Risk Factors Comparison 2024-03-15 to 2023-03-30 Form: 10-K

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To enforce these requirements, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Failure to maintain compliance with applicable requirements, especially security and recordkeeping and as manifested in loss or diversion or inability to account for all controlled substances, can result in administrative, civil, or criminal enforcement action that could have a material adverse effect on our business, results of operations, and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate administrative proceedings to revoke those registrations. The DEA may also reduce or deny quota to manufacturing facilities based on non- compliance with these requirements. In certain circumstances, violations could result in criminal proceedings. Individual states also independently regulate controlled substances. Legislative and Regulatory Initiatives for Opioids In response to widespread prescription opioid abuse, the United States government and a number of state legislatures have enacted legislation and regulations intended to fight the opioid epidemic. The number and scope of legislative and regulatory actions, particularly in the last three years, emphasize the severity of the opioid epidemic and its impact on our society. The FDA has stated that addressing prescription drug abuse is a priority and has reaffirmed that the development of abuse- deterrent opioids is a key part of that strategy. Recent actions to address the opioid abuse epidemic include: ● FDA guidance: In April 2015, the FDA adopted final guidance regarding studies and clinical trials that should be conducted to demonstrate that a given formulation has abuse- deterrent properties, how those studies and clinical trials will be evaluated, and what product labeling claims may be approved based on the results of those studies and clinical trials. The guidance describes four categories of abuse- deterrence studies and clinical trials: Categories 1, 2, and 3 consist of pre- marketing studies and clinical trials designed to evaluate a product candidate' s potentially abuse- deterrent properties under controlled conditions, while Category 4, post- marketing clinical trials and studies, assesses the real- world impact of abuse- deterrent formulations. The final guidance also provides examples of product label claims that may be made based on the results of the corresponding studies and clinical trials. ● FDA Opioids Action Plan: In February 2016, the FDA released an action plan to address the opioid abuse epidemic and reassess the FDA' s approach to opioid medications. The FDA' s plan is part of a broader initiative led by the U. S. Department of Health and Human Services (" HHS "), to address opioid-related overdose, death, and dependence. ● CDC Prescribing Guidelines: In November 2022, the CDC released a new Guideline for Prescribing Opioids for Pain to update their 2016 Guidelines. The new guidance includes recommendations for managing acute (duration of < 1 month), subacute (duration of 1 – 3 months), and chronic (duration of > 3 months) pain. The guideline addresses the following four areas: 1) determining whether or not to initiate opioids for pain, 2) selecting opioids and determining opioid dosages, 3) deciding duration of initial opioid prescription and conducting follow- up, and 4) assessing risk and addressing potential harms of opioid use. The guideline addresses the following four areas: 1) determining whether or not to initiate opioids for pain, 2) selecting opioids and determining opioid dosages, 3) deciding duration of initial opioid prescription and conducting follow- up, and 4) assessing risk and addressing potential harms of opioid use. ● **FDA Drug Safety Communication: In April 2023, the FDA issued a communication that in the ongoing effort to address the nation' s opioid crisis, it was making several updates to the prescribing information of opioid pain medicines to provide additional guidance on their use. The changes include label updates addressing addiction, abuse and misuse as well as life-threatening respiratory depression, accidental ingestion, risks from concomitant use with other CNS depressants, neonatal withdrawal and opioid analgesic risk evaluation and mitigation strategy.** ● Enhanced Warnings and Safety Labeling: In March 2016, the FDA announced required enhanced warnings for immediate- release opioid pain medications related to risks of misuse, abuse, addiction, overdose, and death. Subsequently, there have been several class- wide labeling changes, including the addition of boxed warnings relating to serious risks of using certain opioids medications along with benzodiazepines and other central nervous system depressants, including alcohol (Decembers 2016); and additional information relating to the new class- wide REMS (Septembers 2018). ● Enactment of the Comprehensive Addiction and Recovery Act (" CARA "): In 2016, the CARA was enacted to address the national epidemics of prescription opioid abuse and heroin use. Consistent with the initiatives of HHS, this legislation sought to, among other things, expand the availability of naloxone for law enforcement and other first responders; form an interagency task force to develop best practices for pain management with opioid medications; and provide resources to improve state monitoring of controlled substances, including opioids. In 2018, CARA 2. 