

## Risk Factors Comparison 2024-02-26 to 2023-02-27 Form: 10-K

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Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below in addition to the other information included or incorporated by reference in this Annual Report on Form 10-K for the year ended December 31, ~~2022~~ **2023** (“ Annual Report ”), including our consolidated financial statements and the related notes and “ Management ’ s Discussion and Analysis of Financial Condition and Results of Operations, ” before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Although we have discussed all known material risks, the risks described below are not the only ones that we may face. Additional risks and uncertainties not presently known to us or that we ~~currently~~ deem immaterial may also impair our business operations. Risks Related to the Development and Commercialization of Our Product Candidates We are substantially dependent on the success of our lead products pamrevlumab and roxadustat. To date, we have invested ~~a substantial~~ **substantially** portion of our efforts and financial resources in the research and development of pamrevlumab and roxadustat. ~~Our~~ **The** near- term ~~success~~ **value drivers for the Company** ~~depends~~ **depend** in large part on pamrevlumab, which is in clinical development for ~~idiopathic pulmonary fibrosis (“ IPF ”),~~ locally advanced unresectable pancreatic cancer (“ LAPC ”) ~~;~~ **and** metastatic pancreatic cancer ~~;~~ **and** Duchenne muscular dystrophy (“ DMD ”). **Even if one or both of the Phase 3 clinical trials are successful, Pamrevlumab pamrevlumab will** ~~requires~~ **require** substantial further development and commercialization investments ~~investment~~ **At** ~~;~~ **and,** at this time, we do not have a collaboration partner to support **the development and commercialization of** this compound. ~~In addition, pamrevlumab is~~ **Additionally, as** a monoclonal antibody, which may require greater financial resources **it will cost significantly more to manufacture pamrevlumab** than it would for our ~~a typical~~ **a typical** small molecule ~~drug~~ **drug**, roxadustat. Our near- term prospects ~~value drivers~~ **also include** ~~depend in large part on our~~ continued development and commercialization of roxadustat in the People ’ s Republic of China (“ China ”), Japan, Europe, ~~the United States (“ U. S. ”),~~ and elsewhere. **We** Roxadustat has been approved in the European Union, Great Britain, China, Japan, and other countries for the treatment of anemia in chronic kidney disease (“ CKD ”) for patients who are on dialysis and not on dialysis. However, we received a complete response letter (“ CRL ”) for roxadustat in CKD anemia in the U. S. from the Food and Drug Administration (“ FDA ”). While we continue to co-commercialize roxadustat in China with AstraZeneca AB (“ AstraZeneca ”) and develop roxadustat in **China in chemotherapy-induced** the U. S. for the treatment of anemia in patients with myelodysplastic syndromes (“ MDS-~~CIA~~ ”). **After terminating (except** ~~;~~ we have not been able to agree on a path forward for **South Korea) our** AstraZeneca to fund further roxadustat development in the U. S. for CKD anemia and there is a significant risk we will be unable to do so. There is also a significant risk that the U. S. / RoW Agreement, a collaboration agreement we entered into with AstraZeneca for roxadustat for the treatment of anemia in the U. S. and all territories ~~not except for China and those territories~~ previously licensed to Astellas ~~;~~ ~~except~~ **China Pharma Inc. (“ Astellas ”) (the** “ AstraZeneca U. S. / RoW Agreement ”) **on February 23, 2024, we are** currently investigating new licensing opportunities for roxadustat; **however, there can be no assurance that we will find such a partner or be able to agree to a license on reasonable** ~~amended or terminated~~. With an eye toward our longer- term ~~terms~~ **success**, **As we continue to fulfill our mission to develop novel therapeutics**, we are investing in new drug programs to expand our early ~~oncology~~ **oncology** ~~stage clinical~~ pipeline. While we see great potential value in our early ~~stage~~ **development oncology** pipeline, these programs are years away from commercialization, and the success of any development program is not guaranteed. Our **biggest value drivers in the** near ~~term~~ prospects and the price of our common stock most heavily rely on the success of our lead products pamrevlumab and roxadustat. As a company, we have limited late- stage and commercialization experience, and the time and resources required to develop such experience are significant. We are running multiple Phase 3 clinical trials ~~simultaneously with multiple readouts in 2023 and 2024,~~ while also commercializing roxadustat ~~with our~~ collaboration partners. As a Company, we have limited resources and limited experience handling such a large number of data readouts and possible regulatory filings. For pamrevlumab, which we have not partnered, we do not have a sales infrastructure and we have limited experience in the sales, marketing or distribution of pharmaceutical products in any country. To the extent that we would undertake sales and marketing of any of our products directly, there are risks involved with establishing our own sales, marketing and distribution capabilities. Factors that may inhibit our efforts to commercialize our products on our own include: • our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel; • the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products; • our inability to effectively manage geographically dispersed commercial teams; • the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and • unforeseen costs and expenses associated with creating an independent commercial organization. With respect to roxadustat, we are dependent in part on the commercialization capabilities of our collaboration partners, AstraZeneca and Astellas Pharma Inc. (“ Astellas ”). If either such partner were to terminate its agreement with us, we would have to commercialize on our own or with another third party. We will have limited control over the commercialization efforts of such third parties, and any of them may fail to devote the necessary resources and attention to sell and market roxadustat effectively. Successful development and commercialization of any of our products requires us to establish and further develop our clinical, regulatory, and commercialization capabilities, including but not limited to, medical affairs, marketing, product reimbursement, sales, price reporting, pharmacovigilance, supply chain, and distribution. These efforts require resources and time to either develop or

acquire expertise in these areas and there is a risk that we are unsuccessful or we fail to comply with rules or regulations applicable to development or commercialization of our products. There is also a risk that we are delayed due to the need to develop these capabilities or due to a lack of resources. All of which would adversely affect our business and financial condition.

Drug development and obtaining marketing authorization is a very difficult endeavor and we may ultimately be unable to obtain regulatory approval for our various product candidates in one or more jurisdictions and in one or more indications. The development, manufacturing, marketing, and selling of our products and product candidates are and will continue to be subject to extensive and rigorous review and regulation by numerous government authorities in the U. S. and in other countries where we intend to develop and, if approved, market any product candidates. Before obtaining regulatory approval for the commercial sale of any product candidate, we must demonstrate through extensive preclinical trials and clinical trials that the product candidate is safe and effective for use in each indication for which approval is sought. The drug development and approval processes are expensive and require substantial resources and time, and in general, very few product candidates that enter development ultimately receive regulatory approval. In addition, our collaboration partners for roxadustat have final control over development decisions in their respective territories and they may make decisions with respect to development or regulatory authorities that delay or limit the potential approval of roxadustat, or increase the cost of development or commercialization. Accordingly, we may be unable to successfully develop or commercialize any of our other product candidates in one or more indications and jurisdictions. Moreover, for any clinical trial to support a New Drug Application (“NDA”) / Biologics License Application (“BLA”) submission for approval, the U. S. Food and Drug Administration (“FDA”) and foreign regulatory authorities require compliance with regulations and standards (including good clinical practices (“GCP”) requirements for designing, conducting, monitoring, recording, analyzing, and reporting the results of clinical trials) to ensure that (1) the data and results from trials are credible and accurate; and (2) that the rights, integrity and confidentiality of trial participants are protected. Although we rely on third parties to conduct our clinical trials, we as the sponsor remain responsible for ensuring that each of these clinical trials is conducted in accordance with its general investigational plan and protocol under legal and regulatory requirements, including GCP. Regulatory authorities may take actions or impose requirements that delay, limit or deny approval of our product candidates for many reasons, including, among others:

- our failure to adequately demonstrate to the satisfaction of regulatory authorities or an independent advisory committee that our product candidate is safe and effective in a particular indication, or that such product candidate’s clinical and other benefits outweigh its safety risks;
- our failure of clinical trials to meet the level of statistical significance required for approval;
- the determination by regulatory authorities that additional information (including additional preclinical or clinical data or trials are) is necessary to demonstrate the safety and efficacy of a product candidate;
- disagreement over the design or implementation of our clinical trials;
- our product candidates may exhibit exhibiting an unacceptable safety signal at any stage of development;
- we, failure either by us or the clinical research organizations (“CROs”) or investigators that conduct clinical trials on our behalf, may fail to comply with regulations or GCPs, clinical trial protocols, or contractual agreements, which may adversely impact our clinical trials;
- disagreement over whether to accept results from clinical trial sites in a country where the standard of care is potentially different from that in the U. S.;
- we failure either by us or third-party contractors manufacturing our product candidates to may not maintain current good manufacturing practices (“cGMP”), successfully pass inspection, or meet other applicable manufacturing regulatory requirements;
- requirements by regulatory authorities may require us to exclude the use of patient data from unreliable clinical trials, or disagreement may not agree with our interpretation of the data from our preclinical trials and clinical trials;
- failure by collaboration partners to may not perform or complete their clinical programs in a timely manner, or at all.

Any of these factors, many of which are beyond our control, could delay or jeopardize our or our collaboration partners’ abilities to obtain regulatory approval for our product candidates in one or more indications. The FDA or other regulatory authorities may require more information (including additional preclinical or clinical data to support approval), which may delay or prevent approval or cause us to abandon the development program altogether. Even if we believe our clinical trials are successful, regulatory authorities may not agree that our completed clinical trials provide adequate data on safety or efficacy. Approval by one regulatory authority does not ensure approval by any other regulatory authority. For example, while we have received approval of our marketing authorization applications for roxadustat in the European Union, Great Britain, China, Japan, and other countries for the treatment of anemia in CKD for patients who are on dialysis and not on dialysis, we received a CRL in CKD anemia in the U. S. from the FDA regarding roxadustat’s NDA for the treatment of anemia due to CKD, stating that it could not be approved in its present form. In addition, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process or commercial uptake in other countries. Even if we do obtain regulatory approval, our product candidates may be approved for fewer or more limited indications than we request, approval may be contingent on the performance of costly post-marketing clinical trials, or approval may require labeling that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. In addition, if our product candidates produce undesirable side effects or safety issues, the FDA may require the establishment of Risk Evaluation and Mitigation Strategy (or other regulatory authorities may require the establishment of a similar strategy), that may restrict distribution of our approved products, if any, and impose burdensome implementation requirements on us. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates. The CRL we received from the FDA for roxadustat has decreased the likelihood of approval and successful commercialization of roxadustat in the U. S. and potentially other markets. There is a significant risk that our U. S. / Rest of World Collaboration Agreement with AstraZeneca will be amended or terminated. In August 2021, the FDA issued a CRL regarding roxadustat’s NDA for the treatment of anemia due to CKD in adult patients, stating that it could not be approved in its present form. The CRL and the subsequent delay due to discussions with AstraZeneca have decreased the likelihood of approval and successful commercialization of roxadustat in the U. S. and therefore will decrease and / or delay expected revenue. While we continue to commercialize roxadustat in China with AstraZeneca, and develop roxadustat in the U. S. for the treatment of anemia in patients

with MDS, we have not been able to agree on a path forward for AstraZeneca to fund further roxadustat development in the U.S. and there is a significant risk we will be unable to do so. There is also a significant risk that the AstraZeneca U.S. / RoW Agreement will be amended or terminated. Any of these risks could have a material impact on our business, operating results, and financial condition. Preclinical, Phase 1, and Phase 2 clinical trial results may not be indicative of the results that may be obtained in larger clinical trials. Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Success in preclinical and early clinical trials, which are often highly variable and use small sample sizes, may not be predictive of similar results in humans or in larger, controlled clinical trials, and successful results from clinical trials in one indication may not be replicated in other indications. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we may face similar setbacks. We do not know whether our ongoing or planned clinical trials of roxadustat or pamrevlumab will need to be redesigned based on interim results or if we will be able to achieve sufficient patient enrollment or complete planned clinical trials on schedule. Clinical trials can be delayed, suspended, or terminated by us, by the relevant institutional review boards at the sites at which such trials are being conducted, or by the FDA or other regulatory authorities, for a variety of reasons or factors, including:

- delay or failure to address any physician or patient safety concerns that arise during the course of the trial, including unforeseen safety issues or adverse side effects, or a principal investigator's determination that a serious adverse event could be related to our product candidates;
- delay or failure to obtain required regulatory or institutional review board approval or guidance;
- delay or failure to reach timely agreement on acceptable terms with prospective CROs and clinical trial sites;
- delay or failure to recruit, enroll and retain patients through the completion of the trial;
- patient recruitment, enrollment, or retention, or clinical site initiation or retention problems associated with the Severe Acute Respiratory Syndrome Coronavirus 2 and the resulting Coronavirus Disease ("COVID-19") pandemic;
- patient recruitment, enrollment, or retention, clinical site initiation, or retention problems associated with civil unrest or military conflicts around the world;
- delay or failure to maintain clinical sites in compliance with clinical trial protocols or to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- delay or failure to initiate or add a sufficient number of clinical trial sites;
- delay or failure to manufacture sufficient quantities of product candidate for use in clinical trials;
- difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned;
- inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, warning letter, or other regulatory action; and
- changes in laws or regulations. In particular, identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the rate at which we can recruit and enroll patients in testing our product candidates. Patients may be unwilling to participate in clinical trials of our product candidates for a variety of reasons, some of which may be beyond our control, including:

- severity of the disease under investigation;
- availability of alternative treatments;
- size and nature of the patient population;
- eligibility criteria for and design of the study in question;
- perceived risks and benefits of the product candidate under study;
- ability to enroll patients in clinical trials during the COVID-19 pandemic (particularly for IPF);
- ongoing clinical trials of competitive agents;
- physicians' and patients' perceptions of the potential advantages of our product candidates being studied in relation to available therapies or other products under development;
- our CRO's and our trial sites' efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians; and
- ability to monitor patients and collect patient data adequately during and after treatment.

Any delays in completing our clinical trials will increase the costs of the trial, delay the product candidate development and approval process and jeopardize our ability to commence marketing and generate revenues. Any of these occurrences may materially and adversely harm our business, operations, and prospects. Our product candidates may cause or have attributed to them undesirable side effects or have other properties that delay or prevent their regulatory approval or limit their commercial potential. Undesirable side effects caused by our product candidates or that may be identified as related to our product candidates by physician investigators conducting our clinical trials or even competing products in development that utilize a similar mechanism of action or act through a similar biological disease pathway could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the delay or denial of regulatory approval by the FDA or other regulatory authorities and potential product liability claims. If we determine that there is a likely causal relationship between a serious adverse event and our product candidate, and such safety event is material or significant enough, it may result in:

- our clinical trial development plan becoming longer and more expensive;
- terminating some of our clinical trials for the product candidates or specific indications affected;
- regulatory authorities increasing the data and information required to approve our product candidates and imposing other requirements; and
- our collaboration partners terminating our existing agreements.

The occurrence of any or all of these events may cause the development of our product candidates to be delayed or terminated, which could materially and adversely affect our business and prospects. Clinical trials of our product candidates may not uncover all possible adverse effects that patients may experience. Clinical trials are conducted in representative samples of the potential patient population, which may have significant variability. Pamrevlumab is being studied in patient populations that are at high risk of death and adverse events, and even if unrelated to pamrevlumab, adverse safety findings in these trials may limit its further development or commercial potential. Clinical trials are by design based on a limited number of subjects and of limited duration for exposure to the product used to determine whether, on a potentially statistically significant basis, the planned safety and efficacy of any product candidate can be achieved. As with the results of any statistical sampling, we cannot be sure that all side effects of our product candidates may be uncovered, and it may be the case that only with a significantly larger number of patients exposed to the product candidate for a longer duration, that a more complete safety profile is identified. Further, even larger clinical trials may not identify rare serious adverse effects or the duration of such studies may not be sufficient to identify when those events may occur. There have been other products, including erythropoiesis stimulating agents ("ESAs"), for which safety concerns have been uncovered following approval by regulatory authorities. Such safety concerns have led to labeling changes or withdrawal of ESAs products from the market.

