

Risk Factors Comparison 2024-02-22 to 2023-02-23 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 together with all the other information in this Annual Report on Form 10-K, including the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and related notes appearing at the end of this Annual Report on Form 10-K, in evaluating our company. The risks and uncertainties described below and in our other filings with the SEC, may not be the only ones that we face. The occurrence of any of the events or developments described below, if they actually occur, could harm our business, financial condition, results of operations and growth prospects. As a result, the market price of our common stock could decline, and you may lose all or part of your investment in our common stock. Risks related to our financial position and need for additional capital We are a clinical-stage biopharmaceutical company and have incurred significant losses since our inception. We expect to incur losses over at least the next several years and may never achieve or maintain profitability. We are a clinical-stage biopharmaceutical company with limited operating history. Our net loss was \$ **132.5 million and \$ 128.2 million** and ~~\$ 83.9 million~~ for the years ended December 31, **2023 and 2022** and ~~2021~~, respectively. As of December 31, ~~2022~~ **2023**, we had an accumulated deficit of \$ ~~395.528.94~~ **528.94** million. To date, we have not generated any revenue from product sales and have financed our operations primarily through sales of our equity interests, including public offerings of our common stock, proceeds from our collaborations and debt financing. We are still in the early stages of development of our product candidates. As a result, we expect that it will be several years, if ever, before we have a product candidate ready for regulatory approval and commercialization. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. To become and remain profitable, we must succeed in developing, obtaining marketing approval for, and commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including, without limitation, successfully completing preclinical studies and clinical trials of our product candidates, discovering additional product candidates, establishing arrangements with third parties for the conduct of our clinical trials, procuring clinical- and commercial- scale manufacturing, obtaining marketing approval for our product candidates, manufacturing, marketing and selling any products for which we may obtain marketing approval, identifying collaborators to develop product candidates we identify or additional uses of existing product candidates, and successfully completing development of product candidates for our collaboration partners. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We anticipate that our expenses will increase substantially if and as we: • initiate, conduct, and successfully complete first- in- human and later- stage clinical trials of our product candidates and as we expand the scope of our proprietary research and development portfolios; • leverage our TORPEDO platform to identify and then advance additional product candidates into preclinical and clinical development; • expand the capabilities of our TORPEDO platform; • seek marketing approvals for any product candidates that successfully complete clinical trials; • ultimately establish a sales, marketing, and distribution infrastructure and scale up external manufacturing capabilities to commercialize any products for which we expect to obtain marketing approval; • advance, expand, maintain, and protect our intellectual property portfolio; **and • hire-manage staffing needs to meet the changing needs of the business as we advance additional product candidates** ~~personnel, including in areas such as clinical development, regulatory, quality, scientific, and / general and administrative positions; and • add operational, financial and management information systems and personnel, including personnel to support our~~ **or continue to** ~~ongoing research and development~~ **develop existing product candidates** ~~and potential future commercialization efforts~~. Further, we expect to continue to incur additional costs associated with operating as a public company, including significant legal, accounting, insurance, investor relations, and other expenses. Our expenses could increase beyond our expectations if we are required by the FDA, the European Medicines Agency, or other regulatory authorities to perform trials in addition to those that we currently expect, or if we experience any delays in either establishing appropriate manufacturing arrangements for or completing our clinical trials or the clinical development of any of our product candidates. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses we will incur or when, if ever, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue operations. A decline in the value of our company, or in the value of our common stock, could also cause you to lose all or part of your investment. If one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing those approved product candidates. Even if we are able to generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations. We will need substantial additional funding to pursue our business objectives and continue our operations. If we are unable to raise capital when needed, we may be required to delay, limit, reduce, or terminate our research or product development programs or future commercialization efforts. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we prepare for and initiate, conduct, and complete our ongoing and planned first- in- human Phase 1 / 2 clinical trials of our product candidates, advance our TORPEDO platform and continue research and development activities, expand our proprietary research and development portfolios and initiate and continue clinical trials of, and potentially seek marketing approval for, our current and future preclinical programs. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related

to product manufacturing, marketing, sales, and distribution. Further, we expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we may be required to delay, limit, reduce or terminate our research, product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. We had cash, cash equivalents, and marketable securities of approximately \$ 337.281.47 million as of December 31, 2022-2023. We believe that these funds, together with ~~the funds we~~ **future payments expected to be received in early January 2024 from (i) the settlement of shares sold under existing our "at-the-market" offering, (ii) the closing of the sale of shares to an affiliate of Beta Pharma under the previously disclosed stock purchase agreement, and (iii) the upfront payment from Merck under our December 2023 license and collaboration agreements-** ~~agreement, as well as the anticipated cost savings from the restructuring~~ **will be sufficient to fund our existing-planned operating expenses into plan through the end of 2024-2027.** We have based this estimate on assumptions that may prove to be wrong, and we could deplete our current capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including: • the timing, progress, costs, and results of our ongoing and planned first- in- human Phase 1 / 2 clinical trials for our product candidates and any future clinical development of those product candidates; • the scope, progress, costs, and results of our preclinical and clinical development stage programs and our other product candidates and development programs; • the number and development requirements of other product candidates that we pursue; • the success of our ongoing collaborations ~~with Roche, Biogen and Calico, the research terms of which, in the cases of Biogen and Calico, will expire this year;~~ • the costs, timing, and outcomes of regulatory review of our product candidates; • the costs and timing of future commercialization activities, including product manufacturing, marketing, sales, and distribution, for any of our product candidates for which we receive or expect to receive marketing approval; • the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval and the timing of the receipt of any such revenue; • any delays or interruptions, including ~~delays~~ **due to any global health epidemics** ~~the ongoing COVID-19 pandemic,~~ that we experience in our preclinical studies, clinical trials, and / or supply chain; • the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending any intellectual property- related claims; and • our ability to establish collaboration arrangements with other biotechnology or pharmaceutical companies on favorable terms, if at all, for the development or commercialization of our product candidates or access to our TORPEDO platform. Our current cash, cash equivalents, and marketable securities will not be sufficient for us to fund any of our product candidates through regulatory approval. As a result, we will need to raise substantial additional capital to complete the development and commercialization of our product candidates. Identifying potential product candidates and conducting preclinical studies and clinical trials is a time- consuming, expensive and uncertain process that takes years to complete. We may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for several years, if at all. Adequate additional funds may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. We remain early in the development lifecycle, which may make it difficult for you to evaluate the success of our business to date and assess our future viability. We commenced operations in late 2015 and our activities to date have been limited to organizing and staffing our company, business planning, raising capital, conducting discovery and research activities, filing patent applications, identifying potential product candidates, developing and advancing our TORPEDO platform, undertaking preclinical studies, establishing arrangements with third parties for the manufacture of initial quantities of our product candidates, and preparing for and conducting early- stage clinical trials. While we have several ongoing clinical trials, all of our other product candidates are still ~~in preclinical development or~~ **in preclinical development or** in the discovery stage. We have not yet demonstrated our ability to successfully complete any clinical trials, obtain marketing approvals, manufacture a commercial- scale product directly or through a third party or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or if we had already successfully completed some or all of these types of activities in the past. In addition, as a biopharmaceutical company, we may encounter unforeseen expenses, difficulties, complications, delays, and other known and unknown challenges. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities and we may not be successful in making that transition. We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance. ~~The ongoing global COVID-19 pandemic could continue to adversely impact our business, including our discovery programs, preclinical studies and development programs, supply chain, business development activities, and general corporate matters. The ongoing COVID-19 pandemic continues to have impact, both direct and indirect, on businesses and commerce, including ours, as worker shortages have occurred (including within hospitals such as those who conduct our clinical trials), supply chains have been disrupted, facilities and production have been suspended and demand for certain goods and services such as medical services and supplies has spiked. While vaccines are now generally available throughout the world, new COVID-19 variants continue to spread and the impact of existing COVID-19 vaccines remains uncertain. As a result, the future progression of the pandemic, the definition and establishment of a new normal, and its effects on our business and operations continue to remain uncertain and continue to evolve. Government shutdown orders in the U. S. and / or other countries, including localized shutdowns, if put into effect, may impact our discovery programs, preclinical studies and development programs, as well as our supply chain. In addition, any delays in foreign shipments coming into the United States~~

could also impact our preclinical studies, clinical trial plans, or other business operations. We and our contract manufacturing organizations, or CMOs, and contract research organizations, or CROs, may face disruptions that could affect our ability to initiate, conduct, and complete discovery or preclinical research activities, or clinical trials. These disruptions may arise from staffing shortages or difficulties in procuring items that are essential for our research and development activities, including, due to shortages arising in raw materials used in the manufacturing of our product candidates, laboratory supplies for our preclinical studies and clinical trials or animals that are used for discovery and / or preclinical testing. For example, as recently as February 2022, the FDA acknowledged the worldwide shortage of non-human primates and released guidance encouraging sponsors of clinical trials to consider the use of other non-rodent species in their non-clinical toxicity studies. However, this guidance is in effect only for the duration of the public health emergency related to COVID-19, as declared by the Department of Health and Human Services and the FDA has announced that it intends to revise and replace this guidance within sixty days following the termination of the public health emergency. As a result, if we were to elect to use an alternate species for our non-clinical toxicity studies under this guidance, it is possible that we might not be able to initiate and conduct the necessary non-clinical toxicity studies in non-human primates in a timely and cost-effective manner in the future if or when this temporary FDA guidance expires. We and our CROs and CMOs may face disruptions related to our clinical trials arising from potential delays in IND-enabling studies, manufacturing disruptions and / or the ability to obtain necessary institutional review board, or IRB, or other necessary site approvals, as well as other delays at clinical trial sites, including delays related to site staffing and resource limitations. To date, we have experienced delays at certain clinical sites that, due to staffing constraints or other internal policy requirements, have not been able to complete site activation activities or enroll patients in our clinical trial as quickly as likely would have been possible absent the ongoing COVID-19 pandemic. While we were successfully able to raise capital twice during 2020 and once during 2021, the pandemic has caused significant disruptions in the financial markets and may continue to cause these types of disruptions, which could impact our ability to raise additional funds through public offerings and may also contribute to volatility in our stock price and otherwise impact trading in our stock. Moreover, it is possible the pandemic will significantly impact economies worldwide, which could adversely affect our business prospects, financial condition and results of operations. Any significant disruption of global financial markets, reducing our ability to access capital, could negatively affect our liquidity and ability to continue operations. COVID-19 and actions taken to reduce its spread continue to rapidly evolve. The extent to which COVID-19 may impede the development of our product candidates, reduce the productivity of our employees, disrupt our supply chains, delay our preclinical studies or clinical trials, reduce our access to capital or limit our business development activities, will depend on future developments, which are highly uncertain and cannot be predicted with confidence. To the extent the ongoing COVID-19 pandemic adversely affects our business prospects, financial condition and results of operations, it may also have the effect of heightening many of the other risks described in this "Risk Factors" section, such as those relating to the timing and results of our planned and future clinical trials and our financing needs. Our Credit Agreement with Perceptive Credit contains restrictions that limit our flexibility in operating our business. In June 2020, we entered into a credit agreement and guaranty, or the Credit Agreement, with Perceptive Credit Holdings III, LP, which arrangement matures in June 2024. The Credit Agreement provided for a \$ 20.0 million senior secured delayed draw term loan facility, though we only drew down \$ 12.5 million of that amount and our ability to borrow the remaining \$ 7.5 million tranche expired in June 2021. The Credit Agreement is secured by a lien on substantially all of our and our subsidiaries' assets, including, but not limited to, shares of our subsidiaries, our current and future intellectual property, insurance, trade and intercompany receivables, inventory and equipment, and contract rights. The Credit Agreement requires us to meet specified minimum cash requirements, as described below, and contains various affirmative and negative covenants that limit our ability to engage in specified types of transactions. These covenants, which are subject to customary exceptions, limit our ability to, without Perceptive Credit's prior written consent, effect any of the following, among other things: • sell, lease, transfer or otherwise dispose of certain assets; • acquire another company or business or enter into a merger or similar transaction with third parties; • incur additional indebtedness; • make investments; • enter into certain inbound and outbound licenses of intellectual property, subject to certain exceptions; • encumber or permit liens on certain assets; and • pay dividends and make other restricted payments with respect to our common stock. Our board of directors or management team could believe that taking any one of these actions would be in our best interests and the best interests of our stockholders. If that were the case and if we were unable to complete any of these actions because Perceptive Credit does not provide its consent, that could adversely impact our business, financial condition and results of operations. In addition, we are required to deposit into controlled accounts all cash or other payments received in respect of any and all of our accounts receivable or any other contract or right and interest and, at all times, to maintain a minimum aggregate balance of \$ 3.0 million in cash in one or more such controlled accounts. These accounts are required to be maintained as cash collateral accounts securing our obligations under the Credit Agreement. Until our obligations under the Credit Agreement have been discharged, our ability to use the cash amounts held in these controlled accounts in the operation of our business will be limited. In the event of a default under the Credit Agreement, including, among other things, our failure to make any payment when due or our failure to comply with any provision of the Credit Agreement, subject to customary grace periods, Perceptive Credit could elect to declare all amounts outstanding to be immediately due and payable and terminate all commitments to extend further credit. If we are unable to repay the amounts due under the Credit Agreement, Perceptive Credit could proceed against the collateral granted to it to secure this indebtedness, which could have an adverse effect on our business, financial condition and results of operations. Perceptive Credit's interests as a lender may not always be aligned with our interests. If our interests come into conflict with those of Perceptive Credit, including in the event of a default under the Credit Agreement, Perceptive Credit may choose to act in its self-interest. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. Until the time, if ever, when we can generate substantial revenue from product sales, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution

or licensing arrangements. Although we may receive potential future payments under our collaborations with Biogen, Roche and Calico, we do not currently have any committed external source of funds. If we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted and the terms of any securities we may issue in the future may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions, or capital expenditures or declaring dividends. Covenants in the Credit Agreement impose certain limitations and obligations on us, including restrictions on our ability to incur additional debt and to enter into certain business combinations without Perceptive Credit's prior written consent. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. Risks related to the discovery and development of our product candidates Our approach to the discovery and development of product candidates based on our TORPEDO platform for targeted protein degradation is unproven, which makes it difficult to predict the time, cost of development, and likelihood of successfully developing any products. Treating diseases using targeted protein degradation is a new treatment modality. Our future success depends on the successful development of this novel therapeutic approach. Very few small molecule product candidates using targeted protein degradation, such as those developed through our TORPEDO platform, have been tested in humans and none of the product candidates developed through our TORPEDO platform have been approved in the United States or, Europe, or any other jurisdiction. The data underlying the feasibility of developing these types of therapeutic products is both preliminary and limited. If any adverse learnings are made by other developers of targeted protein degraders, there is a risk that development of our product candidates could be materially impacted. Discovery and development of small molecules that harness the ubiquitin proteasome pathway to degrade protein targets have been impeded largely by the complexities and limited understanding of the functions, biochemistry and structural biology of the specific components of the ubiquitin- proteasome system, including E3 ligases and their required accessory proteins involved in target protein ubiquitination, as well as by challenges of engineering compounds that promote protein- to- protein interactions. The scientific research that forms the basis of our efforts to develop our degrader product candidates under our TORPEDO platform is ongoing and the scientific evidence to support the feasibility of developing TORPEDO platform- derived therapeutic treatments is both preliminary and limited. Further, certain cancer patients have shown inherent primary resistance to approved drugs that inhibit disease- causing proteins and other patients have developed acquired secondary resistance to these inhibitors. Although we believe our product candidates may have the ability to degrade the specific mutations that confer resistance to currently marketed inhibitors of disease- causing enzymes, any inherent primary or acquired secondary resistance to our product candidates in patients, or if the scientific research that forms the basis of our efforts proves to be contradicted, would prevent or diminish their clinical benefit, as would be the case if the scientific research that forms the basis of our efforts proves to be contradicted. While we have several ongoing clinical trials, at this time, we have not yet completed a clinical trial of any product candidate. As a result, we are only starting to assess the safety of our lead product candidates in patients and we have not yet assessed the safety of any of our other earlier- stage product candidates in humans. Although some of our earlier- stage product candidates have produced observable results in animal studies, there is a limited safety data set for their effects in animals. In addition, these product candidates may not demonstrate the same chemical and pharmacological properties in humans and may interact with human biological systems in unforeseen, ineffective or harmful ways. As a result, there could be adverse effects from treatment with any of our current or future product candidates that we cannot predict at this time. Additionally, the regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better- known or extensively studied product candidates. Although other companies are also developing therapeutics based on targeted protein degradation, no regulatory authority has granted approval for any therapeutic of this nature at this time. As a result, it is more difficult for us to predict the time and cost of developing our product candidates and we cannot predict whether the application of our TORPEDO platform, or any similar or competitive protein degradation platforms, will result in the development of product candidates that make it through to marketing approval. Any development problems we experience in the future related to our TORPEDO platform or any of our research programs may cause significant delays or unanticipated costs or may prevent the development of a commercially viable product. Any of these factors may prevent us from completing our preclinical studies or any clinical trials that we may initiate, as well as from commercializing any product candidates we may develop on a timely or profitable basis, if at all. We are a clinical stage biotechnology company and, while we have commenced clinical trials of certain of our product candidates and expect to file an IND for CFT8919, all the majority of our other product candidates are still in preclinical development or in the discovery stage. If we are unable to advance to clinical development, develop, obtain regulatory approval for and commercialize our product candidates or experience significant delays in doing so, our business may be materially harmed. We are a clinical- stage biotechnology company and, while we commenced have several ongoing clinical trials of some of our product candidates and expect to file an IND for CFT8919 in the first half of 2023, all the majority of our other product candidates are currently in preclinical development or in the discovery stage. As a result, their risk of failure is high. We have invested substantially all of our efforts and financial resources into building our TORPEDO platform and identifying and conducting preclinical development of our current product candidates, including our lead programs. Our ability to generate revenue from product sales, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. The success of our product candidates will depend on several factors, including the following: • sufficiency of our financial and other resources; • successful initiations and completion of preclinical studies; • successful submission and clearance of INDs and initiation of clinical trials; • successful patient enrollment in, and conduct and completion of, clinical trials; • receipt and related terms of marketing approvals from applicable regulatory authorities; •

