher levels of evidence of the benefits and clinical outcomes of new technologies and are challenging prices. We cannot be sure that coverage will be available for any products or product candidate that we, or any future collaborator, commercialize and, if available, that the reimbursement rates will be adequate. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from one country to another. An inability to promptly obtain coverage and adequate payment rates from both government- funded and private payors for any of our products or product candidates for which we, or any future collaborator, obtain regulatory approval could significantly harm our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. In some foreign countries, particularly in Canada and European countries, the pricing of prescription pharmaceuticals is subject to strict governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory approval and product launch. To obtain favorable reimbursement for the indications sought or pricing approval in some countries, we may be required to conduct a clinical study that compares the cost- effectiveness of bempedoic acid and the bempedoic acid / ezetimibe combination tablet with other available therapies. If reimbursement for bempedoic acid or the bempedoic acid / ezetimibe combination tablet is unavailable in any country in which we seek reimbursement, if it is limited in scope or amount, if it is conditioned upon our completion of additional clinical studies, or if pricing is set at unsatisfactory levels, our operating results could be materially adversely affected. Recent federal legislation may increase pressure to reduce prices of certain pharmaceutical products paid for by Medicare, which could materially adversely affect our revenue and our results of operations. In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician- administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the scope of coverage and the price that we receive for any approved products and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policies and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may cause a similar reduction in payments from private payors. This legislation may pose an even greater risk to bempedoic acid and the bempedoic acid / ezetimibe combination tablet than some other pharmaceutical products because a significant portion of the patient population for bempedoic acid and the bempedoic acid / ezetimibe combination tablet is over 65 years of age and, therefore, many such patients will be covered by Medicare. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. See “ Business – Coverage, Reimbursement and Healthcare Reform ” for more discussion on healthcare reform efforts. ~~It is unclear how the Biden administration will prioritize and execute initiatives to contain healthcare costs.~~ The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect: • the demand for our products and any products for which we may obtain regulatory approval; • our ability to set a price that we believe is fair for our products; • our ability to obtain coverage and reimbursement approval for a product; • our ability to generate revenues and achieve or maintain profitability; and • the level of taxes that we are required to pay. We expect that changes and challenges to the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies, and additional downward pressure on the price that we receive for our products and any future approved product. Finally, the availability of generic LDL- C lowering treatments may also substantially reduce the **likelihood level** of reimbursement for branded counterparts or other competitive LDL- C lowering therapies, such as bempedoic acid or the bempedoic acid / ezetimibe combination tablet. If we fail to successfully secure and maintain **adequate** reimbursement coverage for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be harmed . **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. 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 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 ACA made significant changes to the Medicaid Drug Rebate program. CMS issued a final regulation, which became effective on April 1, 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. 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 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 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. Data collection is governed by restrictive regulations governing the use, processing and cross-border transfer of personal information. In the event we decide to continue to enroll subjects in our ongoing or future clinical trials, we may be subject to additional privacy restrictions. The collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the EEA, including personal health data, is subject to the EU General Data Protection Regulation 2016 / 679, or EU GDPR, which became effective on May 25, 2018. Following the United Kingdom's ("U. K.")



withdrawal from the EU on January 31, 2020 and the end of the transitional arrangements agreed between the U. K. and EU as of January 1, 2021, the EU GDPR has been incorporated into U. K. domestic law by virtue of section 3 of the European Union (Withdrawal) Act 2018 and amended by the Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019 (“U. K. GDPR” and, together with the EU GDPR, “GDPR”). The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including **stricter** requirements relating to processing health and other sensitive data, **where required obtaining consent of the individuals to whom the personal data relates or ensuring there is a another valid legal basis to justify the process processing the of** personal data, **providing stricter requirements relating to obtaining consent of individuals, expanded disclosures about how personal information is to individuals regarding data processing activities be used, limitations on retention of information**, implementing safeguards to protect the security and confidentiality of personal data, where required providing notification of data breaches, maintaining records of processing activities and documenting data protection impact assessments where there is high risk processing and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EEA or the U. K., including the United States (see below), and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to € 20 million (£ 17. 5 million GBP) or 4 % of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. The GDPR increased our 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 to ensure compliance with the GDPR, including as implemented by **individual national laws of EU Member States which may partially deviate from the EU GDPR and impose different and more restrictive obligations from countries-country to country**. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European and U. K. activities. **The U. K. GDPR and the U. K. Data Protection Act 2018 set out the U. K.'s data protection regime, which is independent from but, currently, aligned to the EU's data protection regime. The EC has adopted an adequacy decision in respect of transfers of personal data to the U. K. for a four- year period (until June 27, 2025). Similarly, the U. K. has determined that it considers all of the EEA to be Adequate-adequate for the purposes of data protection. This ensures that data flows between the U. K. and the EEA remain unaffected. The U. K. Government has also now introduced a Data Protection and Digital Information Bill (or the UK Bill) into the UK legislative process with the intention for this bill to reform the U. K.'s data protection regime which will likely have the effect of further altering the similarities between the U. K. and EU data protection regime. In addition, we must also ensure that we maintain adequate safeguards must be implemented to enable the transfer of personal data outside of the EEA or the U. K., in particular to the U. S., in compliance with GDPR European and U. In some cases K- data protection laws. On June 4, 2021, we rely upon the European Commission (EC 's approved) issued new forms of standard contractual clauses for to legitimize transfers of personal data transfers-out of the EEA from controllers or processors in the EEA (or otherwise subject to the EU GDPR) to controllers or processors established outside the EEA (and not subject to the EU-GDPR) .The new standard contractual clauses replace the standard contractual clauses that were adopted previously under the Data Protection Directive. The U. K. is not subject to the EC 's new standard contractual clauses but has published its own standard clauses-transfer mechanism, the International Data Transfer Agreement, which enable-enables transfers from the U. K. -We may be required to implement these new safeguards when conducting restricted data transfers under the GDPR and doing so will require significant effort and cost. On June 28, 2021, the European Commission announced a decision of “adequacy” concluding that the U. K. ensures an equivalent level of data protection to the GDPR, which provides some relief regarding the legality of continued personal data flows from the EEA, to the U. K. Some uncertainty remains; however, as this adequacy determination must be renewed after four years and may be modified or revoked in the interim. The U. K. Government has confirmed that transfers from the U. K. to the EEA may continue to flow freely. Changes with respect to any of these matters may lead to additional costs and increase our overall risk exposure. The EU and U. S. have adopted its adequacy decision for the EU U. S. Data Privacy Framework (" Framework"), which entered into force on July 11, 2023. This Framework provides that the protection of personal data transferred between the EU and the U. S. is comparable to that offered in the EU. Moreover, on September 21, 2023, the U. K. Government adopted the Data Protection (Adequacy) Regulations 2023, also referred to as the “UK- U. S. Data Bridge”, which will allow companies to transfer personal data from the U. K. to the U. S. on the basis of the EU- U. S. Data Privacy Framework. This provides a further avenue to ensuring transfers to the US are carried out in line with GDPR. The Framework could be challenged like its predecessor frameworks. In addition-the United States, state privacy laws may also have an impact on our business; for example, California enacted the California Consumer Privacy Act, or CCPA, which creates new-broad individual privacy rights for California consumers (as defined in the law) and places increased-stringent privacy and security obligations on business covered by the law entities handling personal data of consumers or households. The CCPA-This law, which took effect on January 1, 2020 and became enforceable by the California Attorney General on July 1, 2020, requires covered companies to provide new-detailed disclosure-disclosures to consumers about such companies' data collection, use and sharing practices, provide-allow such consumers new ways to opt- out of certain sales or transfers-sharing of their personal information, and provide consumers with additional causes of action. The CCPA also provides for civil penalties for violations went into effect on January 1, 2020, and became enforceable by the California Attorney General beginning on July 1-a private right of action for certain data breaches involving personal information, 2020-which is expected to increase the likelihood of, and risks associated with, data breach litigation. While there is an exception for protected health information that is subject to HIPAA and clinical trial regulations, the CCPA may impact our business activities if we become a " Business" regulated by the**

scope of the CCPA or a service provider to a regulated business. **The CCPA was amended by** Additionally, a new California ballot initiative, the California Privacy Rights Act, or CPRA, **was passed in November 2020. As of** Effective starting on January 1, 2023, the **amendments to the CCPA introduced by the** CPRA **have imposed** imposed additional obligations on companies covered by the legislation **and significantly modifies the CCPA**, including by expanding consumers' rights with respect to certain sensitive personal information. The **amendments introduced by the** CPRA also **creates created** a new state agency that **is will be** vested with authority to implement and enforce the CCPA **and the CPRA**. The effects of the CCPA **and the CPRA** are potentially significant and may require us to modify our data collection or processing practices and policies and to incur substantial costs and expenses in an effort to comply and increase our potential exposure to regulatory enforcement and / or litigation. **In addition** **Following California**, **numerous** on March 2, 2021, Virginia enacted the Consumer Data Protection Act (the "CDPA"). The CDPA became effective January 1, 2023. The CDPA regulates how businesses (which the CDPA refers to as "controllers") collect and share personal information. While the CDPA incorporates many similar concepts of the CCPA and CPRA, there are also several key differences in the scope, application, and enforcement of the law that will change the operational practices of controllers. The new law will impact how controllers collect and process personal sensitive data, conduct data protection assessments, transfer personal data to affiliates, and respond to consumer rights requests. Also, on July 8, 2021, Colorado's governor signed the Colorado Privacy Act ("CPA"), into law. The CPA will become effective July 1, 2023. The CPA is rather similar to Virginia's CPDA but also contains additional requirements. In addition, on March 24, 2022, Utah's governor signed the Utah Consumer Privacy Act into law, which will take effect on December 31, 2023 and on May 10, 2022, Connecticut's Governor signed an Act Concerning Personal Data Privacy and Online Monitoring into law. This measure will become effective July 1, 2023. In addition to these laws, many other states have **enacted laws similar to the CCPA and even more have** proposed or enacted **similar laws that have not yet passed. In addition to these comprehensive laws and proposals, their other own versions states have passed or are considering more limited privacy laws that are specifically focused upon the protection** of a broad consumer privacy law **health data, such as Washington's My Health My Data Act**. The existence of comprehensive privacy laws in different states in the country will make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. The effects of **the CCPA, and other similar state privacy laws** are potentially significant and may require us to modify our data processing practices and policies and to incur substantial costs and potential liability in an effort to comply with such legislation. Compliance with U. S. and international data protection **and data security** 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 U. S. and international data protection **and data security** laws and regulations could result in government **and / or data protection authority** enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to 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 business. Artificial intelligence presents risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information, and personal data. Issues in the development and use of artificial intelligence, combined with an uncertain regulatory environment, may result in reputational harm, liability, or other adverse consequences to our business operations. As with many technological innovations, artificial intelligence presents risks and challenges that could impact our business. We may adopt and integrate generative artificial intelligence tools into our systems for specific use cases reviewed by legal and information security. Our vendors may incorporate generative artificial intelligence tools into their offerings without disclosing this use to us, and the providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If we, our vendors, or our third-party partners experience an actual or perceived breach or privacy or security incident because of the use of generative artificial intelligence, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact** our business. Our future success depends on our ability to retain members of our executive management team, and to attract, retain and motivate qualified personnel. We are highly dependent on members of our senior management team. We have entered into employment agreements with these individuals, but any employee may terminate his or her employment with us. Although we do not have any reason to believe that we will lose the services of these individuals in the foreseeable future, the loss of the services of these individuals might impede the achievement of our research, development and commercialization objectives. We rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. Recruiting and retaining qualified scientific personnel and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific personnel from universities and research institutions. Failure to succeed in clinical studies may make it more challenging to recruit and retain