0 was introduced as follow- up legislation to limit initial prescriptions for opioids to 3 days, while exempting initial prescriptions for chronic care, cancer care, hospice or end of life care, and palliative care. ● Enactment of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (" SUPPORT Act "): In November 2018, the SUPPORT Act was enacted as a comprehensive legislative response to the continuing opioid epidemic. It includes a number of measures directed towards regulation and improvement of treatment for substance use- disorder and increased coverage by CMS of medically assisted treatment options. In addition, the SUPPORT Act requires HHS to report to Congress on existing barriers to access to abuse- deterrent opioid formulations by Medicare Part C and D beneficiaries. It also includes a number of requirements directed at reducing the potential for oversupply of opioids to reduce the potential for misuse and diversion. ~~Human Capital Resources As of December 31, 2022, we had seven full- time employees and five consultants. Of these, five have a Ph. D. and two have an M. B. A. From time to time, we also retain independent contractors to support our organization. None of our employees are represented by a labor union or covered by collective bargaining agreements, and we believe our relationship with our employees is good. Identification of Our Executive Officers The Company' s Executive Officers and their age and position are below. Name Age * Officer Since Position Dr. Lynn Kirkpatrick, Ph. D President, Chief~~

Executive Officer and Class III Director Geoffrey Birkett Chief Commercial Officer David Humphrey, CPA Chief Financial Officer, Secretary and Treasurer Dr. Jeffrey Millard, Ph. D. Chief Operating Officer Dr. Linda Pestano, Ph. D. Chief Development Officer Dr. William Schmidt, Ph. D. Chief Medical Officer * Ages presented as of December 31, 2022 Dr. Lynn Kirkpatrick, Ph. D. has served as our Chief Executive Officer since January 2009. Dr. Kirkpatrick has spent over 30 years in drug discovery and development, has initiated the clinical development of four novel drug candidates and now strives to bring highly novel and safe pain therapies to commercialization. She received a Doctor of Philosophy (" Ph. D. ") degree in Medicinal and Biomedicinal Chemistry at the University of Saskatchewan, completed a Post- Doctoral Fellowship at the Yale University School of Medicine, and became a tenured full professor in the Department of Chemistry at the University of Regina. She co-founded ProlX Pharmaceuticals, Corp. (" ProlX ") an oncology discovery company, becoming Chief Executive Officer and successfully bringing three small molecules from discovery into clinical development, two of these her own discoveries from academia. ProlX was acquired by Biomira Inc., and Dr. Kirkpatrick became the Chief Scientific Officer of the merged company to focus on the development of oncology products and vaccines. In 2009, she co- founded PHusis Therapeutics, developing targeted small molecule precision medicines for oncology. At the same time, she became our Chief Executive Officer. Dr. Kirkpatrick has published extensively in the area of targeted drug discovery, abuse deterrent pain products and holds numerous patents for novel drugs and modalities. We believe Dr. Kirkpatrick is qualified to serve on our Board because of her extensive executive experience in our industry and her service as our Chief Executive Officer. Geoffrey Birkett has served as our Chief Commercial Officer since October 2018. He has over 30 years of experience in the Pharmaceutical and Biotechnology area. He started his career as a biochemist at the Royal Victoria Infirmary in Newcastle- upon- Tyne, England. He then moved into the pharmaceutical industry, where he focused on pain / addiction and neuroscience throughout his career. He has developed and launched several groundbreaking therapies, including Nicorette (POM) and (OTC), Lexapro and several other psychiatry agents with Lundbeck. Mr. Birkett assisted on the launch of Prozac and Humatrope (human growth hormone) with Eli Lilly. He assisted in moving Seroquel from Phase 2 to global market leader with multi- billion dollar sales and he also participated in the launch of Zomig for migraines, which became a European market leader. He worked for most of his pharmaceutical career at AstraZeneca plc in both the United Kingdom and the United States, where he held many roles including overseeing the global oncology division. When the AstraZeneca merger took place, Mr. Birkett ran the merger process outside the United States across all markets, and ran a corporate change program to streamline research and development involving 67, 000 staff. Since leaving AstraZeneca, Mr. Birkett has held multiple roles in biotech companies as senior officer or as a consultant. He is co-founder of a novel drug delivery company and has consulted for IPSOS, a large global research and consulting firm. He also served as president for North America / Canada of INDIVIOR, a large company producing addiction treatment drugs. Mr. Birkett joined us in 2018 and is focused on building a world class commercial team. Mr. Birkett attended Henley Business College in London and INSEAD Business School in France where he studied general management and a global leadership. David Humphrey, CPA has served as our Chief Financial Officer since February 2021. Prior to joining the Company, Mr. Humphrey was most recently Chief Financial Officer of Senomyx, Inc. (" Senomyx "), a publicly held biotechnology company focused on taste science. In his previous employment, he guided public company financial reporting, including Forms 10- K, 10- Q, 8- K, S- 3, S- 8, proxy statements and SOX internal controls compliance, and acted as primary liaison with the audit committee and external auditors. Mr. Humphrey advised Senomyx' s board of directors, as part of core executive management team, in a $ 75 million acquisition by Firmenich SA, a private Swiss multinational flavor and fragrance company. Previously, he held finance and accounting leadership positions and consulted at