obtaining and maintaining patent or trade secret protection and regulatory exclusivity for our product candidates; • making suitable arrangements with third- party manufacturers for both clinical and commercial supplies of our product candidates; • developing product candidates that achieve the therapeutic properties desired and appropriate for their intended indications; • establishing sales, marketing and distribution capabilities, and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others; • acceptance of our products, if and when approved, by patients, the medical community, and third- party payors; • obtaining and maintaining third- party coverage and adequate reimbursement; • establishing a continued acceptable safety profile of our products and maintaining that profile following approval; and • effectively competing with other therapies; and • the skill and success of our third- party collaboration partners in accomplishing any of the aforementioned in the markets in which they are developing our product candidate (s) in a timely manner. If we do not successfully achieve one or more of these factors in a timely manner, or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which could materially harm our business. Moreover, if we do not receive regulatory approvals, we may not be able to continue our operations. We have relatively limited experience as a company in completing preclinical studies to enable the filing of INDs, submitting INDs or commencing, enrolling and conducting clinical trials. Our experience as a company in completing IND- enabling preclinical studies comes from our work in commencing clinical development of ~~three~~ **four** product candidates. ~~In addition, we are planning to submit an IND application for a Phase 1 clinical trial of CFT8919 in EGFR L858R NSCLC in 2023.~~ While this work represents a substantial amount of progress, to date, we still have relatively limited experience as a company in commencing, enrolling and conducting clinical trials. In part because of this, while we continue to make strides in this area, we cannot be certain that our ~~preclinical studies will be completed on time, that we will submit INDs in a timely manner, that any INDs we submit will be cleared by the FDA in a timely manner, if at all, or if our planned clinical trials will begin, enroll or be completed on time, if at all.~~ ~~In addition, while these are our current expectations, we may experience manufacturing delays or other delays with IND- enabling studies, we may determine that additional IND- enabling studies are warranted or we may face delays due to the ongoing COVID- 19 pandemic. Moreover, we cannot be sure that submission of an IND will result in the FDA allowing us to commence clinical trials or that, once begun, issues will not arise that lead to the suspension or termination of our clinical trials.~~ Additionally, even if the applicable regulatory authorities agree with the design and implementation of the clinical trials set forth in our INDs **upon initial IND submission**, we cannot guarantee that those regulatory authorities will not change their requirements in the future. These considerations apply to the INDs described above, **additional INDs that we may submit in the future** and also to new clinical trials we may submit as amendments to existing INDs or as part of new INDs in the future. ~~Any failure to file INDs on the timelines we expect or to obtain regulatory approvals for our clinical trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all.~~ Further, large- scale clinical trials would require significant additional financial and management resources and reliance on third- party clinical investigators, **contract research organizations, or CROs**, and consultants. Relying on third- party clinical investigators, CROs and consultants may cause us to encounter delays that are outside of our control and, for each of the product candidates that is currently in clinical development, we have engaged a CRO to lead our first- in- human Phase 1 / 2 clinical trial. Relying on third parties in the conduct of our preclinical studies or clinical trials exposes us to a risk that they may not adequately adhere to study or trial protocols or comply with good laboratory practice or good clinical practice, or GCP, as required for any studies or trials we plan to submit to a regulatory authority. We may also be unable to identify and contract with sufficient investigators, CROs, and consultants on a timely basis or at all, and we may also determine and have in the past determined after a clinical trial has commenced that a change in CRO is warranted. There can be no assurance that we will be able to negotiate and enter into appropriate contractual arrangements without current or potential future CROs, if and when necessary for our other product candidates, on terms that are acceptable to us on a timely basis or at all. Our preclinical studies and clinical trials may fail to demonstrate adequately the safety and efficacy of any of our product candidates, which would prevent or delay development, regulatory approval, and commercialization. Further, the results of preclinical studies may not be predictive of future results in later studies or trials and initial success in clinical trials may not be indicative of results obtained when these trials are completed or in later stage clinical trials. Before obtaining regulatory approval for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex, and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. ~~This Preclinical and clinical testing is expensive and can take many years to complete. Further, the outcome of these activities is inherently uncertain. Failure can occur at any time during the preclinical study and clinical trial development processes.~~ **process** and, because many of our product candidates are in an early stage of development and have never been tested in humans, there is a high risk of failure. In addition, because targeted protein degraders are a relatively new class of product candidates, any failures or adverse outcomes in preclinical or clinical testing seen by other developers in this class could materially impact the success of our programs. We may never succeed in developing marketable products. It is also possible that the results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later- stage clinical trials. Preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Although product candidates may demonstrate promising results in preclinical studies and early clinical trials, they may not prove to be effective or safe in subsequent clinical trials. The results of the dose escalation portion of our ongoing and planned first- in- human Phase 1 / 2 clinical trials of our product candidates may not be predictive of the results of further clinical trials of these product candidates or any ~~of our~~ other product candidates and may not be sufficient to enable us to progress to the Phase 2 portion of a Phase 1 / 2 clinical trial. Testing on animals occurs under different conditions than testing in humans and, therefore, the results of animal studies may not accurately predict human experience. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through preclinical studies and clinical trials. Product candidates in later stages of

clinical trials may fail to show the desired safety and efficacy profile despite having progressed successfully through preclinical studies and / or initial clinical trials. Likewise, early, smaller- scale clinical trials may not be predictive of eventual safety or effectiveness in large- scale pivotal clinical trials. **In particular, the small number of patients in our planned early clinical trials of the designs of these trials may make the results of these trials less predictive of the outcome of later clinical trials.** Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy, insufficient durability of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence preclinical studies and clinical trials are never approved as **marketable** products. Any setbacks of this nature in our clinical development could materially harm our business, financial condition, results of operations and prospects. ~~Further, initial success in our clinical trials may not be indicative of results obtained when those trials are completed or in any later stage clinical trials we may conduct. In particular, the small number of patients in our planned early clinical trials or the designs of these trials may make the results of these trials less predictive of the outcome of later clinical trials.~~ Additionally, we expect that the first clinical trials for our product candidates will be open- label studies, where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. This is the case with our ongoing first- in- human clinical trials and will be the case in the first- in- human clinical trials of the additional product candidates we presently expect to advance into clinical development. **Most typically, open-Open** - label clinical trials **often** test only the investigational product ~~candidate~~ and sometimes do so at different dose levels. Open- label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open- label clinical trials are aware when they are receiving treatment. In addition, open- label clinical trials may be subject to an “ investigator bias ” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. Any preclinical studies or clinical trials that we may conduct **or have conducted** may not demonstrate the safety and efficacy necessary to obtain regulatory approval to market our product candidates. If the results of our ongoing or future preclinical studies or clinical trials are inconclusive with respect to the safety and efficacy of our product candidates, **if evidence of target degradation does not correlate with clinical efficacy**, if we do not meet the clinical endpoints with statistical and clinically meaningful significance or if there are safety concerns associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for those product candidates. In some instances, there can be significant variability in safety or efficacy results between different preclinical studies and clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. While we have commenced ~~a clinical trial trials of each several~~ of our ~~three most advanced~~ product candidates, **and have plans to do the same some of which remain ongoing** for our fourth product candidate, CFT8919, we have not yet initiated clinical trials for any of our other product candidates. As is the case with all drugs, it is likely that there may be side effects associated with the use of our product candidates related to on- target toxicity, off- target toxicity, or other mechanisms of drug toxicity including chemical- based toxicity. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects of this nature. If unacceptable levels of toxicity are observed or if our product candidates have other characteristics that are unexpected, we may need to abandon their development, modify our development plans as to dose level and / or dose schedule or otherwise, or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk- benefit perspective. For example, due to observed safety signals, we previously modified the dosing schedule in our ongoing Phase 1 / 2 clinical trial of CFT7455 as we continue to advance this clinical trial. Further, if we were to observe unacceptable levels of side effects, or if other developers of similar targeted protein degraders were to find an unacceptable severity or prevalence of side effects with their drug candidates, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Drug- related side effects could also affect patient recruitment or the ability of enrolled patients to complete an ongoing trial or result in potential product liability claims. Many compounds that initially showed promise in early- stage testing for treating cancer have later been found to cause side effects that prevented further development of the compound. Any of these occurrences may significantly harm our business, financial condition, and prospects. The conclusions and analysis drawn from announced or published interim top- line and preliminary data from our clinical trials from time to time may change as more patient data become available. Further, all interim data that we provide remains subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publish interim **or** top- line ~~or~~ preliminary data from our clinical trials. Interim data from clinical trials that we may conduct are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. In addition, preliminary or top- line data also **remain remains** subject to audit and verification procedures that may result in the final data being different, potentially in material ways, from the preliminary data we previously announced or published. As a result, interim and preliminary data should be viewed with caution until final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our reputation, business, financial condition, results of operations and prospects. Drug development is a lengthy and expensive process with an uncertain outcome. We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates. While we have commenced clinical trials of **several** our ~~three most advanced~~ product candidates ~~and expect~~, **one of which we elected to file shut down, an and IND for our fourth product candidate, anticipate the commencement of a clinical trial of CFT8919 through our partner Betta Pharma**, in the first half of 2023, all of our other product candidates are still ~~in preclinical development or in the discovery stage at this time and the risk of failure for all of our product candidates remains high. We are unable to predict when or if any of our product candidates will prove effective or safe in humans or will receive marketing~~

approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. ~~Before we can commence clinical trials for a product candidate, we must complete extensive preclinical studies that support our planned INDs in the United States or similar applications in other jurisdictions. We cannot be certain of the timely initiation, completion or outcome of our preclinical studies and, other than in the cases of our three most advanced product candidates where the FDA has cleared the IND for our first-in-human studies of the drug candidate, we cannot predict if the FDA or similar regulatory authorities outside the United States will allow us to commence our proposed clinical trials or if the outcome of our preclinical studies ultimately will support the further development of any of our product candidates.~~ Clinical testing is expensive, difficult to design and implement, can take many years to enroll and complete and is uncertain as to the timing and outcome. A failure of one or more clinical trials can occur at any stage of the process. We may experience numerous unforeseen events during or as a result of clinical trials, which could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- delays in reaching, or the failure to reach, a consensus with regulators on clinical trial design or the inability to produce acceptable preclinical results to enable entry into human clinical trials;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate, including as a result of delays in the testing, validation, manufacturing and delivery of product candidates to the clinical sites by us or by third parties with whom we have contracted to perform certain of those functions;
- delays in reaching, or the failure to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites or CROs;
- the failure of regulators or **institutional review boards, or IRBs**, to authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- difficulty in designing clinical trials and in selecting endpoints for diseases that have not been well studied and for which the natural history and course of the disease is poorly understood;
- the selection of certain clinical endpoints that may require prolonged periods of clinical observation or analysis of the resulting data;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate or fail to return for post-treatment follow-up or we may be unable to recruit suitable patients to participate in our clinical trials;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs to suspend or terminate our clinical trials;
- we may have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- the third parties with whom we contract may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- the requirement from regulators or IRBs that we or our investigators suspend or terminate clinical trials for various reasons, including noncompliance with regulatory requirements or unacceptable safety risks;
- clinical trials of our product candidates may produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional clinical trials, modify our development plans as to dose level and ~~pr or~~ dose schedule or otherwise, or abandon product development programs;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- staffing shortages, including but not limited to the lack of appropriately trained or experienced clinical research associates or medical staff at the institutions where we conduct our clinical trials or the lack of sufficient support personnel at these institutions involved in site contracting and activation, may cause delays or create other challenges to the timely and efficient conduct of our clinical trials;
- imposition of a clinical hold by regulatory authorities as a result of a serious adverse event, concerns with a class of product candidates or after an inspection of our clinical trial operations, trial sites or manufacturing facilities;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits; and
- disruptions caused by **any global health epidemics, such as the recent continuing spread and effects of the ongoing COVID-19 pandemic, which** may increase the likelihood that we encounter these types of difficulties or cause other delays in initiating, enrolling, conducting, ~~or completing our planned clinical trials.~~ We also may encounter challenges **in our clinical development programs** due to evolving regulatory policy **in the United States or other jurisdictions**. For example, **in 2021**, the FDA's Oncology Center of Excellence launched Project Optimus, an initiative ~~by~~ to reform dose selection in oncology drug development, ~~in 2021 and~~ **this initiative** is still being implemented. If the FDA believes we have not sufficiently established that the selected dose or doses for our product candidates maximize efficacy as well as safety and tolerability, the FDA may require us to conduct additional clinical trials or generate additional dosing-related information, which could significantly delay and / or increase the expense of our clinical development programs. If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully enroll or complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns related to our product candidates, we may:
- be delayed in obtaining marketing approval for our product candidates, if at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be required to perform additional clinical trials to support marketing approval;
- have regulatory authorities withdraw or suspend their approval, or impose restrictions on distribution of a product candidate in the form of a risk evaluation and mitigation strategy, or REMS;
- be subject to additional post-marketing testing requirements or changes in the way the product is administered; or
- have our product removed from the market after obtaining marketing approval.