qualified scientific personnel. Risks Related to Sales, Marketing, and Competition Our market is subject to intense competition. If we are unable to compete effectively, our opportunity to generate revenue from the sale of bempedoic acid or the bempedoic acid / ezetimibe combination tablet in the U. S., in Europe and ~~if approved,~~ in other territories will be materially adversely affected. The LDL- C **and cardiovascular risk** lowering therapies market is highly competitive and dynamic and dominated by the sale of inexpensive generic versions of statins. Our success will depend, in part, on our ability to obtain a share of the market, initially, for patient populations consistent with the labeling of our products in jurisdictions where we obtain regulatory approval. Potential competitors in North America, Europe and elsewhere include major pharmaceutical companies, specialty pharmaceutical companies, biotechnology firms, universities and other research institutions and government agencies. Other pharmaceutical companies may develop LDL- C lowering **or cardiovascular risk reducing** therapies for patients that compete with bempedoic acid and the bempedoic acid / ezetimibe combination tablet that do not infringe the claims of our patents, pending patent applications or other proprietary rights, which could materially adversely affect our business and results of operations. Lipid lowering **and cardiovascular risk reducing** therapies currently on the market that ~~would~~ compete with bempedoic acid and the bempedoic acid / ezetimibe combination tablet include the following: • Inexpensive generic versions of statins; • Inexpensive generic versions of ezetimibe, a cholesterol absorption inhibitor; • Injectable PCSK9 inhibitors such as Praluent® (alirocumab) and Repatha® (evolocumab), marketed by Regeneron / Sanofi and Amgen Inc. respectively; • Bile acid sequestrants such as Welchol® (colesevelam), marketed by Daiichi Sankyo Inc.; • MTP inhibitors, such as JUXTAPID® (lomitapide), marketed by Amryt Pharma Plc.; • Apo B Anti- Sense therapy, such as KYNAMRO® (mipomersen), marketed by Kastle Therapeutics LLC; • Inexpensive generic versions of combination tablet therapies, such as ezetimibe and simvastatin; • Triglyceride lowering therapy such as Vascepa® (icosapent ethyl), marketed by Amarin Corporation; • Small interfering RNA therapy, such as Leqvio® (inclisiran), marketed by Novartis; and • Other lipid- lowering monotherapies (including cheaper generic versions), such as Tricor® (fenofibrate) and Niaspan® (niacin extended release), both of which are marketed by AbbVie, Inc. Several other pharmaceutical companies have other LDL- C lowering therapies in development that may be approved for marketing in the U. S. or outside of the U. S. Many of our potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience discovering and developing drug candidates, obtaining FDA and other marketing approvals of products and commercializing those products. Accordingly, our competitors may be more successful than we may be in obtaining regulatory approval for drugs and achieving widespread market acceptance. Our competitors' drugs may be more effective, or more effectively marketed and sold, than bempedoic acid or the bempedoic acid / ezetimibe combination tablet, and may render bempedoic acid or the bempedoic acid / ezetimibe combination tablet obsolete or non- competitive before we can recover the expenses of developing and commercializing it. The bempedoic acid and bempedoic acid / ezetimibe combination tablet may also compete with unapproved and off- label LDL- C lowering treatments, and following the expiration of additional patents covering the LDL- C lowering market, we may also face additional competition from the entry of new generic drugs. We anticipate that we will encounter intense and increasing competition as new drugs enter the market and advanced technologies become available. The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses. If we are found to have improperly promoted off- label uses, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as bempedoic acid or the bempedoic acid / ezetimibe combination tablet. In particular, a product may not be promoted for uses that are not approved by the FDA or other regulatory agencies as reflected in the product' s approved labeling. For instance, we received marketing approval for bempedoic acid and the bempedoic acid / ezetimibe combination tablet as an adjunct to diet and ~~maximally tolerated~~ statin therapy for the treatment of **primary hyperlipidemia in** adults with HeFH or ~~established~~ ASCVD who require additional lowering of LDL- C, the first indication we pursued. Based on the results of the CLEAR Outcomes CVOT, we ~~expect to seek a~~ **have submitted supplemental applications seeking an expanded** cardiovascular risk reduction indication in the U. S. ; **and** Europe ~~and other jurisdictions~~. Physicians may in their practice prescribe bempedoic acid and the bempedoic acid / ezetimibe combination tablet to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off- label uses, we may become subject to public advisory or enforcement letters, reputational damage, and significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion under both the Federal Anti- kickback Statute and False Claims Act and has enjoined several companies from engaging in off- label promotion. The FDA has also requested that companies enter into consent decrees, corporate integrity agreements or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of bempedoic acid and the bempedoic acid / ezetimibe combination tablet across various promotional media and outreach activities to ensure it remains consistent with its approved labeling, we could become subject to significant liability, which would materially adversely affect our business and financial condition. Even though we have received marketing approval for bempedoic acid and the bempedoic acid / ezetimibe combination tablet in the U. S. and Europe, we may never receive regulatory approval to market bempedoic acid or the bempedoic acid / ezetimibe combination tablet outside of the U. S. and Europe. In order to market any product outside of the U. S. and Europe, we must establish and comply with the numerous and varying efficacy, safety and other regulatory requirements of the countries in which we intend to market our product. Approval procedures vary among countries and can involve additional product candidate testing and additional administrative review periods. The time required to obtain approvals in other countries might differ from that required to obtain FDA or EMA approval. The marketing approval processes in other countries may include all of the risks detailed above regarding FDA approval in the U. S. as well as other risks, or vice versa. In particular, in many countries outside of the U. S. and Europe, products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining this approval can result in substantial delays in bringing products to market in such countries. Marketing approval in one country does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may have a negative

effect on the regulatory process in others. Failure to obtain marketing approval in other countries or any delay or other setback in obtaining such approval would impair our ability to commercialize bempedoic acid or the bempedoic acid / ezetimibe combination tablet in such foreign markets. Any such impairment would reduce the size of our potential market, which could have a material adverse impact on our business, results of operations and prospects. Even though we have received marketing approval for bempedoic acid and the bempedoic acid / ezetimibe combination tablet in the U. S. and Europe, they may not achieve broad market acceptance, which would limit the revenue that we generate from their sales. The commercial success of bempedoic acid or the bempedoic acid / ezetimibe combination tablet in the U. S. and Europe, and, if approved, by other regulatory authorities, in other countries in which we pursue regulatory approval, will depend upon the awareness and acceptance of bempedoic acid and the bempedoic acid / ezetimibe combination tablet among the medical community, including physicians, patients and healthcare payors. Market acceptance of bempedoic acid and the bempedoic acid / ezetimibe combination tablet will depend on a number of factors, including, among others: • bempedoic acid and the bempedoic acid / ezetimibe combination tablet's demonstrated ability to treat patients on ~~maximally tolerated~~ statin therapy for LDL- C lowering, or bempedoic acid and the bempedoic acid / ezetimibe combination tablet's ability to achieve CV risk reduction, as compared with other available therapies; • the relative convenience and ease of administration of bempedoic acid and the bempedoic acid / ezetimibe combination tablet, including as compared with other treatments for patients for LDL- C lowering or CV risk reduction; • the prevalence and severity of any adverse side effects such as muscle pain or weakness; • limitations or warnings contained in the labeling approved for bempedoic acid or the bempedoic acid / ezetimibe combination tablet by the FDA; • availability of alternative treatments, including a number of competitive therapies already approved for LDL- C lowering or CV risk reduction, including PCSK9 inhibitors, or expected to be commercially launched in the near future; • pricing and cost effectiveness; • the effectiveness of our, in Europe, DSE's, and in Japan, Otsuka's, sales and marketing strategies, as well as the effectiveness of any other future collaborators; • our ability to increase awareness of bempedoic acid or the bempedoic acid / ezetimibe combination tablet through marketing efforts; • our ability to obtain sufficient third- party coverage or reimbursement; and • the willingness of patients to pay out- of- pocket in the absence of third- party coverage. If bempedoic acid or the bempedoic acid / ezetimibe combination tablet does not achieve an adequate level of acceptance by patients, physicians and payors, we may not generate sufficient revenue from bempedoic acid and the bempedoic acid / ezetimibe combination tablet to become or remain profitable. Our efforts to educate the medical community and third- party payors about the benefits of bempedoic acid and the bempedoic acid / ezetimibe combination tablet may require significant resources and may never be successful. Even though we have obtained marketing approval for bempedoic acid and the bempedoic acid / ezetimibe combination tablet in the U. S. and Europe, physicians and patients using other LDL- C or CV risk lowering therapies may choose not to switch to our products. Physicians are often reluctant to switch their patients from existing therapies even when new and potentially more effective, safe or convenient treatments enter the market. In addition, patients often acclimate to the brand or type of therapy that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch therapies due to lack of reimbursement for existing therapies. If physicians or patients are reluctant to switch from existing therapies to bempedoic acid and the bempedoic acid / ezetimibe combination tablet, our operating results and financial condition would be materially adversely affected.

**Risks Related to Our Business**

**Our internal computer and information technology systems and infrastructure**, or those of our third- party clinical research organizations or other contractors or consultants, may fail or suffer security **compromises or** breaches, which could result in a material disruption of our bempedoic acid or the bempedoic acid / ezetimibe combination tablet commercialization and development programs. Despite the implementation of security measures, our internal computer **and information technology systems and infrastructure** and those of our third- party ~~clinical research organizations~~ **CROs, vendors,** and other contractors and consultants **upon which our business relies** are vulnerable to **breakdown or** damage **or interruption** from **, among other things,** natural disasters, terrorism, war, telecommunication and electrical failures, and sophisticated cyber- attacks, including the theft **, fraud,** and subsequent misuse of employee credentials **, wrongful conduct by insider employees or vendors,** denial- of- service attacks, ransomware attacks, business email compromises, computer malware, **malicious codes, viruses ,** **breakdown, wrongful intrusions, data breaches**, and social engineering (including phishing **attacks**). While we have not experienced any such system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical study data for bempedoic acid or the bempedoic acid / ezetimibe combination tablet could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. **Likewise, we rely on third parties to manufacture our product candidates and will rely on third parties to conduct future clinical trials, and similar events relating to their computer systems and infrastructure could also have similar consequences to our business.** To the extent that any disruption or security **compromise or** breach results in a loss of or damage to **, unauthorized access of, or misuse of** our data **, systems, infrastructure** or applications or other data or applications relating to our technology or our products and product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities **(including in connection with or resulting from litigation or governmental investigations and enforcement actions)** and the further development of bempedoic acid or the bempedoic acid / ezetimibe combination tablet could be delayed **and,** the commercialization of our products could be impacted **and our business could be otherwise adversely affected.** 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, or physical facilities in which data is stored or through which data is transmitted, 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. If a material breach of our information technology systems **and infrastructure** 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, including costs to deploy additional personnel and protection technologies, train employees, and engage third- party experts and consultants, which could materially and adversely affect our business, financial condition and results of operations. 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. 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 **and infrastructure** 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 **compromise or** breach, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm **which could negatively impact our relationship with our customers, partners, vendors and other third parties, and fines and penalties resulting from claims against us by private parties and / or governmental agencies**. Our employees may engage in misconduct or other improper activities, including violating applicable regulatory standards and requirements or engaging in insider trading, which could significantly harm our business. We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with the regulations of the FDA and applicable non- U. S. regulators, provide accurate information to the FDA and applicable non- U. S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of, including trading on, information obtained in the course of clinical studies, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may be ineffective 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 comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. The increasing use of social media platforms presents new risks and challenges. Social media is increasingly being used to communicate about our drugs, clinical development programs, and the diseases our drugs and drug candidates are being developed to treat, and we are utilizing what we believe is appropriate social media in connection with our commercialization efforts for bempedoic acid and the bempedoic acid / ezetimibe combination tablet and we intend to do the same for our future products, if approved. Social media practices in the pharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us. For example, there is a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions, or incur other harm to our business. The effects of enacted tax legislation and other legislative, regulatory, and administrative developments to our business are uncertain. Increased costs related to such developments could adversely affect our financial condition and results of operations. ~~On December 22, 2017, the TCJA was signed into law. The TCJA made major changes to the taxation of corporations, including reduction of the corporate tax rate from 35 % to 21 %, limitation of the tax deduction for interest expense to 30 % of adjusted taxable income (except for certain small businesses), limitation of the deduction for net operating losses to 80 % of annual taxable income and elimination of net operating loss carrybacks, elimination of U. S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. The TCJA included a number of tax provisions that were subjected to sunset for tax years beginning after December 31, 2021. Companies are required to capitalize all domestic and foreign research and development expenditures (including software development costs), and amortize them over a 5 or 15 year period, respectfully. Additionally, taxpayers are no longer able to add back depreciation, amortization, and depletion into their computation of adjusted taxable income when calculating the limitation of deductible business interest expense.~~ In the third quarter of 2022, Pennsylvania House Bill 1342 was enacted, which in part phased in a corporate net income tax (CNIT) rate reduction over nine years. The CNIT rate for the ~~2022-2023~~ tax year is ~~9-8~~. 99 %. The CNIT rate will be reduced to ~~8.99-49~~ % for the ~~2023-2024~~ tax year. Starting with the ~~2024-2025~~ tax year, the rate is reduced by 0. 5 % annually until it reaches 4. 99 % for the 2031 tax year and each year thereafter. The company assessed the impact of the law change but do not expect that it will have a material impact on the