numerous life sciences companies, including ActivX Biosciences, Aurora Biosciences and Gensia. Mr. Humphrey started his career as an accountant at Price Waterhouse. He holds a Bachelor of Science with Honors in Accountancy from the University of Illinois at Urbana- Champaign and is a Certified Public Accountant in California. Dr. Jeffrey Millard, Ph. D. has served as our Chief Operating Officer since January 2019. Dr. Millard has both academic and industrial experience in chemistry and pharmaceutical sciences covering all aspects of chemistry, manufacturing, and controls, or CMC. He has been involved in both start- up biotech as well as small and mid- sized public biopharmaceutical companies. Dr. Millard has been directly responsible for research and development activities and writing of more than seven IND submissions and Investigational Medicinal Product Dossiers, or IMPDs. He has directed the CMC efforts from discovery and in- licensing through commercial launch activities. His experience covers the application programming interface, or API, lifecycle (from synthetic route scouting, process chemistry, analytical chemistry development and validation, cGMP production and release of API, to QbD and process validation), and drug product development through manufacture. Dr. Millard received a Bachelor of Arts from Rice University and a Ph. D. in Pharmaceutical Sciences from the University of Arizona. Dr. Linda Pestano joined Ensysce in October 2021, as Chief Development Officer. Dr. Pestano has worked throughout her career to guide the development of novel therapeutics to improve patient outcomes and quality of life. She has 20 years of experience developing vaccines, drugs and novel biologics for a diverse range of indications. She has been instrumental in guiding new therapies, including small molecules, nucleic acids, and biologicals through development into clinical trials. Dr. Pestano' s expertise spans lead development, pre- clinical and translational studies, and interacting with multiple regulatory agencies. Dr. Pestano received her PhD from Tufts University and undertook a Post- Doctoral Fellowship with Dana Farber Cancer Institute at the Harvard Medical School in Boston. Dr. William K. Schmidt, Ph. D., has served as our Chief Medical Officer since January 2016. He is also the Head of NorthStar Consulting, the Parliamentarian and a former president of the Eastern Pain Association, the largest regional affiliate of the American Pain Society. He has over 25 years of pharmaceutical industry experience with a special emphasis on the discovery and development of novel analgesic and narcotic antagonist drugs. He was previously Vice President of Clinical Development for CrystalGenomics (Seoul, South Korea) and its United States subsidiary, CG Pharmaceuticals (Emeryville, CA); Senior Vice President of Development at Limerick BioPharma; Vice President, Clinical Research, for Renovis, Inc.; and Vice President, Scientific Affairs and acting Vice President, Clinical Research and Development, at Adolor Corporation. At Adolor Corporation, Dr. Schmidt was a key member of the team leading

to the clinical development, NDA filing, and FDA approval of Entereg ® (alvimopan), a peripherally acting opioid antagonist. Currently Dr. Schmidt serves as an expert on pain medicine pharmaceutical development with pharmaceutical and biotech companies throughout North America, Europe, Asia, Latin America, and Australia. Dr. Schmidt received a Bachelor of Arts degree from the University of California Berkeley and his Ph. D. University of California- San Francisco. Item 1A. Risk Factors Risks Related to Our Business, Financial Condition and Capital Requirements The report of our independent registered accounting firm on our audited financial statements for the fiscal year ended December 31, 2022 contains an explanatory paragraph relating to our ability to continue as a going concern. The auditor' s opinion on our audited financial statements for the year ended December 31, 2022 includes an explanatory paragraph stating that the Company does not have revenue generating activities and is dependent on additional financing to fund operations. These conditions raise substantial doubt about the Company' s ability to continue as a going concern. While we believe that we will be able to raise the capital we need to continue our operations, there can be no assurances that we will be successful in these efforts or will be able to resolve our liquidity issues or eliminate our operating losses. If we are unable to obtain sufficient funding, we would need to significantly reduce our operating plans and curtail some or all of our product development activities. Accordingly, our business, prospects, financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all. We are a clinical- stage pharmaceutical company with a limited operating history. We have incurred significant financial losses since our inception and anticipate that we will continue to incur significant financial losses for the foreseeable future. We are a clinical- stage pharmaceutical company with a limited operating history. We have not yet demonstrated an ability to generate revenues, obtain regulatory approvals, engage in clinical development beyond Phase 1 trials, manufacture any product on a commercial scale or arrange for a third party to do so on our behalf or enter into licensing arrangements to commercialize a product, or conduct sales and marketing activities necessary for successful product commercialization. We have no products approved for commercial sale and we have not generated any revenue from product sales to date, nor do we expect to generate any significant revenue from product sales for the next few years. We will continue to incur significant research and development and other expenses related to our product development, preclinical and clinical activities and ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. Our net loss was $ 24. 