Our product development costs also will increase if we experience delays in preclinical studies or clinical trials or in obtaining marketing approvals. While we have commenced clinical trials of **several** our three most advanced product candidates and **anticipate the commencement of a clinical trial of** ~~expect to file an IND for our fourth product candidate, CFT8919~~ **through our partner Beta Pharma** ~~in the first half of 2023~~, we do not know whether any of our other ~~preclinical studies or~~ clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant ~~preclinical study or~~ clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or

could allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates, which may harm our business, results of operations, financial condition and prospects. Further, cancer therapies sometimes are characterized as first- line, second- line or third- line. The FDA often approves new oncology therapies initially only for third- line or later use, meaning for use after two or more other treatments have failed. When cancer is detected early enough, first- line therapy, usually systemic anti- cancer therapy (e. g., chemotherapy), surgery, radiation therapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second- line and third- line therapies are administered to patients when prior therapy has been shown to not be effective. Our ongoing and planned early- stage clinical trials will be with patients who have received one or more prior treatments and we expect that we would initially seek regulatory approval of our lead product candidates as second- line or third- line therapy. Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval potentially as a first- line therapy, but any product candidates we develop, even if approved for second- line or third- line therapy, may not be approved for first- line therapy and, prior to seeking and / or receiving any approvals for first- line therapy, we may have to conduct additional clinical trials. Targeted protein degradation is a novel modality that continues to attract substantial interest from existing and emerging biotechnology and pharmaceutical companies. As a result, we face substantial competition, which may result in others discovering, developing or commercializing products for the same indication and / or patient population before or more successfully than we do. The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face, and will continue to face, competition from third parties that use protein degradation, antibody therapy, inhibitory nucleic acid, immunotherapy, gene editing, or gene therapy development platforms and from companies focused on more traditional therapeutic modalities, such as small molecule inhibitors. The competition we face and will face is likely to come from multiple sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, government agencies and public and private research institutions. Targeted protein degradation is an emerging therapeutic modality that has the potential to deliver therapies that improve outcomes for patients. As a result, a number of biotechnology and pharmaceutical companies are already working to develop degradation- based therapies and the number of companies entering this space continues to increase. We are aware of several biotechnology companies developing product candidates based on chimeric small molecules for targeted protein degradation including Arvinas, Inc., Astellas Pharma Inc., BioTheryX, Inc., Captor Therapeutics, Inc., Cullgen Inc., Foghorn Therapeutics, Inc., Frontier Medicines Corporation, Haisco Pharmaceutical Group **Glubio Therapeutics, Inc.**, Kymera Therapeutics, Inc., Monte Rosa Therapeutics, Inc., Nurix Therapeutics, Inc., **Orum Therapeutics, Inc.**, PhoreMost, Ltd., Plexium, Inc., **Proteovant Therapeutics, Inc.**, Saliarius Pharmaceuticals, Inc., Seed Therapeutics, Inc., **SK Life Science Labs., Ltd. (a subsidiary of SK Biopharmaceuticals)**, and Vividion Therapeutics, Inc. (a subsidiary of Bayer AG). Further, several large pharmaceutical companies and academic institutions have disclosed investments and research in this field including Amgen, AstraZeneca plc, Bristol- Myers Squibb Company (and its subsidiary Celgene Corporation), GlaxoSmithKline plc, Genentech, Inc., and Novartis International AG. In addition to competition from other protein degradation therapies, any products that we develop may also face competition from other types of therapies, such as small molecule, antibody, T cell or gene therapies. ~~For example, we understand that Adaptimmune Limited, Foghorn Therapeutics, Inc. and GlaxoSmithKline plc are pursuing the development of therapies for patients with synovial sarcoma.~~ Many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our product candidates. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors, the scale of which could be difficult to compete against. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any product candidate that we may develop. Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third- party payors seeking to encourage the use of generic products. There are generic products currently on the market for certain of the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years. If our product candidates are approved, we expect that they will be priced at a significant premium over competitive generic products. Our ability to use our net operating loss carryforwards and research and development tax credit carryforwards may be limited. As of December 31, ~~2022~~ **2023**, we had \$ ~~171.214~~ **6.9** million federal net operating loss carryforwards and \$ ~~273.315~~ **6.3** million gross in U. S. state net operating loss carryforwards, portions of which expire at various dates through ~~2041~~ **2043**. Under current law, federal net operating losses generated in tax years beginning after 2017, if any, will not expire and may be carried forward indefinitely, but our ability to deduct such federal net operating losses in tax years beginning after December 31, 2020 will be limited to the lesser of the net operating loss carryover or 80 % of the corporation' s adjusted taxable income (subject to Section 382 of the Internal Revenue Code of 1986, as amended). ~~The Coronavirus Aid, Relief, Economic Security Act, or CARES Act, temporarily allows us to carryback net operating losses arising in 2018, 2019 and 2020 to the five prior years.~~ It is uncertain ~~how~~ **if and to what extent** various states will ~~respond~~ **conform** to the ~~CARES Act or any newly enacted~~ federal tax ~~law~~ **laws**. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As of December 31, ~~2022~~ **2023**, we also

had U. S. federal and state research and development tax credit carryforwards of \$ 9.12. +6 million and \$ 5.2 -9-million, respectively, which expire at various dates through 2041-2043. These tax credit carryforwards could expire unused and be unavailable to offset our future income tax liabilities. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if a corporation undergoes an “ ownership change, ” which is generally defined as a greater than 50 % change, by value, in its equity ownership over a three- year period, the corporation’ s ability to use its pre- change net operating loss carryforwards and other pre- change tax attributes to offset its post- change income or taxes may be limited. In 2021, we completed a study of ownership changes from inception through December 31, 2020, which concluded that we experienced ownership changes as defined by Section 382 of the Code. However, there were no net operating loss carryforwards that were limited or expired unused. We have not updated the study to assess whether a change of ownership has occurred during 2022 and through 2023. We may have experienced additional ownership changes that have not been identified that could result in the expiration of our net operating loss and tax credit carryforwards before utilization and we may experience subsequent shifts in our stock ownership, some of which are outside our control. As a result, if we earn net taxable income and determine that an ownership change has occurred and our ability to use our historical net operating loss and tax credit carryforwards is materially limited, that will harm our future operating results by effectively increasing our future tax obligations. If serious adverse events, undesirable side effects or unexpected characteristics or results are identified during the development of any product candidates we may develop, we may need to modify, abandon, or limit our further clinical development of those product candidates. While we have commenced clinical trials of several of our most advanced product candidates, and expect to expect to file an IND for our fourth product candidate, anticipate the commencement of a clinical trial of CFT8919 through our partner Betta Pharma, in the first half of 2023, all of our other product candidates are still in the preclinical or discovery stages stage at this time, which means that we have not yet evaluated any of our other product candidates in human clinical trials. It is impossible to predict when or if any product candidates we may develop will prove safe in humans. There can be no assurance that any of the product candidates developed through our TORPEDO platform will not cause undesirable side effects, which could arise at any time during preclinical or clinical development. A potential risk with product candidates developed through our TORPEDO platform, or in any protein degradation product candidate, is that healthy proteins or proteins not targeted for degradation will be degraded or that the degradation of the targeted protein in and of itself could cause adverse events, undesirable side effects or unexpected characteristics or results. There is also the potential risk of delayed adverse events following treatment using product candidates developed through our TORPEDO platform. If any product candidates we develop are associated with serious adverse events or undesirable side effects or have other characteristics or results that are unexpected, we may choose or need to abandon their development, modify our development plans as to dose level and / or dose schedule of or otherwise, or limit development to certain uses or subpopulations in which the adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk- benefit perspective. The occurrence of any of these types of events would have an adverse effect on our business, financial condition, results of operations, and prospects. Many product candidates that initially showed promise in early- stage testing for treating cancer or other diseases have later been found to cause side effects that prevented further clinical development of the product candidates or limited their competitiveness in the market. For example, single agent BRAF inhibitors can cause a secondary malignancy called keratocanthoma, which is a skin cancer caused by paradoxical activation of BRAF upon inhibitor binding. If we experience delays or difficulties in the enrollment of patients in our clinical trials, our timelines for submitting applications for and receiving necessary marketing approvals could be delayed, or we may be prevented from obtaining marketing approvals altogether. We may not be able to initiate clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials, as required by the FDA or similar regulatory authorities outside of the United States. We have progressed our three most advanced product candidates, CFT7455, CFT8634, and CFT1946, into first- in- human clinical trials in June 2021, May 2021-2022, and December 2022, respectively. In addition, we are planning to file with clinical trials currently ongoing for CFT7455 and IND CFT1946 and planned for CFT8919 during the first half of 2023, after which we plan to initiate a first- in- human Phase 1 /2 clinical trial for that program. While we believe that we will be able to enroll a sufficient number of patients into each of these our ongoing and planned clinical trials, we cannot predict with certainty how difficult it will be to enroll patients for trials, some of which are in rare indications, either generally or specifically during the ongoing COVID- 19 pandemic. Our ability to identify and enroll eligible patients for clinical trials of our product candidates may turn out to be limited or we may be slower in enrolling these trials than we anticipate. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates and, as a result, patients who would be eligible for our clinical trials may instead elect to enroll in clinical trials of our competitors’ product candidates. Patient enrollment in clinical trials is also affected by other factors including: • the severity of the disease under investigation; • the eligibility criteria for the trial in question; • the perceived risks and benefits of the product candidates offered in the clinical trials; • the efforts to facilitate timely enrollment in clinical trials; • the patient referral practices of physicians; • the availability of suitable and sufficient staffing at clinical trial sites; • the burden on patients due to the scope and invasiveness of required procedures under clinical trial protocols, some of which may be inconvenient and / or uncomfortable; • the ability to monitor patients adequately during and after treatment; • the proximity and availability of clinical trial sites for prospective patients; and • the impact of any global health epidemics, such as the ongoing recent COVID- 19 pandemic, which may affect the conduct of a clinical trial, including by slowing potential enrollment or reducing the number of eligible patients for clinical trials or by interfering with patients’ ability to return to the clinical trial site for required monitoring, procedures, or follow- up. Our inability to enroll a sufficient number of patients for our planned clinical trials, or our inability to do so on a timely basis, would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may also result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our

ability to obtain additional financing. We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. We **or our partners** may develop our product candidates in combination with other drugs. If the FDA or similar regulatory authorities outside of the United States do not approve these other drugs, revoke their approval of these other drugs or if safety, efficacy, manufacturing or supply issues arise with the drugs we choose to evaluate in combination with our product candidates, we may be unable to obtain approval of or market our product candidates. Based on the study design for a number of our product candidates, once a recommended dose is identified from the dose escalation portion of our first-in-human Phase 1 / 2 clinical trial, we often plan to conduct a portion of that clinical trial in combination with one or more other medicines. We did not develop or obtain marketing approval for, nor do we manufacture or sell, any of the currently approved drugs that we may study in combination with our product candidates. If the FDA or similar regulatory authorities outside of the United States revoke their approval of the drug or drugs we intend to deliver in combination with our product candidates, we will not be able to market our product candidates in combination with those revoked drugs. If safety or efficacy issues arise with any of these drugs, we could experience significant regulatory delays and the FDA or similar regulatory authorities outside of the United States may require us to redesign or terminate certain of our clinical trials. If the drugs we use are replaced as the standard of care for the indications we choose for our product candidates, the FDA or similar regulatory authorities outside of the United States may require us to conduct additional clinical trials. In addition, if manufacturing or other issues result in a shortage of supply of the drugs with which we determine to combine with our product candidates, we may not be able to complete clinical development of our product candidates on our current timeline or at all. Even if our product candidates were to receive marketing approval or be commercialized for use in combination with other existing drugs, we would continue to be subject to the risks that the FDA or similar regulatory authorities outside of the United States could revoke approval of the drugs used in combination with our product candidates or that safety, efficacy, manufacturing or supply issues could arise with these existing drugs. Combination therapies are commonly used for the treatment of cancer and we would be subject to similar risks if we were to elect to develop any of our other product candidates for use in combination with other drugs or for indications other than cancer. This could result in our own products being removed from the market or being less successful commercially. We may not be successful in our efforts to identify or discover additional potential product candidates. While our **four most advanced-current clinical stage** programs are focused on oncology targets, a key element of our strategy is to apply our TORPEDO platform to develop product candidates that address a broad array of targets and new therapeutic areas, such as neurodegeneration, diseases of aging and infectious disease. The therapeutic discovery activities that we are conducting may not be successful in identifying product candidates that are useful in treating cancer or other diseases. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including: • potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be drugs that will receive marketing approval or achieve market acceptance; • potential product candidates may not be effective in treating their targeted diseases; or • the market size for the target indications of a potential product candidate may diminish over time due to improvements in the standard of care to the point that further development is not warranted. Research programs to identify new product candidates require substantial technical, financial and human resources. We may choose to focus our efforts and resources on a potential product candidate that ultimately proves to be unsuccessful. If we are unable to identify suitable product candidates for preclinical and clinical development, we will not be able to obtain revenues from sale of products in future periods, which likely would result in significant harm to our financial position and adversely impact our stock price. If we do not achieve our projected development goals in the timeframes we announce and expect, the commercialization of our products may be delayed and, as a result, our stock price may decline. From time to time, we may estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory, and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of preclinical studies and clinical trials and the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. Each of these milestones is and will be based on numerous assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, or at all, our revenue may be lower than expected or the commercialization of our products may be delayed or never achieved and, as a result, our stock price may decline. Risks related to dependence on third parties We expect to rely on third parties to conduct our future clinical trials and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials. We currently rely on CROs to conduct our clinical trials, as we currently do not plan to independently conduct clinical trials of any of our product candidates. Additionally, we must contract with third-party research sites for the conduct of our clinical trials. **Just as we rely on Betta Pharma to develop CFT8919 in Greater China in an efficient and effective manner, we may also similarly rely on other third party collaboration partners in the future to develop one or more of our products in various territories on certain timelines.** Our agreements with these CROs **and, sites, and other third parties** might terminate for a variety of reasons, including a failure to perform by the third parties. If we were ever to need to enter into alternative

arrangements, or if we were to need to change a CRO for an ongoing clinical trial, which we have done in the past, we might experience delays in our clinical development activities. Our reliance on CROs for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities for how these activities are performed. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols in the applicable IND. Moreover, the FDA requires compliance with standards, commonly referred to as GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, safety, and confidentiality of trial participants are protected. GCP compliance extends not only to sponsors of clinical research but also to third parties including CROs and sites involved in the conduct of clinical research. **Similarly, other regulators throughout the world require compliance with similar standards that are also applicable to clinical trial sponsors and other third parties like CROs and clinical trial sites.** Further, these CROs or sites may have relationships with other entities, some of which may be our peers or competitors. If the CROs or sites with whom we work do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. Manufacturing pharmaceutical products is complex and subject to product delays or loss for a variety of reasons. We contract with third parties for the manufacture of our product candidates for preclinical testing and clinical trials and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or that we will not have the quantities we desire or require at an acceptable cost or quality or at the right time, which could delay, prevent, or impair our development or commercialization efforts. We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely on and expect to continue to rely on CMOs for both drug substance and finished drug product. This reliance on third parties may increase the risk that we will not have sufficient quantities of our product candidates or products or that we will not have the quantities we desire or require at an acceptable cost or quality, which could delay, prevent, or impair our development or commercialization efforts, including where a pre-approval inspection or an inspection of manufacturing sites is required and ~~due to the ongoing COVID-19 pandemic and travel restrictions, if still then in effect,~~ FDA is unable to complete those required inspections during the review period **for any reason.** We may be unable to establish agreements with CMOs or to do so on acceptable terms. Even if we are able to establish agreements with CMOs, reliance on third-party manufacturers entails additional risks, including: • reliance on the third party for regulatory, compliance, quality assurance, and manufacturing success; • the possible breach of the manufacturing agreement by the third-party CMO; • the possible risk that the CMO will cease offering the services we require or shut down operations altogether, either temporarily or permanently, due to a regulatory concern, financial insolvency, non-compliance with applicable law or another reason; • the possible misappropriation of our proprietary information, including our trade secrets and know-how; and • the possible termination or non-renewal of the agreement by the third party at a time that is costly or inconvenient for us or the inability of the CMO to provide us with a manufacturing slot when we need it. We have only limited technology transfer agreements in place with respect to our product candidates and these existing arrangements do not extend to commercial supply. We acquire many key materials on a purchase order basis. As a result, we do not have long-term committed arrangements with respect to our product candidates and other materials. If we anticipate receiving or receive marketing approval for any of our product candidates, we will need to establish or have established an agreement for commercial manufacture with one or more third parties. Third-party manufacturers may not be able to comply with current good manufacturing practices, or cGMP, regulations or similar regulatory requirements outside of the United States. Some of our molecules are highly potent and, in the absence of additional safety data, they receive a high occupational exposure band, or OEB. These assigned OEBs dictate the containment and other precautions that must be taken as part of the manufacture of our product candidates and, for molecules with high OEB designations, serve to limit the number of CMOs who are qualified to manufacture our molecules. Our failure, or the failure of our CMOs, to comply with applicable regulations, including the ability of our CMOs to work with our highly potent materials and the safety protocols in connection therewith, could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. As a result, we may not obtain access to these facilities on a priority basis or at all. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us, particularly, in some cases, given the potency or OEB of our compounds. Any performance failure or delay in performance on the part of our existing or future manufacturers could delay clinical development or marketing authorization. For example, in the past, a CMO with whom we work had a mechanical issue arise in connection with a manufacturing step for a manufacturing run for our CFT7455 product candidate. While this issue did not ultimately delay the timing of submission of our IND for CFT7455, in the future, we could experience a manufacturing issue that would have a material impact on development of our product candidates and the occurrence of an event of this nature would largely be outside of our control. We do not currently have arrangements in place for redundant supply or a second source for drug substance or drug product. If our current CMOs cannot perform as agreed, we may be required to replace them. ~~Although~~ **While** we ~~have identified~~ believe that there are several potential alternative manufacturers ~~vendors~~ who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any replacement manufacturers or we may not be able to reach agreement with any alternative manufacturer. ~~While we have identified alternate vendors for some~~ **or all** of the manufacturing work related to certain of our product candidates, switching vendors could result in significant additional costs of materials and significant delays to our operations **as we select and qualify a replacement manufacturer,** we may be constrained in the vendors we can select, particularly for compounds