~~While roxadustat is chemically unique from ESAs, it or any of our product candidates may be subject to known or unknown risks.~~ Patients treated with our products, if approved, may experience adverse reactions and it is possible that the FDA or other regulatory authorities may ask for additional safety data as a condition of, or in connection with, our efforts to obtain approval of our product candidates. If safety problems occur or are identified after our product candidates reach the market, we may, or regulatory authorities may require us to amend the labeling of our products, recall our products or even withdraw approval for our products. If our manufacturers or we cannot properly manufacture the appropriate volume of product, we may experience delays in development, regulatory approval, launch or successful commercialization. Completion of our clinical trials and commercialization of our products require access to, or development of, facilities to manufacture and manage our product candidates at sufficient yields, quality and at commercial scale. Although we have entered into commercial supply agreements for roxadustat and pamrevlumab, we will need to enter into additional commercial supply agreements, including for backup or second source third- party manufacturers. We may not be able to enter into these agreements with satisfactory terms or on a timely manner. In addition, we may experience delays or technical problems associated with technology transfer of manufacturing processes to any new suppliers. We have relatively limited experience manufacturing or managing third parties in manufacturing any of our product candidates in the volumes that are expected to be necessary to support large- scale clinical trials and sales. In addition, we have limited experience forecasting supply requirements or coordinating supply chain (including export and customs management) for launch or commercialization, which is a complex process involving our third- party manufacturers and logistics providers, and for roxadustat, our collaboration partners. We may not be able to accurately forecast supplies for commercial launch or do so in a timely manner and our efforts to establish these manufacturing and supply chain management capabilities may not meet our requirements as to quantities, scale- up, yield, cost, potency or quality in compliance with cGMP, particularly if the marketing authorization or market uptake is more rapid than anticipated or we have an unanticipated surge in demand. We have a limited amount of roxadustat and pamrevlumab in storage, limited capacity reserved at our third- party manufacturers, and, even if we have or are able to put sufficient supply agreements in place for our development and commercialization plan, there are long lead times required to manufacture and scale- up the manufacture of additional supply, as well as for raw materials and components for manufacture of our products, as required for both late- stage clinical trials, post- approval trials, and commercial supply. There is a general risk of delayed drug supply due to delays experienced by any third- party provider in the supply chain, including raw material and components suppliers, export and customs locations, and shipping companies. In addition, if we **or a partner** are not able to obtain regulatory approval of roxadustat in the U. S. in **CKD anemia associated with MDS**, we may have excess supply manufactured in anticipation of commercialization. Such roxadustat excess supply could be wasted, for example, if it expires prior to being used in other clinical trials or prior to being used in other territories where such roxadustat formulation is approved. If we are unable to forecast, order or manufacture sufficient quantities of roxadustat or pamrevlumab on a timely basis, it may delay our development, launch or commercialization in some or all indications we are currently pursuing. Insufficient supply could be a particular risk if we were to obtain regulatory approval of pamrevlumab in **all the** indications being studied (**HPF, LAPC, and metastatic pancreatic cancer, and DMD**). Any delay or interruption in the supply of our product candidates or products could have a material adverse effect on our business and operations. Our commercial drug product and the product we use for clinical trials must be produced under applicable cGMP regulations. Failure to comply with these regulations by us or our third- party manufacturers may require us to recall commercial product or repeat clinical trials, which would impact sales revenue and / or delay the regulatory approval process. We or our partners may add or change manufacturers, change our manufacturing processes, or change packaging specifications to accommodate changes in regulations, manufacturing equipment or to account for different processes at new or second source suppliers. Changes made to roxadustat or pamrevlumab including, but not limited to, demonstration of comparability to regulatory approved / in approval products and processes, additional clinical trials, delays in development or commercialization, earlier expiration dates, shorter shelf life, or specification failures, may materially impact our operations and potential profitability. We, and even an experienced third- party manufacturer, may encounter difficulties in production. Difficulties may include: • costs and challenges associated with scale- up and attaining sufficient manufacturing yields, in particular for biologic products such as pamrevlumab, which is a monoclonal antibody; • contracting with additional suppliers and validation / qualification of additional facilities to meet growing demand; • supply chain issues, including coordination of multiple contractors in our supply chain and securing necessary licenses (such as export licenses); • the timely availability and shelf -life requirements of raw materials and supplies ~~including delays in availability due to the COVID-19 pandemic~~; • limited stability and product shelf life; • equipment maintenance issues or failure; • quality control and quality assurance issues; • shortages of qualified personnel and capital required to manufacture large quantities of product; • compliance with regulatory requirements that vary in each country where a product might be sold; • capacity or forecasting limitations and scheduling availability in contracted facilities; • natural disasters, such as pandemics, ~~including the COVID-19 pandemic~~, floods, storms, earthquakes, tsunamis, and droughts, or accidents such as fire, that affect facilities, possibly limit or postpone production, and increase costs; and • failure to obtain license to proprietary starting materials **. FibroGen may also elect to transition its manufacturing responsibilities to another party. There may be risks underlying this manufacturing transition, as well as new risks that may emerge after the new organization takes over manufacturing, if that were to happen**. Regulatory authorities will do their own benefit risk analysis and may reach a different conclusion than we or our partners have, and these regulatory authorities may base their approval decision on different analyses, data, and statistical methods than ours. Even if we believe we have achieved positive clinical results, **regulatory authorities** such as superiority or non- inferiority, in certain endpoints, populations or sub- populations, or using certain statistical methods of analysis, the FDA and European Medicines Agency (“EMA”) will each conduct their own benefit- risk analysis and may reach different conclusions **. Regulatory authorities may use, using among other things,** different statistical methods, different endpoints or definitions thereof, ~~or and~~ different patient populations or sub- populations **. For example, the Precision Promise study employs a Bayesian statistical**

**methodology for analysis of the study primary endpoint, and while PanCAN consulted with the FDA regarding the study design and statistical methodology, there is a risk that the FDA may employ different statistical methodologies in their review, and may not view positive study results as sufficient for regulatory approval.** Furthermore, while we may seek

regulatory advice or agreement in key commercial markets prior to and after application for marketing authorization, regulatory authorities may change their approvability criteria based on the data, their internal analyses and external factors, including discussions with expert advisors. For example, while we have received approval of our marketing authorization applications for roxadustat in the European Union, Great Britain, China, Japan, and other countries for the treatment of anemia in CKD for patients who are on dialysis and not on dialysis, we received a CRL in CKD anemia in the U. S. from the FDA. Regulatory authorities may approve one of our product candidates for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-approval clinical trials. ~~While we have and will present to regulatory authorities certain pre-specified and post hoc (not pre-specified) sub-populations, sub-group, and sensitivity analyses (for example, incident dialysis), multiple secondary endpoints, and multiple sets of stratification factors and analytical methods (such as long-term follow up analyses), including adjusted and censored data, regulatory authorities may reject these analyses, methods, or even parts of our trial design or certain data from our studies, the rationale for our pre-specified non-inferiority margins or other portions of our statistical analysis plans.~~ In addition, even if we are able to provide positive data with respect to certain analyses, regulatory authorities may not include such claims on any approved labeling. The failure to obtain regulatory approval, or any label, population or other approval limitations in any jurisdiction, may significantly limit or delay our ability to generate revenues, and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenue. ~~Even if we are able to obtain regulatory approval of our product candidates, the label we obtain may limit the indicated uses for which our product candidates may be marketed. With respect to roxadustat, regulatory approvals obtained could limit the approved indicated uses for which roxadustat may be marketed. For example, our label approved in Japan, includes the following warning: "Serious thromboembolism such as cerebral infarction, myocardial infarction, and pulmonary embolism may occur, possibly resulting in death, during treatment with roxadustat." Additionally, in the U. S., ESAs have been subject to significant safety warnings, including the boxed warnings on their labels. The safety concerns relating to ESAs may result in labeling for roxadustat containing similar warnings. Any label for roxadustat may contain other warnings or limit the market opportunity or approved indications for roxadustat. These warnings could include warnings against exceeding specified hemoglobin targets and other warnings that derive from the safety issues associated with ESAs, even if our Phase 3 clinical trials do not themselves raise safety concerns.~~ We face substantial competition in the discovery, development and commercialization of product candidates. The development and commercialization of new pharmaceutical products is highly competitive. Our future success depends on our ability and / or the ability of our collaboration partners to achieve and maintain a competitive advantage with respect to the development and commercialization of our product candidates. Our objective is to discover, develop and commercialize new products with superior efficacy, convenience, tolerability, and safety. We expect that in many cases, the products that we commercialize will compete with existing marketed products of companies that have large, established commercial organizations. We face competition from generics that could enter the market after expiry of our **composition of matter patents - patent. As of the end of 2023, the Chinese health authority has accepted abbreviated New Drug Applications for 19 generic roxadustat applicants.** In addition, we will likely face competition from other companies developing products in the same diseases or indications in which we are developing or commercializing products. We will also face competition for patient recruitment ~~and~~ enrollment for clinical trials. ~~Refer to Item 1. "Business Competition" in our Annual Report for a discussion of the specific companies that are on the market or in late-stage development with which we may compete.~~ The success of any or all of these potential competitive products may negatively impact the development and potential for success of our products. Moreover, many of our competitors have significantly greater resources than we do. Large pharmaceutical companies have extensive experience, greater scale, and efficiency, in clinical testing, obtaining regulatory approvals, recruiting patients, manufacturing pharmaceutical products, and commercialization. If our collaboration partners and we are not able to compete effectively against existing and potential competitors, our business and financial condition may be materially and adversely affected. Our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors, and others in the medical community necessary for commercial success. Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, healthcare payors, and others in the medical community. Demonstrating safety and efficacy of our product candidates and obtaining regulatory approvals will not guarantee future revenue. The degree of market acceptance of any of our approved product candidates will depend on several factors, including: • the efficacy of the product candidate as demonstrated in clinical trials; • the safety profile and perceptions of safety of our product candidates relative to competitive products; • acceptance of the product candidate as a safe and effective treatment by healthcare providers and patients; • the clinical indications for which the product candidate is approved; • the potential and perceived advantages of the product candidate over alternative treatments, including any similar generic treatments; • the inclusion or exclusion of the product candidate from treatment guidelines established by various physician groups and the viewpoints of influential physicians with respect to the product candidate; • the cost of the product candidate relative to alternative treatments; • adequate pricing and reimbursement by third parties and government authorities as described below; • the relative convenience and ease of administration; • the frequency and severity of adverse events; • the effectiveness of sales and marketing efforts; and • any unfavorable publicity relating to the product candidate. In addition, see the risk factor titled "Our product candidates may cause or have attributed to them undesirable side effects or have other properties that delay or prevent their regulatory approval or limit their commercial potential" above. If any product candidate is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from that product candidate and may not become or remain profitable. No or limited reimbursement or insurance coverage of our approved products, by third-party payors may

render our products less attractive to patients and healthcare providers. Market acceptance and sales of any approved products will depend significantly on reimbursement or coverage of our products by government or third- party payors and may be affected by existing and future healthcare reform measures or prices of related products for which the government or third- party reimbursement applies. Coverage and reimbursement by the government or a third- party payor may depend upon a number of factors, including the payor’ s determination that use of a product is: • a covered benefit under applicable health plan; • safe, effective and medically necessary; • appropriate for the specific patient; • cost- effective; and • neither experimental nor investigational. Obtaining coverage and reimbursement approval for a product from a government or other third- party payor is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost- effectiveness data for the use of our products to the payor, which we may not be able to provide. Furthermore, the reimbursement policies of governments and third- party payors may significantly change in a manner that renders our clinical data insufficient for adequate reimbursement or otherwise limits the successful marketing of our products. Even if we obtain coverage for our product candidates, the pricing may be subject to re- negotiations or third- party payors may not establish adequate reimbursement amounts, which may reduce the demand for, or the price of, our products. For example, our current National Reimbursement Drug List reimbursement pricing for China is effective for a standard two- year period (between January 1, 2022 to December 31, 2023), after which time we will have to renegotiate a new price for roxadustat. Reference pricing is used by various Europe member states and parallel distribution, or arbitrage between low- priced and high- priced member states, can further reduce prices. In some countries, our partner or we may be required to conduct a clinical trial or other studies that compare the cost- effectiveness of our product candidates to other available products in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third- party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unacceptable levels, our partner or we may elect not to commercialize our products in such countries, and our business and financial condition could be adversely affected.

**Risks Related to Our Reliance on Third Parties** If our collaborations were terminated or if **Astellas or our AstraZeneca partners** were **unwilling or unable** to **prioritize contribute or participate in** other **the initiatives over their** collaborations with us, our ability to successfully develop and commercialize **our the relevant** product candidates **candidate** would suffer. We have entered into **an Evaluation Agreement with Fortis Therapeutics, Inc. (“ Fortis ”) under which we rely, in part, on Fortis and its development partners, including UCSF, for the continued development of FOR46 (now referred to as “ FG- 3246 ”).** While we control development of FG- 3246 up to the 4- year evaluation period, we will be doing so under Fortis’ s **investigational new drug application. If Fortis were unable or unwilling to continue their development efforts, our ability to develop FG- 3246 would be delayed. We rely on the Pancreatic Cancer Action Network (“ PanCAN ”) to run its Precision PromiseSM Phase 2 / 3 registration study in metastatic pancreatic cancer. While this study includes pamrevlumab in combination with standard of care chemotherapy, PanCAN is the sponsor of the study and we do not run or control its conduct. Therefore, pamrevlumab’ s success in this indication is highly dependent on PanCAN’ s ability and willingness to run the Precision Promise study. Similarly, we depend on PanCAN to perform certain analyses of the study data and provide these to us to support the submission of a market authorization application to applicable regulatory authorities, if appropriate. While we have recently terminated the AstraZeneca U. S. / RoW Agreement (except for South Korea), we have active** collaboration agreements with respect to the development and commercialization of our lead product candidate, roxadustat, with Astellas and **with AstraZeneca in China and South Korea**. These agreements provide for reimbursement of our development costs by our collaboration partners and also provide for **the** commercialization of roxadustat throughout the major territories of the world. Our **current** agreements with Astellas and AstraZeneca provide **each of** them with the right to terminate their **respective** agreements with us, upon the occurrence of negative clinical results, delays in the development and commercialization of our product candidates or adverse regulatory requirements or guidance. In addition, each of those agreements provides our **respective** partners the right to terminate any of those agreements upon written notice for convenience. The termination of any of our collaboration agreements would require us to fund and perform the further development and commercialization of roxadustat in the affected territory, or pursue another collaboration, which we may be unable to do, either of which could have an adverse effect on our business and operations. Moreover, if Astellas or AstraZeneca, or any successor entity, were to determine that their collaborations with us are no longer a strategic priority, or if either of them or a successor were to reduce their level of commitment to their collaborations with us, our ability to **develop and** commercialize roxadustat could suffer. **In For instance, the AstraZeneca U. S. / RoW Agreement was terminated on February 23, 2021- 2024 (except** we received a CRL for **South Korea).**, **Although our ongoing collaboration agreement with AstraZeneca for the development and commercialization of roxadustat for the treatment of anemia in China (the “ AstraZeneca China Agreement ”) continues in full force and is unaffected, this eliminates any additional potential milestones or other payments AstraZeneca would have made under the AstraZeneca U. S. / RoW Agreement except for potentially in South Korea. Such payments were remote** due to **our withdrawal of CKD in adult patients in the U. S. NDA** While we continue to **co- commercialize roxadustat in China with AstraZeneca and develop roxadustat in the U. S. for the treatment of anemia in patients with MDS, we have not been able to agree on a potential path forward for AstraZeneca to fund further roxadustat development in the U. S. for CKD anemia and**. **And while we are now investigating new licensing opportunities for roxadustat, there is a significant risk can be no assurance that we will find such a partner or be unable-- able to agree to do so. There is also a significant risk that license on reasonable terms. In addition, if our collaboration partners are unsuccessful in the their AstraZeneca U. S. / RoW Agreement commercialization efforts (particularly in Europe and China), our results will be negatively affected** amended or terminated. Our collaborations are exclusive for roxadustat and preclude us from entering into additional collaboration agreements with other parties in those geographies and indications already licensed. If we do not establish and maintain strategic collaborations related to our product candidates, we will bear all