financial statements. On August 16, 2022, H. R. 5376 (commonly called the Inflation Reduction Act of 2022) was signed into law, which, among other things, implemented a corporate alternative minimum tax (CAMT) of 15 percent-% on book income of certain large corporations. The CAMT imposes a minimum tax on net income adjusted for certain items prescribed by the legislation and is effective for tax years beginning after December 31, 2022. The company does not anticipate being subjected to the new CAMT. It cannot be predicted whether, when, in what form, or with what effective dates, tax laws, regulations, and rulings may be enacted, promulgated, or issued, which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law. Changes in tax law could adversely affect our business and financial condition. The rules dealing with U. S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U. S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect our business. In recent years, many such changes have been made and changes are likely to continue to occur in the future. **For example, under Section 174 of the U. S. Internal Revenue Code of 1986, as amended, or the Code, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development in the U. S. will be capitalized and amortized, which may have an adverse effect on our cash flow.** Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock. Our ability to use our net operating loss carryforwards may be subject to limitation. At December 31, ~~2022~~ **2023**, we had United States federal net operating loss carryforwards of approximately \$ ~~950~~ **1,027.85** million and state net operating loss carryforwards of approximately \$ ~~698~~ **696.41** million. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes, such as research tax credits, to offset its post-change income may be limited. In general, an "ownership change" will occur if there is a cumulative change in our ownership by "5-percent shareholders" that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. As a result of prior equity issuances and other transactions in our stock, we have previously experienced "ownership changes" under section 382 of the Code and comparable state tax laws in those years. Some of the U. S. Federal and State net operating loss and credit carryforwards are subject to annual limitations due to ownership changes. The annual limitation may result in the expiration of net operating losses or credit carryforwards before utilization. As of result of stock transactions, we expect the Company experienced an ownership change in **2017, 2021 and 2023**. We may also experience ownership changes in the future as a result of future transactions in our stock. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards or other pre-change tax attributes to offset United States federal and state taxable income is subject to further limitations. We or the third parties upon whom we depend may be adversely affected by natural disasters, **geopolitical developments** or global health crises and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster. **The occurrence of unforeseen or catastrophic events, including extreme weather events, Natural natural disasters, geopolitical developments or global health crises, including depending on the their scale ongoing COVID-19 pandemic, may cause different degrees of damage to the national and local economies, such as recessions, rising interest rates, inflation, fuel prices, foreign currency fluctuations, international tariffs, boycotts, curtailment of trade and other business restrictions, and** could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition, and prospects. If a natural disaster, global health crisis, power outage, or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted our operations or the operations of our vendors, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster, health crisis, or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, could have a material adverse effect on our business. Risks Related to Clinical Development, Regulatory Review, and Approval of Our Drugs and Future Drug Candidates Failures or delays in the completion of any of our future clinical trials could result in increased costs to us and could delay, prevent or limit our ability to generate revenue and continue our business. In December 2022, we announced completion of the CLEAR Outcomes CVOT. In the future, we **or our partners** may conduct additional clinical studies of bempedoic acid and the bempedoic acid / ezetimibe combination tablet, as well as clinical studies of additional product candidates we may develop. The conduct and completion of any of our future clinical studies can be delayed or prevented for a number of reasons, including, among others: • the FDA, EMA or any other regulatory authority may not agree to the study design or overall program; • the FDA, EMA or any other regulatory authority may place a clinical study on hold; • delays in reaching or failing to reach agreement on acceptable terms with prospective CROs and study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and study sites; • inadequate quantity or quality of a product candidate or other materials necessary to conduct clinical studies; • difficulties or delays obtaining institutional review board, or IRB, approval to conduct a clinical study at a prospective site or sites; • severe or unexpected drug-related side effects experienced by patients in a clinical study, including instances of muscle pain or weakness or other side effects; • reports from preclinical or clinical testing of other cardiometabolic therapies that raise safety or efficacy concerns; and • difficulties retaining patients who have enrolled in a clinical study but may be prone to withdraw due to rigors of the study, lack of efficacy, side effects, personal issues or loss of interest. Clinical studies may also be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical study may be suspended or terminated by us, the FDA, the EMA, the IRBs at the sites where the IRBs are overseeing a clinical study, a data safety monitoring committee, or DMC, overseeing the clinical study at issue or any other regulatory authorities due to a number of factors, including, among others: • failure to conduct the clinical

study in accordance with regulatory requirements or our clinical protocols; • inspection of the clinical study operations or study sites by the FDA, EMA or any other regulatory authorities that reveals deficiencies or violations that require us to undertake corrective action, including the imposition of a clinical hold; • unforeseen safety issues; • changes in government regulations or administrative actions; • problems with clinical supply materials; and • lack of adequate funding to continue the clinical study. Positive results from completed Phase 1, Phase 2 and Phase 3 clinical studies of bempedoic acid and the bempedoic acid / ezetimibe combination tablet **and our CLEAR Outcomes CVOT of bempedoic acid** are not necessarily predictive of the ~~full results of our CLEAR Outcomes CVOT of bempedoic acid or any other~~ of our future clinical studies, nor do they guarantee approval of bempedoic acid and the bempedoic acid / ezetimibe combination tablet by the FDA, EMA or any other regulatory agency for additional indications such as a CVD risk reduction indication. Although we have announced positive ~~topline~~ results from our CLEAR Outcomes CVOT, we may be unable to successfully obtain regulatory approval for and commercialize bempedoic acid and the bempedoic acid / ezetimibe combination tablet for additional indications. There is a high failure rate for drugs proceeding through clinical studies. The positive results from our completed Phase 1, Phase 2 and Phase 3 clinical studies of bempedoic acid ~~and~~, our Phase 3 1002FDC- 053 clinical study of the bempedoic acid / ezetimibe combination tablet, ~~may not be replicated in~~ our CLEAR Outcomes CVOT or any future studies of bempedoic acid and the bempedoic acid / ezetimibe combination tablet, ~~nor do~~ **not the positive topline results we announced from our CLEAR Outcomes CVOT in December 2022** guarantee approval of bempedoic acid and the bempedoic acid / ezetimibe combination tablet by the FDA for additional indications such as a CVD risk reduction indication, or by the EMA or any other regulatory authorities for any future indications in a timely manner or at all. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late- stage clinical studies after achieving positive results earlier in development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical studies were underway or safety or efficacy observations made in clinical studies, including previously unreported adverse events. In addition, regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy during the period of product development. If we fail to obtain positive results in any future clinical studies, the regulatory status of our product candidates or future product candidates, and correspondingly, our business and financial prospects, may be materially adversely affected. Undesirable side effects caused by our product candidates could cause us, **our partners** or regulatory authorities to interrupt, delay or halt non- clinical studies and clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. Clinical trials by their nature utilize a sample of the potential patient population. ~~With a limited number of patients and limited duration of exposure,~~ **rare Rare** and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate **over a significant period of time**. If our product candidates receive marketing approval and we or others identify undesirable side effects caused by such products (or any other similar products) after such approval, a number of potentially significant negative consequences could result, including: • regulatory authorities may withdraw or limit their approval of such products; • regulatory authorities may require the addition of labeling statements, such as a “ boxed ” warning or a contraindication; • we may be required to change the way such products are distributed or administered, conduct additional clinical trials or change the labeling of the products; • we may be subject to regulatory investigations and government enforcement actions; • we may decide to recall or remove such products from the marketplace; or • we could be sued and held liable for injury caused to individuals exposed to or taking our products and product candidates; and our reputation may suffer. We believe that any of these events could prevent us from achieving or maintaining market acceptance of the affected products, and could substantially increase the costs of commercializing our products and significantly impact our ability to successfully commercialize our products and generate revenues. Changes in regulatory requirements, FDA or EMA guidance or unanticipated events may occur, which may result in changes to clinical study protocols or additional clinical study requirements, which could result in increased costs to us and could delay our development timeline. Changes in regulatory requirements, FDA or EMA guidance or unanticipated events during our clinical studies may force us to amend clinical study protocols or the FDA or EMA may impose additional clinical study requirements. Significant amendments to our clinical study protocols may require resubmission to the FDA and / or IRBs for review and approval, which may adversely impact the cost, timing and / or successful completion of these studies. If we are required to conduct clinical studies in addition to our **CLEAR Outcomes** CVOT to support a CV risk reduction indication, the commercial prospects for bempedoic acid and the bempedoic acid / ezetimibe combination tablet may be harmed and our ability to generate product revenue will be impaired. ~~Even though we have completed our CVOT, we may not ultimately be able to demonstrate sufficient clinical benefits from bempedoic acid or the bempedoic acid / ezetimibe combination tablet, and our failure to do so may delay or hinder our ability to obtain FDA or EMA approval for a CV risk reduction indication.~~ Our future product development programs for candidates other than bempedoic acid or the bempedoic acid / ezetimibe combination tablet may require substantial financial resources and may ultimately be unsuccessful. In addition to the development of bempedoic acid and the bempedoic acid / ezetimibe combination tablet, we may pursue the development of other early- stage programs, such as our program to develop ~~an oral small molecule PCSK9 inhibitor and our next generation ACL inhibitor~~ **inhibitors**. If we conduct any clinical studies for our future product candidates, there will be a number of FDA requirements that we must satisfy before we can commence such clinical studies. Satisfaction of these requirements will entail substantial time, effort and financial resources. We may never satisfy these requirements. Any time, effort and financial resources we expend on any early- stage development programs that we may pursue may adversely affect our ability to continue development and commercialization of bempedoic acid and the bempedoic acid / ezetimibe combination tablet, and we may never commence clinical studies of such development programs despite expending significant resources in pursuit of their development. If we do commence clinical studies of our other potential product candidates, such product candidates may never be approved by the FDA. **Inadequate funding for the FDA, the SEC and other government agencies, including from government shutdowns, or other disruptions to these agencies'**

operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for product applications to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs, if the FDA is required to furlough review staff or necessary employees, or if the agency operations are otherwise impacted, it could significantly affect the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

**Risks Related to Litigation** We face potential product liability exposure, and, if claims are brought against us, we may incur substantial liability. The use of bempedoic acid and the bempedoic acid / ezetimibe combination tablet in clinical studies and the sale of bempedoic acid and the bempedoic acid / ezetimibe combination tablet exposes us to the risk of product liability claims. Product liability claims might be brought against us by patients, healthcare providers or others selling or otherwise coming into contact with bempedoic acid or the bempedoic acid / ezetimibe combination tablet. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, including as a result of interactions with alcohol or other drugs, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we become subject to product liability claims and cannot successfully defend ourselves against them, we could incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in, among other things: • withdrawal of patients from our clinical studies; • substantial monetary awards to patients or other claimants; • decreased demand for bempedoic acid or the bempedoic acid / ezetimibe combination tablet or any future product candidates following marketing approval, if obtained; • damage to our reputation and exposure to adverse publicity; • increased FDA warnings on product labels; • litigation costs; • distraction of management' s attention from our primary business; • loss of revenue; and • the inability to successfully commercialize bempedoic acid or the bempedoic acid / ezetimibe combination tablet or any future product candidates, if approved. We maintain product liability insurance coverage for our clinical studies with a \$ 10. 0 million annual aggregate coverage limit, in addition to insurance coverage in specific local jurisdictions. Nevertheless, our insurance coverage may be insufficient to reimburse us for any expenses or losses we may suffer. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses, including if insurance coverage becomes increasingly expensive. We expanded our insurance coverage to include the sale of commercial products. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. The cost of any product liability litigation or other proceedings, even if resolved in our favor, could be substantial, particularly in light of the size of our business and financial resources. A product liability claim or series of claims brought against us could cause our stock price to decline and, if we are unsuccessful in defending such a claim or claims and the resulting judgments exceed our insurance coverage, our financial condition, business and prospects could be materially adversely affected. We may be at an increased risk of securities class action litigation. Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. ~~For example, a purported securities class action lawsuit was filed in January 2016 naming us and certain of our officers as defendants. On March 12, 2021, the parties agreed to a settlement in principle of the securities class action, and on April 26, 2021, the parties entered into a stipulation of settlement to resolve all legal claims, in which defendants expressly deny that they have committed any act or omission giving rise to any liability under Section 10 (b) of the Securities Exchange Act of 1934. Under the terms of the stipulation of settlement, which the court approved on August 24, 2021, the Company and certain of the Company' s insurance carriers caused a payment of \$ 18. 25 million to be made to the plaintiff class. As a result of this settlement agreement, during the three months ended March 31, 2021, the Company recorded a loss on settlement of \$ 13. 25 million in selling, general, and administrative expenses on the statements of operations and comprehensive loss, which represents the litigation settlement of \$ 18. 25 million offset by \$ 5. 0 million in insurance claim proceeds from our insurance carriers.~~ Any lawsuit to which we or our directors or officers are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our offerings or business practices. Any of these results could adversely affect our business. In addition, defending claims is costly and can impose a significant burden on our management. Any proceeding in which we are or may become involved could result in substantial costs and a diversion of management' s attention and resources, which could harm our business. We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing bempedoic acid and the bempedoic acid / ezetimibe combination tablet. Our success will depend in part on our ability to operate without infringing the intellectual property and proprietary rights of third parties. We cannot assure you that our business, products and methods do not or will not infringe the patents or other intellectual property rights of third parties. The pharmaceutical industry is characterized by extensive litigation regarding patents