2 million for the year ended December 31, 2022 and $ 29. 1 million for the year ended December 31, 2021. As of December 31, 2022, we had an accumulated deficit of $ 110. 9 million. We expect to continue to incur significant losses for the foreseeable future as we continue our research and development of, and seek regulatory approvals for, our product candidates. If we continue to suffer losses as we have since inception, investors may not receive any return on their investment and may lose their entire investment. In addition, as a public company, we incur significant additional legal, accounting and other expenses that we did not incur as a private company as we: ● meet the requirements and demands of being a public company; ● expand our operational, financial and management systems and increases personnel to support our operations; ● hire additional clinical, quality control, medical, scientific and other technical personnel to support our clinical operations; ● advance our clinical- stage product candidate PF614 through clinical development; ● advance our preclinical stage product candidates into clinical development; ● seek regulatory approvals for any product candidates that successfully complete clinical trials; ● undertake any pre- commercialization activities to establish sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own or jointly with third parties; ● maintain, expand and protect our intellectual property portfolio; and ● make milestone, royalty or other payments due under any future in- license or collaboration agreements. Pharmaceutical product development entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, secure market access and reimbursement and become commercially viable. Therefore, any investment in us would be highly speculative. Our prospects are subject to the costs, uncertainties, delays and difficulties frequently encountered by companies in clinical development, especially clinical- stage pharmaceutical companies such as ours. Any predictions you make about our future success or viability may not be as accurate as they would otherwise be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products. We will likely encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. Additionally, our expenses could increase beyond our expectations if we are required by the United States Food and Drug Administration, or FDA, or other regulatory authorities to perform clinical trials in addition to those that we currently expect to conduct, or if there are any delays in establishing appropriate manufacturing arrangements for or in completing our clinical trials or the development of any of our product candidates. Our ability to generate revenue from any of our potential products is subject to our ability to obtain regulatory approval and fulfill numerous other requirements and we may never be successful in generating revenues or becoming profitable. Our ability to become and remain profitable depends on our ability to generate revenue or execute other business development arrangements. We do not expect to generate significant revenue, if any, unless and until we are able to obtain regulatory approval for, and successfully commercialize the product candidates we are developing or may develop. Successful commercialization, to the extent it occurs, will require achievement of many key milestones, including demonstrating safety and efficacy in clinical trials, obtaining regulatory approval for these product candidates, manufacturing, marketing and selling, or entering into other agreements to commercialize, those products for which we may obtain regulatory approval, satisfying any post- marketing requirements and obtaining reimbursement for our products from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we cannot accurately and precisely predict the timing and amount, if any, of revenues, the extent of any further losses or when we might achieve profitability. We may never succeed in

these activities and, even if we do, we may never generate revenues that are sufficient enough for us 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 may depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. We require substantial additional funding. If we are unable raise capital when needed, we could be forced to delay, reduce or terminate our product discovery and development programs or commercialization efforts. We are a clinical stage pharmaceutical company that will need to raise additional capital to continue to operate as a going concern. Our quarterly operating results are likely to show continued losses in the future. Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the clinical and preclinical development of our product candidates, including our planned Phase 2 program for nafamostat and planned clinical trials for PF614 and PF614- MPAR ™. We will need to raise additional capital to complete our currently- planned clinical trials and any future clinical trials. Other unanticipated costs may arise during our development efforts. If we can obtain marketing approval for product candidates that we develop, we would require significant additional amounts of funding to launch and commercialize such product candidates. We cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we develop and we will require substantial additional funding to complete the development and commercialization of our product candidates. Our future need for additional funding depends on many factors, including: ● the scope, progress, results and costs of researching and developing our current product candidates, as well as other additional