of the risk and costs related to the development and commercialization of any such product candidate, and we may need to seek additional financing, hire additional employees and otherwise develop expertise at significant cost. This in turn may negatively affect the development of our other product candidates as we direct resources to our most advanced product candidates. ~~Our collaboration partners also have certain rights to control decisions regarding the development and commercialization of our product candidates with respect to which they are providing funding. If we have a disagreement over strategy and activities with our collaboration partners, our plans for obtaining regulatory approval may be revised and negatively affect the anticipated timing and potential for success of our product candidates. Even if a product under a collaboration agreement receives regulatory approval, we will remain substantially dependent on the commercialization strategy and efforts of our collaboration partners, and our collaboration partners have limited or no experience in commercialization of an anemia drug. If our collaboration partners are unsuccessful in their commercialization efforts, our results will be negatively affected. With respect to our collaboration agreements for roxadustat, there are additional complexities in that our collaboration partners, Astellas and AstraZeneca, and we must reach consensus on certain portions of our development programs and regulatory activities. In addition, there are aspects of commercial operations that require cooperation among the collaboration partners, including safety data reporting. Multi-party decision-making is complex and involves significant time and effort, and there can be no assurance that the parties will cooperate or reach consensus, or that one or both of our partners will not ask to proceed independently in some or all of their respective territories or functional areas of responsibility in which the applicable collaboration partner would otherwise be obligated to cooperate with us. Any disputes or lack of cooperation with us by either Astellas or AstraZeneca, or both, may negatively impact the timing or success of our regulatory approval applications.~~ We may conduct proprietary research programs in specific disease areas that are not covered by our collaboration agreements. Our pursuit of such opportunities could, however, result in conflicts with our collaboration partners in the event that any of our collaboration partners ~~takes~~ **take** the position that our internal activities overlap with those areas that are exclusive to our collaboration agreements. Moreover, disagreements with our collaboration partners could develop over rights to our intellectual property, including the enforcement of those rights. In addition, our collaboration agreements may have provisions that give rise to disputes regarding the rights and obligations of the parties. Any conflict with our collaboration partners could lead to the termination of our collaboration agreements, delay collaborative activities, reduce our ability to renew agreements or obtain future collaboration agreements, **or result in litigation or arbitration and would negatively impact our relationship with existing collaboration partners, and could as well as potentially impact** our commercial results. Certain of our collaboration partners could also become our competitors in the future. If our collaboration partners develop competing products, fail to obtain necessary regulatory approvals, terminate their agreements with us prematurely, **or fail to devote sufficient resources to the development and commercialization of our product candidates, the development and commercialization of our product candidates and products could be delayed.** If our preclinical and clinical trial contractors do not properly perform their agreed upon obligations, we may not be able to obtain or may be delayed in receiving regulatory approvals for our product candidates. We rely heavily on university, hospital, ~~dialysis centers~~ and other institutions and third parties, including the principal investigators and their staff, to carry out our clinical trials in accordance with our clinical protocols and designs. We also rely on a number of third-party CROs to assist in undertaking, managing, monitoring and executing our ongoing clinical trials. We expect to continue to rely on CROs, clinical data management organizations, medical institutions and clinical investigators to conduct our development efforts in the future. We compete with many other companies for the resources of these third parties, and **other large pharmaceutical companies often may** have significantly more extensive agreements and relationships with such third-party providers, and such third-party providers may prioritize **the these relationships requirements of such large pharmaceutical companies** over ours. The third parties on whom we rely may terminate their engagements with us at any time, which may cause delay in the development and commercialization of our product candidates. If any such third party terminates its engagement with us or fails to perform as agreed, we may be required to enter into alternative arrangements, which would result in significant cost and delay to our product development program. Moreover, our agreements with such third parties generally do not provide assurances regarding employee turnover and availability, which may cause interruptions in the research on our product candidates by such third parties. Despite our reliance on third parties for certain development and management activities, such as clinical trials, we, as the sponsor, remain responsible for ensuring that these activities are conducted in accordance with the FDA and foreign regulatory authorities' investigational plans and protocols, including GCP requirements. Regulatory enforcement of GCP requirements can occur through periodic inspections of trial sponsors, principal investigators, and trial sites. To ensure the quality and accuracy of our data remains uncompromised and reliable, our third-party service providers must comply with applicable GCP requirements, regulations, protocols, and agreements. Failures to do so by such third-party partners, or needing to replace such third-party service providers, may delay, suspend or terminate development of our product candidates, result in exclusion of patient data from approval applications, or require additional clinical trials before approval of marketing applications. Such events may ultimately prevent regulatory approval for our product candidates on a timely basis, at a reasonable cost, or at all. We currently rely, and expect to continue to rely, on third parties to conduct many aspects of our product manufacturing and distribution, and these third parties may terminate these agreements or not perform satisfactorily. We do not have operating manufacturing facilities at this time other than our roxadustat manufacturing facilities in China, ~~and our current commercial manufacturing plants in China are not expected to satisfy the requirements necessary to support development and commercialization outside of China. Other than in and for China specifically, we do not expect to independently manufacture our products.~~ We currently rely, and expect to continue to rely, on third parties to scale-up, manufacture and supply roxadustat and our other product candidates **outside of China for drug product in Europe and other countries, and on our partner Astellas for drug product in Japan**. We rely on third parties for distribution, including our collaboration partners and their vendors, except in China where we have established a jointly owned entity with AstraZeneca to manage most of the distribution in China. Risks arising from our reliance on third-party manufacturers include: • reduced

control and additional burdens of oversight as a result of using third- party manufacturers and distributors for all aspects of manufacturing activities, including regulatory compliance and quality control and quality assurance; • termination of manufacturing agreements, termination fees associated with such termination, or nonrenewal of manufacturing agreements with third parties may negatively impact our planned development and commercialization activities; • significant financial commitments we may be required to make with third- party manufacturers for early- stage clinical or pre- clinical programs that may fail to produce scientific results that would justify further development (without the ability to mitigate the manufacturing investments); • the possible misappropriation of our proprietary technology, including our trade secrets and know- how; ~~and~~ • disruptions to the operations of our third- party manufacturers, distributors or suppliers unrelated to our product, including the merger, acquisition, or bankruptcy of a manufacturer or supplier or a catastrophic event, ~~including disruption resulting from the COVID-19 pandemic~~, affecting our manufacturers, distributors or suppliers ; **and • inability for FibroGen to meet timing and volume obligations to Astellas due to insufficient resources** . Any of these events could lead to development delays or failure to obtain regulatory approval or affect our ability to successfully commercialize our product candidates. Some of these events could be the basis for action by the FDA or another regulatory authority, including injunction, recall, seizure or total or partial suspension of production. Considering we do not control our contract manufacturers' facilities and operations used to manufacture our product candidates, but are still responsible for cGMP adherence, if our contract manufacturers cannot successfully manufacture material that conforms to our or our collaboration partners' specifications, or the regulatory requirements, our development and commercialization plans and activities may be adversely affected. Although our longer- term agreements are expected to provide for requirements to meet our quantity and quality requirements (e. g., through audit rights) to manufacture our products candidates for clinical studies and commercial sale, we have limited or minimal direct control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If our contract manufacturers' facilities do not pass inspection, are not approved or have their approvals withdrawn by regulatory authorities, we would need to identify and qualify alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our products, if approved. Moreover, any failure of our third- party manufacturers, to comply with applicable regulations could result in legal sanctions / penalties being imposed on us or adverse regulatory consequences, which would be expected to significantly and adversely affect our product supplies. If any third- party manufacturers terminate their engagements with us or fail to perform as agreed, we may be required to identify, qualify, and contract with replacement manufacturers (including entering into technical transfer agreements to share know- how), which process may result in significant costs and delays to our development and commercialization programs. We may ~~experience~~ **have shortfalls**, ~~delays or technical problems associated with technology transfer, scale- up, or validation of our~~ ~~or~~ **biologics excesses in** manufacturing. We have entered into an initial commercial supply agreement for the manufacture of pamrevlumab with Samsung Biologics Co., Ltd. (" Samsung ") ~~and are transitioning our manufacturing of pamrevlumab from Boehringer Ingelheim to Samsung. However, we may experience delays or technical problems associated with:~~ • technology transfer of the manufacturing process to Samsung; • scale- up and production of cGMP batches; • analytical method validation and transfer to Samsung; • process validation, including process characterization and process performance qualification batches; ~~and~~ • set up ~~and execution of appropriate stability studies~~ . We have made certain manufacturing commitments to Samsung, and there is a contractual risk we will not require the quantities of pamrevlumab we have committed to, particularly if we ~~cease some of our~~ **do not submit a Biologics License Application (" BLA ") for** pamrevlumab ~~clinical trials~~ . In addition, our product candidates and any products that we may develop may compete with other product candidates and products for access and prioritization to manufacture. Certain third- party manufacturers may be contractually prohibited from manufacturing our product due to non- compete agreements with our competitors or a commitment to grant another party priority relative to our products. There are a limited number of third- party manufacturers that operate under cGMP and that might be capable of manufacturing to meet our requirements. Due to the limited number of third- party manufacturers with the contractual freedom, expertise, required regulatory approvals and facilities to manufacture our products on a commercial scale, identifying and qualifying a replacement third- party manufacturer would be expensive and time- consuming and may cause delay or interruptions in the production of our product candidates or products, which in turn may delay, prevent or impair our development and commercialization efforts. We also carry the risk that we may need to pay termination fees to Samsung or other manufacturers in the event that we have to manufacture lower volumes or not at all depending on the results of our clinical trials. **We may be subject to payments to Samsung to cover portions or all of the committed manufacturing campaigns even if we do not need the material for clinical or commercial usage.** In addition, third - party manufacturers tend to change their upfront fees or postponement / cancelation fees over time or upon initiation of additional contracts, and this may lead to unanticipated financial loss for FibroGen. ~~We~~ **There may** also carry the risk that if all three indications are successful, the commercial demand may exceed planned production supply at Samsung. In this event, it may be necessary to find third party manufacturers who have the capacity and capability to produce the required quantities of pamrevlumab. This may be subject to availability of such manufacturers since there are only a limited number of suppliers who have the larger scale bioreactors that are needed for commercial pamrevlumab supply. ~~If we need to find a supplier in China, there may be additional delays in importing custom- or~~ **exporting products, intermediates, or** raw materials **between countries** ~~and supplements into China~~ . Certain components of our products are acquired from single- source suppliers or without long- term supply agreements. The loss of these suppliers, or their failure to supply, would materially and adversely affect our business. ~~Entering~~ **We do not have an alternative supplier of** certain components of our commercial products and product candidates. While we have obligations for second- source suppliers in our roxadustat collaboration agreements, we may be unable to enter into **new** long- term commercial supply arrangements for some of our other products, or do so on commercially reasonable terms, which could **take significant time** have a material adverse impact upon our ~~or~~ **business may not be possible** . Although we have entered into long- term clinical and commercial supply arrangements for pamrevlumab, we currently rely on our contract manufacturers to purchase from third- party suppliers



some of the materials necessary to produce our product candidates. We do not have direct control over the acquisition of those materials by our contract manufacturers. The logistics of our supply chain, which include shipment of materials and intermediates from countries such as China and India add additional time and risk (including risk of loss) to the manufacture of our product candidates. While we have in the past maintained sufficient inventory of materials, **active pharmaceutical ingredients (“API”)**, and drug product to meet our and our collaboration partners’ needs to date, the lead- time and regulatory approvals required to source from and into countries outside of the U. S. increase the risk of delay and potential shortages of supply. **In addition, one of our suppliers, Catalent, was recently acquired by a private company, which could add additional risk to our ability to manufacture at such supplier, including entering into new or extended agreements with this supplier.** Risks Related to Our Intellectual Property If our efforts to protect our proprietary **and exclusively licensed** technologies are not adequate, we may not be able to compete effectively in our market. We rely upon a combination of patents, trade secret protection, and contractual arrangements to protect the intellectual property related to our technologies. We will only be able to protect our products and proprietary information and technology to the extent that our patents, trade secrets, contractual position, and governmental regulations and laws allow us to do so. Any unauthorized use or disclosure of **our** proprietary information or technology could compromise our competitive position. Moreover, we are, have been, and may in the future be involved in legal proceedings ~~involving our intellectual property and~~ initiated by third parties **involving our intellectual property**, which proceedings can be associated with significant costs and commitment of management time and attention. We have in the past been involved, and may in the future be involved, in initiating legal or administrative proceedings involving the product candidates and intellectual property of our competitors. These proceedings can result in significant costs and commitment of management time and attention, and there can be no assurance that our efforts would be successful in preventing or limiting the ability of our competitors to market competing products. Composition- of- matter patents are generally considered the strongest form of intellectual property protection for pharmaceutical products, as such, patents provide protection not limited to any one method of use. Method- of- use patents protect the use of a product for the specified method (s), and do not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. We rely on a combination of these and other types of patents to protect our product candidates, and there can be no assurance that our intellectual property will create and sustain the competitive position of our product candidates. Biotechnology and pharmaceutical product patents involve highly complex legal and scientific questions and can be uncertain. Any patent applications we own or license may fail to result in granted or issued patents. Even if patents do successfully issue from our applications, third parties may challenge their validity or enforceability, which may result in such patents being narrowed, invalidated, or held unenforceable. Even if our patents and patent applications are not challenged by third parties, those patents and patent applications may not prevent others from designing around our claims and may not otherwise adequately protect our product candidates. If the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product candidates is threatened, **generic manufacturers and** competitors with significantly greater resources could threaten our ability to commercialize our product candidates. **Intellectual property protecting our roxadustat product is either being challenged or will expire at various times in the coming years, raising the possibility of generic competition. The introduction of generic competition for a patented branded medicine typically results in a significant and rapid reduction in net sales and operating income for the branded product because generic manufacturers typically offer their unpatented versions at sharply lower prices. Such competition can occur after successful challenges to intellectual property rights or the regular expiration of the term of the patent or other intellectual property rights. Such competition can also result from a Declaration of Public Interest or the compulsory licensing of our drugs by governments, or from a general weakening of intellectual property laws in certain countries around the world. In addition, generic manufacturers sometimes take an aggressive approach to challenging intellectual property rights, including conducting so- called " launches at risk" of products that are still under legal challenge for infringement before final resolution of legal proceedings. In China, numerous generic manufacturers have filed abbreviated new drug applications (ANDAs) seeking marketing approval for generic versions of our EVRENZOTM product (爱瑞卓®, roxadustat). While we are taking steps to both defend our roxadustat patents and challenge these ANDA filers, the outcome is uncertain**. Discoveries are generally published in the scientific literature well after their actual development, and patent applications in the U. S. and other countries are typically not published until 18 months after their filing, and in some cases are never published. Therefore, we cannot be certain that our licensors or we were the first to make the inventions claimed in our owned and licensed patents or patent applications, or that our licensors or we were the first to file for patent protection covering such inventions. Subject to meeting other requirements for patentability, for U. S. patent applications filed prior to March 16, 2013, the first to invent the claimed invention is entitled to receive patent protection for that invention while, outside the U. S., the first to file a patent application encompassing the invention is entitled to patent protection for the invention. The U. S. moved to a “ first to file ” system under the Leahy- Smith America Invents Act, effective March 16, 2013. This system also includes procedures for challenging issued patents and pending patent applications, which creates additional uncertainty. We have, are, and may again become involved in, opposition, **invalidation**, or interference proceedings challenging our patents and patent applications, or the patents and patent applications of others, and the outcome of any such proceedings are highly uncertain. An unfavorable outcome in any such proceedings could reduce the scope of or invalidate our patent rights, allow third parties to commercialize our technology and compete directly with us, or result in our inability to manufacture, develop or commercialize our product candidates without infringing the patent rights of others. In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know- how, information, or technology that is not covered by our patents. Although our agreements require employees to acknowledge ownership by us of inventions conceived as a result of employment from the point of conception and, to the extent necessary, perfect such ownership by assignment, and we require employees, consultants, advisors and third parties who have