that have high OEB designations, **or we may not be able to reach agreement with an alternative manufacturer on acceptable terms**. Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis. Additionally, we currently rely on single source suppliers for a portion of our supply chain for our preclinical and clinical trial supplies. If our current or future suppliers, whether for raw materials, drug substance, or drug product, are unable to supply us with sufficient materials for our preclinical studies and clinical trials, we may experience delays in our development efforts as we locate and qualify new suppliers or manufacturers. The third-party manufacturers on whom we rely may incorporate their own proprietary processes into our product candidate manufacturing processes. We have limited control and oversight of a third party's proprietary manufacturing processes. If a third-party manufacturer were to modify its processes, those modifications could negatively impact our manufacturing, including product loss or failure that requires additional manufacturing runs or a change in manufacturer, both of which could significantly increase the cost of and significantly delay the manufacture of our product candidates. As our product candidates progress through preclinical studies and clinical trials towards approval and commercialization, we expect that various aspects of the product development and manufacturing process will evolve in an effort to optimize processes and results. Some of those product and manufacturing process changes may involve the use of third-party proprietary technology, which could then cause us to need to obtain a license from third parties. In addition, these types of changes may require that we make amendments to our regulatory applications, which could further delay the timeframes under which modified manufacturing processes can be used for any of our product candidates. In addition, as we advance our product candidates into later stage clinical trials and plan for the potential commercialization of our product candidates, we may determine that it is necessary or appropriate to bring on additional suppliers of drug product and / or drug substance, which could result in changes to the manufacturing processes for our product candidates and may require us to provide additional information to regulatory authorities. If we were to bring on additional CMOs for our product candidates, we may also be required to demonstrate analytical comparability and / or conduct additional bridging studies or trials, all of which would require additional time and expense. We have existing collaborations with third parties under which we are engaged in the research, development and commercialization of certain product candidates. If any of these collaborations are not successful, we may not be able to capitalize on the market potential of those product candidates. In addition, these collaborations could impact our intellectual property rights. **Previously As of December 31, 2023, we have four ongoing entered into the following collaborations, which involve involving** our research programs: • a collaboration agreement with Roche **that we entered into** in December 2015, which we amended and restated in December 2018 and further amended in November 2020 and updated **periodically thereafter, with collaboration activities ongoing** as to ~~included two~~ targets in November 2021; • a collaboration agreement with Calico **that we entered into** in March 2017, which was extended in respect of one program in September 2021 and ~~which will expire as to~~ the research term **of which expired** in March 2023; ~~and~~ • a collaboration agreement with Biogen **that we entered into** in December 2018, which was amended in February 2020 and will expire as to, **with certain research activities on the nominated targets continuing for a period of time beyond the end of** the research term in June 2023, **as contemplated by the Biogen Agreement; and** • **a collaboration agreement with Merck that we entered into in December 2023, for the development and commercialization of degrader-antibody conjugates, or DACs, with respect to one initial target, with the option for Merck to add up to three additional targets over a stated period of time**. Under these collaboration agreements, we are generally responsible for developing drug candidates leveraging our TORPEDO platform based on partner-selected targets. Further, these agreements provide that our collaboration partners have exclusive rights to develop degraders for their selected and reserved targets. As a result, we are not permitted to pursue a target of potential interest – either alone or with another partner – while that target is bound by these restrictions. Further, if our collaborations do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us or elects not to pursue a program within a collaboration, we may not receive any future research funding or milestone or royalty payments under that collaboration or in respect of that terminated program. If that were to happen, we might decide to abandon the program or to move the program forward on our own, which would require us to devote additional resources to the program on a going-forward basis. In addition, if one of our collaborators terminates its agreement with us generally, which they are permitted to do for convenience with between 90 and 270 days' notice, or with respect to a specific target or in connection with a material breach of the agreement by us that remains uncured for a specified period of time, we may find it more difficult to attract new collaborators and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, marketing approval and commercialization described in this report apply to the activities of our collaborators. It is also possible that our collaborators may not properly obtain, maintain, enforce, or defend the intellectual property or proprietary rights arising out of our licensed programs or may use our proprietary information in a way that could jeopardize or invalidate our proprietary information or expose us to potential litigation. For example, Roche, Biogen ~~and~~, Calico, ~~and Merck~~ have the first right to enforce, ~~and Roche also has the first right to defend~~, certain intellectual property rights under the applicable collaboration arrangement with respect to particular licensed programs and, although we may have the right to assume the enforcement and defense of these intellectual property rights if our collaborator does not, our ability to do so may be compromised by their actions. In addition, if any licensed program were later to revert to us, our ability to protect any intellectual property or other proprietary rights associated with that program would be impacted by the intellectual property filings made or other steps taken by our collaborator prior to program reversion. Further, our collaborators may own or co-own intellectual property covering our products that results from our collaborating with them and, in cases where that applies, we would not have the exclusive right to commercialize the collaboration intellectual property. We may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future and we may not realize the benefits of those collaborations, alliances, or licensing arrangements. ~~We may~~ **In May 2023, we entered into the Betta Pharma License**

Agreement with Betta Pharma under which we are collaborating on the development and commercialization of CFT8919 in Greater China, while retaining rights to develop and commercialize CFT8919 in the rest of the world. Similarly, in the future, **we may** form or seek strategic alliances, create joint ventures, or **other** collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Our likely collaborators in any other collaboration arrangements we may enter into include large and mid- size pharmaceutical companies and biotechnology companies. However, it is possible that we will not be able to enter into a collaboration agreement of this nature or that the terms of any potential new collaboration arrangement may not be favorable. For example, we may seek to enter into collaboration arrangements to advance our CFT7455 product candidate in MM or other indications or we may form or seek to form collaboration arrangements to enable our development and commercialization of a product candidate in a specified geographic area, **as we have done in the case of CFT8919 and our collaboration with Betta Pharma**. In addition, **as we did in our collaboration agreement with Merck**, we may seek to enter into collaboration ~~arrangements~~ **agreements** that enable other companies to access and leverage our TORPEDO platform to develop medicines directed at targets selected by our collaboration partners. Any of these relationships may require us to incur non- recurring and other charges, increase our near and long- term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process for these sorts of transactions is time- consuming, complex, and expensive. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy and obtain marketing approval. Additionally, our existing partners may decide to acquire or partner with other companies developing targeted protein degraders or directed at the targets or indications to which our product candidates are directed, which may have an adverse impact on our business prospects, financial condition and results of operations. As a result, if we enter into additional collaboration agreements and strategic partnerships or license our product candidates, we may not be able to realize the benefit of those transactions if we are unable to successfully integrate them with our existing operations and company culture. Risks related to the commercialization of our product candidates Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third- party payors, and others in the medical community necessary for commercial success. If any of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third- party payors, and others in the medical community. For example, current cancer treatments, such as chemotherapy and radiation therapy, are well- established in the medical community and doctors may continue to rely on these treatments. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant revenue from product sales and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including: • the efficacy and potential advantages compared to alternative treatments; • the prevalence and severity of any side effects, in particular compared to alternative treatments; • our ability to offer our products for sale at competitive prices **and the ability of governmental authorities to require that we negotiate the pricing of our products, as well as the timing of these mandatory negotiations**; • the convenience and ease of administration compared to alternative treatments; • the willingness of the target patient population to try new therapies and of physicians treating these patients to prescribe these therapies; • the strength of marketing, sales, and distribution support; • the availability of third- party insurance coverage and adequate reimbursement; • the timing of any marketing approval in relation to other product approvals; • support from patient advocacy groups; and • any restrictions on the use of our products together with other medications. As a company, we currently have no marketing and sales organization and no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, if approved, we may not be able to generate product revenue. As a company, we currently have no sales, marketing, or distribution capabilities and no experience in marketing products. We intend to develop an in- house marketing organization and sales force, which will require significant capital expenditures, management resources, and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train, and retain marketing and sales personnel. If we are unable or decide not to establish internal sales, marketing, and distribution capabilities, we will pursue arrangements with third- party sales, marketing, and distribution collaborators regarding the sales and marketing of our products, if approved. However, there can be no assurance that we will be able to establish or maintain these types of arrangements on favorable terms or if at all, or if we are able to do so, that these third- party arrangements will provide effective sales forces or marketing and distribution capabilities. Any revenue we receive will depend upon the efforts of these third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of these third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates. There can be no assurance that we will be able to develop in- house sales and distribution capabilities or establish or maintain relationships with third- party collaborators to commercialize any product in the United States or overseas. The market opportunities for our product candidates may be relatively small as we expect that they will initially be approved only for those patients who are ineligible for other approved treatments or have failed prior treatments. In addition, our estimates of the prevalence of our target patient populations may be inaccurate. **Our We are developing** product candidates **may to** target cancer, but cancer therapies are sometimes characterized as first- line, second- line, third- line, or subsequent line and the FDA often approves new therapies initially only for a particular line of use. When cancer is detected early enough, first- line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first- line therapy – usually chemotherapy, antibody drugs, tumor- targeted small molecules, immunotherapy, hormone therapy, radiation therapy, surgery, other targeted therapies, or a combination of these therapies –

proves unsuccessful, second- line therapy may be administered. Second- line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor- targeted small molecules, or a combination of these. Third- line therapies can include chemotherapy, antibody drugs and small molecule tumor- targeted therapies, more invasive forms of surgery, and new technologies. We expect initially to seek approval of our product candidates in most instances as a second- or third- line therapy, for use in patients with relapsed or refractory cancer. Subsequently, for those product candidates that prove to be sufficiently safe and beneficial, if any, we would expect to seek approval as a second- line therapy and potentially as a first- line therapy, but there is no guarantee that any of our product candidates, even if approved as a second- or third- or subsequent line of therapy, would subsequently be approved for an earlier line of therapy. Further, it is possible that, prior to getting any approvals for our product candidates in earlier lines of treatment, we might have to conduct additional clinical trials. Our projections of both the number of people who have the cancers we are targeting, who may have their tumors genetically sequenced, as well as the subset of people with these cancers in a position to receive a particular line of therapy and who have the potential to benefit from treatment with our product candidates, are based on our reasonable beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research and may prove to be incorrect or out of date. Further, new therapies may change the estimated incidence or prevalence of the cancers that we are targeting. Consequently, even if our product candidates are approved for a second- or third- line of therapy, the number of patients that may be eligible for treatment with our product candidates may turn out to be much lower than expected. In addition, we have not yet conducted market research to determine how treating physicians would expect to prescribe a product that is approved for multiple tumor types if there are different lines of approved therapies for each of those tumor types. Even if we **or, in the case of CFT8919, Betta Pharma,** receive marketing approval of any of our product candidates, our products may become subject to unfavorable pricing regulations, third- party reimbursement practices, or healthcare reform initiatives, any of which would **harm-impact** our business. The regulations that govern marketing approvals, pricing, coverage, and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost- effectiveness of our product candidate to other available therapies. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we **or, in the case of CFT8919, Betta Pharma,** might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay **our-the** commercial launch of the product, possibly for lengthy time periods, which would negatively impact the revenues, if any, we are able to generate from the sale of the product in that country. Adverse pricing limitations may, therefore, hinder our ability to recoup our investment in one or more of our product candidates, even if our product candidates obtain marketing approval. Our **and, in the case of CFT8919, Betta Pharma's** ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government healthcare programs, private health insurers and other organizations. Government authorities and third- party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U. S. healthcare industry and elsewhere is cost containment. The **IRA's** Medicare Drug Price Negotiation Program, administered by CMS **as part of the Inflation Reduction Act of 2022,** **potentially commonly referred to as the IRA,** may apply to our products **if they are approved** if they are selected for negotiation, which could materially reduce the amount of revenue we can generate from our products **if they are approved**. Government authorities and third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, government authorities and third- party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Reimbursement may affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining coverage and adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. In addition, in light of the requirements of the IRA, we may be required to negotiate pricing for our product candidates, if approved, with Medicare, with those negotiated prices going into effect nine years after product approval. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. There may be significant delays in obtaining coverage and reimbursement for newly approved drugs. In addition, coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside of the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. In the United States, no uniform policy for coverage and reimbursement for products exists among third- party payors. Therefore, coverage and reimbursement for our products can differ significantly from payer to payer. The process for determining whether a payer will provide coverage for a product may be separate from the

process for setting the reimbursement rate that the payor will pay for the product. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product. Third-party payors may also limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA- approved products for a particular indication. Third- party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and adequate reimbursement rates from both government- funded and private payors for any approved products that we develop could have an adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop. We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if or when we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: • decreased demand for any product candidates or products that we may develop; • termination of clinical trials; • withdrawal of marketing approval, product recall, restriction on the approval or a "black box" warning or contraindication for an approved drug; • withdrawal of clinical trial participants; • significant costs to defend the related litigation and / or increased product liability insurance costs; • substantial monetary awards to trial participants or patients; • loss of revenue; • injury to our reputation and significant negative media attention; • reduced resources of our management to pursue our business strategy; and • the inability to commercialize any products that we may develop. We currently maintain product liability insurance coverage to support our clinical development activities. We may need to purchase additional product liability insurance coverage as we expand our clinical trials and if and when we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Risks related to our intellectual property If we are unable to obtain and maintain patent protection for our technology, product candidates, and products or if the scope of the patent protection obtained is not sufficiently broad or enforceable, our competitors could develop and commercialize technology, product candidates, and products similar or identical to ours, our ability to successfully commercialize our technology, product candidates, and products may be impaired or we may not be able to compete effectively in our market. We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect our intellectual property and prevent others from exploiting our platform technologies, our pipeline drug product candidates, any future drug product candidates we may develop and their use or manufacture. Our commercial success depends in part on our ability to obtain and maintain patents and other proprietary protection in the United States and other countries with respect to our proprietary technology, product candidates, and products. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and product candidates. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Moreover, the patent applications we own, co- own or license may fail to result in issued patents in the United States or in other foreign countries. The patent prosecution process is expensive and time consuming and we may not be able to file, prosecute, and maintain all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents and patent applications, covering technology that we license from third parties or that we license to our collaborators. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. The patent position of the biopharmaceutical industry generally is highly uncertain, involves complex legal and factual questions and has been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned, co- owned or licensed patents or pending patent applications, or that we were the first inventors to file for patent protection of those inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights or those of our collaborators are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our technology, product candidates, or products, in whole or in part, or that effectively prevent others from commercializing competitive technologies, product candidates, and products. Changes in either the patent laws or interpretation of the patent or other laws in the United States and other countries may diminish the value of our patents and potential applications, narrow the scope of our patent protection, or cause us to be required to pay royalties to third parties. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Our owned, co- owned and licensed patent estate consists principally of patent applications, many of which are at an early stage of prosecution. Even if our owned, co- owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned, co- owned or licensed patents by developing similar or alternative technologies, product candidates, or products in a non- infringing manner. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned, co- owned and licensed patents or patents obtained by our collaborators may be challenged in the courts or patent offices in the United States and abroad. These challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing

similar or identical technology, product candidates, and products or limit the duration of the patent protection of our technology, product candidates and products. Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting our drug product candidates might expire before or shortly after they are commercialized. As a result, our owned, co- owned and licensed patent portfolio, or that of our collaborators, may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Changes in patent laws or patent jurisprudence could diminish the value of our patents in general or increase third party challenges to our patents, thereby impairing our ability to protect our product candidates. Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy- Smith America Invents Act, or the Leahy- Smith Act, was signed into law and made a number of significant changes to U. S. patent law. These changes include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The U. S. Patent and Trademark Office, or the USPTO, developed new regulations and procedures to govern administration of the Leahy- Smith Act and many of the substantive changes to patent law associated with the Leahy- Smith Act, including the first- inventor- to- file provisions, became effective on March 16, 2013. The Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business and financial condition. The first- to- file provision of the Leahy- Smith Act requires us to act promptly during the period from invention to filing of a patent application, as there is always a risk that a third party could file a patent application that could be blocking to our patent filings. However, even with the intention to act promptly, circumstances could prevent us from promptly filing or prosecuting patent applications on our inventions. The Leahy- Smith Act also enlarged the scope of disclosures that qualify as prior art, which can impact our ability to receive patent protection for an invention. The Leahy- Smith Act created, for the first time, new procedures under which third parties may challenge issued patents in the United States, including post- grant review, inter partes review and derivations proceedings, all of which are adversarial proceedings conducted at the USPTO. Since the effectiveness of the Leahy- Smith Act, some third parties have been using these types of actions to seek and achieve the cancellation of selected or all claims of issued patents of their competitors. Under the Leahy- Smith Act, for a patent with a priority date of March 16, 2013 or later (which is the case for all of our patent filings), a third party can file a petition for post- grant review at any time during a nine- month window commencing at the time of issuance of the patent. In addition, for a patent with a priority date of March 16, 2013 or later, a third party can file a petition for inter partes review after the nine- month period for filing a post- grant review petition has expired. Post- grant review proceedings can be brought on any ground of challenge, whereas inter partes review proceedings can only be brought to raise a challenge based on published prior art. Under applicable law, the standard of review for these types of adversarial actions at the USPTO are conducted without the presumption of validity afforded to U. S. patents, which is the standard that applies if a third party were to seek to invalidate a patent through a lawsuit filed in the federal courts of the United States. The USPTO issued a Final Rule on November 11, 2018 announcing that it will now use the same claim construction currently used in the federal courts of the United States — which is the plain and ordinary meaning of words used — to interpret patent claims in these USPTO proceedings. As a result of this regulatory landscape, if any of our patents are challenged by a third party in a USPTO proceeding of this nature, there is no guarantee that we will be successful in defending the challenged patent, which could result in our losing rights under the challenged patent in part or in whole. As a result of this legislation, the issuance, scope, validity, enforceability and commercial value of our patent rights, or those of our collaborators, are highly uncertain, which could have an adverse effect on our business, financial condition, results of operations and prospects. We may become involved in lawsuits to protect or enforce our patents, the patents of our licensors or other intellectual property, which could be expensive, time- consuming and unsuccessful. Competitors may infringe our issued patents, the patents of our licensors or collaborators or our other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive, time- consuming and unpredictable. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours or our licensors or collaborators is invalid or unenforceable, in whole or in part, construe the patent’ s claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being or actually invalidated, held unenforceable or interpreted narrowly. Even if we successfully assert our patents, a court may not award remedies that sufficiently compensate us for our losses. In addition, we may not have sufficient financial or other resources to seek to enforce our patents adequately against perceived infringers, which could have a material and adverse effect on the profitability of our products. We may need to license intellectual property from third parties and licenses of this nature may not be available or may not be available on commercially reasonable terms. A third party may hold intellectual property, including patent rights, that are important or necessary to the development or manufacture of our products or our collaborators’ products. It may, therefore, be necessary for us to use the patented or proprietary technology of a third party to commercialize our own technology or products or those of our collaborators, in which case we or our collaborators would be required to obtain a license from that third party. A license to that intellectual property may not be available or may not be available on commercially reasonable terms, which could have an adverse effect on our business and financial condition. The licensing and acquisition of third- party intellectual property rights is a competitive practice. Companies that may be more established or have greater resources than we do may also be pursuing strategies to license or acquire third- party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. We may not be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire. Third parties may initiate legal proceedings alleging that we are infringing their

intellectual property rights, the outcome of which would be uncertain and could have an adverse effect on the success of our business. Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market, and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biopharmaceutical industry, as well as administrative proceedings for challenging patents, including reexamination, post-grant review, inter partes review, derivation proceedings, or interference proceedings before the USPTO and oppositions and other comparable proceedings in foreign jurisdictions. We may become party to or threatened with future adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and technology, including derivation, reexamination, post-grant review, inter partes review, or interference proceedings before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. As the bio-pharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our drug candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that our product candidates or use of our technologies infringes upon these patents. If we are found by a court of competent jurisdiction to infringe a third party's intellectual property rights, we could be required to obtain a license from the applicable third-party intellectual property holder to continue developing and marketing our product candidates, products, and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. A number of other companies, as well as universities and other organizations, file and obtain patents in the same areas as our products, which are targeted protein degraders, or our platform technologies and these patent filings could be asserted against us or our collaborators in the future, which could have an adverse effect on the success of our business and, if successful, could lead to expensive litigation that could affect the profitability of our products and / or prohibit the sale or use of our products. Our MonoDAC and BiDAC product candidates are small molecule pharmaceuticals, which degrade specific proteins. A number of companies and institutions have patent applications and issued patents in this general area, such as, for example, Accutar Biotechnology, Inc., Amgen Inc., Amphista Therapeutics, Ltd., Araxes Pharma, LLC, Arvinas, Inc., Astellas Pharma Inc., AstraZeneca PLC, Aurigen Discovery Technologies, Ltd., Bayer AG (and its subsidiary Vividion Therapeutics, Inc.), Beigene Co. Ltd., BioTheryX, Inc., Boehringer Ingelheim International GmbH, Bristol Myers Squibb Company (and its subsidiary Celgene Corporation), Captor Therapeutics Inc., Cullgen Inc., the Dana-Farber Cancer Institute and its Center for Protein Degradation, Dialectic Therapeutics, Inc., Foghorn Therapeutics, Inc., Frontier Medicines Corporation, GlaxoSmithKline PLC, **Genentech, Inc., Glubio Therapeutics, Inc.,** Hinova Pharmaceuticals, Inc., Janssen Biotech, Inc., Kymera Therapeutics, Inc., Monte Rosa Therapeutics, Inc., Novartis **International AG,** Nurix Therapeutics, Inc., **Orum Therapeutic, Inc.,** Otsuka Pharmaceuticals, Inc., Phoremest, Ltd., **Plexium, Inc.,** Prelude Therapeutics, Inc., **Proteovant Therapeutics, Inc.,** Roche AG, Salarius Pharmaceuticals **Inc., Salarius Pharmaceuticals, Inc.,** Seed Therapeutics, Inc., Sichuan Haisco Pharmaceutical Co., Ltd., **SK Life Science Labs, Inc. (a subsidiary of SK Biopharmaceuticals Co. Ltd)**, the University of Michigan School of Medicine, Vertex Pharmaceuticals, Inc., and others. If any of these companies or institutions or others not included in this list were to assert that one of its patents is infringed by any product candidate or product we might develop or its use or manufacture, we or our collaborators may be drawn into expensive litigation, which could adversely affect our business prospects, financial condition and results of operations, require extensive time from and cause the distraction of members of our management team and employees at large. Further, if litigation of this nature were successful, that could have a material and adverse effect on the profitability of our products or prohibit their sale. We may not be aware of patent claims that are currently or may in the future be pending that could affect our business or products. Patent applications are typically published between six and eighteen months from filing and the presentation of new claims in already pending applications can sometimes not be visible to the public, which would include us, for a period of time. In addition, even after a patent application is publicly available, we may not yet have seen that patent application and may, therefore, not be aware of the claims or scope of filed and published patent applications. As a result, we cannot provide any assurance that a third party practicing in the general area of our technology will not present or has not presented a patent claim that covers one or more of our product candidates or products or their methods of use or manufacture. If that were to occur, we or our collaborators, as applicable, may have to take steps to try to invalidate the applicable patent or application and, in a situation of that nature, we or our collaborators may either choose not to do so or our attempt may not be successful. **For example, on May 1, 2023, we filed a petition with the USPTO Patent Trial and Appeal Board, or PTAB, seeking a post-grant review of all the claims of U. S. patent number 11, 414, 416 (referred to as the ' 416 patent), and on October 23, 2023, we filed a petition with PTAB seeking post-grant review of all the claims of U. S. patent number 11, 560, 381 (referred to as the ' 381 patent). Both the ' 416 patent and the ' 381 patent relate to compounds for the treatment of BRD9- related disorders. The ' 416 patent challenge was successfully resolved as a result of the patent owner filing, on August 21, 2023, a statutory disclaimer of all the ' 416 patent claims, thereby relinquishing all their legal rights to and under the ' 416 patent. The ' 381 patent challenge was successfully resolved as a result of the patent owner filing, on January 17, 2024, a statutory disclaimer of all the ' 381 patent claims, thereby relinquishing all their rights to and under**

the' 381 patent. If we determine that we require a license to a third party's patent or patent application, we may discover that a license may not be available on reasonable terms, or at all, which could prevent us or our collaborators from selling a product or using our proprietary technologies. Our ~~products-~~ **product are candidates, if and when approved, will be** subject to The Drug Price Competition and Patent Term Restoration Act of 1984, which is also referred to as the Hatch- Waxman Act, in the United States, which can increase the risk of litigation with generic companies trying to sell our products and may cause us to lose patent protection. Because our clinical candidates are pharmaceutical molecules that will be reviewed by the Center for Drug Evaluation and Research of the FDA, after commercialization they will be subject in the United States to the patent litigation process of the Hatch- Waxman Act, as amended to date, which allows a generic company to submit an Abbreviated New Drug Application, or ANDA, to the FDA to obtain approval to sell a generic version of our drug using bioequivalence data only. Under the Hatch- Waxman Act, we will list patents that cover our drug products or their respective methods of use in the FDA's compendium of "Approved Drug Products with Therapeutic Equivalence Evaluation," sometimes referred to as the **FDA's** Orange Book. There are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Orange Book. We may be unable to obtain patents covering our product candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. Even if we submit a patent for listing in the Orange Book, the FDA may decline to list the patent or a generic drug manufacturer, **the U. S. Federal Trade Commission or another entity** may challenge the listing. If one of our product candidates is approved and a patent covering that product candidate is not listed in the Orange Book, with respect to any unlisted patent, a generic drug manufacturer would not have to provide advance notice to us of any ANDA filed with the FDA to obtain permission to sell a generic version of that product candidate. Currently, in the United States, the FDA may grant five years of data exclusivity for new chemical entities, or NCEs, which are drugs that contain no active portion that has been approved by the FDA in any other new drug application, or NDA. We expect that all of our products will qualify as NCEs; however, the FDA will not conduct an assessment for NCE status until it is reviewing a marketing application for that drug. A generic company can submit an ANDA to the FDA four years after approval of any of our drug products designated as an NCE. The submission of an ANDA by a generic company is considered a technical act of patent infringement. The generic company can certify that it will wait until the natural expiration date of our listed patents to sell a generic version of our product or can certify that one or more of our listed patents are invalid, unenforceable or not infringed. If the generic manufacturer elects the latter, we will have 45 days to bring a patent infringement lawsuit against the generic company. If we were to do so, that would likely initiate a challenge to one or more of our Orange Book listed patents based on arguments from the generic manufacturer that our listed patents are invalid, unenforceable, or not infringed. If a lawsuit is brought, the FDA is prevented from issuing a final approval of an ANDA for the generic drug until 30 months from our receipt of the generic manufacturer's certification notice, or such shorter or longer time as the presiding court might order based on certain behaviors of the parties, or a final decision of a court holding that our asserted patent claims are invalid, unenforceable, or not infringed. If we do not properly list our relevant patents in the Orange Book or if we fail to file a lawsuit in response to a certification from a generic company under an ANDA in a timely manner, or if we do not prevail in the resulting patent litigation, we can lose our ability to benefit from a proprietary market based on patent protection covering our drug products and we may find that physicians will switch to prescribing and dispensing generic versions of our drug products. Further, even if we were to list our relevant patents in the Orange Book correctly, bring a lawsuit in a timely manner, and prevail in that lawsuit, the generic litigation may come at a significant cost to us, both in terms of attorneys' fees and employee time and distraction over a long period. Further, it is common for more than one generic company to try to sell an innovator's drug at the same time and, as a result, we may face the cost and distraction of multiple lawsuits from generic manufacturers at the same time. We may also determine that it is necessary to settle these types of lawsuits in a manner that allows the generic company to enter our market prior to the expiration of our patent or otherwise in a manner that adversely affects the strength, validity or enforceability of our patents. A number of pharmaceutical companies have been the subject of intense review by the U. S. Federal Trade Commission or a corresponding agency in another country based on how they have conducted or settled patent litigation related to pharmaceutical products. In fact, certain reviews have led to an allegation of an anti- trust violation, sometimes resulting in a fine or loss of rights. We cannot be sure that we would not also be subject to a review of this nature or that the result of a review of this nature would be favorable to us, or that any review of this nature would not result in a fine or penalty. The U. S. Federal Trade Commission, or FTC, has brought a number of lawsuits in federal court in the past few years to challenge ANDA litigation settlements reached between innovator companies and generic companies as anti- competitive. As an example, the FTC has taken an aggressive position that anything of value is a payment, whether money is paid or not. Under their approach, if an innovator, as part of a patent settlement, agrees not to launch or delay its launch of an authorized generic during the 180-day period granted to the first generic company to challenge an Orange Book listed patent covering an innovator drug, or negotiates a delay in entry without payment, the FTC may consider it an unacceptable reverse payment. Companies in the pharmaceutical industry have argued that these types of agreements are rational business decisions entered into by drug innovators as a way to address risk and that these settlements should, therefore, be immune from antitrust attack if the terms of the settlement are within the scope of the exclusionary potential of the patent. In 2013, the U. S. Supreme Court in a five- to- three decision in *FTC v. Actavis, Inc.* rejected both the pharmaceutical industry's and FTC's arguments with regard to so- called reverse payments. Instead, the Supreme Court held that whether a "reverse payment" settlement involving the exchange of consideration for a delay in entry is subject to an anti- competitive analysis depends on five considerations: (a) the potential for genuine adverse effects on competition; (b) the justification of payment; (c) the patentee's ability to bring about anti- competitive harm; (d) whether the size of the payment is a workable surrogate for the patent's weakness; and (e) that antitrust liability for large unjustified payments does not prevent litigating parties from settling their lawsuits, for example, by allowing the generic drug to enter the market before the patent expires on the branded drug without the patentee paying the generic manufacturer. Further, whether a reverse payment is justified depends upon its size, scale in relation to the patentee's

anticipated future litigation costs, and independence from other services for which it might represent payment (as was the case in Actavis), as well as the lack of any other convincing justification. The Supreme Court instead held that reverse payment settlements can potentially violate antitrust laws and are subject to the standard antitrust rule-of-reason analysis, with the burden of proving that an agreement is unlawful on the FTC. In reaching this decision, the Supreme Court left to the lower courts the structuring of this rule of reason analysis. If we are faced with drug patent litigation, including Hatch-Waxman litigation with a generic company, we could be faced with an FTC challenge of this nature, which challenge could impact how or whether we settle the case and, even if we strongly disagree with the FTC's position, we could face a significant expense or penalty. Any litigation settlements we enter into with generic companies under the Hatch-Waxman Act could also be challenged by third-party payors such as insurance companies, direct purchasers or others who consider themselves adversely affected by the settlement. These kinds of follow-on lawsuits, which may be class action suits, can be expensive and can continue over multiple years. If we were to face lawsuits of this nature, we may not be successful in defeating these claims and we may, therefore, be subject to large payment obligations, which we may not be able to satisfy in whole or in part. We may not be able to obtain patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 in the United States and, as a result, our product candidates, if approved, may not have patent protection for a sufficient period. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits one patent term extension of up to five years beyond the normal expiration of one patent per product, which if related to a method of treatment patent, is limited to the approved indication. The length of the patent term extension is typically calculated as one-half of the clinical trial period plus the entire period of time during the review of the NDA by the FDA, minus any time of delay by us during these periods. There is also a limit on the patent term extension to a term that is no greater than fourteen years from the date of drug approval. Therefore, if we select and are granted a patent term extension on a recently filed and issued patent, we may not receive the full benefit of a possible patent term extension, if at all. We might also not be granted a patent term extension at all, because of, for example, our failure to apply within the applicable period, failure to apply prior to the expiration of relevant patents or other failure to satisfy any of the numerous applicable requirements. In addition, the regulatory review period of an FDA-approved product may not serve as the basis for a patent term extension if the active ingredient of such product was subject to regulatory review and approval in an earlier product approved by the FDA. Moreover, the applicable authorities, including the FDA and the USPTO in the United States and any equivalent regulatory authority in other countries, may not agree with our assessment of whether extensions of this nature are available and may refuse to grant extensions to our patents or may grant more limited extensions than we request. If this occurs, our competitors may be able to obtain approval of competing products following our patent expiration by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. If this were to occur, it could have an adverse effect on our ability to generate product revenue. In Europe, supplementary protection certificates are available to extend a patent term up to five years to compensate for patent term lost during regulatory review, and this period can be extended to five and a half years if data from clinical trials is obtained in accordance with an agreed Pediatric Investigation Plan. Although all countries in Europe must provide supplementary protection certificates, there is no unified legislation among European countries and, as a result, drug developers must apply for supplementary protection certificates on a country-by-country basis. As a result, a company may need to expend significant resources to apply for and receive these certificates in all relevant countries and may receive them in some, but not all, countries, if at all. Weakening patent laws and enforcement by courts in the United States and foreign countries may impact our ability to protect our markets. The U. S. Supreme Court has issued opinions in patent cases in the last few years that many consider may weaken patent protection in the United States, either by narrowing the scope of patent protection available in certain circumstances, holding that certain kinds of innovations are not patentable or generally otherwise making it easier to invalidate patents in court. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce our proprietary technology. Depending on future actions by the U. S. Congress, the U. S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed. For example, we could become a party to foreign opposition proceedings, such as at the European Patent Office, or patent litigation and other proceedings in a foreign court. If so, uncertainties resulting from the initiation and continuation of such proceedings could have an adverse effect on our ability to compete in the marketplace. The cost of foreign adversarial proceedings can also be substantial, and in many foreign jurisdictions, the losing party must pay the attorney fees of the winning party. We may be subject to claims by third parties asserting that we, our employees, consultants or contractors have misappropriated the applicable third party's intellectual property or claiming ownership of what we regard as our own intellectual property. We employ individuals who were previously employed at universities as well as other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We have received confidential and proprietary information from collaborators, prospective licensees, and other third parties that may be subject to contractual confidentiality and non-use obligations. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these employees or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. We may not be successful in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose

valuable intellectual property rights, such as exclusive ownership of or right to use valuable intellectual property. Even if we are successful, litigation could result in substantial cost and reputational loss and be a distraction to our management and other employees. In addition, while it is our policy to require our employees, consultants, and contractors who may be involved in the development of intellectual property to execute agreements assigning any resulting intellectual property to us, we may be unsuccessful in executing an agreement to that effect with each party who in fact develops intellectual property that we regard as our own. Assignment agreements of this nature may not be self-executing or may be breached and we may be forced to bring claims against third parties or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. In addition, an employee or contractor could create an invention but not inform us of it, in which case we could lose the benefit of the invention and the employee or contractor may leave to develop the invention elsewhere. Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims 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, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Litigation or proceedings of this nature could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of litigation or proceedings of this nature more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace. Obtaining and maintaining patent protection depends on compliance with various procedural, documentary, fee payment, and other requirements imposed by governmental patent offices, and the protection of our patents could be reduced or eliminated if we fail to comply with these requirements. Periodic maintenance fees on any issued patent are due to be paid to the USPTO and patent offices in foreign countries in several stages over the lifetime of a patent application and any resulting patent. The USPTO and patent offices in foreign countries require compliance with many procedural, documentary, fee payment, and other requirements during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of a patent or patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have an adverse effect on our business. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology, and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors, and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. These agreements may not effectively prevent disclosure of confidential information nor result in the effective assignment to us of intellectual property and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information or other breaches of the agreements. In addition, others may independently discover our trade secrets and proprietary information. In that case, we could not assert any trade secret rights against that third party. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome of a dispute of this nature is inherently unpredictable. Costly and time-consuming litigation could be necessary to seek to enforce and determine the scope of our proprietary rights, and our failure to obtain or maintain trade secret protection could adversely affect our competitive business position. In addition, some courts outside of the United States are less willing or unwilling to protect trade secrets. The Defend Trade Secrets Act of 2016 is a U.S. federal law that allows an owner of a trade secret to sue in federal court when its trade secret has been misappropriated. Congress passed this law in an attempt to strengthen the rights of trade secret owners whose valuable assets are taken without authorization. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate them, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed. We only have limited geographical protection with respect to certain of our patents and we may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting, maintaining, and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive. As a result, our intellectual property rights in some countries outside the United States can be less extensive than the protection we might have in the United States. In-licensing patents covering our product candidates in all countries throughout the world may similarly be prohibitively expensive, if these in-licensing opportunities are available to us at all. Further, in-licensing or filing, prosecuting, maintaining, and defending patents even in only those jurisdictions in which we develop or commercialize our product candidates may be prohibitively expensive or impractical. Competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection or licensed patents to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors have patent protection, but enforcement is not as strong as that in the United States or the European Union. These products may compete with our product candidates, and our or

our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. In addition, we may decide to abandon national and regional patent applications while they are still pending. The grant proceeding of each national or regional patent is an independent proceeding that may lead to situations in which applications may be rejected by the relevant patent office, while substantively similar applications are granted by others. For example, relative to other countries, China has a heightened detailed description requirement for patentability. Further, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other proceedings. Generic drug manufacturers may develop, seek approval for and launch generic versions of our products. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology. The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or regulations in the United States and the European Union, and many companies have encountered significant difficulties in protecting and defending proprietary rights in such jurisdictions. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets or other forms of intellectual property, which could make it difficult for us to prevent competitors in some jurisdictions from marketing competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, are likely to result in substantial costs and divert our efforts and attention from other aspects of our business, and could additionally put our or our licensors' patents at risk of being invalidated or interpreted narrowly, could increase the risk of our or our licensors' patent applications not issuing or could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, while damages or other remedies may be awarded to the adverse party, which may be commercially significant. If we prevail, damages or other remedies awarded to us, 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. Further, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in these countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we or our licensors encounter difficulties in protecting or are otherwise precluded from effectively protecting the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition in those jurisdictions. In some jurisdictions, compulsory licensing laws compel patent owners to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties under patents relevant to our business, or if we or our licensors are prevented from enforcing patent rights against third parties, our competitive position may be substantially impaired in such jurisdictions. Risks related to regulatory matters

Receiving regulatory approval from the FDA and foreign regulatory authorities is lengthy, time-consuming and inherently unpredictable and, if we are ultimately unable to obtain marketing approval for our product candidates, our business will be substantially harmed. The amount of time required to obtain approval by the FDA and foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval standards, 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. We have not obtained marketing approval for any product candidate, and it is possible that none of our existing product candidates, or any product candidates we may seek to develop in the future (independently or with one of our collaboration partners), will ever obtain marketing approval. Our product candidates could fail to receive **or retain** marketing approval for many reasons, including the following:

- the FDA or foreign regulatory authority, each referred to here as a health authority, may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the health authority that a product candidate is safe and effective for its proposed indication, or that it is of sufficient strength, identity, or quality in accordance with the health authority's standards;
- results of clinical trials may not meet the level of statistical significance required by the health authority for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the health authority may disagree with our interpretation of data from preclinical studies or clinical trials;
- data collected from clinical trials of our product candidates may not be sufficient valid or of sufficient quality to support the submission of an NDA to the FDA or other submission to a foreign regulatory authority or to obtain marketing approval in the United States or any other country or jurisdiction;
- the health authority may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval standards, policies, or regulations of a health authority may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy drug development process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to allow us to market any of our product candidates, which would significantly harm our business, results of operations, and prospects. The FDA and other health authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be obtained for any of our product candidates, including in the context of accelerated approvals. Even if we believe the data collected from clinical trials of our product candidates are promising, that data may not be sufficient to support approval by the FDA or any other health authority. In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful

commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates. Even if we obtain FDA approval for any of our product candidates in the United States, we may never obtain approval for or commercialize any of them in any other jurisdiction, which would limit our ability to realize their full market potential. In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country- by- country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation, and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials, which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience as a company in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized. Even if we receive regulatory approval of any product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates. If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record- keeping, conduct of post- marketing studies, and submission of safety, efficacy and other post- market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, we **may be required to conduct post- approval studies in special populations that are difficult to conduct or complete. We** will also be subject to continued compliance with cGMP and GCP requirements for any clinical trials that we conduct post- approval. Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations and applicable product tracking and tracing requirements. As such, we and our CMOs will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, other marketing application, and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, and quality control. Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post- marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS program as a condition of approval of our product candidates, which could entail requirements for long- term patient follow- up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. Comparable foreign regulatory authorities may also have programs similar to REMS. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post- marketing information and reports and registration. The FDA may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third- party CMOs or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post- market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things: • restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls; • fines, warning letters, or holds on clinical trials; • refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals; • product seizure or detention or refusal to permit the import or export of our product candidates; and • injunctions or the imposition of civil or criminal penalties. The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses and a company that is found to have improperly promoted off- label uses may be subject to significant liability. However, physicians may, in their independent medical judgment, prescribe legally available products for off- label uses. The FDA does not regulate the behavior of physicians in their choice of treatments, but the FDA does restrict manufacturers' communications on the subject of off- label use of their products. The policies of the FDA and of comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. A Breakthrough Therapy designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or

regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval. We may seek Breakthrough Therapy designation for ~~some of our~~ **or all of our current and future product candidates, including** CFT7455 and **CFT1946** ~~CFT8634 product candidates, and some or all of our future product candidates.~~ A Breakthrough Therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for other expedited approval programs, including accelerated approval. Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such a designation. In any event, although Breakthrough Therapy designation is designed to expedite the development and review of drugs that receive such designation, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to candidate products considered for approval under non-expedited FDA review procedures and does not assure ultimate approval by the FDA of a product candidate. In addition, even if one or more of our product candidates qualify as Breakthrough Therapies, the FDA may later decide that the product no longer meets the conditions for qualification. Thus, even though we intend to seek Breakthrough Therapy designation for our lead product candidates and some or all of our future product candidates for the treatment of various cancers, there can be no assurance that we will receive Breakthrough Therapy designations. A Fast Track designation by the FDA, even if granted for one or all of our lead product candidates, or any of our other current or future product candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval. At various times, we may seek Fast Track designation for one or more of our product candidates. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA Fast Track designation for a particular indication. We may seek Fast Track designation for one or all of our lead product candidates and / or certain of our future product candidates, but there is no assurance that the FDA will grant this status to any of our proposed product candidates and we might only be successful in receiving a Fast Track designation from the FDA for a product candidate after applying on more than one occasion. Marketing applications filed by sponsors of products in Fast Track development may qualify for priority review under the policies and procedures offered by the FDA, but the receipt of a Fast Track designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion whether or not to grant a Fast Track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive a Fast Track designation, and even though Fast Track designation is designed to expedite the development and review of drugs that receive such designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a Fast Track designation does not provide assurance of ultimate FDA approval. In addition, the FDA may withdraw a Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. In addition, the FDA may withdraw any Fast Track designation at any time. We have obtained Orphan Drug Designation for CFT7455 and ~~CFT8634~~, and if we decide to seek Orphan Drug Designation for any other current or future product candidates, we may be unsuccessful or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for supplemental market exclusivity. In August 2021, the FDA granted Orphan Drug Designation to CFT7455 for the treatment of MM, ~~and in March 2022, the FDA granted Orphan Drug Designation to CFT8634 for the treatment of soft tissue sarcoma.~~ We may seek Orphan Drug Designation for one or more of our other current or future product candidates. Regulatory authorities in some jurisdictions, including the United States and ~~the Europe~~ **European Union**, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may grant an Orphan Drug Designation to a drug intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug in the United States will be recovered from sales in the United States for that drug. In the United States, receipt of an Orphan Drug Designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. After the FDA grants Orphan Drug Designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Although Orphan Drug Designation is intended to incent drug development for rare diseases or conditions, Orphan Drug Designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. **In addition, while receipt of Orphan Drug Designation may result in a waiver of any obligation by FDA to conduct studies in pediatric populations, such waiver may not apply to oncology drugs.** If a product that has an Orphan Drug Designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including an NDA, to market the same drug for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even if one of our product candidates receives orphan drug exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease. Further, the FDA can waive orphan drug exclusivity if we are unable to manufacture sufficient supply of our product. We may also seek

Orphan Drug Designations for our other lead candidates and / or some or all of our other current or future product candidates in additional orphan indications in which there is a medically plausible basis for the use of these product candidates. Even when we obtain an Orphan Drug Designation, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we, through our manufacturer, are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. In addition, even if we seek Orphan Drug Designation for other product candidates, we may never receive these designations. For example, the FDA has expressed concerns regarding the regulatory considerations for Orphan Drug Designation as applied to tissue agnostic therapies and the FDA may interpret the FDCA and its orphan drug regulations, in a way that limits or blocks our ability to obtain an Orphan Drug Designation or orphan drug exclusivity, if our product candidates are approved, for our targeted indications. We may seek approval of our product candidates, where applicable under the FDA's accelerated approval pathway. This pathway may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval. We plan to seek accelerated approval of our lead product candidates and may seek approval of future product candidates, where applicable, using the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit. Under **the Food and Drug Omnibus Reform Act, commonly referred to as FDORA**, the FDA is permitted to require, as appropriate, that a post-approval confirmatory study or studies be underway prior to approval or within a specified time period after the date of approval for a product that is granted accelerated approval. FDORA also requires sponsors to send updates to the FDA every 180 days on the status of ~~such these~~ studies, including progress ~~toward~~ **towards** enrollment targets, and the FDA must promptly post this information publicly. FDORA also gives the FDA increased authority to withdraw accelerated approval on an expedited basis if the sponsor fails to conduct such ~~studies~~ **activities** in a timely manner, send the necessary updates to the FDA, or if such post-approval studies fail to verify the drug's predicted clinical benefit; and to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress. In addition, the FDA generally requires pre-approval of promotional materials for products receiving accelerated approval, which could adversely impact the timing of the commercial launch of the product. Thus, even if we seek to utilize the accelerated approval pathway for any of our product candidates, we may not be able to obtain accelerated approval, and even if we do, that product may not experience a faster development or regulatory review or approval process. In addition, receiving accelerated approval does not assure the product's accelerated approval will eventually be converted to a traditional approval. The FDA may identify in a written request that pediatric information would be beneficial for a product candidate for which we obtained approval and request that we conduct pediatric studies. We may elect not to perform these studies or, if we opted to conduct these studies, we may not be able to complete them or the data generated from these studies may not be acceptable to the FDA. Section 505 (A) of the Food, Drug, and Cosmetic Act, or the FDC Act, provides incentives to drug manufacturers who conduct studies of drugs in children. Referred to as the "pediatric exclusivity provision," this law provides an additional six months of non-patent exclusivity to pharmaceutical manufacturers that conduct acceptable pediatric studies of new and currently-marketed drug products for which pediatric data would be beneficial pursuant to a written request by the FDA. As a result, if we received a written request for pediatric studies from the FDA, conducted pediatric clinical studies and submitted reports that were accepted by the FDA within the statutory time limits, we could receive an additional six-months of regulatory exclusivity beyond all other types of patent and non-patent exclusivity then in effect for all our approved drug products that contain the active moiety for which pediatric exclusivity was granted. However, even if we received a written request for pediatric studies from the FDA for one or more of our drug products, we may determine not to or be unable to carry out pediatric studies that comply with Section 505 (A) of the FDC Act, or we may carry out studies that are not accepted by the FDA for this purpose. If this situation were to arise, we would not receive this additional six-month regulatory exclusivity extension. Our relationships with customers, healthcare providers, and third-party payors are or will be subject, directly or indirectly, to **foreign**, federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply or have not fully complied with these laws, we could face substantial penalties. Healthcare providers and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers, and third-party payors subject us to various federal and state fraud and abuse laws and other healthcare laws that may constrain the business or financial arrangements and relationships through which we research, sell, market, and distribute our product candidates, if we obtain marketing approval. In particular, the research of our product candidates, as well as the promotion, sales, and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to: (i) prevent fraud, kickbacks, self-dealing, and other abusive practices, (ii) guarantee the security and privacy of health information, and (iii) increase transparency around the financial relationships between physicians, teaching hospitals, and manufacturers of drugs, medical devices, and biologics. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs, and other business or financial arrangements. See the sections entitled "Business — Other Healthcare Laws" and "Business — Healthcare Reform" ~~included above in this filing~~ **our 2022 Annual Report**. Ensuring that our business arrangements and practices with third parties comply with applicable healthcare laws and regulations will likely be costly. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or

case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government funded healthcare programs such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, and the curtailment or restructuring of our operations. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements. If the physicians or other providers or entities with whom we expect to do business are found not to comply with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. 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. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Litigation or proceedings of this nature could substantially increase our operating losses and reduce the resources available for development, manufacturing, sales, marketing or distribution activities. Uncertainties resulting from the initiation and continuation of litigation or other proceedings relating to applicable healthcare laws and regulations could have an adverse effect on our ability to compete in the marketplace. The successful commercialization of our product candidates in the United States and abroad will depend in part on the extent to which third-party payors, including governmental authorities and private health insurers, provide coverage and adequate reimbursement levels, as well as implement pricing policies favorable for our product candidates. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue. Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. In the United States and in other countries, patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. The availability of coverage and adequacy of reimbursement for our products by third-party payors, including government health care programs (e. g., Medicare, Medicaid or TRICARE in the United States), managed care providers, private health insurers, health maintenance organizations, and other organizations is essential for most patients to be able to afford medical services and pharmaceutical products such as our product candidates. Third-party payors decide which medications they will pay for and establish reimbursement levels. See the section entitled “~~Business~~—Coverage and Reimbursement” included above in this filing **our 2022 Annual Report**. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for our products and related treatments will be available from third-party payors. Moreover, a payor’s decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. A decision by a third-party payor not to cover or not to separately reimburse for our medical products or therapies using our products could reduce physician utilization of our products once approved. We cannot be sure that coverage and reimbursement in the United States and other countries will be available for our current or future product candidates or for any procedures using our current or future product candidates, and any reimbursement that may become available may not be adequate or may be decreased or eliminated in the future. In the United States, no uniform policy for coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for our products can differ significantly from payor to payor. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. One payor’s determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product. Third-party payors may also limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. The principal decisions about reimbursement for new medicines in the United States are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the United States Department of Health and Human Services, or HHS. CMS will decide whether and to what extent our products will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Factors considered by payors in determining reimbursement are based on whether the product is: • a covered benefit under its health plan; • safe, effective, and medically necessary; • appropriate for the specific patient; • cost-effective; and • neither experimental nor investigational. We cannot be sure that coverage and reimbursement will be available for or accurately estimate the potential revenue from our product candidates or assure that coverage and reimbursement will be available for any product that we may develop. Further, increasing efforts by third-party payors in the United States and abroad to cap or reduce healthcare costs may cause payor organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA or comparable regulatory approvals. Additionally, we may also need to provide discounts to purchasers, private health plans or government healthcare programs. Our product candidates may nonetheless not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of