and other intellectual property rights. Other parties may allege that bempedoic acid or the bempedoic acid / ezetimibe combination tablet or the use of our technologies infringe patent claims or other intellectual property rights held by them or that we are employing their proprietary technology without authorization. For example, we are aware of U. S. patents relating to compositions containing ezetimibe. Although we believe that our bempedoic acid / ezetimibe combination tablet would not infringe a claim of such patents, the owner of such patents may disagree and initiate a patent infringement action against us. Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcome is uncertain. Any claim relating to intellectual property infringement that is successfully asserted against us may require us to pay substantial damages, including treble damages and attorney' s fees if we are found to be willfully infringing another party' s patents, for past use of the asserted intellectual property and royalties and other consideration going forward if we are forced to take a license. In addition, if any such claim were successfully asserted against us and we could not obtain such a license, we may be forced to stop or delay developing, manufacturing, selling or otherwise commercializing bempedoic acid or the bempedoic acid / ezetimibe combination tablet. Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court, or redesign our products. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, intellectual property litigation or claims could force us to do one or more of the following: • cease developing, selling or otherwise commercializing bempedoic acid or the bempedoic acid / ezetimibe combination tablet; • pay substantial damages for past use of the asserted intellectual property; • obtain a license from the holder of the asserted intellectual property, which license may not be available on reasonable terms, if at all; and • redesign, or rename in the case of trademark claims, bempedoic acid or the bempedoic acid / ezetimibe combination tablet to avoid infringing the intellectual property rights of third parties, which may not be possible and, even if possible, could be costly and time- consuming. Any of these risks coming to fruition could have a material adverse effect on our business, results of operations, financial condition and prospects. We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers. Our employees have been previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we are not aware of any claims currently pending against us, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of the former employers of our employees. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying money claims, we may lose valuable intellectual property rights or personnel. A loss of key personnel or their work product could hamper or prevent our ability to commercialize bempedoic acid or the bempedoic acid / ezetimibe combination tablet, which would materially adversely affect our commercial development efforts. Risks Related to Our Financial Position, Capital Needs and Ownership of Our Stock We have incurred significant operating losses since our inception, and anticipate that we will incur continued losses for the foreseeable future. Pharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We were incorporated in January 2008. Our operations to date have included organizing and staffing our company, conducting research and development activities for bempedoic acid and the bempedoic acid / ezetimibe combination tablet, as well as commercializing these products. Since the launch of our products, we have generated \$ ~~108.1~~ **187.9** million in ~~net~~ revenue from product sales in the U. S. We have obtained regulatory approval for both products from the FDA in the U. S., the EC in Europe and Swissmedic in Switzerland, but have not received approval for bempedoic acid and the bempedoic acid / ezetimibe combination tablet from any other regulatory agency. As such, we are subject to all the risks incident to the development, regulatory approval and commercialization of new pharmaceutical products and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors. Since our inception, we have focused substantially all of our efforts and financial resources on developing bempedoic acid. We have funded our operations to date primarily through proceeds from sales of preferred stock, public offerings of common stock and warrants, convertible promissory notes and warrants, the incurrence of indebtedness, milestone payments from collaboration agreements and revenue interest purchase agreements, and we have incurred losses in each year since our inception. Our net losses were \$ **209.2 million and \$ 233.7 million and \$ 269.1 million** for the years ended December 31, **2023 and 2022 and 2021**, respectively. As of December 31, **2022-2023**, we had an accumulated deficit of \$ **1.35** billion. Substantially all of our operating losses resulted from costs incurred in connection with our development program and from selling, general and administrative costs associated with our operations. We will continue to manage our spending for clinical trials, marketing approvals, and commercialization, and we may attempt to secure additional cash resources or reduce spend in certain areas as needed to continue commercialization and further development of bempedoic acid and the bempedoic acid / ezetimibe combination tablet. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital. We expect to ~~continue to~~ **continue to** incur significant expenses and ~~increasing~~ **increasing** operating losses for the foreseeable future related to our **commercialization of NEXLETOL and NEXLIZET and pursuing other research and development expenses and commercialization activities**, as well as other related personnel and activities. Our research and development expenses are expected to be reduced in the foreseeable future after ~~we having report reported~~ **we having report reported** the full results of the CLEAR Outcomes CVOT **and submitting regulatory filings to the FDA and EMA in 2023**. We expect to continue to incur research and development expenses related to costs associated with obtaining CV risk reduction indications and as they relate to any other early- stage development programs or additional indications we choose to pursue. We also expect **our selling, general and administrative expenses to incur significant increase in 2024 in anticipation of potential additional global regulatory approvals for new product indications, expanded commercialization initiatives for NEXLETOL and NEXLIZET, including marketing, and increases in our headcount for our sales team expansion**, marketing and

~~outsourced manufacturing expenses and expect further significant general and administration expenses in connection with the commercialization of bempedoic acid and the bempedoic acid / ezetimibe combination tablet, respectively.~~ Even though bempedoic acid and the bempedoic acid / ezetimibe combination tablet are approved in the U. S. and Europe for commercial sale, and despite expending these costs, bempedoic acid or the bempedoic acid / ezetimibe combination tablet may not be commercially successful drugs. As a public company, we have incurred and will continue to incur additional costs associated with operating as a public company. As a result, we expect to continue to incur ~~significant and increasing~~ operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

**Risks Related to our Capital Needs** We may need substantial additional capital in the future. If additional capital is not available, we will have to delay, reduce or cease operations. In February 2020 we announced that the FDA approved NEXLETOL and NEXLIZET. In April 2020, we announced that the EC approved NILEMDO and NUSTENDI. We expect that our continued commercialization efforts and any additional clinical studies that we undertake for the further clinical development of bempedoic acid and the bempedoic acid / ezetimibe combination tablet or any other product candidate we pursue will consume substantial additional financial resources. We expect that our existing cash and cash equivalents **, including the cash received in January 2024 in conjunction with the Settlement Agreement and the January 2024 Offering,** and proceeds to be received in the future for product sales and under our collaboration agreements are sufficient to fund operations for the foreseeable future. We may look to secure additional cash resources should positive corporate events or milestones provide sufficient opportunities. We may, however, need to secure additional cash resources to continue to fund the commercialization and further clinical development of bempedoic acid and the bempedoic acid / ezetimibe combination tablet. Our future capital requirements may be substantial and will depend on many factors including:

- our ability to secure a CV risk reduction indication for bempedoic acid and the bempedoic acid / ezetimibe combination tablet in the U. S. and Europe;
- our commercial sales, and our ability to secure and maintain **adequate** reimbursement coverage, in the United States, and in Europe;
- **the service and payment of potential debt maturities**;
- the costs associated with commercializing bempedoic acid and the bempedoic acid / ezetimibe combination tablet or any future product candidates if we receive marketing approval, including the cost and timing of developing sales and marketing capabilities or entering into strategic collaborations to market and sell bempedoic acid and the bempedoic acid / ezetimibe combination tablet or any future product candidates;
- DSE, DS, and Otsuka's ability to successfully commercialize bempedoic acid and the bempedoic acid / ezetimibe combination tablet in their respective territories;
- our ability to receive milestone payments from our collaboration partners;
- the number and characteristics of any additional product candidates we develop or acquire;
- the **outcome, timing and cost of meeting regulatory requirements established by the FDA, the EMA and other comparable foreign regulatory authorities;**
- the cost of manufacturing bempedoic acid and the bempedoic acid / ezetimibe combination tablet or any future product candidates and any products we successfully commercialize; and
- the costs associated with general corporate activities, such as the **cost costs** of filing, prosecuting and enforcing patent claims. Changing circumstances may cause us to consume capital significantly faster than we currently anticipate. Because the outcome of any clinical study is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development, regulatory approval and commercialization of bempedoic acid and the bempedoic acid / ezetimibe combination tablet and any future product candidates. Additional financing may not be available when we need it or may not be available on terms that are favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. If adequate funds are unavailable to us on a timely basis, or at all, we may not be able to continue the development of bempedoic acid and the bempedoic acid / ezetimibe combination tablet or any future product candidate, or to commercialize bempedoic acid and the bempedoic acid / ezetimibe combination tablet or any future product candidate, if approved. If we do not establish successful collaborations, we may have to alter our development and commercialization plans for bempedoic acid and the bempedoic acid / ezetimibe combination tablet. Our drug development programs and commercialization plans for bempedoic acid and the bempedoic acid / ezetimibe combination tablet will require substantial additional cash to fund expenses. We developed and commercialized bempedoic acid and the bempedoic acid / ezetimibe combination tablet in the United States without a partner. However, in order to pursue the broader cholesterol modifying market in the United States, we may also enter into a partnership or co- promotion arrangement with an established pharmaceutical company that has a larger sales force. We are continuing to establish our commercialization and distribution capabilities to support the sales, marketing and distribution of our pharmaceutical products, including through our arrangements with DSE, DS and Otsuka. In order to market bempedoic acid and the bempedoic acid / ezetimibe combination tablet in the U. S. and, if approved by any other regulatory body, we must continue to manage our sales, marketing, managerial, and other non- technical capabilities or make arrangements with third parties to perform these services. We will face significant competition in seeking appropriate collaborators and these collaboration agreements are complex and time- consuming to negotiate. We may not be able to negotiate collaborations on acceptable terms, or at all. **We also could be required to seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be acceptable or relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.** If that were to occur, we may have to curtail the development or delay commercialization of bempedoic acid or the bempedoic acid / ezetimibe combination tablet in certain geographies, reduce the scope of our sales or marketing activities, reduce the scope of our commercialization plans, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities outside of the United States, the DSE Territory, the DS Territory and Japan on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms,