access to our trade secrets, proprietary know-how and other confidential information and technology to enter into appropriate confidentiality agreements, we cannot be certain that our trade secrets, proprietary know-how and other confidential information and technology will not be subject to unauthorized disclosure, use, or misappropriation or that our competitors will not otherwise gain access to or independently develop substantially equivalent trade secrets, proprietary know-how and other information and technology. Furthermore, the laws of some foreign countries, in particular, China, where we have operations, do not protect proprietary rights to the same extent or in the same manner as the laws of the U. S. As a result, we may encounter significant problems in protecting and defending our intellectual property globally. If we cannot prevent unauthorized disclosure of our intellectual property related to our product candidates and technology to third parties, we may not establish or maintain a competitive advantage in our market, which could materially and adversely affect our business and operations. Intellectual property disputes may be costly, time consuming, and may negatively affect our competitive position. Our commercial success may depend on our avoiding infringement of the patents and other proprietary rights of third parties as well as on enforcing our patents and other proprietary rights against third parties. Our collaboration partners or we may be subject to patent infringement claims from third parties. We attempt to ensure that our product candidates do not infringe third-party patents and other proprietary rights. However, the patent landscape in competitive product areas is highly complex, and there may be patents of third parties of which we are unaware that may result in claims of infringement. Accordingly, there can be no assurance that our product candidates do not infringe proprietary rights of third parties, and parties making claims against us may seek and obtain injunctive or other equitable relief, which could potentially block further efforts to develop and commercialize our product candidates, including roxadustat or, pamrevlumab or FG- 3246. Any litigation involving defense against claims of infringement, regardless of the merit of such claims, would involve substantial litigation expense and would be a substantial diversion of management time. We may consider administrative proceedings and other means for challenging third-party patents and patent applications. An unfavorable outcome in any such challenge could require us to cease using the related technology and to attempt to license rights to it from the prevailing third party, which may not be available on commercially reasonable terms, if at all, in which case our business could be harmed. Third parties have challenged and may again challenge our patents and patent applications. For example **In particular**, various patent challenges **have been** against our HIF anemia-related technologies patent portfolio are ongoing in several territories, including Europe, the United Kingdom, and Japan. **Regardless of final outcome, the potential narrowing or revocation of any of the HIF anemia-related technology patents does not affect our exclusivity for roxadustat or our freedom to operate with respect to use of roxadustat for the treatment of anemia in these or other territories. Oppositions were filed against our crystal form patents in Europe and China, and against our photostable formulations patent in Europe. While** European Patent No. 2872488 (the “ 488 Patent ”), which claims **a the commercial** crystalline form of roxadustat, **was originally revoked in opposition, the decision is currently under appeal. While both the` 397 Patent` and against our` European Patent No. 3003284 (the “ 284 Patent ”), which claims photostable formulations of roxadustat. Similar challenges, were upheld in opposition, the opponents have been filed appealed the decision in the` 284 Patent and we anticipate the opponents will appeal the decision in the` 397 Patent. In China against, three roxadustat crystal form patents which claim a crystalline form of roxadustat were revoked in first-round proceedings and two revocations were upheld on first appeal; however, all decisions currently remain on appeal.** Final resolution of ~~such these~~ proceedings **in Europe and China** will take time, and we cannot be assured that these patents will ultimately survive **these proceedings** as originally granted or at all. Furthermore, there is a risk that any public announcements concerning the status or outcomes of intellectual property litigation or administrative proceedings may adversely affect the price of our stock. If securities analysts or our investors interpret such status or outcomes as negative or otherwise creating uncertainty, our common stock price may be adversely affected. Our reliance on third parties and agreements with collaboration partners requires us to share our trade secrets, which increases the possibility that a competitor may discover them or that our trade secrets will be misappropriated or disclosed. Our reliance on third-party contractors to develop and manufacture our product candidates is based upon agreements that limit the rights of the third parties to use or disclose our confidential information, including our trade secrets and know-how. Despite the contractual provisions, the need to share trade secrets and other confidential information increases the risk that such trade secrets and information are disclosed or used, even if unintentionally, in violation of these agreements. In the highly competitive markets in which our product candidates are expected to compete, protecting our trade secrets, including our strategies for addressing competing products **and generic competition**, is imperative, and any unauthorized use or disclosure could impair our competitive position and may have a material adverse effect on our business and operations. In addition, our collaboration partners are larger, more complex organizations than ours, and the risk of inadvertent disclosure of our proprietary information may be increased despite their internal procedures and contractual obligations that we have in place with them. Despite our efforts to protect our trade secrets and other confidential information, a competitor’s discovery of such trade secrets and information could impair our competitive position and have an adverse impact on our business. The cost of maintaining our patent protection is high and requires continuous review and diligence. We may not be able to effectively maintain our intellectual property position throughout the major markets of the world. The U. S. Patent and Trademark Office and foreign patent authorities require maintenance fees and payments as well as continued compliance with a number of procedural and documentary requirements. Noncompliance may result in abandonment or lapse of the subject patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance may result in reduced royalty payments for lack of patent coverage in a particular jurisdiction from our collaboration partners or may result in competition, either of which could have a material adverse effect on our business. We have made, and will continue to make, certain strategic decisions in balancing costs and the potential protection afforded by the patent laws of certain countries. As a result, we may not be able to prevent third parties from practicing our inventions in all countries throughout the world, or from selling or importing products made using our inventions in and into the U. S. or other countries. Third parties may use our technologies in territories in which we have not obtained patent protection to develop their own products and,

further, may infringe our patents in territories which provide inadequate enforcement mechanisms, even if we have patent protection. Such third-party products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. The laws of some foreign countries do not protect proprietary rights to the same extent as do the laws of the U. S., and we may encounter significant problems in securing and defending our intellectual property rights outside the U. S. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain countries. The legal systems of certain countries do not always favor the enforcement of patents, trade secrets, and other intellectual property rights, particularly those relating to pharmaceutical and biotechnology products, which could make it difficult for us to stop infringement of our patents, misappropriation of our trade secrets, or marketing of competing products in violation of our proprietary rights. In China, our intended establishment of significant operations will depend in substantial part on our ability to effectively enforce our intellectual property rights in that country. Proceedings to enforce our intellectual property rights in foreign countries could result in substantial costs and divert our efforts and attention from other aspects of our business, and could put our patents in these territories at risk of being invalidated or interpreted narrowly, or our patent applications at risk of not being granted, and could provoke third parties to assert claims against us. We may not prevail in all legal or other proceedings that we may initiate and, if we were to prevail, 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. Intellectual property rights do not address all potential threats to any competitive advantage we may have. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and intellectual property rights may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make compounds or independently develop similar or alternative technologies that are the same as or similar to our current or future product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.
- Patent protection on our product candidates may expire before we are able to develop and commercialize the product, or before we are able to recover our investment in the product.
- Our competitors might conduct research and development activities in the U. S. and other countries that provide a safe harbor from patent infringement claims for such activities, as well as in countries in which we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in markets where we intend to market our product candidates. The existence of counterfeit pharmaceutical products in pharmaceutical markets may compromise our brand and reputation and have a material adverse effect on our business, operations and prospects. Counterfeit products, including counterfeit pharmaceutical products, are a significant problem, particularly in China. Counterfeit pharmaceuticals are products sold or used for research under the same or similar names, or similar mechanism of action or product class, but which are sold without proper licenses or approvals, and are often lower cost, lower quality, different potency, or have different ingredients or formulations, and have the potential to damage the reputation for quality and effectiveness of the genuine product. Such products may be used for indications or purposes that are not recommended or approved or for which there is no data or inadequate data with regard to safety or efficacy. Such products divert sales from genuine products. If counterfeit pharmaceuticals illegally sold or used for research result in adverse events or side effects to consumers, we may be associated with any negative publicity resulting from such incidents. Consumers may buy counterfeit pharmaceuticals that are in direct competition with our pharmaceuticals, which could have an adverse impact on our revenues, business and results of operations. In addition, the use of counterfeit products could be used in non-clinical or clinical studies, or could otherwise produce undesirable side effects or adverse events that may be attributed to our products as well, which could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the delay or denial of regulatory approval by the FDA or other regulatory authorities and potential product liability claims. With respect to China, although the government has recently been increasingly active in policing counterfeit pharmaceuticals, there is not yet an effective counterfeit pharmaceutical regulation control and enforcement system in China. As a result, we may not be able to prevent third parties from selling or purporting to sell our products in China. ~~The proliferation of counterfeit pharmaceuticals has grown in recent years and may continue to grow in the future.~~ The existence of and any increase in the sales and production of counterfeit pharmaceuticals, or the technological capabilities of counterfeiters, could negatively impact our revenues, brand reputation, business and results of operations.

**Risks Related to Government Regulation** The regulatory approval process is highly uncertain and we may not obtain regulatory approval for our product candidates. The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable, but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. ~~For example, while we have received approval of our marketing authorization applications for roxadustat in the European Union, Great Britain, China, Japan, and other countries for the treatment of anemia in CKD for patients who are on dialysis and not on dialysis, we received a CRL for roxadustat in CKD anemia in the U. S. from the FDA.~~ It is possible that roxadustat will not obtain regulatory approval in additional countries or indications. It is possible that our other product candidates we may discover, in-license or acquire and seek to develop in the future, will not obtain regulatory approval in any particular jurisdiction. Our current and future relationships with customers, physicians, and third-party payors are subject to healthcare fraud and abuse laws, false claims laws, transparency laws, and other regulations. If we are unable to comply with such laws, we could face substantial penalties. Our current and future relationships with customers, physicians, and third-party payors are subject to health care laws and regulations, which may constrain the business or financial arrangements and relationships through which we research, as well as, sell, market and distribute any products for which we obtain marketing approval. If we obtain approval in the U. S. for any of our product candidates, the regulatory requirements applicable to our operations, in

particular our sales and marketing efforts, will increase significantly with respect to our operations and the potential for administrative, civil and criminal enforcement by the federal government and the states and foreign governments will increase with respect to the conduct of our business. The laws that may affect our operations in the U. S. include: the federal Anti-Kickback Statute; federal civil and criminal false claims laws and civil monetary penalty laws; the Health Insurance Portability and Accountability Act, including as amended by Health Information Technology for Economic and Clinical Health Act, and its implementing regulations; the federal physician sunshine requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act; and the Trade Agreement Act. In addition, foreign and state law equivalents of each of the above federal laws that may apply to items or services reimbursed by any third- party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, **imprisonment**, disgorgement, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could materially adversely affect our ability to operate our business and our financial results. Even if resolved in our favor, litigation or other legal proceedings relating to healthcare laws and regulations may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. Such actions could have a substantial adverse effect on the price of our common shares and could have a material adverse effect on our operations. We are subject to stringent and evolving U. S. and foreign laws, regulations, rules, contractual obligations, **industry standards**, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation **(including class claims) and mass arbitration demands**; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences. In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share confidential, proprietary, and sensitive information, including personal **information data**, business data, trade secrets, intellectual property, information we collect about trial participants in connection with clinical trials, sensitive third- party data, business plans, transactions, and financial information. Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security. In the ~~United~~ **U. S., there are States- State, federal, state, and local governments have enacted numerous** data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e. g., Section 5 of the Federal Trade Commission Act), and **the Federal Health Insurance Portability and Accountability Act, and** other similar laws (e. g., wiretapping laws). For example, the California Consumer Privacy Act of 2018, **as amended by the California Privacy Rights Act of 2020 ( collectively, " CCPA ")** applies to personal data of consumers, business representatives, and employees, and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA provides for civil penalties of up to \$ 7, 500 per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. In addition, the California Privacy Rights Act of 2020 expands the CCPA' s requirements, including by adding a new right for individuals to correct their personal data and establishing a new regulatory agency to implement and enforce the law. ~~Although Other-~~ **the CCPA exempts some states, such as Virginia and Colorado, have also passed comprehensive data privacy and security laws processed in the context of clinical trials, the CCPA increases compliance costs and potential liability.** ~~Similar~~ **Similar** laws are being considered in several other states, as well as at the federal and local levels, **and we expect more states to pass similar laws in the future**. These developments ~~may~~ further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely. Outside the U. S., ~~an increasing number of~~ laws, regulations, and industry standards ~~may~~ govern data privacy and security. For example, the European Union' s General Data Protection Regulation (" **EU-GDPR** "), the United Kingdom' s **GDPR (" UK 's) GDPR "**), Brazil' s General Data Protection Law (Lei Geral de Proteção de Dados Pessoais) (Law No. 13, 709 / 2018), and China' s Personal Information Protection Law ("**PIPL** ") impose strict requirements for processing personal data, including health-related information. For example, under the **EU-European Union** GDPR, companies may face **temporary or definitive bans on data processing and other corrective actions**; fines of up to 20 million Euros or 4 % of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. We also target customers in Asia and have operations in China and **are** ~~may be~~ subject to new and emerging data privacy regimes in Asia, including China' s **PIPL Personal Information Protection Law**, Japan' s Act on the Protection of Personal Information, and Singapore' s Personal Data Protection Act. ~~In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the U. S. or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (" EEA ") and the United Kingdom (" UK ") have significantly restricted the transfer of personal data to the U. S. and other countries whose data privacy and security laws they believe are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the U. S. in compliance with law, such as the EEA and UK'~~

s standard contractual clauses, **the UK's International Data Transfer Agreement / Addendum, and the EU- U. S. Data Privacy Framework and the UK extension thereto**, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the **United States U. S.** If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the **United States U. S.**, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the U. S., are subject to increased scrutiny from regulators, individual litigants, and activities groups. Some European regulators have ordered **Our employees and personnel could use generative artificial intelligence ("AI") technologies to perform certain work, and the disclosure and use** companies to suspend or permanently cease certain transfers of personal data **in generative AI technologies is subject** out of Europe for allegedly violating the EU-GDPR's cross-border data transfer limitations. In addition to data **various** privacy and security laws, we **and other privacy obligations. Governments have passed and are likely** or may become contractually subject to industry standards adopted by industry groups and may become subject to such obligations **pass additional laws regulating generative AI. Our use of this technology could result** in the future **additional compliance costs, regulatory investigations and actions, and lawsuits**. We are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We publish privacy policies, marketing materials, and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences. **Obligations related to data privacy and security are quickly changing, becoming increasingly stringent, and creating regulatory uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions.** Preparing for and complying with these obligations requires us to devote **significant** resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. **We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations.** If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e. g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims); additional reporting requirements and / or oversight; bans on processing personal data; and orders to destroy or not use personal data. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; **interruptions or stoppages in our business operations including clinical trials;** inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations. We are subject to laws and regulations governing corruption, which require us to maintain costly compliance programs. We must comply with a wide range of laws and regulations to prevent corruption, bribery, and other unethical business practices, including the U. S. Foreign Corrupt Practices Act ("FCPA"), anti-bribery and anti-corruption laws in other countries, particularly China. The implementation and maintenance of compliance programs is costly and such programs may be difficult to enforce, particularly where reliance on third parties is required. Compliance with these anti-bribery laws is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the anti-bribery laws present particular challenges in the pharmaceutical industry because in many countries including China, hospitals are state-owned or operated by the government, and doctors and other hospital employees are considered foreign government officials. Furthermore, in certain countries (China in particular), hospitals and clinics are permitted to sell pharmaceuticals to their patients and are primary or significant distributors of pharmaceuticals. Certain payments to hospitals in connection with clinical studies, procurement of pharmaceuticals and other work have been deemed to be improper payments to government officials that have led to vigorous anti-bribery law enforcement actions and heavy fines in multiple jurisdictions, particularly in the U. S. and China. It is not always possible to identify and deter violations, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In the pharmaceutical industry, corrupt practices include, among others, acceptance of kickbacks, bribes or other illegal gains or benefits by the hospitals and medical practitioners from pharmaceutical manufacturers, distributors or their third-party agents in connection with the prescription of certain pharmaceuticals. If our employees, partners, affiliates, subcontractors, distributors or third-party marketing firms violate these laws or otherwise engage in illegal practices with respect to their sales or marketing of our products or other activities involving our products, we could be required to pay damages or heavy fines by multiple jurisdictions where we operate, which could materially and adversely affect our financial condition and results of operations. The Chinese government has also sponsored anti-corruption campaigns from time to time, which could have a chilling effect on any future marketing efforts by us to new hospital customers. There have been recent occurrences in which certain hospitals have denied access to sales representatives from pharmaceutical companies because the hospitals wanted to avoid the perception of corruption. If this attitude becomes widespread among our potential customers, our ability to promote our products to hospitals may be adversely affected. Considering our current presence and potential expansion in international jurisdictions, the creation, implementation,