payment may not be sufficient to allow a company to sell its products at a profit. We expect to experience pricing pressures from third-party payors in connection with the potential sale of any of our product candidates. Lastly, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, countries in the ~~European Union, or EU~~, Member States can restrict the range of medicinal products for which their national health insurance systems provide reimbursement and they can control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. An EU Member State may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Approaches between EU Member States are diverging. For example, in France, effective market access will be supported by agreements with hospitals and products may be reimbursed by the Social Security Fund. The price of medicines is negotiated with the Economic Committee for Health Products. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the ~~EU European Union~~ do not follow price structures of the United States and generally prices in the ~~EU European Union~~ tend to be significantly lower than prices in the United States. Enacted and future healthcare legislation may increase the difficulty and cost for us to progress our clinical programs and obtain marketing approval of and commercialize our product candidates and may affect the prices we may set. In the United States and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U. S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. Individual states in the United States have also increasingly passed legislation and implemented 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. See the section entitled “ Business — **Government Regulation- Healthcare Reform** ” ~~included above in this filing~~ **our 202 Annual Report**. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the extent to which state and federal governments cover particular healthcare products and services and could limit the amounts that the federal and state governments will pay for healthcare products and services. This could result in reduced demand for any product candidate we develop or could result in additional pricing pressures. In markets outside of the United States, reimbursement and healthcare payment systems vary significantly by country and many countries have instituted price ceilings on specific products and therapies. The price control regulations outside of the United States can have a significant impact on the profitability of a given market, and further uncertainty is introduced if and when these laws change. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. ~~#~~ **The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and / or impose price controls may adversely affect: • the demand for our product candidates, if we obtain regulatory approval; • our ability to set a price that we believe is fair for our approved products; • our ability to generate revenue and achieve or maintain profitability; • the ongoing COVID-19 pandemic level of taxes that we are required to pay; and • the availability of capital.** If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or these third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability. We may face potential liability under applicable privacy laws, **in the United States as well as other jurisdictions**, if we obtain identifiable patient health information from clinical trials sponsored by us. Most healthcare providers, including certain research institutions from which we may obtain patient health information, are subject to privacy and security regulations promulgated under the Health Insurance Portability and Accountability Act of 1966, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act. Depending on the facts and circumstances, we could be subject to civil, criminal, and administrative penalties if we obtain, use, or disclose individually identifiable health information maintained by a HIPAA- covered entity in a manner that is not authorized or permitted by HIPAA. In addition, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. The global data protection landscape is rapidly evolving, and we may be or become subject to or affected by numerous federal, state, and foreign laws and regulations, as well as regulatory guidance, governing the collection, use, disclosure, transfer, security and processing of personal data, such as information that we collect about participants and healthcare providers in connection with clinical trials. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, which may create uncertainty in our business, affect our or our service providers’ ability to operate in certain jurisdictions or to collect, store, transfer use and share personal data, result in liability or impose additional compliance or other costs on us. Any failure or perceived failure by us to comply with federal, state or foreign laws or self- regulatory standards could result in negative publicity, diversion of management time and effort, and proceedings against us by governmental entities or others. In the United States, the California Consumer Privacy Act of 2018, or the CCPA, went into effect in January 2020. The CCPA provides new data privacy rights for consumers and new operational requirements for companies, including placing increased privacy and security obligations on entities handling certain personal data of consumers or households. These requirements could increase our compliance costs and potential liability. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and

receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact certain of our business activities. Additionally, **the CCPA was amended by a new California ballot initiative**, the California Privacy Rights Act, or **CPRA**, was passed in November 2020. The CPRA, which became effective on January 1, 2023 **imposes**. **The amendments introduced by the CPRA significantly modified the CCPA, including by imposing** additional obligations on **companies covered businesses** by the legislation and significantly modifies the CCPA, including by expanding consumers' rights **and imposing new obligations** with respect to certain sensitive personal information. The CPRA also **creates created** a new state agency that **is will be** vested with authority to implement and enforce the CCPA **and the CPRA**. The effects of the CCPA **and the CPRA, as amended**, are potentially significant and may require us to modify our data collection or processing practices and policies and to incur substantial costs and expenses in an effort to comply and increase our potential exposure to regulatory enforcement and / or litigation. **Also Furthermore, numerous states have passed broad** on March 2, 2021, Virginia enacted the Consumer **consumer** Data Protection Act, or CDDPA, which became effective January 1, 2023. In addition, on July 8, 2021, Colorado's governor signed the Colorado Privacy **privacy** Act, or CPA, into law and on March 24, 2022, Utah's governor signed into law the Utah Consumer Privacy Act (UCPA) which will take effect on December 31, 2023. Finally, in May 2022, Connecticut Governor Lamont signed the Connecticut Data Privacy Act, or CTDPA, into laws. **The that are similar in many respects to the UCPA CCPA and with many CTDPA draw heavily upon their other** predecessors in Virginia and Colorado. With the CTDPA, Connecticut became the fifth state **states proposing similar** to enact a comprehensive privacy law **laws**, but it is quite possible that other states will follow suit and **also pass comprehensive** **privacy- focused** bills have been proposed in many states. Such proposed legislation, **if, If** enacted, **this type of legislation** may add additional complexity, further variation in requirements, restrictions, and potential legal risk, require additional investment of resources in compliance programs, impact **data collection** strategies and the availability of previously useful data and could result in increased compliance costs and / or changes in business practices and policies. The existence of comprehensive privacy laws in different states **in within** the country **United States** will make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. **Further, in addition to comprehensive laws at the state level, some states have been proposing or passing laws that target particular aspects of privacy. For example, the state of Washington has passed a wide- ranging law that protects the privacy of medical and health- related information that is not covered by HIPAA and a small number of states have passed laws specifically focused on biometric information.** The increasing number and complexity of privacy and data protection laws, and other changes in laws or regulations across the globe, especially those associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from our clinical trials, could lead to government enforcement actions and significant penalties against us and could have a material adverse effect on our business, financial condition, or results of operations. Outside of the United States, we also face the challenge of stringent privacy and data protection laws. For example, legislators in the European Economic Area, or **the EEA**, adopted the **European Union, or EU**, General Data Protection Regulation, or **GDPR**, which became effective on May 25, 2018 and the **EU GDPR**, and **the EU GDPR**, as transposed into the laws of the **UK United Kingdom**, the UK GDPR, collectively referred to as the GDPR. The GDPR imposes more stringent data protection compliance requirements on controllers and processors of personal data **of subjects located in the EEA and UK**, including special protections for **" " special category data, " "** which includes health, biometric, and genetic information **of data subjects located in the EEA and UK** and provides for **more** significant penalties for noncompliance. Further, the GDPR provides a broad right for EEA Member States to create supplemental national laws, **such** as laws relating to the processing of health, genetic, and biometric data, which could further limit our ability to use and share such data or could cause our costs to increase, and harm our business and financial condition. The GDPR **includes** **creates new** compliance obligations that may be applicable to our business, which could cause us to change our business practices, and increases financial penalties for noncompliance (including possible fines of up to the greater of € 20 million (£ 17. 5 million under the UK GDPR) and 4 % of our global annual turnover for the preceding financial year for the most serious violations, as well as the right to compensation for financial or non- financial damages claimed by any individuals under Article 82 of the GDPR). In addition to such fines, we may be **the subject of to** litigation and / or adverse publicity, which could have a material adverse effect on our reputation and business. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross- border data transfers. The GDPR may increase our responsibility and liability in relation to personal data that we process where that processing is subject to the GDPR. In addition, we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including GDPR requirements as implemented by individual countries. **As a result of the implementation of the GDPR, we are required to put in place a number of measures to ensure compliance with the data protection regime.** The GDPR requires us to inform data subjects of how we process their personal data and how they can exercise their rights, ensure we have a valid legal basis to process personal data (if this is consent, the requirements for obtaining consent carries a higher threshold), and appoint a data protection officer where sensitive personal data (i. e., health data) is processed on a large scale. In addition, the GDPR introduces mandatory data breach notification requirements throughout the EEA and UK, requires us to maintain records of our processing activities and to document data protection impact assessments where there is high risk processing, imposes additional obligations on us when we are contracting with service providers, requires appropriate technical and organizational measures be put in place to safeguard personal data and requires us to adopt appropriate privacy governance including policies, procedures, training and data audit. We are taking steps to comply with the GDPR as appropriate and as and when applicable to us, but this is an ongoing compliance process. Compliance with the GDPR will be a rigorous and time-

intensive process that may increase our cost of doing business or require us to change our business practices. If our efforts to comply with GDPR or other applicable EU EEA and UK laws and regulations are not successful, or are perceived to be unsuccessful, it could adversely affect our business in the EU EEA and / or the UK. Significantly, the GDPR imposes strict rules on the transfer of personal data out of the EEA and UK to the United States or other regions outside the EEA / UK, or third countries, that have not been deemed to offer “adequate” privacy protections by the past competent data protection authorities, including companies in the United States in certain circumstances were able to rely upon the EU–United States, unless a derogation exists or adequate international UK–United States, and the Swiss–United States Privacy Shield frameworks to legitimize data transfers – transfer safeguards (for example from the EU and the UK to the United States In July 2020, the Court of Justice of the European Union, or CJEU, in Case C-311/18 (Data Protection Commissioner – Commission approved v Facebook Ireland and Maximilian Schrems, or Schrems II) invalidated the EU–United States Privacy Shield on the grounds that the Privacy Shield failed to offer adequate protections to EU personal data transferred to the United States. The CJEU, in the same decision, deemed that the Standard Contractual Clauses, or the EU SCCs, and published by the European Commission UK International Data Transfer Agreement / Addendum, or the EC, UK IDTA) are valid put in place. However, Where relying on the CJEU ruled that EU SCCs or UK IDTA for data transfers, we may also be required to carry out transfer impact assessments on the transfers made pursuant to the EU SCCs need to be assessed and UK IDTA, on a case-by-case basis, to ensure the law in the recipient country provides “essentially equivalent” protections to safeguard the transferred personal data as provided in the EEA EU, and UK, and may be required businesses to adopt supplementary measures if this standard is not met. The international Subsequent guidance published by the European Data Protection Board in June 2021 described what these supplementary measures must be, and stated that businesses should avoid or cease transfers – transfer of obligations under the EEA and UK data protection regimes will require significant effort and cost, and may result in us needing to make strategic considerations around where EEA and UK personal data is located and if, in the absence of supplementary measures, equivalent protections cannot be afforded. On June 4, 2021, the EC published new versions of the SCCs, which service seek to address the issues identified by the CJEU’s Schrems II decision and provide providers we can utilize for further details regarding the transfer assessments that the parties are required to conduct when implementing the new SCCs. However, there – the processing continue to be concerns about whether the SCCs and other mechanisms will face additional challenges. Similarly, the Swiss data protection authority determined the Swiss–United States Privacy Shield framework was no longer a valid mechanism for Swiss–United States data transfers and also raised questions about the validity of EEA and UK the SCCs as a mechanism for transferring personal data from Switzerland. While the SCCs provide an alternative to the Privacy Shield certification for EU–United States data flows, the decision (and certain regulatory guidance issued in its wake) casts doubt on the legality of EU–United States data flows in general. Any inability to transfer personal data from the EU EEA to the United States in compliance with data protection laws may impede our ability to conduct trials and may adversely affect our business and financial position. Although the UK is regarded as one of the third countries under the EU GDPR, the European Commission has adopted an adequacy decision in favor of the UK, enabling data transfers from EEA member states to the UK without additional safeguards. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing. The relationship between the UK and the EU in relation to certain aspects of data protection law remains unclear, and it is not subject to unclear how UK data protection laws and regulations will develop in the EC medium to longer term, and how data transfers to and from the UK will be regulated in the long term. Further, the UK government has introduced a Data Protection and Digital Information Bill, or the UK Bill, into the UK legislative process. The aim of the UK Bill is to reform the UK’s new SCCs but has published its own transfer mechanism, the International Data Transfer Agreement or International Data Transfer Addendum protection regime following Brexit. If passed, which enables transfers from the final version of the UK Bill may. On March 25, 2022, the EC and the US announced that they have reached a political agreement on a new “Trans-Atlantic the effect of further altering the similarities between the UK and EEA Data-data protection regime Privacy Framework,” which will replace the invalidated Privacy Shield and threaten, on December 13, 2022, the UK EC published a draft adequacy decision on from the European Commission Trans-Atlantic Data Privacy Framework. In addition, EEA Member States have adopted national laws to implement the GDPR that may partially deviate from the GDPR. Further, the competent authorities in the EEA Member States may interpret GDPR obligations slightly differently from country to country and therefore we do not expect to operate in a uniform legal landscape in the EEA. The potential of the respective provisions and enforcement of the EU GDPR and UK GDPR further diverging in the future creates additional regulatory challenges and uncertainties for us. This lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations could add legal risk, complexity and cost to our handling of personal data and our privacy and data security compliance programs and could require us to implement different compliance measures for the UK and the EEA. Outside of the United States and Europe, many jurisdictions in which we have CROs or otherwise do business are also considering and / or have enacted comprehensive data protection legislation. In addition, the UK has announced plans to reform the country’s data protection legal framework in its Data Reform Bill, but these have been put on hold. We may, however, incur liabilities, expenses, costs, and other operational losses under the GDPR and applicable EEA Member States and the UK privacy laws in connection with any measures we take to comply with them. We are may be subject to the supervision of local data protection authorities in those jurisdictions where we are processing personal data in the EEA and UK, including where our business activities involve monitoring the behavior of individuals in the EEA or UK (for example i.e., when undertaking clinical trials). We depend on a number of third parties in relation to the provision of our services, a number of which process personal data of EEA and / or UK individuals on our behalf. With each such provider we enter or intend to enter into contractual arrangements under which they are contractually obligated to only process personal data according to our instructions, and conduct or intend to conduct diligence to ensure that they have sufficient technical and organizational security measures in place. Further, certain health privacy laws, data breach

notification laws, consumer protection laws and genetic testing laws may apply directly to our operations and / or those of our collaborators and may impose restrictions on our collection, use and dissemination of individuals' health information. Patients about whom we or our collaborators may obtain health information, as well as the providers who may share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time- consuming to defend and could result in adverse publicity that could harm our business. If we or third- party CMOs, CROs or other contractors or consultants fail to comply with applicable federal, state / provincial or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or our contractors' ability to develop and commercialize our therapeutic candidates and could harm or prevent sales of any affected therapeutics that we are able to commercialize, or could substantially increase the costs and expenses of developing, commercializing, and marketing our therapeutics. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business. Increasing use of social media could give rise to liability, breaches of data security or reputational damage. Additionally, we are subject to state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor. If we or our third- party manufacturers and suppliers fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have an adverse effect on the success of our business. We are subject to numerous environmental, health, and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment, and disposal of hazardous materials and wastes. Our research and development activities involve the use of biological and hazardous materials and produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean- up and liabilities under applicable laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third- party CMOs for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. Upon an event of this nature, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and / or interrupt our business operations. Further, environmental laws and regulations are complex, change frequently, and have tended to become more stringent. We cannot predict the impact of any changes of this nature and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development, or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties, or other sanctions. Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials or other work- related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological waste or hazardous waste insurance coverage, workers compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological or hazardous waste exposure or contamination. We are subject to United States and certain foreign export and import controls, sanctions, embargoes, anti- corruption laws and anti- money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business. We are subject to export control and import laws and regulations, including the U. S. Export Administration Regulations, U. S. Customs regulations, various economic and trade sanctions regulations administered by the U. S. Treasury Department' s Office of Foreign Assets Controls, the U. S. Foreign Corrupt Practices Act of 1977, as amended, the U. S. domestic bribery statute contained in 18 U. S. C. § 201, the U. S. Travel Act, the USA PATRIOT Act of 2001 and other state and national anti- bribery and anti- money laundering laws in the countries in which we conduct activities. Anti- corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. In the future, we may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase and / or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We may also have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of these activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. Risks related to employee matters, managing growth, and operational matters We are highly dependent on our key personnel and anticipate hiring new key personnel. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific, medical personnel, sales and marketing, and other personnel. We are highly dependent on our management, scientific and medical personnel, including our President and Chief Executive Officer, Chief Scientific Officer, Chief Medical Officer, Chief Financial Officer, Chief Legal Officer, Chief People Officer, and Chief Business Officer. Our Chief **The loss of the services of any of our executive officers, other key employees, and other scientific and Medical**