or at all. Our payment obligations under the Revenue Interest Purchase Agreement with Oberland may adversely affect our financial position or results of operations and our ability to raise additional capital which in turn may increase our vulnerability to adverse regulatory developments or economic or business downturns. On June 26, 2019, we entered into the RIPA with Oberland and the Purchasers named therein. Pursuant to the RIPA, Oberland paid us \$ 125. 0 million on closing, less certain transaction expenses, and, Oberland paid us an additional \$ 25. 0 million in March 2020 upon receiving regulatory approval of NEXLETOL. Pursuant to the RIPA Amendment, we received the final \$ 50. 0 million in April 2021. As consideration for the payments, Oberland has the right to receive certain revenue interests from us based on the net sales of certain products, once approved, which will be tiered payments initially ranging from 3. 33 % to 10 % of our net sales in the covered territory. See in Note 10" Liability Related to the Revenue Interest Purchase Agreement" in the notes to our financial statements included elsewhere in this Annual Report on Form 10 - K for a further discussion on the RIPA. The RIPA and the revenue interest stream payable to Oberland could have important negative consequences to the holders of our securities. For example, a portion of our cash flow from operations will be needed to pay certain revenue interests to Oberland and will not be available to fund future operations. Further, as we failed to achieve the Specified Net Revenue thresholds for the quarter ended September 30, 2021, we deposited \$ 50 million into the Blocked Account, which reduced our unrestricted cash. On November 23, 2022, we entered into Amendment # 3 to the RIPA and agreed to make a one- time partial call payment with regards to the Revenue Interests (as defined in the RIPA) in an amount equal to \$ 50 million paid from the Blocked Account. Payment requirements under the RIPA will increase our cash outflows. **In 2025, the percent of net revenue paid to Oberland could reset to a higher amount if certain revenue milestones are not met. This could result in substantially higher payments starting in 2025.** Our future operating performance is subject to market conditions and business factors that are beyond our control. If our cash inflows and capital resources are insufficient to allow us to make required payments, we may have to reduce or delay capital expenditures, sell assets or seek additional capital. If we raise funds by selling additional equity, such sale would result in dilution to our stockholders. There is no assurance that if we are required to secure funding we can do so on terms acceptable to us, or at all. Failure to pay certain amounts to Oberland when due would result in a default under the RIPA and result in foreclosure on certain of our assets which would have a material adverse effect. The RIPA contains customary affirmative and negative non-financial covenants and events of default, including, covenants and restrictions that among other things, grant a senior security interest in our assets and restrict our ability to incur liens, incur additional indebtedness, make loans and investments, engage in mergers and acquisitions, and engage in asset sales. Additionally, the Purchasers under the RIPA have an option (the " Put Option ") to terminate the RIPA and to require the Company to repurchase future Revenue Interests upon enumerated events such as a bankruptcy event, an uncured material breach, a material adverse effect (which can include adverse developments related to the regulatory approval of our product candidates) or a change of control. The triggering of the Put Option, including by our failure to comply with these covenants, could permit the Purchasers to declare certain amounts to be immediately due and payable. If we default under the terms of the RIPA, including by failure to make such accelerated payments, the Purchasers take control of our pledged assets. Further, if we are liquidated, the Purchasers' right to repayment would be senior to the rights of the holders of our common stock. Any triggering of the Put Option or other declaration by the Purchasers of an event of default under the RIPA could significantly harm our financial condition, business and prospects and could cause the price of our common stock to decline. Risks Related to our Convertible Notes Servicing our debt may require a significant amount of cash. We may not have sufficient cash flow from our business to pay our indebtedness. In November 2020, we completed a private offering of Notes, issuing an aggregate principal amount of \$ 280. 0 million of 4. 00 % convertible senior subordinated notes due 2025. The interest rate is fixed at 4. 00 % per annum and is payable semi- annually in arrears on May 15 and November 15 of each year, beginning on May 15, 2021. In October 2021, we announced that we had negotiated an exchange agreement with two co- managed holders of the notes to exchange with the Company \$ 15. 0 million aggregate principal amount of Notes held in the aggregate by them (and accrued interest thereon) for shares of the Company' s common stock, par value \$ 0. 001 per share. Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the Notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional debt financing or equity capital on terms that may be onerous or highly dilutive. Our ability to refinance any future indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations. In addition, any of our future debt agreements may contain restrictive covenants that may prohibit us from adopting any of these alternatives. Our failure to comply with these covenants could result in an event of default which, if not cured or waived, could result in the acceleration of our debt. We may not have the ability to raise the funds necessary for cash settlement upon conversion of the Notes or to repurchase the Notes for cash upon a fundamental change, and our future debt may contain limitations on our ability to pay cash upon conversion of the Notes or to repurchase the Notes. Holders of the Notes have the right to require us to repurchase their Notes upon the occurrence of a fundamental change (as defined in the indenture governing the Notes) at a repurchase price equal to 100 % of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest, if any. Upon conversion of the Notes, unless we elect to deliver solely shares of our common stock to settle such conversion (other than paying cash in lieu of delivering any fractional share), we will be required to make cash payments in respect of the Notes being converted. We may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of Notes surrendered or Notes being converted. In addition, our ability to repurchase the Notes or to pay cash upon conversions of the Notes may be limited by law, by regulatory authority or by agreements governing our future indebtedness. Our failure to repurchase Notes at a time when the repurchase is required by the indenture governing such notes or to pay any cash payable on future conversions of the Notes as required by such indenture

would constitute a default under such indenture. A default under the indenture governing the Notes or the fundamental change itself could also lead to a default under agreements governing our future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the Notes or make cash payments upon conversions. In addition, our indebtedness, combined with our other financial obligations and contractual commitments, could have other important consequences. For example, it could: • make us more vulnerable to adverse changes in general U. S. and worldwide economic, industry and competitive conditions and adverse changes in government regulation; • limit our flexibility in planning for, or reacting to, changes in our business and our industry; • place us at a disadvantage compared to our competitors who have less debt; • limit our ability to borrow additional amounts to fund acquisitions, for working capital and for other general corporate purposes; and • make an acquisition of our company less attractive or more difficult. Any of these factors could harm our business, results of operations and financial condition. In addition, if we incur additional indebtedness, the risks related to our business and our ability to service or repay our indebtedness would increase. The conditional conversion feature of the Notes, if triggered, may adversely affect our financial condition and results of operations. In the event the conditional conversion feature of the Notes is triggered, holders of the Notes will be entitled to convert the Notes at any time during specified periods at their option. If one or more holders elect to convert their Notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than paying cash in lieu of delivering any fractional share), we would be required to settle a portion or all of our conversion obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the notes as a current rather than long- term liability, which would result in a material reduction of our net working capital. Transactions relating to our Notes may affect the value of our common stock. The conversion of some or all of the Notes would dilute the ownership interests of existing stockholders to the extent we satisfy our conversion obligation by delivering shares of our common stock upon any conversion of such Notes. Our Notes may become in the future convertible at the option of their holders under certain circumstances. If holders of our Notes elect to convert their notes, we may settle our conversion obligation by delivering to them a significant number of shares of our common stock, which would cause dilution to our existing stockholders. In addition, in connection with the issuance of the Notes, we entered into the Capped Calls with certain financial institutions, or the Option Counterparties. The Capped Calls are generally expected to reduce potential dilution to our common stock upon any conversion or settlement of the Notes and / or offset any cash payments we are required to make in excess of the principal amount of converted Notes, with such reduction and / or offset subject to a cap. In connection with establishing their initial hedges of the Capped Calls, the Option Counterparties or their respective affiliates entered into various derivative transactions with respect to our common stock and / or purchased shares of our common stock concurrently with or shortly after the pricing of the Notes. From time to time, the Option Counterparties or their respective affiliates may modify their hedge positions by entering into or unwinding various derivative transactions with respect to our common stock and / or purchasing or selling our common stock or other securities of ours in secondary market transactions prior to the maturity of the Notes (and are likely to do so following any conversion of the Notes, any repurchase of the Notes by us on any fundamental change repurchase date, any redemption date, or any other date on which the Notes are retired by us, in each case, if we exercise our option to terminate the relevant portion of the Capped Calls). This activity could cause a decrease and / or increased volatility in the market price of our common stock. We do not make any representation or prediction as to the direction or magnitude of any potential effect that the transactions described above may have on the price of the Notes or our common stock. In addition, we do not make any representation that the Option Counterparties will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice. We are subject to counterparty risk with respect to the Capped Calls. The Option Counterparties are financial institutions, and we will be subject to the risk that any or all of them might default under the Capped Calls. Our exposure to the credit risk of the Option Counterparties will not be secured by any collateral. Past global economic conditions have resulted in the actual or perceived failure or financial difficulties of many financial institutions. If an Option Counterparty becomes subject to insolvency proceedings, we will become an unsecured creditor in those proceedings with a claim equal to our exposure at that time under the Capped Calls with such Option Counterparty. Our exposure will depend on many factors but, generally, an increase in our exposure will be correlated to an increase in the market price and in the volatility of our common stock. In addition, upon a default by an Option Counterparty, we may suffer adverse tax consequences and more dilution than we currently anticipate with respect to our common stock. We can provide no assurances as to the financial stability or viability of the Option Counterparties. Risks Related to Ownership of Our Common Stock Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights. We may seek additional cash resources through a combination of collaborations with third parties, strategic alliances, licensing arrangements, permitted debt financings, permitted royalty- based financings, private and public equity offerings or through other sources. To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest in our company will be diluted. In addition, the terms of any such securities may include liquidation or other preferences that materially adversely affect your rights as a stockholder. Debt financing, if available and permitted under the terms of our RIPA, would increase our fixed payment obligations. Debt or royalty- based financings may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration, strategic partnerships and licensing arrangements with third parties, such as the collaboration arrangements with DSE, Otsuka and DS and the RIPA with Oberland, we may have to relinquish valuable rights to bempedoic acid or the bempedoic acid / ezetimibe combination tablet, our intellectual property, future revenue streams or grant licenses on terms that are not favorable to us. For instance, as part of the RIPA with Oberland, Oberland has the right to receive certain revenue interests from us based on the net sales of certain products and we have granted Oberland a senior security interest in

certain of our assets. If our cash flows and capital resources are insufficient to allow us to make required payments, we may have to reduce or delay capital expenditures, sell assets or seek additional capital. If we raise funds by selling additional equity, such sale would result in dilution to our stockholders. If we are unable to raise additional funds through equity or permitted debt financings or through collaborations, strategic alliances or licensing arrangements or permitted royalty- based financing arrangements when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market bempedoic acid and the bempedoic acid / ezetimibe combination tablet that we would otherwise prefer to develop and market ourselves. Our executive officers, directors, and principal stockholders, if they choose to act together, will continue to have the ability to exert significant influence over matters subject to stockholder approval. At December 31, ~~2022~~ **2023**, our executive officers, directors, combined with our stockholders who own more than 5 % of our outstanding capital stock, and entities affiliated with certain of our directors beneficially owned approximately ~~67-37~~ % of our outstanding voting common stock. These stockholders have the ability to influence us through their ownership position. These stockholders may be able to determine the outcome of all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. Anti- takeover provisions in our charter documents and under Delaware law could make an acquisition of us, even one that may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our certificate of incorporation and bylaws may delay or prevent an acquisition of us or a change in our management. These provisions include a classified board of directors, a prohibition on actions by written consent of our stockholders and the ability of our board of directors to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15 % of our outstanding voting stock to merge or combine with us. Although we believe these provisions collectively provide for an opportunity to obtain greater value for stockholders by requiring potential acquirors to negotiate with our board of directors, they would apply even if an offer rejected by our board were considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. We do not intend to pay dividends on our common stock and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock. We have never declared or paid any cash dividend on our common stock and do not currently intend to do so in the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends in the foreseeable future. Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in their value. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which you purchased them. **Our stock price may be volatile and an investment in our stock may decline. If we fail to comply with the continuing listing standards of Nasdaq, our securities could be delisted. Our common stock has experienced, and may continue to experience, substantial price volatility. The trading price of common stock may fluctuate significantly in response to a number of factors, many of which are beyond our control. For instance, if our financial results are below the expectations of securities analysts and investors, the market price of common stock could decrease, perhaps significantly. Other factors that may affect the market price of common stock, including announcements relating to significant corporate transactions, fluctuations in quarterly and annual financial results, operating and stock price performance of companies that investors deem comparable to us, changes in government regulation or related proposals and international conflict. In addition, the U. S. securities markets have experienced significant price and volume fluctuations, and these fluctuations often have been unrelated to the operating performance of companies in these markets. Any volatility of or a significant decrease in the market price of common stock could also limit our ability to raise capital by issuing additional equity. Further, if we were to be the object of securities class action litigation as a result of volatility in common stock price or for other reasons, it could result in substantial costs and diversion of management' s attention and resources, which could negatively affect our financial results. The occurrence of any one or more of the factors noted in these risk factors could cause the market price of our common stock to be below the \$ 1. 00 Nasdaq minimum price requirement.**

**Risks Related to our Intellectual Property** If we are unable to adequately protect our proprietary technology or maintain issued patents which are sufficient to protect bempedoic acid and the bempedoic acid / ezetimibe combination tablet, others could compete against us more directly, which would have a material adverse impact on our business, results of operations, financial condition and prospects. Our commercial success will depend in part on our success obtaining and maintaining issued patents and other intellectual property rights in the United States and elsewhere and protecting our proprietary technology. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. As of December 31, ~~2022~~ **2023**, our patent estate, including patents we own, on a worldwide basis, included approximately ~~26-10~~ issued United States patents and ~~16-17~~ pending United States patent applications and over 25 issued patents and over ~~130-80~~ pending patent applications in other foreign jurisdictions. Of our worldwide patent estate, only a subset of our patents and pending patent applications relates to our bempedoic acid program. Bempedoic acid is claimed in U. S. Patent No. 7, 335, 799 that is scheduled to expire in December 2025, which includes 711 days of patent term adjustment, and may be eligible for a patent term extension period of up to five years. We have requested a five year patent term extension of U. S. Patent No. 7, 335, 799, and we believe that this patent could also be the subject of an additional six month pediatric exclusivity period. **We** In addition, U. S. Patent Nos. 9, 000, 041, 8, 497, 301, 9,