and maintenance of anti-corruption compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required. Violation of the FCPA and other anti-corruption laws can result in significant administrative and criminal penalties for us and our employees, including substantial fines, suspension or debarment from government contracting, prison sentences, or even the death penalty in extremely serious cases in certain countries. The **U. S. Securities and Exchange Commission (“SEC”)** also may suspend or bar us from trading securities on U. S. exchanges for violation of the FCPA’s accounting provisions. Even if we are not ultimately punished by government authorities, the costs of investigation and review, distraction of our personnel, legal defense costs, and harm to our reputation could be substantial and could limit our profitability or our ability to develop or commercialize our product candidates. In addition, if any of our competitors are not subject to the FCPA, they may engage in practices that will lead to their receipt of preferential treatment from foreign hospitals and enable them to secure business from foreign hospitals in ways that are unavailable to us. If we fail to maintain an effective system of internal control, it may result in material misstatements in our financial statements. Our management is responsible for establishing and maintaining adequate internal control over financial reporting and for evaluating and reporting on the effectiveness of our system of internal control. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external reporting purposes in accordance with generally accepted accounting principles. As a public company, we are required to comply with the Sarbanes-Oxley Act and other rules that govern public companies. **Remediation efforts** **Efforts** required to remediate an ineffective system of control over financial reporting may place a significant burden on management and add increased pressure on our financial resources and processes. Moreover, we ~~are implementing~~ **implemented** an enterprise resource planning (“ERP”) system in the first quarter of 2023, which ~~will replace~~ **replaced** our existing operating and financial systems, to improve the efficiency of certain financial and transactional processes. **However, there is an increased risk that changing controls may be ineffective during the implementation and** ~~This this~~ ERP system may place additional burdens on employees to learn and adapt our processes to effectively operate under the ERP system, ~~and potential risks during such implementation.~~ If the ERP system does not operate as intended, the effectiveness of our internal control over financial reporting could be negatively impacted. If we experience material weaknesses or otherwise fail to maintain an effective system of internal control over financial reporting, the accuracy and timing of our financial reporting and subsequently our liquidity and our access to capital markets may be adversely affected, we may be unable to maintain or regain compliance with applicable securities laws and the Nasdaq Stock Market LLC listing requirements, we may be subject to regulatory investigations and penalties, investors may lose confidence in our financial reporting, and our stock price may decline. The impact of U. S. healthcare reform may adversely affect our business model. In the U. S. and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could affect our operations. In particular, the commercial potential for our approved products could be affected by changes in healthcare spending and policy in the U. S. and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations, or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition. Further, in the U. S. there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several presidential executive orders, Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs. For example, in July 2021, the Biden administration released an executive order that included multiple provisions aimed at prescription drugs. In response to Biden’s executive order, on September 9, 2021, the U. S. Department of Health and Human Services (“HHS”) released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform. The plan sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions ~~the HHS can take to advance these principles.~~ In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (“IRA”) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. Further, the IRA (1) directs HHS to negotiate the price of certain single-source drugs or biologics covered under Medicare, and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions ~~will take effect progressively starting in fiscal year 2023, although they~~ ~~the may be~~ **Medicare drug price negotiation program is currently** subject to legal challenges. **HHS has and will continue to issue and update guidance as these programs are implemented.** It is currently unclear how the IRA ~~of 2022~~ will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, ~~the Biden administration~~ **on February 14, 2023, HHS** released ~~a an~~ additional executive order on October 14, 2022, directing U. S. Department of Health and Human Services to report **outlining** ~~on how the~~ **three** Center for Medicare and Medicaid Innovation can be further leveraged to test new models for ~~lowering drug costs~~ **testing by the Centers for Medicare and Medicaid beneficiaries (“CMS”) Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care.** It is unclear whether ~~the models~~ ~~this executive order or similar policy initiatives~~ ~~will be implemented~~ **utilized in any health reform measures** in the future. **Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it**

**is uncertain if that will continue under the new framework**. At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products if approved or additional pricing pressures, **or otherwise adversely affect our business**. Roxadustat is considered a Class 2 substance on the 2019 World Anti-Doping Agency Prohibited List that could limit sales and increase security and distribution costs for our partners and us. Roxadustat is considered a Class 2 substance on the World Anti-Doping Agency Prohibited List. There are enhanced security and distribution procedures we and our collaboration partners and third-party contractors will have to take to limit the risk of loss of product in the supply chain. As a result, our distribution, manufacturing and sales costs for roxadustat, as well as for our partners, will be increased which will reduce profitability. In addition, there is a risk of reduced sales due to patient access to this drug. Our employees may engage in misconduct or improper activities, which could result in significant liability or harm our reputation. We are exposed to the risk of employee fraud or other misconduct, including intentional failure to: • comply with FDA regulations or similar regulations of comparable foreign regulatory authorities; • provide accurate information to the FDA or comparable foreign regulatory authorities; • comply with manufacturing standards we have established; • comply with data privacy and security laws protecting personal data; • comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities; • comply with the FCPA and other anti-bribery laws; • report financial information or data accurately; or • disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions, delays in clinical trials, or serious harm to our reputation. We have adopted a code of conduct for our directors, officers and employees, but it is not always possible to identify and deter employee misconduct. The precautions we take to detect and prevent this activity may not be effective in protecting us from the negative impacts of governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. An unfavorable outcome or settlement in connection with a governmental investigation or other action or lawsuit may result in a material adverse impact on our business, results of operations, financial condition, prospects, and stock price. Regardless of the outcome, litigation and governmental investigations can be costly, time-consuming, and disruptive to our business, results of operations, financial condition, reputation, and prospects. If we fail to comply with environmental, health or safety laws and regulations, we could incur fines, penalties or other costs. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations applicable to our operations in the U. S. and foreign countries. These current or future laws and regulations may impair our research, development or manufacturing efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. Risks Related to Our International Operations We have established operations in China and are seeking approval to commercialize our product candidates outside of the U. S., and a number of risks associated with international operations could materially and adversely affect our business. A number of risks related to our international operations, many of which may be beyond our control, include: different regulatory requirements in different countries, including for drug approvals, manufacturing, and distribution; potential liability resulting from development work conducted by foreign distributors; economic weakness, including inflation, or foreign currency fluctuations, which could result in increased operating costs and expenses and reduced revenues, and other obligations incident to doing business in another country; workforce uncertainty in countries where labor unrest is more common than in the U. S.; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; political instability in particular foreign economies and markets; and business interruptions resulting from geopolitical actions specific to an international region, including war and terrorism, or natural disasters, including **the differing impact of the COVID-19 pandemic pandemics on each region**. The pharmaceutical industry in China is highly regulated and such regulations are subject to change. The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. In recent years, many aspects of pharmaceutical industry regulation have undergone significant reform, and reform may continue. For example, the Chinese government implemented regulations that impact distribution of pharmaceutical products in China, where at most two invoices may be issued throughout the distribution chain, a change that required us to change our distribution paradigm. Any regulatory changes or amendments may result in increased compliance costs to our business or cause delays in or prevent the successful development or commercialization of our product candidates in China. Any failure by us or our partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in China. The China- operations portion of our audit is conducted by **PricewaterhouseCoopers Zhong Tian LLP**, an independent registered public accounting firm **headquartered in** that is not subject to inspection by the Public Company Accounting Oversight Board (“PCAOB”), which may negatively impact investor

sentiment towards FibroGen or our China operations, which could adversely affect the market price of our common stock. The majority of audit work incurred for the audit report included in the 2021-2023 Form 10-K was performed by the U. S.- based independent registered public accounting firm we have retained, PricewaterhouseCoopers LLP, which is headquartered in the U. S. and was not identified in the report issued by the PCAOB on December 16, 2021 as a firm that the PCAOB was unable to inspect. However, we estimate that between 20 % and 30 % and 40-% of the total audit hours for our December 31, 2022-2023 audit were provided by PricewaterhouseCoopers Zhong Tian LLP located, which is headquartered in China. PricewaterhouseCoopers Zhong Tian LLP was identified in the report issued by the PCAOB on December 16, 2021 as a firm the PCAOB was unable to inspect. On December 18, 2020, the Holding Foreign Companies Accountable Act (the “ HFCAA ”) was signed into law. The HFCAA requires that the SEC identify issuers that retain an auditor that has a branch or office that is located in a foreign jurisdiction and that the PCAOB determines it is unable to inspect or investigate completely because of a position taken by an authority in that foreign jurisdiction. As PricewaterhouseCoopers Zhong Tian LLP is located in China, a jurisdiction where the PCAOB has been unable to conduct inspections without the approval of the Chinese authorities, they are not currently subject to inspection. Among other things, the HFCAA requires the SEC to prohibit the securities of any issuer from being traded on any of the U. S. national securities exchanges, such as The Nasdaq Global Select Market, or on the U. S. “ over-the-counter ” markets, if the auditor of the issuer’s financial statements is not subject to PCAOB inspections for three consecutive “ non-inspection ” years after the law became effective. On December 29, 2022, (such period further reduced to two years by the enactment of the Accelerating Holding Foreign Companies Accountable Act (the “ AHFCAA ”) was signed into law as part of a package of bills. The AHFCAA reduces the number of consecutive non-inspection years required for triggering the listing and trading prohibitions under the HFCA Act from three years to two years, thus reducing the time period before our securities may be prohibited from trading or delisted. On December 16-29, 2021-2022, the PCAOB issued a report on..... for purposes of Section 104 (i) of the Sarbanes-Oxley Act and the Commission’s determination of whether the registrant should be a Commission Identified Issuer.” The principal accountant, as defined, that we have retained is PricewaterhouseCoopers LLP. The HFCAA does not apply to registrants that retain a principal accountant that is headquartered in the U. S. and subject to PCAOB inspection. the PCAOB issued a report on its determination that it is unable to inspect or investigate completely PCAOB-registered accounting firms headquartered in China and in Hong Kong. PricewaterhouseCoopers Zhong Tian LLP was named in this report. On December 2, 2021, the SEC adopted final amendments to its rules implementing the HFCAA and established procedures to identify issuers and prohibit the trading of the securities of certain registrants as required by the HFCAA. This rule stated that only the principal accountant, as defined by Rule 2-05 of Regulation S-X and PCAOB AS 1205, is “ deemed ‘ retained’ for purposes of Section 104 (i) of the Sarbanes-Oxley Act and the Commission’s determination of whether the registrant should be a Commission Identified Issuer.” The principal accountant, as defined, that we have retained is PricewaterhouseCoopers LLP. Accordingly, the HFCAA does not currently apply to us. On December 16, 2021 on its determination that it was unable to inspect or investigate completely PCAOB-registered accounting firms headquartered in China and in Hong Kong, such as PricewaterhouseCoopers Zhong Tian LLP, on December 15, 2022, it the PCAOB announced that it was able to conduct inspections and investigations completely of such PCAOB-registered public accounting firms headquartered in mainland China and Hong Kong in 2022 and. The PCAOB vacated its previous 2021 determinations accordingly. While vacating those determinations, however, the PCAOB noted that, should it encounter any impediment to conducting an inspection or investigation of auditors in mainland China or Hong Kong as a result of a position taken by any authority there, the PCAOB would act to immediately reconsider the need to issue new determinations consistent with the HFCAA and PCAOB’s Rule 6100. If Even though we currently view the likelihood to be remote, if our operations fundamentally change in a way that requires our independent registered public accounting firm be located in China or Hong Kong in order to comply with the standards of the PCAOB regarding principal auditor, then the HFCAA would apply to us, which consequences could include the potential delisting of our stock from The the Nasdaq Global Select Market and prohibition from trading in the over-the-counter market in the U. S. Such a restriction would negatively impact our ability to raise capital. We view the likelihood to be remote that our operations will fundamentally change so as to require our principal auditor to be located in China or Hong Kong. Additionally, it is possible we cannot rule out the possibility that in the future Congress could amend the HFCAA or the SEC could modify its regulations to apply the restrictions, including trading prohibitions and delisting, under the HFCAA in situations in which an independent registered public accounting firm in China or Hong Kong performs part of the audit such as in our current situation. There are currently no such proposals. Inspections of auditors conducted by the PCAOB in territories outside of China have at times identified deficiencies in those auditors’ audit procedures and quality control procedures, which may be addressed as part of the inspection process to improve future audit quality. The lack of PCAOB inspections of audit work undertaken in China prevents the PCAOB from evaluating the effectiveness of such audits and such auditors’ quality control procedures. The component of our audit that was performed by PricewaterhouseCoopers Zhong Tian LLP and the work papers associated with such audit work is not currently subject to inspection by the PCAOB. As a result, investors are deprived of the potential benefits of such PCAOB inspections for this portion of our audit, which could cause investors and potential investors in our common stock to lose confidence in the audit procedures conducted by our U. S. auditor’s China-based subsidiary, which may negatively impact investor sentiment towards us or our China operations, which in turn could adversely affect the market price of our common stock. Changes in U. S. and China relations, as well as relations with other countries, and / or regulations may adversely impact our business. The U. S. government, including the SEC, has made statements and taken certain actions that have led to changes to U. S. and international relations, and will impact companies with connections to the U. S. or China, including imposing several rounds of tariffs affecting certain products manufactured in China, imposing certain sanctions and restrictions in relation to China, and issuing statements indicating enhanced review of companies with significant China-based operations. It is unknown whether and to what extent new legislation, executive orders, tariffs,