medical advisors, Officer resigned in February 2023 and we have engaged an interim Chief Medical Officer while we complete a search for a permanent Chief Medical Officer inability to find suitable replacements could result in delays in product development, and harm our business. While we expect to engage in an orderly transition process if and when we integrate newly appointed officers and managers, we face a variety of risks and uncertainties relating to management transition, including diversion of management attention from business concerns, failure to retain other key personnel, or loss of institutional knowledge. ~~In addition, the loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and an inability to find suitable replacements could result in delays in product development, and harm our business.~~ We conduct our operations at our facilities in Watertown, Massachusetts. The Massachusetts region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. Changes to U. S. immigration and work authorization laws and regulations, including those that restrain the flow of scientific and professional talent, can be significantly affected by political forces and levels of economic activity. Our business may be materially adversely affected if legislative or administrative changes to immigration or visa laws and regulations impair our hiring processes and goals or projects involving personnel who are not U. S. citizens. To encourage valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options and other equity awards that vest over time or based on the achievement of milestones. The value to our employees of equity awards that vest over time may be significantly affected by movements in our stock price that are beyond our control and may, at any time, be insufficient to counteract more lucrative offers from other companies. The same may be true in respect of equity awards that vest based on the achievement of milestones. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our executive employees, these employment agreements provide for at- will employment, which means that any of our executive employees could leave our employment at any time, with or without notice. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid- level, and senior managers, as well as junior, mid- level, and senior scientific, medical, and general and administrative personnel. In addition, we have scientific and clinical advisors who assist us in formulating our development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours. ~~We will need to grow the size of our organization and we may experience difficulties in managing this growth, which could disrupt our operations. We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, manufacturing, regulatory affairs and, if any of our product candidates receives or is expected to receive marketing approval, sales, marketing, and distribution. In the future, we may need to increase the size of our general and administrative teams to support the growth of our business, our stage of company and / or the requirements of being a publicly traded company. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational, and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Future growth would impose significant added responsibilities on members of management, including:~~ • identifying, recruiting, integrating, maintaining, and motivating additional employees; • managing our internal development efforts effectively, including the clinical and FDA review process for our lead product candidates and any other product candidates we develop, while complying with our contractual obligations to contractors and other third parties; and • improving our operational, financial and management controls, reporting systems, and procedures. Our future financial performance and our ability to advance into clinical development and, if approved, commercialize our lead product candidates and any of our other product candidates we develop will depend, in part, on our ability to effectively manage any future growth. Due to our limited financial resources and the limited experience of our management team in managing a company with this type of anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. Further, research at our Chinese and Indian CROs also exposes us to various risks, including regulatory, economic, and political instability, potentially unfavorable tax, import and export policies, fluctuations in foreign exchange and inflation rates, international and civil hostilities, terrorism, natural disasters, and pandemics. Our internal computer systems, or those of any of our collaborators, vendors, contractors, or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs and could harm our reputation or subject us to liability, and adversely affect our business and financial results. Our internal computer systems and those of any collaborators, vendors, contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. While we have not experienced any material system failure, accidents, or security breaches of this nature to date, if an event of this nature were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications or the inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed, and the further development and commercialization of our product candidates could be delayed. Additionally, we may have data security obligations with respect to the information of third parties that we store. Unauthorized access or use of any third- party data or information of this nature could result in fines or other penalties that may impact our relationships with these third parties and our operations. Any actual or perceived security breach of our platform, systems, and networks could

damage our reputation and brand, expose us to a risk of litigation and possible liability, and require us to expend significant capital and other resources to respond to and alleviate problems caused by the security breach. Our ability to maintain adequate cyber- crime and liability insurance may be reduced. Some jurisdictions have enacted laws requiring companies to notify individuals of data security breaches involving certain types of personal data and our agreements with certain partners require us to notify them in the event of a security incident. These types of mandatory disclosures are costly, could lead to negative publicity, and may cause our partners to lose confidence in the effectiveness of our data security measures. Any of these events could harm our reputation or subject us to liability, and materially and adversely affect our business and financial results. Although we maintain cyber liability insurance, we cannot be certain that its coverage will be adequate for liabilities actually incurred or that insurance will continue to be available to us on economically reasonable terms, or at all. Our employees, independent contractors, vendors, principal investigators, CROs, and consultants may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements, and insider trading laws. We are exposed to the risk that our employees, independent contractors, vendors, principal investigators, CROs, CMOs, and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include, among other things: • intentional, reckless, or negligent conduct or disclosure of unauthorized activities that violate study and trial protocols or the regulations of the FDA or similar foreign regulatory authorities; • violations of healthcare fraud and abuse laws and regulations in the United States and abroad; • violations of U. S. federal securities laws relating to trading in our common stock; and • failures to report financial information or data accurately. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing, and other abusive practices. These laws and regulations regulate a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Other forms of misconduct could involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of business conduct and ethics and other corporate governance and compliance documents, policies and charters applicable to all of our employees. However, it is not always possible to identify and deter misconduct by employees and other third parties. Further, the precautions we take to detect and prevent this type of 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 comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege fraud or other misconduct, even if none occurred. If any actions of this nature are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and / or curtailment of our operations, any of which could adversely affect our business prospects, financial condition, and results of operations. Risks related to our common stock If we were to determine to raise additional capital in the future, you would suffer dilution of your investment. We may choose to raise additional capital in the future through the sale of shares or other securities convertible into shares, depending on market conditions, strategic considerations, and operational requirements. To the extent we raise additional capital in this manner, our stockholders will be diluted. Future issuances of our common stock or other equity securities, or the perception that sales of this nature may occur, could adversely affect the trading price of our common stock, and impair our ability to raise capital through future offerings of shares or equity securities. No prediction can be made as to the effect, if any, that future sales of common stock or the availability of common stock for future sales will have on the trading price of our common stock. **Currently** ~~We do not know whether an active, liquid, and orderly trading market will be sustained for our common stock or what the market price of our common stock will be and, as a result, it may be difficult for you to sell your shares of our common stock. Prior to our initial public offering, there was no public trading market for shares of our common stock. Although~~ our common stock is listed on The Nasdaq Global Select Market. **However, there may not be enough liquidity in such market to enable you to sell your shares of our common stock. Currently, our common stock is listed on The Nasdaq Global Select Market. If** an active trading market for our shares ~~may is not be sustained. You, you~~ may not be able to sell your shares quickly or at the market price ~~if~~. **We cannot predict the extent to which investor interest in us will lead to sustaining an active, liquid trading market** ~~in shares of our common stock is not active~~. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration. If securities or industry analysts do not publish or cease publishing research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price, and trading volume could decline. The trading market for our common stock is and will continue to be influenced by the research and reports that industry or securities analysts publish about us, our business or the targeted protein degradation space. We do not have control over these analysts. There can be no assurance that existing analysts will continue to provide research coverage or that new analysts will begin to provide coverage. Although we have obtained analyst coverage, if any of the analysts who cover us were to issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our preclinical studies and future clinical trials and results of operations fail to meet the expectations of any of these analysts, our stock price would likely decline. If one or more of these covering analysts were to cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause a decline in our stock price or trading volume. The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock. The trading price of shares of our common stock has been and may continue to be volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. The stock market in general, and the market for smaller biopharmaceutical companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of

particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the price at which you acquired it. The market price for our common stock may be influenced by many factors, including: • the degree of success of competitive products or technologies or changes in standard of care regimens; • results of preclinical studies and clinical trials of our product candidates or those of our competitors; • the timing and progress of our clinical development activities **and the timing of our release of data from our clinical trials**; • regulatory or legal developments in the United States and other countries; • developments or disputes concerning patent applications, issued patents, or other proprietary rights; • the recruitment or departure of key personnel; • the level of expenses related to any of our product candidates or clinical development programs and the value of the cash, cash equivalents, and marketable securities we hold; • the results of our efforts to discover, develop, acquire, or in-license additional technologies or product candidates; • actual or anticipated changes in estimates as to financial results, development timelines, or recommendations by securities analysts; • variations in our financial results or those of companies that are perceived to be similar to us; • changes in the structure of healthcare payment systems; • market conditions in the pharmaceutical and biotechnology sectors; • effects of public health crises, pandemics and epidemics, such as **the recent COVID-19 pandemic**; • general economic, industry, and market conditions; and • the other factors described in this “Risk Factors” section. If any of the foregoing factors were viewed as likely to have a negative impact on our business, prospects or operations or if our operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. In the past, following periods of volatility in the market price of a company’s securities, securities class-action litigation often has been instituted against that company. Litigation of this nature, if instituted against us, could cause us to incur substantial costs to defend these claims and divert management’s attention and resources, which could seriously harm our business, financial condition, results of operations, and prospects. Further, our director and officer liability insurance cost may increase as a result of litigation of this nature and our insurance deductible may be significant before our insurers are required to provide any coverage to us. We have broad discretion in the use of the capital we have raised and may not use our capital effectively. Our management has broad discretion in the application of the net proceeds from our prior financings, including our initial and follow-on public offerings, and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have an adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest the net proceeds from our financing activities in a manner that does not produce income or that loses value. Our executive officers, directors, and principal stockholders will have the ability to control or significantly influence matters submitted to stockholders for approval. Our executive officers and directors, combined with our stockholders who have reported through filings made with the Securities and Exchange Commission that they own more than 5% of our outstanding common stock, in the aggregate, beneficially own a significant percentage of our shares. As a result, our executive officers and directors, combined with our greater than 5% stockholders, have the ability to control us through this ownership position. These stockholders, if acting together, will consequently continue to control matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership control may: • delay, defer, or prevent a change in control; • entrench our management and the board of directors; or • impede a merger, consolidation, takeover, or other business combination involving us that other stockholders may desire. Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control, which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management. Our amended and restated certificate of incorporation and amended and restated by-laws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include: • a board of directors divided into three classes serving staggered three-year terms, the result of which is that not all members of the board will be elected at one time; • a prohibition on stockholder action through written consent, the result of which is that all stockholder actions will have to be taken at a meeting of our stockholders; • a requirement that special meetings of stockholders be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office; • advance notice requirements for stockholder proposals and nominations for election to our board of directors; • a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors; • a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any by-laws by stockholder action or to amend specific provisions of our certificate of incorporation; and • the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated by-laws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer, or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline. We will continue to incur additional costs as a result of operating as a public company and our management will be required to devote substantial time to new-compliance initiatives and corporate governance practices. As a public

company, we will continue to incur significant legal, accounting, and other expenses that we ~~did~~ would not have to incur as a private company. The Sarbanes- Oxley Act of 2002, or Sarbanes- Oxley, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Stock Market LLC and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance and insurance costs and make some activities more time- consuming and costly. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors. We continually evaluate these rules and regulations and cannot always predict or estimate the amount of additional costs we may incur or the timing of these costs. These rules and regulations are also often subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. Pursuant to Section 404 of Sarbanes- Oxley, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, as a “~~“~~ smaller reporting company ~~”~~,” we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm until we are no longer a smaller reporting company. As of the end of our fiscal year ended December 31, ~~2022~~ **2023**, we qualified as a “ non- accelerated filer ” as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act and as a “~~“~~ smaller reporting company ~~”~~.” Our compliance with Section 404 necessitates that we incur substantial accounting expense and expend significant management efforts. We will need to continue to dedicate internal resources, potentially engage outside consultants, and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk ~~we~~ will be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. Further, we cannot assure you that the measures we have taken in the past or will take in the future will prevent the occurrence of future material weaknesses or significant deficiencies in our internal control over financial reporting. If we identify one or more material weaknesses in the future, it could result in an adverse reaction in the financial markets and restrict our future access to the capital markets due to a loss of confidence in the reliability of our ~~condensed~~ consolidated financial statements. Our amended and restated by- laws designate specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us. Pursuant to our amended and restated by- laws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for state law claims for (i) any derivative action or proceeding brought on our behalf; (ii) 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; (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or our amended and restated certificate of incorporation or amended and restated by- laws; (iv) any action to interpret, apply, enforce, or determine the validity of our amended and restated certificate of incorporation or amended and restated by- laws; or (v) any action asserting a claim governed by the internal affairs doctrine. We refer to this provision in our amended and restated by- laws as the Delaware Forum Provision. The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act of 1933, as amended, the Securities Act, or the Exchange Act of 1934, as amended, or the Exchange Act. Our amended and restated by- laws further provide that unless we consent in writing to the selection of an alternative forum, the U. S. District Court for the District of Massachusetts shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, as our headquarters are located in Watertown, Massachusetts. We refer to this provision in our amended and restated by- laws as the Federal Forum Provision. In addition, our amended and restated by- laws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the Delaware Forum Provision and the Federal Forum Provision. The Delaware Forum Provision and the Federal Forum Provision in our amended and restated by- laws may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, these forum selection clauses may limit our stockholders’ ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, and may discourage the filing of lawsuits against us and our directors, officers, and employees, even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are “~~“~~ facially valid ~~”~~” under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the U. S. District Court for the District of Massachusetts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders. Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain. We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. ~~In addition, the terms of our Credit Agreement with Perceptive Credit also preclude us from paying dividends.~~ As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Unstable market conditions and downturn in economic

and market conditions may have serious adverse consequences on our business, financial condition and stock price. Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, the global financial crisis caused extreme volatility and disruptions in the capital and credit markets. Similarly, the recent significant volatility associated with the ongoing COVID- 19 pandemic has **and recent geopolitical tensions, including the conflicts between Russia and Ukraine and Israel and Hamas, have** caused significant instability and disruptions in the capital and credit markets. **Global** In recent months, we have observed increased economic **conditions continue to be volatile and uncertainty-- uncertain** in the United States and abroad. Our operations could be adversely affected by economic and political changes in the markets, including higher inflation **rates, increasing interest** rates, supply chain disruptions, recessions, trade restrictions, tariff increases or potential new tariffs, and economic embargoes imposed by the United States. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for our product candidates, and could also impact our ability to raise additional capital when needed on acceptable terms, if at all. Our general business strategy may be adversely affected by any economic downturn of this nature, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, costly and dilutive, or not available at all. Failure to secure any necessary financing in a timely manner and on favorable terms could have an adverse effect on our growth strategy, financial performance, and stock price –and could require us to delay, modify, or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers, and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget –. The outstanding debt under our term loan with Perceptive Credit Holdings III, LP bears interest at a variable rate using the greater of LIBOR or 1.75 %, plus 9.50 %. The loan is secured by a lien on substantially all of our assets. Continued increases in interest rates could increase the cost of servicing or refinancing our outstanding indebtedness, and could adversely affect our results of operations, financial condition, liquidity, and cash flows. Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management’s attention and resources, which could adversely affect our business prospects, financial condition, and results of operations. **Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non- performance by financial institutions or transactional counterparties, could adversely affect the Company’s current and projected business operations and its financial condition and results of operations. Actual events involving limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market- wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank, or SVB, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or the FDIC, as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. Although a statement by the Department of the Treasury, the Federal Reserve and the FDIC indicated that all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB, Signature Bank or any other financial institution that is placed into receivership by the FDIC may be unable to access undrawn amounts thereunder. While none of these bank closures presented a material exposure to the Company, if any of our lenders or counterparties to any such instruments were to be placed into receivership, we may be unable to access the funds held by those institutions. In addition, if any of our partners, suppliers or other parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties’ ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. In this regard, uncertainty remains over liquidity concerns in the broader financial services industry. Similar impacts have occurred in the past, such as during the 2008- 2010 financial crisis. Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to \$ 25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. Additionally, there is no guarantee that the U. S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion. We periodically assess our banking and other relationships as we believe necessary or appropriate, including to ensure that we have appropriate diversification in these relationships. Nonetheless, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the Company, the financial institutions with which the Company has credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which**

the Company has financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.