624, 152, 10, 118, 881 and 10, 941, 095, which are scheduled to expire in December 2023, claim methods of using bempedoic acid. There are currently seven issued patents in countries outside the United States, including, Brazil, Canada, Europe, Japan and Mexico, that relate to bempedoic acid and its use. Furthermore, of the seven granted patents, we have ~~two~~ **one** granted European ~~patents~~ **patent** that ~~have has~~ been validated in numerous European countries including France, Germany, Great Britain, Ireland, Italy, the Netherlands, Spain, Sweden and Switzerland. We ~~obtained~~ **are seeking** five year patent term extensions via supplementary protection certificates for 24 national patents validated from ~~one of~~ the granted European ~~patents~~ **patent**, which, ~~if approved, could extend~~ **extends** our patent protection in those countries until 2028. Additionally, we have one patent family that includes U. S. Patent No. 11, 407, 705, directed to the method of manufacturing high purity bempedoic acid, one pending U. S. patent application directed to the same, ~~two pending U. S. patent~~ **Patent applications No. 11. 613. 511** directed to compositions of matter of high purity bempedoic acid, **one pending U. S. patent application directed to the same, U. S. Patent No. 11, 760, 714 directed to pharmaceutical formulations containing the same, one pending U. S. patent application directed to methods of treatment using the same,** and ~~25-15~~ pending patent applications outside of the United States. U. S. Patent ~~No Nos~~ . 11, 407, 705, **11, 613, 511, and 11, 760, 714,** and the other patent family members, if issued, are scheduled to expire in June 2040. In addition, we have three patent families in which we are pursuing patent protection for our bempedoic acid and bempedoic acid / ezetimibe combination tablet in combination with one or more statins. Methods of treating familial hypercholesterolemia with the bempedoic acid / ezetimibe combination tablet are claimed in U. S. Patent ~~No Nos~~ . 10, 912, 751 **and 11, 744, 816** that ~~is are~~ scheduled to expire in March 2036. We also have one pending U. S. patent application, ~~7-9~~ issued patents and ~~17-14~~ pending applications outside the U. S. with claims directed to methods of treatment using the bempedoic acid / ezetimibe combination tablet. Additionally, we have one pending U. S. patent application, ~~and 25-7~~ **issued patents and 23** pending applications outside the U. S. directed to the manufacturing of our bempedoic acid / ezetimibe combination tablet. We also have one issued U. S. patent, **i. e., U. S. Patent No. 11, 116, 739,** one pending U. S. patent application, and ~~six-9~~ issued patents and ~~21-15~~ pending applications outside the U. S., with claims directed to fixed dose combinations of bempedoic acid and one or more statins and / or methods of using said fixed dose combinations **. U. S. Patent No. 11, 116, 739 is scheduled to expire in March 2036**. We may not have identified all patents, published applications or published literature that affect our business either by blocking our ability to commercialize our products and drug candidates, by preventing the patentability of one or more aspects of our products and drug candidates to us or our licensors or co- owners, or by covering the same or similar technologies that may affect our ability to market our products and drug candidates. For example, we (or the licensor of a drug candidate to us) may not have conducted a patent clearance search to identify potentially obstructing third party patents. Moreover, patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U. S. Patent and Trademark Office, or the USPTO, for the entire time prior to issuance as a U. S. patent. Patent applications filed in countries outside of the United States are not typically published until at least 18 months from their first filing date. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. We cannot be certain that we or our licensors or co- owners were the first to invent, or the first to file, patent applications covering our products and drug candidates. We also may not know if our competitors filed patent applications for technology covered by our pending applications or if we were the first to invent the technology that is the subject of our patent applications. Competitors may have filed patent applications or received patents and may obtain additional patents and proprietary rights that block or compete with our patents. Others may have filed patent applications or received patents that conflict with patents or patent applications that we own, have filed or have licensed, either by claiming the same methods, compounds or uses or by claiming methods, compounds or uses that could dominate those owned by or licensed to us. In addition, we may not be aware of all patents or patent applications that may affect our ability to make, use or sell any of our products or drug candidates. Any conflicts resulting from third- party patent applications and patents could affect our ability to obtain the necessary patent protection for our products or processes. If other companies or entities obtain patents with conflicting claims, we may be required to obtain licenses to these patents or to develop or obtain alternative technology. We may not be able to obtain any such licenses on acceptable terms or at all. Any failure to obtain such licenses could delay or prevent us from using discovery- related technology to pursue the development or commercialization of our products or drug candidates, which would adversely affect our business. We cannot assure you that any of our patents have, or that any of our pending patent applications will mature into issued patents that will include, claims with a scope sufficient to protect bempedoic acid or the bempedoic acid / ezetimibe combination tablet or any other product candidates. Others have developed technologies that may be related or competitive to our approach, and may have filed or may file patent applications and may have received or may receive patents that may overlap or conflict with our patent applications, either by claiming the same methods or formulations or by claiming subject matter that could dominate our patent position. The patent positions of biotechnology and pharmaceutical companies, including our patent position, involve complex legal and factual questions, and, therefore, the issuance, scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, invalidated, or circumvented. U. S. patents and patent applications may also be subject to interference proceedings, ex parte reexamination, inter partes review and post- grant review proceedings, supplemental examination and may be challenged in district court. Patents granted in certain other countries may be subjected to revocation, opposition or comparable proceedings lodged in various national and regional patent offices, and national courts. These proceedings could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. For example, a European Unified Patent Court (UPC) ~~is scheduled to come~~ **came** into force during 2023. The UPC ~~is will be~~ a common patent court to hear patent infringement and revocation proceedings effective for member states of the European Union. This could enable third parties to seek revocation of any of our European patents in a single proceeding at the UPC rather than through multiple proceedings in each of the jurisdictions in which the European patent is validated. Any such revocation and loss of patent protection could have

a material adverse impact on our business and our ability to commercialize or license our technology and products. Moreover, the controlling laws and regulations of the UPC will develop over time, and may adversely affect our ability to enforce our European patents or defend the validity thereof. We may decide to opt out our European patents and patent applications from the UPC. If certain formalities and requirements are not met, however, our European patents and patent applications could be challenged for non-compliance and brought under the jurisdiction of the UPC. We cannot be certain that our European patents and patent applications will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC. Moreover, such interference, re-examination, post-grant review, inter partes review, supplemental examination, opposition, or revocation proceedings may be costly. Thus, any patents that we may own or exclusively license may not provide any protection against competitors. Furthermore, an adverse decision in an interference proceeding can result in a third-party receiving the patent right sought by us, which in turn could affect our ability to develop, market or otherwise commercialize bempedoic acid and the bempedoic acid / ezetimibe combination tablet. Furthermore, the issuance of a patent, while presumed valid and enforceable, is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors may also be able to design around our patents. Other parties may develop and obtain patent protection for more effective technologies, designs or methods. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, vendors, former employees and current employees. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries. If these developments were to occur, they could have a material adverse effect on our sales. Furthermore, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We have submitted a request for a patent term extension in the United States for U. S. Patent No. 7, 335, 799 and have **obtained** ~~been seeking~~ supplementary protection certificates for one of the granted, counterpart European patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, but the total patent term including the restoration period must not exceed 14 years following FDA approval. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. Our ability to enforce our patent rights depends on our ability to detect infringement. It is difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product. Any litigation to enforce or defend our patent rights, if any, even if we were to prevail, could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful. In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If, in any proceeding, a court invalidated or found unenforceable our patents covering bempedoic acid or the bempedoic acid / ezetimibe combination tablet, our financial position and results of operations would be materially and adversely impacted. In addition, if a court found that valid, enforceable patents held by third parties covered bempedoic acid or the bempedoic acid / ezetimibe combination tablet, our financial position and results of operations would also be materially and adversely impacted. Furthermore, it is possible that, in February 2024, one or more of our competitors may file with the FDA, an ANDA for a generic version of, or an 505 (b) (2) NDA that references, one or both of bempedoic acid or bempedoic acid / ezetimibe combination tablet, in which the competitor would claim that our patents are invalid or not infringed. Competition that our approved products could face from an approved generic and other versions of our approved products could materially and adversely affect our future revenue, profitability, and cash flows and substantially limit our ability to obtain a return on the investments we have made in developing bempedoic acid or bempedoic acid / ezetimibe combination tablet. For further details, please see our risk factor entitled " If the FDA, EMA or other comparable foreign regulatory authorities approve generic or other versions of bempedoic acid or the bempedoic acid / ezetimibe combination tablet, the sales of our approved products could be adversely affected. " The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that: • any of our patents, or any of our pending patent applications, if issued, will include claims having a scope and patent term sufficient to protect bempedoic acid or the bempedoic acid / ezetimibe combination tablet; • any of our pending patent applications will result in issued patents; • we will be able to successfully commercialize bempedoic acid or the bempedoic acid / ezetimibe combination tablet in all of the jurisdictions we intend to pursue before our relevant patents expire; • we were the first to make the inventions covered by each of our patents and pending patent applications; • we were the first to file patent applications for these inventions; • others will not develop similar or alternative technologies that do not infringe our patents; • any of our patents will be valid and enforceable; • any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties; • we will develop additional proprietary technologies or product candidates that are separately patentable; or • that our commercial activities or products, or those of our licensors, will not infringe upon the patents of others. We rely upon unpatented trade secrets, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us. It is possible that technology relevant to our business will

be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees and consultants who are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could otherwise become known or be independently discovered by our competitors. If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and products could be significantly diminished. We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, contract manufacturers, vendors and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, we cannot guarantee that we have executed these agreements with each party that may have or have had access to our trade secrets. Moreover, because we acquired certain rights from Pfizer, we must rely on Pfizer's practices, and those of its predecessors, with regard to parties that may have had access to our trade secrets related thereto before our incorporation. Any party with whom we or they have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they disclose such trade secrets, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed, either intentionally or unintentionally, to or independently developed by a competitor or other third-party, our competitive position would be harmed. Changes in U. S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products. The United States has enacted the America Invents Act of 2011, which is wide-ranging patent reform legislation. The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U. S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case. We could become dependent on licensed intellectual property. If we were to lose our rights to licensed intellectual property, we may not be able to continue developing or commercializing bempedoic acid or the bempedoic acid / ezetimibe combination tablet or other product candidates, if approved. In the future, we may enter into license(s) to third-party intellectual property that are necessary or useful to our business. Such license agreement(s) will likely impose various obligations upon us, and our licensor(s) may have the right to terminate the license thereunder in the event of a material breach or, in some cases, at will. Future licensor(s) may allege that we have breached our license agreement with them and accordingly seek to terminate our license or decide to terminate our license at will. If successful, this could result in our loss of the right to use the licensed intellectual property, which could materially adversely affect our ability to develop and commercialize our products and product candidates as well as harm our competitive business position and our business prospects. We do not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection. Filing, prosecuting and defending patents on our products and product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing with us. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to emerging pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and even if successful the damages or other remedies awarded, if any, may not be commercially



meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Risks Related to our Dependence on Third Parties If a collaborative partner terminates or fails to perform its obligations under an agreement with us, the commercialization of bempedoic acid and the bempedoic acid / ezetimibe combination tablet could be delayed or terminated. In January 2019, we entered into a license and collaboration agreement with DSE, pursuant to which DSE will be responsible for the commercialization of bempedoic acid and the bempedoic acid / ezetimibe combination tablet in the DSE Territory. In April 2020, we entered into a license and collaboration agreement with Otsuka, pursuant to which Otsuka will be responsible for the commercialization of bempedoic acid and the bempedoic acid / ezetimibe combination tablet in Japan. Otsuka will be responsible for all development and regulatory activities in Japan. In addition, Otsuka will fund all clinical development costs associated with the program in Japan, if approved. In April 2021, we entered into a license and collaboration agreement with DS, pursuant to which DS will be responsible for the commercialization of bempedoic acid and the bempedoic acid / ezetimibe combination in South Korea, Taiwan, Hong Kong, Thailand, Vietnam, Brazil, Macao, Cambodia and Myanmar, or the DS Territory. Except for certain development activities in South Korea and Taiwan, DS will be responsible for development and commercialization in these territories. We may also enter into similar arrangements with other partners or collaborators to commercialize bempedoic acid and the bempedoic acid / ezetimibe combination tablet, outside of the United States, Europe, Japan, or the DS Territory, or to further commercialize bempedoic acid or the bempedoic acid / ezetimibe combination tablet in the broader cholesterol modifying market in the United States. If DSE, Otsuka, DS or any of our future collaborative partners does not devote sufficient time and resources to the collaboration arrangement with us, we may not realize the potential commercial benefits of the arrangement, and our results of operations may be materially adversely affected. In addition, if DSE, Otsuka or DS or any such future collaboration partner were to breach or terminate its arrangements with us, the commercialization of bempedoic acid or the bempedoic acid / ezetimibe combination tablet could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue commercialization of bempedoic acid or the bempedoic acid / ezetimibe combination tablet on our own in such locations . **On March 27, 2023, we filed a complaint in the United States District Court for the Southern District of New York seeking declaratory judgment against DSE regarding the Company's right to receive a \$ 300 million milestone payment upon inclusion of cardiovascular risk reduction in the EU label that correlates with a relative risk reduction rate of at least 20 %, based on the results of the CLEAR Outcomes CVOT. On May 4, 2023, we filed an amended complaint against DSE in the Southern District of New York seeking a judicial declaration, on an expedited basis, that DSE is contractually required to make a \$ 300 million milestone payment to the Company upon applicable regulatory approval. On June 20, 2023, DSE filed a response to our amended complaint. On January 2, 2024, we entered into a settlement agreement with DSE to amicably resolve and dismiss the commercial dispute then pending in the Southern District of New York, or the Settlement Agreement. Under the Settlement Agreement, DSE agreed to pay us an aggregate of \$ 125 million, including (1) a \$ 100- million payment within 15 business days of the effective date of the Settlement Agreement and (2) a \$ 25- million payment in the calendar quarter immediately following the calendar quarter in which the EMA renders a decision on the application that was filed with the EMA for a Type II (a) variation for our oral non- statin products marketed as NILEMDO ® (bempedoic acid) tablets and NUSTENDI ® (bempedoic acid and ezetimibe) tablets in Europe. The application asks the EMA to approve both NILEMDO and NUSTENDI to reduce cardiovascular risk in patients with or at high risk for atherosclerotic cardiovascular disease. The legal action pending in the United States District Court for the Southern District of New York has now been dismissed. Pursuant to the Settlement Agreement, also on January 2, 2024, we entered into a 3rd Amendment to the License and Collaboration Agreement dated January 2, 2019 with DSE, and a 1st Amendment to the License and Collaboration Agreement dated April 26, 2021 with DS. Each of these amendments grant each of DSE and DS exclusive rights for clinical development, regulatory activities, manufacture and commercialization of a bempedoic acid / ezetimibe / statin triple combination pill in their existing respective territories of the European Economic Area, UK, Switzerland and Turkey (the " DSE Territory ") and South Korea, Taiwan, Hong Kong, Thailand, Vietnam, Brazil, Macao, Cambodia and Myanmar (the " DS Territory "). Further, after a transition period, DSE and DS will assume sole responsibility for the manufacture of NILEMDO and NUSTENDI for, respectively, the DSE Territory and DS Territory. As of January 2, 2024, DSE shall have sole authority and control of regulatory communications with the EMA regarding the pending marketing authorization applications for NILEMDO and NUSTENDI .** Pursuant to the collaboration arrangement with DSE, we will receive significant commercial and regulatory milestone payments, as well as tiered fifteen percent (15 %) to twenty- five percent (25 %) royalties on certain net DSE Territory sales. Pursuant to the collaboration arrangement with Otsuka, we will receive significant commercial and regulatory milestone payments, as well as tiered fifteen percent (15 %) to thirty percent (30 %) royalties on certain net sales in Japan. Pursuant to the collaboration agreement with DS, we will receive significant commercial milestone payments, as well as tiered royalties ranging from five percent (5 %) to twenty percent (20 %) on net sales in the DS Territory. Similar to these collaboration arrangements, much of the potential revenue from future collaborations may consist of contingent payments, such as payments for achieving regulatory milestones or royalties payable on sales of drugs. The milestone and royalty revenue that we may receive under these collaborations will depend upon our collaborators' ability to successfully introduce, market and sell new products, and on our ability to obtain the relevant regulatory approvals. In addition, collaborators may decide to enter into arrangements with third parties to commercialize products developed under collaborations using our technologies, which could reduce the milestone and royalty revenue that we may receive, if any. DSE, Otsuka, DS and our future collaboration partners may fail to develop or effectively commercialize products using our products or technologies because they: • decide not to devote the necessary resources due to internal constraints, such as limited personnel with the requisite expertise, limited cash resources or specialized equipment limitations, or the belief that other drug development programs may have a higher likelihood

of obtaining marketing approval or may potentially generate a greater return on investment; • decide to pursue other technologies or develop other product candidates, either on their own or in collaboration with others, including our competitors, to treat the same diseases targeted by our own collaborative programs; • do not have sufficient resources necessary to carry the product candidate through clinical development, marketing approval and commercialization; or • cannot obtain the necessary marketing approvals. **Receipt of any milestone payment amounts is subject to risks and uncertainties, including our obtaining the relevant regulatory approvals and marketing authorizations, the absence of any material disagreements or disputes with regulators or our collaboration partners and the ultimate timing and payment of such milestone payment amounts by our collaboration partners. In addition, while we expect that we will be entitled to the foregoing milestone payments, our inability to receive some or all of our milestone payments and other royalty amounts from our collaboration partners may significantly impact our future capital needs.** Competition may negatively impact a partner's focus on and commitment to bempedoic acid or the bempedoic acid / ezetimibe combination tablet and, as a result, could delay or otherwise negatively affect the commercialization of bempedoic acid or the bempedoic acid / ezetimibe combination tablet outside of the United States or in the broader cholesterol modifying market in the United States. If DSE, Otsuka, DS and our future collaboration partners fail to develop or effectively commercialize bempedoic acid or the bempedoic acid / ezetimibe combination tablet for any of these reasons, our sales of bempedoic acid or the bempedoic acid / ezetimibe combination tablet may be limited, which would have a material adverse effect on our operating results and financial condition. We will be unable to directly control all aspects of our clinical studies due to our reliance on CROs and other third parties that assist us in conducting clinical studies. We relied on CROs in our prior clinical studies, including our global pivotal Phase 3 clinical studies and our pivotal Phase 3 1002FDC- 053 clinical study and the CLEAR Outcomes CVOT, as well as any future clinical studies we may undertake. As a result, we will have less direct control over the conduct, timing and completion of ~~these future~~ clinical studies and the management of data developed through the clinical studies than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may: • have staffing difficulties; • fail to comply with contractual obligations; • experience regulatory compliance issues; • undergo changes in priorities or become financially distressed; or • form relationships with other entities, some of which may be our competitors. These factors may materially adversely affect the willingness or ability of third parties to conduct our clinical studies and may subject us to unexpected cost increases that are beyond our control. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording, and reporting the results of clinical studies to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical study participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Problems with the timeliness or quality of the work of any CRO may lead us to seek to terminate our relationship with any such CRO and use an alternative service provider. Making this change may be costly and may delay our clinical studies, and contractual restrictions may make such a change difficult or impossible to effect. If we must replace any CRO that is conducting our clinical studies, our clinical studies may have to be suspended until we find another CRO that offers comparable services. The time that it takes us to find alternative organizations may cause a delay in the commercialization of bempedoic acid or the bempedoic acid / ezetimibe combination tablet or may cause us to incur significant expenses to replicate data that may be lost. Although we do not believe that any CRO on which we may rely will offer services that are not available elsewhere, it may be difficult to find a replacement organization that can conduct our clinical studies in an acceptable manner and at an acceptable cost. Any delay in or inability to complete our clinical studies could significantly compromise our ability to secure regulatory approval of bempedoic acid or the bempedoic acid / ezetimibe combination tablet for additional indications we may seek and preclude our ability to commercialize bempedoic acid or the bempedoic acid / ezetimibe combination tablet, thereby limiting or preventing our ability to generate revenue from its sales. We rely completely on third-party suppliers to manufacture our clinical drug supplies for bempedoic acid and the bempedoic acid / ezetimibe combination tablet and rely on third parties to produce commercial supplies of bempedoic acid and the bempedoic acid / ezetimibe combination tablet and preclinical, clinical and commercial supplies of any future product candidate. We do not currently have, nor do we plan to acquire, the infrastructure or capability to internally manufacture our commercial supply and clinical drug supply of bempedoic acid and the bempedoic acid / ezetimibe combination tablet, or any future product candidates, for use in the commercialization and conduct of our preclinical studies and clinical studies, and we lack the internal resources and the capability to manufacture any product candidates on a commercial or clinical scale. In addition, we have no control over the production of ezetimibe for the bempedoic acid / ezetimibe combination tablet. The facilities used by our contract manufacturers to manufacture the active pharmaceutical ingredient and final drug for bempedoic acid, or any future product candidates, must be approved by the FDA and other comparable foreign regulatory agencies pursuant to inspections that would be conducted after submission of our NDA or relevant foreign regulatory submission to the applicable regulatory agency. **We While we have monitoring measures and quality agreements in place with our suppliers, we** do not control the manufacturing process of, and are completely dependent on, our contract manufacturers to comply with current Good Manufacturing Practices for manufacture of both active drug substances and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or applicable foreign regulatory agencies, they will not be able to secure and / or maintain regulatory approval for their manufacturing facilities. In addition, we have no direct control over our contract manufacturers' ability to maintain adequate quality control, quality assurance and qualified personnel. Furthermore, all of our contract manufacturers are engaged with other companies to supply and / or manufacture materials or products for such companies, which exposes our manufacturers to regulatory risks for the production of such materials and products. As a result, failure to satisfy the regulatory requirements for the production of those materials and products may affect the regulatory clearance of our contract manufacturers' facilities generally. If the FDA or a comparable foreign regulatory agency does not approve these facilities for

the manufacture of our products and product candidates or if it withdraws its approval in the future, we may need to find alternative manufacturing facilities, which would adversely impact our ability to commercialize, develop, obtain regulatory approval for or market our products and product candidates. If any contract 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 contract manufacturer, which we may not be able to do on reasonable terms, if at all. In either scenario, our commercialization supply or clinical trials supply 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 contract 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 contract manufacturers for any reason, we will be required to verify that the new contract 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 products and product candidates according to the specifications previously submitted to or approved by the FDA or another regulatory authority. The delays associated with the verification of a new contract manufacturer could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a contract manufacturer may possess technology related to the manufacturing of our products and product candidates that such contract manufacturer owns independently. This would increase our reliance on such contract manufacturer or require us to obtain a license from such contract manufacturer in order to have another contract manufacturer manufacture our product and product candidates. In addition, in the case of the contract manufacturers that supply our 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.