laws or regulations will be adopted, or the effect that any such actions would have on companies with significant connections to the U. S. or to China, our industry or on us. We conduct **contract** manufacturing and development activities and have business operations both in the U. S. and China. Any unfavorable government policies on cross- border relations and / or international trade, including increased scrutiny on companies with significant China- based operations, capital controls or tariffs, may affect the competitive position of our drug products, the hiring of scientists and other research and development personnel, the demand for our drug products, the import or export of products and product components, our ability to raise capital, the market price of our common stock, or prevent us from commercializing and selling our drug products in certain countries. While we do not operate in an industry that is currently subject to foreign ownership limitations in China, China could decide to limit foreign ownership in our industry, in which case there could be a risk that we would be unable to do business in China as we are currently structured. In addition, our periodic reports and other filings with the SEC may be subject to enhanced review by the SEC and this additional scrutiny could affect our ability to effectively raise capital in the U. S. If any new legislation, executive orders, tariffs, laws and / or regulations are implemented, if existing trade agreements are renegotiated or if the U. S. or Chinese governments take retaliatory actions due to the recent U. S.- China tension, such changes could have an adverse effect on our business, financial condition and results of operations, our ability to raise capital and the market price of our common stock. We use our own manufacturing facilities in China to produce roxadustat API and drug product for the market in China. There are risks inherent to operating commercial manufacturing facilities, and with these being our single source suppliers, we may not be able to continually meet market demand. We have two manufacturing facilities in China, with one located in Beijing and the other in Cangzhou, Hebei. We ~~are will be~~ obligated to comply with ~~continuing~~ cGMP requirements ~~and but~~ there can be no assurance that we will maintain all of the appropriate licenses required to manufacture our product candidates for clinical and commercial use in China. In addition, ~~to~~ our product suppliers ~~and~~, we must continually spend time, money and effort in production, record- keeping and quality assurance and appropriate controls in order to ensure that any products manufactured in our facilities meet applicable specifications and other requirements for product safety, efficacy and quality ~~and but~~ there can be no assurance that our efforts will continue to be successful in meeting these requirements. Manufacturing facilities in China are subject to periodic unannounced inspections by the National Medical Products Administration and other regulatory authorities. We expect to depend on these facilities for our product candidates and business operations in China, and we do not yet have a secondary source supplier for either roxadustat API or drug product in China. Consequently, we also carry single source supplier risk for **all countries we or our partners are selling in, the other than Ex-China market**. Natural disasters or other unanticipated catastrophic events, including power interruptions, water shortages, storms, fires, pandemics (~~including the COVID-19 pandemic~~), earthquakes, terrorist attacks, government appropriation of our facilities, and wars, could significantly impair our ability to operate our manufacturing facilities. ~~Further, the climate of geopolitical tensions in China affecting global supply chains may impact our ability to continually meet market demand~~. Certain equipment, records and other materials located in these facilities would be difficult to replace or would require substantial replacement lead- time that would impact our ability to successfully commercialize our product candidates in China. **Further, the climate of geopolitical tensions in China affecting global supply chains may impact our ability to continually meet market demand. For example, certain U. S. lawmakers have encouraged sanctions and introduced legislation that could affect WuXi AppTec (Hong Kong) Limited, and our current supplier of FG- 3246, WuXi Biologics (Hong Kong) Limited (“ WuXi Biologics ”) and companies that do business with WuXi Biologics. While the current legislation does not affect our roxadustat supplier Shanghai SynTheAll Pharmaceutical Co., Ltd. (“ WuXi STA ”), there is a risk that FibroGen could face consequences from contracting with WuXi Biologics, could be forced to find an alternative supplier for FG- 3246, and there is a risk that such legislation could expand to include WuXi STA.** The occurrence of any such event could materially and adversely affect our business, financial condition, results of operations, cash flows and prospects. We may experience difficulties in successfully growing and sustaining sales of roxadustat in China. AstraZeneca and we have a profit- sharing arrangement with respect to roxadustat in China and any difficulties we may experience in growing and sustaining sales will affect our bottom line. Difficulties may be related to **competition and** our ability to maintain reasonable pricing and reimbursement, obtain and maintain hospital listing, or other difficulties related to distribution, marketing, and sales efforts in China. **Our current Roxadustat’ s recent inclusion in the 2023 National Reimbursement Drug List came with a limited 7 % price reduction. Such reimbursement pricing for China is effective for a standard two- year period (between January 1, 2022-2024 to, and December 31, 2023-2025 ). However , after which time we will have to negotiate four generics are approved in China, there is a new price- substantial risk of being subject to the country’ s volume- based purchasing program whereby a national tender could be called for roxadustat. If a tender is called for roxadustat, our access to the market as the originator drug would be significantly constrained and our price would be further reduced.** Sales of roxadustat in China may ~~ultimately also~~ be limited due to the complex nature of the healthcare system, low average personal income, pricing controls, still developing infrastructure , and potentially rapid competition from other products. The retail prices of any product candidates that we develop will be subject to pricing control in China and elsewhere. The price ~~for of~~ pharmaceutical products is highly regulated in China, both at the national and provincial level. Price controls may reduce prices to levels significantly below those that would prevail in less regulated markets or limit the volume of products that may be sold, either of which may have a material and adverse effect on potential revenues from sales of roxadustat in China. Moreover, the process and timing for the implementation of price restrictions ~~is are~~ unpredictable, which may cause potential revenues from the sales of roxadustat to fluctuate from period to period. FibroGen (China) Medical Technology Development Co., Ltd. (“ FibroGen Beijing ”) would be subject to restrictions on paying dividends or making other payments to us, which may restrict our ability to satisfy our liquidity requirements. We plan to conduct all of our business in China through FibroGen China Anemia Holdings, Ltd., FibroGen Beijing and its branch offices, and our joint venture distribution entity, Beijing Falikang Pharmaceutical Co., Ltd. (“ Falikang ”). We ~~do not currently rely on revenue from China to fund our operations outside of China. However, we~~ may in the future rely on dividends and royalties paid by FibroGen Beijing

for a portion of our cash needs, including the funds necessary to service any debt we may incur and to pay our operating costs and expenses. The payment of dividends by FibroGen Beijing is subject to limitations. Regulations in China currently permit payment of dividends only out of accumulated profits as determined in accordance with applicable accounting standards and regulations in China. FibroGen Beijing is not permitted to distribute any profits until losses from prior fiscal years have been recouped and in any event must maintain certain minimum capital requirements. FibroGen Beijing is also required to set aside at least 10.0 % of its after-tax profit based on Chinese accounting standards each year to its statutory reserve fund until the cumulative amount of such reserves reaches 50.0 % of its registered capital. Statutory reserves are not distributable as cash dividends. In addition, if FibroGen Beijing incurs debt on its own behalf in the future, the agreements governing such debt may restrict its ability to pay dividends or make other distributions to us. As of December 31, ~~2022~~ **2023**, approximately \$ ~~71.32~~ **21** million of our cash and cash equivalents is held in China. Any capital contributions from us to FibroGen Beijing must be approved by the Ministry of Commerce in China, and failure to obtain such approval may materially and adversely affect the liquidity position of FibroGen Beijing. The Ministry of Commerce in China or its local counterpart must approve the amount and use of any capital contributions from us to FibroGen Beijing, and there can be no assurance that we will be able to complete the necessary government registrations and obtain the necessary government approvals on a timely basis, or at all. If we fail to do so, we may not be able to contribute additional capital or find suitable financing alternatives within China to fund our Chinese operations, and the liquidity and financial position of FibroGen Beijing may be materially and adversely affected. We may be subject to currency exchange rate fluctuations and currency exchange restrictions with respect to our operations in China as well as our partner's operations in Japan and Europe, which could adversely affect our financial performance. Most of our and our partner's product sales will occur in local currency and our operating results will be subject to volatility from currency exchange rate fluctuations. To date, we have not hedged against the risks associated with fluctuations in exchange rates and, therefore, exchange rate fluctuations could have an adverse impact on our future operating results. Changes in the value of the Renminbi, Euro or Yen against the U. S. dollar and other currencies are affected by, among other things, changes in political and economic conditions. Any significant currency exchange rate fluctuations may have a material adverse effect on our business and financial condition. In addition, the Chinese government imposes controls on the convertibility of the Renminbi into foreign currencies and the remittance of foreign currency out of China for certain transactions. Shortages in the availability of foreign currency may restrict the ability of FibroGen Beijing to remit sufficient foreign currency to pay dividends or other payments to us, or otherwise satisfy their foreign currency-denominated obligations. Under existing Chinese foreign exchange regulations, payments of current account items, including profit distributions, interest payments and balance of trade, can be made in foreign currencies without prior approval from the State Administration of Foreign Exchange by complying with certain procedural requirements. However, approval from the State Administration of Foreign Exchange or its local branch is required where Renminbi is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of loans denominated in foreign currencies. The Chinese government may also at its discretion restrict access in the future to foreign currencies for current account transactions. If the foreign exchange control system prevents us from obtaining sufficient foreign currency to satisfy our operational requirements, our liquidity and financial position may be materially and adversely affected. Because FibroGen Beijing's funds are held in banks that do not provide insurance, the failure of any bank in which FibroGen Beijing deposits its funds could adversely affect our business. Banks and other financial institutions in China do not provide insurance for funds held on deposit. As a result, in the event of a bank failure, FibroGen Beijing may not have access to funds on deposit. Depending upon the amount of money FibroGen Beijing maintains in a bank that fails, its inability to have access to cash could materially impair its operations. We may be subject to tax inefficiencies associated with our offshore corporate structure. The tax regulations of the U. S. and other jurisdictions in which we operate are extremely complex and subject to change. New laws, new interpretations of existing laws, such as the Base Erosion Profit Shifting project initiated by the Organization for Economic Co-operation and Development, and any legislation proposed by the relevant taxing authorities, or limitations on our ability to structure our operations and intercompany transactions may lead to inefficient tax treatment of our revenue, profits, royalties, and distributions, if any are achieved. For example, the Biden administration has proposed to increase the U. S. corporate income tax rate from 21 %, increase the U. S. taxation of our international business operations and impose a global minimum tax, although the recently enacted Inflation Reduction Act of 2022 omitted to include any of these proposals but included only a minimum tax on certain large corporations and a tax on certain repurchases of stock on the corporations doing those repurchases. Such proposed changes, as well as regulations and legal decisions interpreting and applying these changes, may adversely impact our effective tax rate. In addition, our foreign subsidiaries and we have various intercompany transactions. We may not be able to obtain certain benefits under relevant tax treaties to avoid double taxation on certain transactions among our subsidiaries. If we are not able to avail ourselves to the tax treaties, we could be subject to additional taxes, which could adversely affect our financial condition and results of operations. On December 22, 2017, the Tax Cuts and Jobs Act (Tax Act) was enacted which instituted various changes to the taxation of multinational corporations. Since inception, various regulations and interpretations have been issued by governing authorities and we continue to examine the impacts to our business, which could potentially have a material adverse effect on our business, results of operations or financial conditions. Our foreign operations, particularly those in China, are subject to significant risks involving the protection of intellectual property. We seek to protect the products and technology that we consider important to our business by pursuing patent applications in China and other countries, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. We note that the filing of a patent application does not mean that we will be granted a patent, or that any patent eventually granted will be as broad as requested in the patent application or will be sufficient to protect our technology. There are a number of factors that could cause our patents, if granted, to become invalid or unenforceable or that could cause our patent applications not to be granted, including known or unknown prior art, deficiencies in the patent application, or lack of originality of the technology. Furthermore, the terms of our patents are limited. The patents we hold and

the patents that may be granted from our currently pending patent applications have, absent any patent term adjustment or extension, a twenty-year protection period starting from the date of application. Intellectual property rights and confidentiality protections in China may not be as effective as those in the U. S. or other countries for many reasons, including lack of procedural rules for discovery and evidence, low damage awards, and lack of judicial independence. Implementation and enforcement of China intellectual property laws have historically been deficient and ineffective and may be hampered by corruption and local protectionism. Policing unauthorized use of proprietary technology is difficult and expensive, and we may need to resort to litigation to enforce or defend patents issued to us or to determine the enforceability and validity of our proprietary rights or those of others. The experience and capabilities of China courts in handling intellectual property litigation varies and outcomes are unpredictable. An adverse determination in any such litigation could materially impair our intellectual property rights and may harm our business. Uncertainties with respect to the China legal system and regulations could have a material adverse effect on us. The legal system of China is a civil law system primarily based on written statutes. Our financial condition and results of operations may be adversely affected by government control, perceived government interference and / or changes in tax, cyber and data security, capital investments, cross-border transactions and other regulations that are currently or may in the future be applicable to us. In 2022, Chinese regulators announced regulatory actions aimed at providing China's government with greater oversight over certain sectors of China's economy, including the for-profit education sector and technology platforms that have a quantitatively significant number of users located in China. Although the biotech industry is already highly regulated in China and while there has been no indication to date that such actions or oversight would apply to companies that are similarly situated as us and that are pursuing similar portfolios of drug products and therapies as us, China's government may in the future take regulatory actions that may materially adversely affect the business environment and financial markets in China as they relate to us, our ability to operate our business, our liquidity and our access to capital. Unlike in a common law system, prior court decisions may be cited for reference but are not binding. Because the China legal system continues to rapidly evolve, the interpretations of many laws, regulations and rules are not always uniform and enforcement of these laws, regulations and rules involve uncertainties, which may limit legal protections available to us. Moreover, decision makers in the China judicial system have significant discretion in interpreting and implementing statutory and contractual terms, which may render it difficult for FibroGen Beijing to enforce the contracts it has entered into with our business partners, customers and suppliers. Different government departments may have different interpretations of certain laws and regulations, and licenses and permits issued or granted by one government authority may be revoked by a higher government authority at a later time. Furthermore, new laws or regulations may be passed, in some cases with little advance notice, that affect the way we or our collaboration partner do business in China (including the manufacture, sale, or distribution of roxadustat in China). Our business may be affected if we rely on laws and regulations that are subsequently adopted or interpreted in a manner different from our understanding of these laws and regulations. Navigating the uncertainty and change in the China legal and regulatory systems will require the devotion of significant resources and time, and there can be no assurance that our contractual and other rights will ultimately be maintained or enforced. Changes in China's economic, governmental, or social conditions could have a material adverse effect on our business. Chinese society and the Chinese economy continue to undergo significant change. Changes in the regulatory structure, regulations, and economic policies of the Chinese government could have a material adverse effect on the overall economic growth of China, which could adversely affect our ability to conduct business in China. The Chinese government continues to adjust economic policies to promote economic growth. Some of these measures benefit the overall Chinese economy, but may also have a negative effect on us. For example, our financial condition and results of operations in China may be adversely affected by government control over capital investments or changes in tax regulations. Recently, Chinese regulators announced regulatory actions aimed at providing China's government with greater oversight over certain sectors of China's economy, including the for-profit education sector and technology platforms that have a quantitatively significant number of users located in China. Although the biotech industry is already highly regulated in China and while there has been no indication to date that such actions or oversight would apply to companies that are similarly situated as us and that are pursuing similar portfolios of drug products and therapies as us, China's government may in the future take regulatory actions that may materially adversely affect the business environment and financial markets in China as they relate to us. As the Chinese pharmaceutical industry grows and evolves, the Chinese government may also implement measures to change the regulatory structure and structure of foreign investment in this industry. We are unable to predict the frequency and scope of such policy changes and structural changes, any of which could materially and adversely affect FibroGen Beijing's development and commercialization timelines, liquidity, access to capital, and its ability to conduct business in China. Any failure on our part to comply with changing government regulations and policies could result in the loss of our ability to develop and commercialize our product candidates in China. In addition, the changing government regulations and policies could result in delays and cost increases to our development, manufacturing, approval, and commercialization timelines in China. We may be subject to additional Chinese requirements, approvals or permissions in the future. We are incorporated in the state of Delaware. To operate our general business activities currently conducted in China, each of our Chinese subsidiaries (and our joint venture with AstraZeneca, Falikang) is required to and does obtain a business license from the local counterpart of the State Administration for Market Regulation. Such business licenses list the business activities we are authorized to carry out and we would be noncompliant if we act outside of the scope of business activities set forth under the relevant business license. Due to China's regulatory framework in general and for the pharmaceutical industry specifically, we are required to apply for and maintain many approvals or permits specific to many of our business activities, including but not limited to manufacturing, distribution, environment protection, workplace safety, cybersecurity, from both national and local government agencies. For example, FibroGen Beijing is required to maintain a Drug Product Production Permit that allows it to manufacture API and roxadustat capsules. Falikang, our joint venture with AstraZeneca, is required to maintain a Drug Product Distribution Permit in order to be able to distribute our drug product roxadustat in China. For certain of our clinical trials conducted in China, we need

to obtain, through the clinical sites, permits from the Human Genetic Resources Administration of China to collect samples that include human genetic resources, such as blood samples. We may also be required to obtain certain approvals from Chinese authorities before transferring certain scientific data abroad or to foreign parties or entities established or actually controlled by them. None of our subsidiaries or our joint venture in China are required to obtain approval or prior permission from the China Securities Regulatory Commission, Cyberspace Administration of China, or any other Chinese regulatory authority under the Chinese laws and regulations currently in effect to issue securities to our investors. However, the approvals and permits we do have to comply with are numerous and there are uncertainties with respect to the Chinese legal system and changes in laws, regulations and policies, including how those laws and regulations will be interpreted or implemented. For further information, see the risk factor titled “Uncertainties with respect to the China legal system and regulations could have a material adverse effect on us.” There can be no assurance that we will not be subject to new or changing requirements, approvals or permissions in the future in order to operate in China. If we are unable to obtain the necessary approvals or permissions in order to operate our business in China, if we inadvertently conclude that such approvals or permissions are not required, or if we are subject to additional requirements, approvals, or permissions, it could have an adverse effect on our business, financial condition and results of operations, our ability to raise capital and the market price of our common stock. If the Chinese government determines that our corporate structure does not comply with Chinese regulations, or if Chinese regulations change or are interpreted differently in the future, the value of our common stock may decline. In July 2021, the Chinese government provided new guidance on China-based companies raising capital outside of China, including through arrangements called variable interest entities. We do not employ a variable interest entity structure for purposes of replicating foreign investment in Chinese-based companies where Chinese law prohibits direct foreign investment. We do not operate in an industry that is currently subject to foreign ownership limitations in China. However, there are uncertainties with respect to the Chinese legal system and there may be changes in laws, regulations and policies, including how those laws and regulations will be interpreted or implemented. For further information, see the risk factor titled “Uncertainties with respect to the China legal system and regulations could have a material adverse effect on us.” If in the future the Chinese government determines that our corporate structure does not comply with Chinese regulations, or if Chinese laws or regulations change or are interpreted differently from our understanding of these laws and regulations, the value of our common stock may decline. Our operations in China subject us to various Chinese labor and social insurance laws, and our failure to comply with such laws may materially and adversely affect our business, financial condition and results of operations. We are subject to China Labor Contract Law, which provides strong protections for employees and imposes many obligations on employers. The Labor Contract Law places certain restrictions on the circumstances under which employers may terminate labor contracts and require economic compensation to employees upon termination of employment, among other things. In addition, companies operating in China are generally required to contribute to labor union funds and the mandatory social insurance and housing funds. Any failure by us to comply with Chinese labor and social insurance laws may subject us to late fees, fines and penalties, or cause the suspension or termination of our ability to conduct business in China, any of which could have a material and adverse effect on business, results of operations and prospects.

~~Risks Related to COVID-19 Our business could continue to be adversely affected by the ongoing COVID-19 global pandemic. The COVID-19 pandemic may continue to negatively impact our and / or our partners’ sales of roxadustat, clinical programs and timelines, and general productivity, the magnitude of which will depend, in part, on the progression of the disease, the efficacy of various mitigation efforts, including vaccines and other therapeutics in preventing and treating current and future COVID-19 variants, and restrictions (including lockdowns) governments impose in response to new outbreaks of COVID-19 variants. During the pandemic, we have seen impacts from COVID-19 on various parts of our operations and at varying degrees. Currently, the greatest risks from COVID-19 are regarding enrollment of our ZEPHYRUS-2 Phase 3 IPF trial and our sales and manufacturing operations in China. There is a risk that our sales, manufacturing, clinical trials and operations could be further affected by additional or continued COVID-19 outbreaks or lockdowns, which could slow or pause enrollment, site initiation, manufacturing or sales. In addition, while we are trying to mitigate the effect of COVID-19 on existing patients, it is possible that some patients may not be able to continue to comply with protocols, which could further delay our clinical trial progress. We believe we have sufficient stock of roxadustat and pamrevlumab supplies for our near-term expected commercial and clinical requirements. However, we only have a limited stockpile of these products, and therefore, further outbreaks of COVID-19, lockdowns like the ones in China, disruptions in shipping, or product expiration due to slowed clinical trials, could create supply shortages in our global supply chains. COVID-19 has also created increased demand for the limited global biologics manufacturing capacity, and for manufacturing supplies, including vials, reagents, supplements and media. Any such supply disruptions could adversely impact our clinical development and ability to generate revenues from our approved products and our business, financial condition, results of operations and growth prospects could be materially adversely affected. Due to these and potentially additional business disruptions, there may be delays to any of our business areas including those outlined above, as well as in regulatory, distribution, warehousing and other development, commercialization and launch efforts. In addition, COVID-19 presents an ongoing health risk to our employees, including members of senior management. Health risks and remote work could affect the productivity of our workforce. The full extent of these potential effects is unknown, but any of which could have a material impact on our business, operating results, and financial condition. To the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this “Risk Factors” section.~~

~~Risks Related to the Operation of Our Business We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future and may never achieve or sustain profitability. We may require additional financing in order to fund our operations, which may be dilutive to our shareholders, restrict our operations or require us to relinquish rights to our intellectual property or product candidates. If we are unable to raise capital when needed or on acceptable terms, we may be forced to delay, reduce or eliminate our research and development programs and / or our commercialization efforts. We are a biopharmaceutical company with two~~

lead product candidates in clinical development, roxadustat for ~~anemia~~ **CIA** in **China**, ~~CKD, MDS, and chemotherapy-induced anemia~~, and pamrevlumab for ~~IPF, pancreatic cancer, and DMD~~. Most of our revenue generated to date has been based on our collaboration agreements and we have limited commercial drug product sales to date. We continue to incur significant research and development and other expenses related to our ongoing operations. Our net loss for the years ended December 31, **2023**, ~~2022~~, ~~and 2021 and 2020~~ were \$ **284.2 million**, \$ 293.7 million, ~~and~~ \$ 290.0 million ~~and~~ \$ 189.3 million, respectively. As of December 31, ~~2022~~ **2023**, we had an accumulated deficit of \$ 1.68 billion. As of December 31, ~~2022~~ **2023**, we had capital resources consisting of cash, cash equivalents and short-term investments of \$ ~~422.235.06~~ million ~~plus~~ \$ 4.3 million of ~~long-term investments classified as available for sale securities~~. In addition, as of December 31, ~~2022~~ **2023**, we had \$ 16 ~~12.36~~ million of accounts receivable in our current assets. Despite contractual development and cost coverage commitments from our collaboration partners, AstraZeneca and Astellas, and the potential to receive milestone and other payments from these partners, and despite commercialization efforts for roxadustat for the treatment of anemia caused by CKD, we anticipate we will continue to incur losses on an annual basis for the foreseeable future. If we do not successfully develop and continue to obtain regulatory approval for our existing or any future product candidates and effectively manufacture, market and sell the product candidates that are approved, we may never achieve or sustain profitability on a quarterly or annual basis. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity (deficit) and working capital. Our failure to become and remain profitable would depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. We believe that we will continue to expend substantial resources for the foreseeable future as we continue to grow our operations in China, ~~expand~~ **continue** our clinical development efforts on pamrevlumab, continue to seek regulatory approval, establish commercialization capabilities of our product candidates, and pursue additional indications. These expenditures will include costs associated with research and development, conducting preclinical trials and clinical trials, obtaining regulatory approvals in various jurisdictions, and manufacturing and supplying products and product candidates for our partners and ourselves. The outcome of any clinical trial and / or regulatory approval process is highly uncertain and we are unable to fully estimate the actual costs necessary to successfully complete the development and regulatory approval process for our compounds in development and any future product candidates. We believe that our existing cash and cash equivalents, short-term and long-term investments and accounts receivable, cash flows from commercial sales and sales of drug product, and expected third-party collaboration revenues will allow us to fund our operating plans through at least 12 months from the date of issuance of these consolidated financial statements. Our operating plans or third-party collaborations may change as a result of many factors, including the success of our development and commercialization efforts, operations costs (including manufacturing and regulatory), competition, and other factors that may not currently be known to us, and we therefore may need to seek additional funds sooner than planned, through offerings of public or private securities, debt financing or other sources, such as revenue interest monetization or other structured financing. Future sales of equity or debt securities may result in dilution to stockholders, imposition of debt covenants and repayment obligations, or other restrictions that may adversely affect our business. We may also seek additional capital due to favorable market conditions or strategic considerations even if we currently believe that we have sufficient funds for our current or future operating plans. Accordingly, we may seek additional funds sooner than planned. We may also seek additional capital due to favorable market conditions or strategic considerations even if we currently believe that we have sufficient funds for our current or future operating plans. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize any of our product candidates. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all or that we will be able to satisfy the performance, financial and other obligations in connection with any such ~~financings~~ **financing**. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. We could also be required to seek funds through additional collaborations, partnerships, licensing arrangements with third parties or otherwise at an earlier stage than would be desirable and we may be required to relinquish rights to intellectual property, future revenue streams, research programs, product candidates or to grant licenses on terms that may not be favorable to us, any of which may have a material adverse effect on our business, operating results and prospects. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. If we raise additional funds by issuing equity securities, dilution to our existing stockholders will result. In addition, as a condition to providing additional funding to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Moreover, any debt financing, if available, may involve restrictive covenants that could limit our flexibility in conducting future business activities and, in the event of insolvency, would be paid before holders of equity securities received any distribution of corporate assets. For example, in 2022 we entered into a **Revenue Interest financing Financing arrangement Agreement ("RIFA")** with an affiliate of NovaQuest Capital Management ("NovaQuest") ~~that~~ **and in 2023 we entered into a debt financing agreement with investment funds managed by Morgan Stanley Tactical Value, each of which** imposes certain performance and financial obligations on our business. Our ability to satisfy and meet any future debt service obligations will depend upon our future performance, which will be subject to financial, business and other factors affecting our operations, many of which are beyond our control. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate our research and development efforts or other operations or activities that may be necessary to commercialize our product candidates. **We may be required to recognize an impairment of our long-lived assets, which could adversely affect our financial performance. Our long-lived assets group is subject to an impairment assessment at least annually, or when certain triggering events or circumstances indicate that its carrying value may be impaired. Prolonged market declines or other factors negatively impacting the performance of our businesses could adversely affect our evaluation of the recoverability of our long-lived assets. If, as a result of the impairment test, we determine**

that the fair value of our long-lived asset group is less than its carrying amount, we may incur an impairment charge, which could materially and adversely affect our results of operations or financial position. Our non-dilutive transaction transactions with Morgan Stanley Tactical Value and NovaQuest could limit cash flow available for our operations, expose us to risks that could adversely affect our business, financial condition and results of operations, and contain various covenants and other provisions, which, if violated, could result in the acceleration of payments due in connection with such transaction or the foreclosure on security interest. On November 4, 2022, we entered into a revenue interest \$ 50 million RIFA financing agreement (“RIFA”) with NovaQuest with respect to our revenues from Astellas’ sales of roxadustat in Europe, Japan and the other Astellas territories. Pursuant to the RIFA, we received \$ 49.8 million from NovaQuest, representing the gross proceeds of \$ 50.0 million net of initial issuance costs, in consideration for a portion of future revenues we will receive from Astellas. As material inducement for NovaQuest to enter into the RIFA, we granted NovaQuest a security interest over our rights, title and interest in and to the revenue interest payments and intellectual property related to roxadustat and the Astellas territories. In addition, the RIFA includes customary reporting obligations and events of default by us. Upon the occurrence of an event of default, NovaQuest may exercise all remedies available to it at law or in equity in respect of the security interest. On April 29, 2023, we entered into a financing agreement (“Financing Agreement”) with a \$ 75 million senior secured term loan with investment funds managed by Morgan Stanley Tactical Value, as lenders, and Wilmington Trust, National Association, as the administrative agent. Our Financing Agreement with Morgan Stanley Tactical Value requires us to maintain a minimum balance of \$ 30 million of unrestricted cash and cash equivalents held in accounts in the U. S. and, while any portion of the term loans or any other obligations under the Financing Agreement remain outstanding, we must comply with certain customary affirmative and negative covenants set forth in the Financing Agreement and related loan documents. The Financing Agreement also provides for customary events of default triggers. Upon an event of default, the administrative agent under the Financing Agreement may, and at the direction of the majority lenders shall, accelerate all of our outstanding obligations under the Financing Agreement and related loan documents, terminate all outstanding funding commitments and / or exercise remedies available at law or equity or under contract for secured creditors. The term loans are secured by substantially all of our and our non-Chinese subsidiaries’ assets, subject to customary exceptions. For additional details about these financing transactions, see Note 8-9, Senior Secured Term Loan Facilities and Note 10, Liability Related to Sale of Future Revenues, to the consolidated financial statements. Our obligations under these RIFA financing transactions could have significant negative consequences for our shareholders, and our business, results of operations and financial condition by, among other things: • increasing our vulnerability to adverse economic and industry conditions; • limiting our ability to obtain additional non-dilutive financing or enter into collaboration or partnership agreements of a certain size; • requiring the dedication of a portion of our cash flow from operations to service our indebtedness, which will reduce the amount of cash available for other purposes; • limiting our flexibility to plan for, or react to, changes in our business; and • placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital. Our ability; and if we fail to comply with the terms above covenants may be affected by events beyond our control, and future breaches of any of the covenants could result in a default under the RIFA, resulting in the Financing Agreement, or an any event of default that is future financing agreements. If not cured or waived, future defaults could cause all of the outstanding indebtedness under either financing transaction to become immediately due and payable and NovaQuest or Morgan Stanley Tactical Value could seek to enforce their security interest in assets relating to roxadustat that secures secure such indebtedness. To the extent we incur additional debt, the risks described above could increase. A default in one of such agreements could trigger a default in the other. Any of the above risks would negatively impact our ability to operate our business and obtain additional debt or equity financing on favorable terms. Most of our recent revenue has been earned from through our roxadustat collaboration collaborations partners for our product candidates under development. If either or both of our Astellas and collaboration or our AstraZeneca China collaborations collaboration were to be terminated, we could have a sudden decrease of revenue and require significant additional capital in order to proceed with development and commercialization of our product candidates, including with respect to our potential commercialization of roxadustat for the treatment of anemia caused by CKD or MDS, or we may require additional partnering in order to help fund such development and commercialization. While we continue to commercialize roxadustat in China with AstraZeneca, and develop roxadustat in the U. S. for the treatment of anemia in patients with MDS, we have not been able to agree on a path forward for AstraZeneca to fund further roxadustat development in the U. S. for CKD anemia and there is a significant risk we will be unable to do so. There is also a significant risk that the AstraZeneca U. S. / RoW Agreement will be amended or our terminated operations. If adequate funds or partners are not available to us on a timely basis or on favorable terms, we may be required to delay, limit, reduce or terminate our development or commercialization efforts or other operations. We may encounter difficulties in managing our growth and expanding our operations, successfully. As we seek to advance our product candidates through clinical trials and commercialization, we will need to expand our development, regulatory, manufacturing, commercialization and administration capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to increase the responsibilities of management. Our failure to accomplish any of these steps could prevent us from successfully implementing our strategy and maintaining the confidence of investors in us. Loss of senior management and key personnel could adversely affect our business. We are highly dependent on members of our senior management team, including Enrique Conterno, our Chief Executive Officer. The loss of the services of Mr. Conterno or any of our senior management could significantly impact the development and commercialization of our products and product candidates and our ability to successfully implement our business strategy. Recruiting and retaining qualified commercial, development, scientific, clinical, and manufacturing personnel are and will continue to be critical to our success, particularly as we expand our commercialization operations. Furthermore, replacing executive officers and key employees may be difficult and may take an

extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize product candidates. We may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the intense competition among numerous biopharmaceutical companies for similar personnel. There is also significant competition, in particular in the San Francisco Bay Area, for the hiring of experienced and qualified personnel, which increases the importance of retention of our existing personnel. **On July 14, 2023 and December 11, 2023, FibroGen approved a reduction to its U. S. workforce of approximately 32 % and 7. 4 % to lower its operating expenses, causing the loss of valuable skills, experience, and productivity. Furthermore, employee turnover and other risks described above may be exacerbated by the restructuring as well as recent stock performance.** If we are unable to continue to attract and retain personnel with the quality and experience applicable to our product candidates, our ability to pursue our strategy will be limited and our business and operations would be adversely affected. We are exposed to the risks associated with litigation, investigations, regulatory proceedings, and other legal matters, any of which could have a material adverse effect on us. We are currently and may in the future face legal, administrative and regulatory proceedings, claims, demands, investigations and / or other dispute- related matters involving, among other things, our products, product candidates, or other issues relating to our business as well as allegations of violation of U. S. and foreign laws and regulations relating to intellectual property, competition, securities, consumer protection, and the environment. For example, we and certain of our current and former executive officers have been named as defendants in a consolidated putative class action lawsuit (“ Securities Class Action Litigation ”) and certain of our current and former executive officers and directors have been named as defendants in several derivative lawsuits (“ Derivative Litigation ”). The complaint filed in the Securities Class Action Litigation alleges violations of the securities laws, including, among other things, that the defendants made certain materially false and misleading statements about our Phase 3 clinical studies data and prospects for FDA approval. The complaints filed in the Derivative Litigation asserts claims based on some of the same alleged misstatements and omissions as the Securities Class Action Litigation and seeks, among other things, unspecified damages. We intend to vigorously defend the claims made in the Securities Class Action Litigation and Derivative Litigation; however, the outcome of these matters cannot be predicted, and the claims raised in these lawsuits may result in further legal matters or actions against us, including, but not limited to, government enforcement actions or additional private litigation. In the fourth quarter of 2021, FibroGen received a subpoena from the SEC requesting documents related to roxadustat’ s pooled cardiovascular safety data. We have been fully cooperating with the SEC’ s investigation. Our Board of Directors also received ~~three~~ litigation demands from our purported shareholders, asking the Board of Directors to investigate and take action against certain current and former officers and directors of ours for alleged wrongdoing based on the same allegations in the pending derivative and securities class action lawsuits. We may in the future receive such additional demands. We cannot predict whether any particular legal matter will be resolved favorably or ultimately result in charges or material damages, fines or other penalties, government enforcement actions, bars against serving as an officer or director, or civil or criminal proceedings against us or certain members of our senior management. For additional information regarding our pending litigation and SEC investigation, see Note **10-12**, Commitments and Contingencies, to the consolidated financial statements. Legal proceedings in general, and securities and class action litigation and regulatory investigations in particular, regardless of their merits or their ultimate outcomes, are costly, divert management’ s attention and may materially adversely affect our business, results of operations, financial condition, prospects, and stock price. In addition, such legal matters could negatively impact our reputation among our customers, collaboration partners or our shareholders. Furthermore, publicity surrounding legal proceedings, including regulatory investigations, even if resolved favorably for us, could result in additional legal proceedings or regulatory investigations, as well as damage to our reputation. If product liability lawsuits are brought against us, we may incur substantial liabilities and may have to limit commercial operations. We face an inherent risk of product liability as a result of the clinical testing, manufacturing and commercialization of our product candidates. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in a product, negligence, strict liability or breach of warranty. Claims could also be asserted under state consumer protection acts. If we are unable to obtain insurance coverage at levels that are appropriate to maintain our business and operations, or if we are unable to successfully defend ourselves against product liability claims, we may incur substantial liabilities or otherwise cease operations. Product liability claims may result in: • termination of further development of unapproved product candidates or significantly reduced demand for any approved products; • material costs and expenses to defend the related litigation; • a diversion of time and resources across the entire organization, including our executive management; • product recalls, product withdrawals or labeling restrictions; • termination of our collaboration relationships or disputes with our collaboration partners; and • reputational damage negatively impacting our other product candidates in development. If we fail to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims, we may not be able to continue to develop our product candidates. We maintain product liability insurance in a customary amount for the stage of development of our product candidates. Although we believe that we have sufficient coverage based on the advice of our third-party advisors, there can be no assurance that such levels will be sufficient for our needs. Moreover, our insurance policies have various exclusions, and we may be in a dispute with our carrier as to the extent and nature of our coverage, including whether we are covered under the applicable product liability policy. If we are not able to ensure coverage or are required to pay substantial amounts to settle or otherwise contest the claims for product liability, our business and operations would be negatively affected. Our business and operations would suffer in the event of computer system failures. Despite implementing security measures, our internal computer systems, and those of our CROs, collaboration partners, and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. We upgraded our disaster and data recovery capabilities in 2022, and continue to maintain and upgrade these capabilities. However, to the extent that any disruption or security breach, in particular with our

partners' operations, results in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and it could result in a material disruption and delay of our drug development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. If our information technology systems or data, or those of third parties upon which we rely, are or were compromised **by a cybersecurity incident**, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences. In the ordinary course of our business, we and the third parties upon which we rely process confidential, proprietary, and sensitive data, and, as a result, we and the third parties upon which we rely face a variety of evolving threats, including but not limited to ransomware attacks, which could cause security incidents. Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our confidential, proprietary, and sensitive data and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our services. We and the third parties upon which we rely are subject to a variety of evolving **cybersecurity** threats, including but not limited to social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of confidential, proprietary, and sensitive data and income, reputational harm, and diversion of funds. **While it is possible that Extortion-extortion** payments may alleviate the negative impact of a ransomware attack, ~~but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting~~ such payments. In addition, our reliance on third-party service providers could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks, and other threats to our business operations. We rely on third-party service providers and technologies to operate critical business systems to process confidential, proprietary, and sensitive data in a variety of contexts, including, without limitation, CROs, CMOs, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. We also rely on third-party service providers to provide other products, services, parts, or otherwise to operate our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised. Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our confidential, proprietary, and sensitive data or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our services. **In the third quarter of 2023, we were notified that a service provider of our third-party service provider had a security breach and certain of our pseudo-anonymized clinical data was exfiltrated. Our incident response assessment was unable to determine a material impact to our Company (including the fact that we have found no personally identifiable information involved, and there is no business continuity risk). However, there is a risk that we discover a material impact in the future.** We may expend significant resources or modify our business activities to try to protect against security incidents. Additionally, certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and confidential, proprietary, and sensitive data. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps **designated** to detect and remediate vulnerabilities, but we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. These vulnerabilities pose material risks to our business. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. Applicable data privacy and security obligations may require us to notify relevant stakeholders, such as governmental authorities, partners, and affected individuals, of security incidents. Such disclosures may involve inconsistent requirements and are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and



/ or oversight; restrictions on processing confidential, proprietary, and sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); **delays in our development or other business plans**; financial loss; and other similar harms. Security incidents and attendant consequences may cause customers to stop using our services, deter new customers from using our services, and negatively impact our ability to grow and operate our business. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that ~~reveals~~ **reveal** competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Our headquarters are located near known earthquake fault zones. We and some of the third-party service providers on which we depend for various support functions are vulnerable to damage from catastrophic events, such as power loss, natural disasters, terrorism and similar unforeseen events beyond our control. Our corporate headquarters and other facilities are located in the San Francisco Bay Area, which in the past has experienced severe earthquakes and fires, ~~and has been affected by the COVID-19 pandemic, including economic disruption resulting from the related shelter-in-place and stay-at-home governmental orders~~. After a comprehensive earthquake risk analysis conducted by Marsh Risk, we decided not to purchase earthquake or flood insurance. Based upon (among other factors) the Marsh Risk analysis, the design and construction of our building, the expected potential loss, and the costs and deductibles associated with earthquake and flood insurance, we chose to self-insure. However, earthquakes or other natural disasters could severely disrupt our operations, or have a larger cost than expected, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, damaged critical infrastructure, or otherwise disrupted operations, all critical systems and services can be accessible from the disaster recovery site, but 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 are in draft and are unlikely to provide adequate protection in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business. Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events, ~~such as the COVID-19 pandemic~~. If such an event were to affect our supply chain, it could have a material adverse effect on our business. Risks Related to Our Common Stock The market price of our common stock may be highly volatile, and you may not be able to resell your shares at or above your purchase price. **The market price of our common stock has at times experienced price volatility and may continue to be volatile. For example, during 2023, the closing price of our common stock on The Nasdaq Global Select Market has ranged from \$ 0.38 per share to \$ 25.18 per share**. In general, pharmaceutical, biotechnology and other life sciences company stocks have been highly volatile in the current market. The volatility of pharmaceutical, biotechnology and other life sciences company stocks is sometimes unrelated to the operating performance of particular companies and biotechnology and life science companies stocks often respond to trends and perceptions rather than financial performance. In particular, the market price of shares of our common stock could be subject to wide fluctuations in response to the following factors: • results of clinical trials of our product candidates, including roxadustat and pamrevlumab; • the timing of the release of results of and regulatory updates regarding our clinical trials; • the level of expenses related to any of our product candidates or clinical development programs; • results of clinical trials of our competitors' products; • safety issues with respect to our product candidates or our competitors' products; • regulatory actions with respect to our product candidates and any approved products or our competitors' products; • fluctuations in our financial condition and operating results, which will be significantly affected by the manner in which we recognize revenue from the achievement of milestones under our collaboration agreements; • adverse developments concerning our collaborations and our manufacturers; • the termination of a collaboration or the inability to establish additional collaborations; • the inability to obtain adequate product supply for any approved drug product or inability to do so at acceptable prices; • disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies; • changes in legislation or other regulatory developments affecting our product candidates or our industry; • fluctuations in the valuation of the biotechnology industry and particular companies perceived by investors to be comparable to us; • speculation in the press or investment community; • announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us; • activities of the government of China, including those related to the pharmaceutical industry as well as industrial policy generally; • performance of other U. S. publicly traded companies with significant operations in China; • changes in market conditions for biopharmaceutical stocks; and • the other factors described in this "Risk Factors" section. As a result of fluctuations caused by these and other factors, comparisons of our operating results across different periods may not be accurate indicators of our future performance. Any fluctuations that we report in the future may differ from the expectations of market analysts and investors, which could cause the price of our common stock to fluctuate significantly. Moreover, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. We are currently subject to such litigation and it has diverted, and could continue to result in diversions of, our management's attention and resources and it could result in significant expense, monetary damages, penalties or injunctive relief against us. For a description of our pending litigation and SEC investigation, see Note ~~10-12~~ **10-12**, Commitments and Contingencies, to the consolidated financial statements. We may engage in acquisitions that could dilute stockholders and harm our business. We may, in the future, make acquisitions of or investments

in companies that we believe have products or capabilities that are a strategic or commercial fit with our present or future product candidates and business or otherwise offer opportunities for us. In connection with these acquisitions or investments, we may: • issue stock that would dilute our existing stockholders' percentage of ownership; • incur debt and assume liabilities; and • incur amortization expenses related to intangible assets or incur large and immediate write-offs. We may not be able to complete acquisitions on favorable terms, if at all. If we do complete an acquisition, we cannot assure you that it will ultimately strengthen our competitive position or that it will be viewed positively by customers, financial markets or investors. Furthermore, future acquisitions could pose numerous additional risks to our operations, including: • problems integrating the purchased business, products or technologies, or employees or other assets of the acquisition target; • increases to our expenses; • disclosed or undisclosed liabilities of the acquired asset or company; • diversion of management's attention from their day-to-day responsibilities; • reprioritization of our development programs and even cessation of development and commercialization of our current product candidates; • harm to our operating results or financial condition; • entrance into markets in which we have limited or no prior experience; and • potential loss of key employees, particularly those of the acquired entity. We may not be able to complete any acquisitions or effectively integrate the operations, products or personnel gained through any such acquisition. Provisions in our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, and may prevent attempts by our stockholders to replace or remove our current directors or management. Provisions in our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may have the effect of discouraging, delaying or preventing a change in control of us or changes in our management. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our Board of Directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors. Among other things, these provisions: • authorize "blank check" preferred stock, which could be issued by our Board of Directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock; • create a classified Board of Directors whose members serve staggered three-year terms; • specify that special meetings of our stockholders can be called only by our Board of Directors pursuant to a resolution adopted by a majority of the total number of directors; • prohibit stockholder action by written consent; • establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our Board of Directors; • provide that our directors may be removed prior to the end of their term only for cause; • provide that vacancies on our Board of Directors may be filled only by a majority of directors then in office, even though less than a quorum; • require a supermajority vote of the holders of our common stock or the majority vote of our Board of Directors to amend our bylaws; and • require a supermajority vote of the holders of our common stock to amend the classification of our Board of Directors into three classes and to amend certain other provisions of our certificate of incorporation. These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our 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. Moreover, because we are incorporated in Delaware, we are governed by certain anti-takeover provisions under Delaware law which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. We are subject to the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Any provision of our amended and restated certificate of incorporation, our amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock. Changes in our tax provision or exposure to additional tax liabilities could adversely affect our earnings and financial condition. As a multinational corporation, we are subject to income taxes in the U. S. and various foreign jurisdictions. Significant judgment is required in determining our global provision for income taxes and other tax liabilities. In the ordinary course of a global business, there are intercompany transactions and calculations where the ultimate tax determination is uncertain. Our income tax returns are subject to audits by tax authorities. Although we regularly assess the likelihood of adverse outcomes resulting from these examinations to determine our tax estimates, a final determination of tax audits or tax disputes could have an adverse effect on our results of operations and financial condition. We are also subject to non-income taxes, such as payroll, withholding, excise, customs and duties, sales, use, value-added, net worth, property, gross receipts, and goods and services taxes in the U. S., state and local, and various foreign jurisdictions. We are subject to audit and assessments by tax authorities with respect to these non-income taxes and the determination of these non-income taxes is subject to varying interpretations arising from the complex nature of tax laws and regulations. Therefore, we may have exposure to additional non-income tax liabilities, which could have an adverse effect on our results of operations and financial condition. The tax regulations in the U. S. and other jurisdictions in which we operate are extremely complex and subject to change. Changes in tax regulations could have an adverse effect on our results of operations and financial condition. Tariffs imposed by the U. S. and those imposed in response by other countries could have a material adverse effect on our business. Changes in U. S. and foreign governments' trade policies have resulted in, and may continue to result in, tariffs on imports into and exports from the U. S. Throughout 2018 and 2019, the U. S. imposed tariffs on imports from several countries, including China. In response, China has proposed and implemented their own tariffs on certain products, which may impact our supply chain and our costs of doing business. If we are impacted by the changing trade relations between the U. S. and China, our business and results of operations may be negatively impacted. Continued diminished trade relations between the U. S. and other countries, including potential reductions in trade

with China and others, as well as the continued escalation of tariffs, could have a material adverse effect on our financial performance and results of operations. Our certificate of incorporation designates courts located in Delaware as the sole forum for certain proceedings, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our amended and restated certificate of incorporation provides that, subject to limited exceptions, the Court of Chancery of the State of Delaware is the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated by-laws, or (4) any other action asserting a claim against us that is governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. While the Delaware courts determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than that designated in the exclusive forum provisions. For example, one of the Derivative Litigation was brought in federal court in California, despite the exclusive forum provision. We are currently moving to dismiss that lawsuit on the basis of improper forum and we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation in any additional litigations that are brought in a venue other than that designated in the exclusive forum provision. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. If a court were to find these provisions of our amended and restated certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition. We do not plan to pay dividends. Capital appreciation will be your sole possible source of gain, which may never occur. You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any cash dividends to holders of our common stock in the foreseeable future and investors seeking cash dividends should not purchase our common stock. We plan to retain any earnings to invest in our product candidates and maintain and expand our operations. Therefore, capital appreciation, or an increase in your stock price, which may never occur, may be the only way to realize any return on your investment. Our business or our share price could be negatively affected as a result of shareholder proposals or actions. Public companies are facing increasing attention from stakeholders relating to environmental, social and governance matters, including corporate governance, executive compensation, environmental stewardship, social responsibility, and diversity and inclusion. Key stakeholders may advocate for enhanced environmental, social and governance disclosures or policies or may request that we make corporate governance changes or engage in certain corporate actions that we believe are not currently in the best interest of FibroGen or our stockholders. Responding to challenges from stockholders, such as proxy contests or media campaigns, could be costly and time consuming and could have an adverse effect on our reputation, which could have an adverse effect on our business and operational results, and could cause the market price of our common stock to decline or experience volatility.