~~Throughout the COVID-19 pandemic, there has been public concern over the availability and accessibility of critical medical products, and the CARES Act enhances 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 FDA review during an inspection. If we experience shortages in the supply of our marketed products, our results could be materially impacted.~~

~~**Risks Related to the COVID-19 Pandemic** The ongoing COVID-19 pandemic, including recurring surges, new variants and waves of infection, and the future outbreak of other highly infectious or contagious diseases, could have a material adverse impact on our business, financial condition and results of operations, including the commercial performance of NEXLETOL and NEXLIZET, our commercial performance of NILEMDO and NUSTENDI led by DSE in the EU, and operations and sales in general. Broad-based business or economic disruptions could adversely affect our ongoing or planned research and development and commercialization activities. For example, in December 2019, an outbreak of a novel strain of coronavirus spread to the majority of countries around the world, including the U. S. New variants of coronavirus have continued to emerge, including, for example, the Omicron strain at the end of 2021. To date, the COVID-19 pandemic has caused significant disruptions to the U. S. and global economy and has contributed to significant volatility and negative pressure in financial markets. The global impact of the pandemic continues to evolve as additional cases of the virus are identified, public health officials learn more about the spread of the virus and the efficacy of containment measures, and vaccines and treatments against the virus are developed, approved and distributed. Many countries, as well as certain states and cities in the U. S., have reacted by instituting varying levels of quarantine and social distancing requirements, restrictions on travel, and mandatory closures of and/or occupancy limits for businesses. Although many of these restrictions have been eased or lifted, in response to local surges and new waves of infection, some countries, states, and local governments have reinstated, or may reinstate, these restrictions, and additional, more restrictive orders, proclamations, and/or directives may be issued in the future. In response to the spread of SARS-CoV-2 and COVID-19, our commercial and medical organizations as well as our home office personnel are following internal guidelines and respective state and local guidelines when interacting with physicians and customers. As a result of the current pandemic, or future pandemics, we may not be able to meet expectations with respect to the net product sales of NEXLETOL and NEXLIZET or attain or maintain profitability and positive cash flow from operations. To date, most of our manufacturing partners and CROs have continued to produce at anticipated levels despite these COVID-19 challenges, but we may experience other delays, such as delays in the timing for the review and approval of expanded indications such as cardiovascular risk reduction in various jurisdictions. The extent to which the ongoing COVID-19 pandemic, or the future outbreak of any other highly infectious or contagious diseases, impacts our business, including our commercialization efforts, preclinical studies, and clinical trial operations, will depend on continuously changing circumstances, which are highly uncertain and cannot be predicted with confidence, such as the duration of such pandemic including future waves of infection, new variants of the disease, or the broad availability and utilization of an effective vaccine, the actions taken to contain the pandemic or mitigate its impact, and the direct and indirect economic effects of the pandemic and containment measures, among others. The ongoing fluidity of this situation precludes any prediction as to the full impact of the COVID-19 pandemic, but it could have a material adverse effect on our business, financial condition, and results of operations. The continuing COVID-19 pandemic may also have the effect of heightening many of the risks described herein, including the below:~~

- Our ability to successfully commercialize, and generate net product sales from NEXLETOL and NEXLIZET may be adversely affected by the economic impact of the ongoing COVID-19 pandemic. In addition, social distancing requirements and precautionary measures due to COVID-19 have impacted the ability of our sales personnel to interact in-person with physicians and customers. As a result, in many circumstances we have needed to limit our interactions with physicians and payors and adapt our commercial strategies and tactics to include a virtual model, including developing and

deploying various technology-enabled platforms for virtual engagement such as remote detailing, digital and non-personal marketing channels, and social media. These circumstances may adversely affect the ability of our sales professionals and our partner's sales professionals to effectively market NEXLETOL, NEXLIZET, NILEMDO and NUSTENDI to physicians and the rates of uptakes for NEXLETOL, NEXLIZET, NILEMDO and NUSTENDI, which may have a negative impact on our sales and our market penetration. In addition, patient visits with physicians have decreased as a result of COVID-19, due to travel restrictions, social distancing requirements, prioritization of healthcare resources to address the pandemic, and/or fear of exposure to the virus, which could have a material adverse impact on new patient starts and overall patient treatment volume. • Business interruptions from the current or future pandemics may adversely impact the third parties we solely rely on to sufficiently manufacture bempedoic acid tablets and the bempedoic acid / ezetimibe combination tablets and to produce our products in quantities we require, which may impair the commercialization of NEXLETOL, NEXLIZET, NILEMDO and NUSTENDI. Since the beginning of the COVID-19 pandemic, several vaccines for COVID-19 have received Emergency Use Authorization by the FDA and a number of those later received marketing approval. Additional vaccines may be authorized or approved in the future. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials and commercial product, which could lead to delays in these trials and/or issues with our commercial supply. • Health regulatory agencies globally may experience disruptions in their operations as a result of the ongoing COVID-19 pandemic. The FDA and comparable foreign regulatory agencies may have slower response times or be under-resourced and, as a result, review, inspection, and other timelines may be materially delayed. Since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. Should 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 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. • Health regulatory agencies may refuse to accept data from our clinical trials due to mitigation strategies we utilize in response to the COVID-19 pandemic and current regulatory guidance, which could delay, limit, or prevent marketing approval or label expansion of our drugs or drug candidates. While it is not possible at this time to estimate the entirety of the impact that the ongoing COVID-19 pandemic will have on our business or operations, the continued spread or future waves of COVID-19, measures taken by governments, actions taken to protect employees, and the broad impact of the pandemic on all business activities may materially and adversely affect our preclinical activities, clinical development progress, data and timelines, regulatory approvals, commercialization efforts including any revenue from sales or milestone payments from partners, supply chain continuity, and general business operations, and our business, prospects, financial condition, and results of operations could be materially harmed as a result.

**General Risk Factors** The price of our common stock is likely to be volatile, which could result in substantial losses for purchasers of our common stock. The trading price of our common stock has been, and may continue to be, volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including: • announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments; • the timing and results of clinical trials of product candidates, or our competitors' product candidates; • regulatory actions with respect to our product candidates or our competitors' products and product candidates; • commencement or termination of collaborations for our development programs; • failure or discontinuation of any of our development programs; • regulatory or legal developments in the United States and other countries; • developments or disputes concerning patent applications, issued patents or other proprietary rights; • the recruitment or departure of key personnel; • the level of expenses related to any of our product candidates or clinical development programs; • the results of our efforts to develop additional product candidates; • actual or anticipated changes in estimates as to financial results or development timelines; • announcement or expectation of additional financing efforts; • sales of our common stock by us, our insiders or other stockholders, including shares issuable upon exercise of outstanding stock options and upon vesting of stock units under our stock incentive plans; • variations in our financial results or results of companies that are perceived to be similar to us; • whether an active trading market for our shares is sustained; • changes in estimates, evaluations or recommendations by securities analysts, that cover our stock or the failure by one or more securities analysts to continue to cover our stock; • changes in the structure of healthcare payment systems; • the societal and economic impact of **any future** public health epidemics, **such as the ongoing COVID-19 pandemic**, **pandemics or outbreaks of infectious disease** and any recession, depression or sustained market event resulting from **the pandemic such public health crises**; • market conditions in the pharmaceutical and biotechnology sectors; • general economic, **political**, industry and market conditions; and • the other factors described in this "Risk Factors" section. We also cannot guarantee that an active trading market for our shares will be sustained. An inactive trading market for our common stock may impair our ability to raise capital to continue to fund our operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration. Complying with public company reporting and other obligations may strain our financial and managerial resources. Additionally, we are obligated to maintain proper and effective internal control over financial reporting. If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired,

which could harm our operating results, investors' views of us and, as a result, the value of our common stock. As a public company, we are required to comply with applicable provisions of the Sarbanes- Oxley Act of 2002, as well as other rules and regulations promulgated by the SEC and the NASDAQ Stock Market LLC, or NASDAQ, which results in significant continuing legal, accounting, administrative and other costs and expenses. The listing requirements of the NASDAQ Global Market require that we satisfy certain corporate governance requirements relating to director independence, distributing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel need to devote a substantial amount of time to ensure that we comply with all of these requirements. We are subject to Section 404 of the Sarbanes- Oxley Act of 2002, or Section 404, and the related rules of the SEC that generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Section 404 requires an annual management assessment, as well as an opinion from our independent registered public accounting firm, on the effectiveness of our internal control over financial reporting. During the **2023 and** 2022 year end audit, due to a change in filing status our independent registered public accounting firm was not required and did not issue a report on the effectiveness of our internal controls over financial reporting. Management assessed our internal controls over financial reporting, including by using a third- party firm, and determined that their internal controls were effective as of December 31, **2022-2023**. During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, we are required to timely file accurate quarterly and annual reports with the SEC under the Securities Exchange Act of 1934, or the Exchange Act, as amended. In order to report our results of operations and financial statements on an accurate and timely basis, we depend on CROs to provide timely and accurate notice of their costs to us. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from the NASDAQ Global Market or other adverse consequences that would materially harm our business. **We are a “ smaller reporting company ” and have elected to comply with reduced public company reporting requirements, which could make our common stock less attractive to investors. Because our annual revenue was less than \$ 100. 0 million during the most recently completed fiscal year and the market value of our voting and non- voting common stock held by non- affiliates was less than \$ 560. 0 million measured on the last business day of our most recently completed second fiscal quarter, we qualify as a “ smaller reporting company ” as defined in the Exchange Act. Accordingly, we may provide less public disclosure than larger public companies, including the inclusion of only two years of audited financial statements and only two years of related selected financial data and management’ s discussion and analysis of financial condition and results of operations disclosure. We are also no longer required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests. We cannot predict if investors will find our common stock less attractive as a result of our reliance on these exemptions. If some investors find our common stock less attractive as a result of any choice we make to reduce disclosure, there may be a less active trading market for our common stock and the market price for our common stock may be more volatile.** If securities or industry analysts cease publishing research or reports or publish misleading, inaccurate or unfavorable research about us, our business or our market, our stock price and trading volume could decline. The trading market for our common stock is influenced by the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. If one or more of the industry analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, or provides more favorable relative recommendations about our competitors, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price or trading volume to decline. **Increased attention to, and evolving expectations for, environmental, climate change, social, and governance (ESG) initiatives could increase our costs, harm our reputation, or otherwise adversely impact our business. Companies across industries are facing increasing scrutiny from a variety of stakeholders related to their ESG and sustainability practices, including practices associated with climate change. Expectations regarding voluntary ESG initiatives and disclosures may result in increased costs (including but not limited to increased costs related to compliance, stakeholder engagement, contracting and insurance), enhanced compliance or disclosure obligations, or other adverse impacts to our business, financial condition, or results of operations. While we may at times engage in voluntary initiatives (such as voluntary disclosures, certifications, or goals, among others) to improve the ESG profile of the Company, such initiatives may be costly and may not have the desired effect. Moreover, we may not be able to successfully complete such initiatives due to factors that are within or outside of our control. Even if this is not the case, our actions may subsequently be determined to be insufficient by various stakeholders, and we may be subject to investor or regulator engagement on our ESG efforts, even if such initiatives are currently voluntary. Certain market participants, including major institutional investors and capital providers, use third- party benchmarks and scores to assess companies’ ESG profiles in making investment or voting decisions. Unfavorable ESG ratings could lead to increased negative investor sentiment towards us, which could negatively impact our share price as well as our access to and cost of capital. To the extent ESG matters negatively impact our reputation, it may also impede our ability to compete as effectively to attract and retain employees, which may adversely impact our operations. In addition, we expect there will likely be increasing levels of regulation, disclosure- related and otherwise, with respect to ESG matters. For example, the SEC has published propose rules that would require companies to provide significantly expanded**

climate-related disclosures in their periodic reporting, which may require us to incur significant additional costs to comply, including the implementation of significant additional internal controls processes and procedures regarding matters that have not been subject to such controls in the past, and impose increased oversight obligations on our management and board of directors. These and other changes in stakeholder expectations will likely lead to increased costs as well as scrutiny that could heighten all of the risks identified in this risk factor. Additionally, our business partners may be subject to similar expectations, which may augment or create additional risks, including risks that may not be known to us. A decline in the federal budget, changes in spending or budgetary priorities of the U. S. government, a prolonged U. S. government shutdown or delays in contract awards may significantly and adversely affect our future revenues, cash flow and financial results. In recent years, U. S. government appropriations have been affected by larger U. S. government budgetary issues and related legislation. As a result, the Department of Defense funding levels have fluctuated and have been difficult to predict. Future spending levels are subject to a wide range of factors, including Congressional action. In addition, in recent years, the U. S. government has been unable to complete its budget process before the end of its fiscal year, resulting in both a government shutdown and continuing resolutions to extend sufficient funds only for U. S. government agencies to continue operating. Most recently, the federal government was shut down due to a lack of funding for over one month between late 2018 and early 2019. Additionally, the national debt has recently threatened to reach the statutory debt ceiling in 2023, and such an event in future years could result in the U. S. government defaulting on its debts. As a result, government spending levels are difficult to predict beyond the near term due to numerous factors, including the external threat environment, future government priorities and the state of government finances. Significant changes in government spending or changes in U. S. government priorities, policies and requirements could have a material adverse effect on our results of operations, financial condition or liquidity. Unfavorable macroeconomic conditions or market volatility resulting from global economic conditions, including those affecting the financial services industry, could adversely affect our business, financial condition or results of operations. Adverse market or macroeconomic conditions or market volatility resulting from global economic developments, political unrest, high inflation, rising interest rates, changes in international trade relationships and military conflicts, such as the ongoing conflict between Russia and Ukraine and the conflict between Israel and Hamas, the post- COVID environment or other factors, could materially and adversely affect our business operations. For instance, actual events involving limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market- wide liquidity problems. A severe or prolonged economic downturn or additional global financial crises could result in a variety of risks to our business, including weakened demand for any product candidates we develop or our ability to raise additional capital when needed on acceptable terms, if at all. In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by our suppliers, which in turn, could have a material adverse effect on our current and / or planned business operations and our current or projected results of operations and financial condition. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.