product candidates we may develop and pursue in the future, including the costs related to preclinical and clinical development of the product; ● the timing of, and the costs involved in, obtaining marketing approvals for our product candidates and any other additional product candidates we may develop and pursue in the future; ● the number of future product candidates that we may pursue and their development requirements; ● subject to receipt of regulatory approval, the costs of commercialization activities for our product candidates, to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities; ● subject to receipt of regulatory approval, the amount of revenue, if any, received from commercial sales of our product candidates or any other additional product candidates we may develop and pursue in the future; ● the extent to which we in- license or acquire rights to other products, product candidates or technologies; ● our ability to establish collaboration arrangements for the development of our product candidates on favorable terms, if at all; ● dependent on financing, our headcount growth and associated costs as we expand our research and development and establishes a commercial infrastructure; ● the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and ● the costs of operating as a public company. A change in the outcome of any of these or other factors with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate, and many of these factors are outside of our control. Identifying potential product candidates and conducting preclinical studies and clinical trials is a time- consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory and marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. We cannot be certain that additional funding will be available on acceptable terms, or at all. Please see the risk factors under " Risks Related to the Ownership of Common Stock and Financial Reporting. " We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2023, while advancing our main product candidates such as, PF614 and PF614 MPAR ™ and nafamostat through their respective next phases of clinical development. Our estimate may prove to be wrong, and we could use our available capital resources, if any, sooner than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. To the extent this occurs, it could impose significant dilution on our stockholders. 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. Attempting to secure additional financing may divert our management from our day- to- day activities, which may adversely affect our ability to develop our product candidates. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our platforms, programs, planned clinical trials or future commercialization efforts. We may incur additional dilution upon repayment of the Investor Notes with common stock. Under the terms of the Securities Purchase Agreement, we are permitted to repay principal and interest on the Investor Notes by issuing additional shares of common stock. In addition, the conversion price of the Investor Notes, and the exercise price of the Prior Warrants, are subject to downward revision in the event we make certain issuances of our common stock at prices below the conversion price. The conversion price of the 2022 Notes and exercise price of the Prior Warrants have been reset, but not below a price of $ 2. 006 for the Prior Warrants issued in 2022, $ 15. 60 for the Prior Warrants issued in 2021 and $ 2. 006 for the 2022 Notes (temporarily reduced for the 2022 Notes to $ 0. 7512 for the period from January 12, 2023 until May 12, 2023). In such case, stockholders will have dilution in amounts exceeding the straight conversion of the Investor Notes or, with respect to the Prior Warrants, the Company will receive a reduced level of proceeds from the exercise of the Prior Warrants. Please see the discussion of conversion and exercise prices under " Description of Capital Stock — Convertible Promissory Notes " and " — Warrants. " The price of our common stock on Nasdaq and Public Warrants on the OTC Pink Open Market may be volatile. The price of our common stock on Nasdaq and our Public Warrants on the OTC Pink Open Market may fluctuate due to a variety of factors, including: ● changes in the industries in which we and our customers operate; ● variations in our operating performance and the performance of our competitors in general; ● material and adverse impact of the COVID- 19 pandemic on the markets and the broader global

economy; ● actual or anticipated fluctuations in our quarterly or annual operating results; ● publication of research reports by securities analysts about us, our competitors or our industry; ● the public' s reaction to our press releases, other public announcements and filings with the SEC; ● our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market; ● additions and departures of key personnel; ● changes in laws and regulations affecting our business; ● commencement of, or involvement in, litigation involving us; ● news about, among other things, the results of our clinical trials or other developments, or the use or abuse of opioids, ● changes in our capital structure, such as future issuances of securities or the incurrence of additional debt; ● sales, or anticipated sales, of large blocks of our common stock; ● the volume of shares of our common stock available for public sale; and ● general economic and political conditions such as recessions, interest rates, fuel prices, foreign currency fluctuations, international tariffs, social, political and economic risks and acts of war or terrorism. These and other factors, many of which are beyond our control, may cause the market price and demand for our shares of common stock to fluctuate substantially. Low trading volume could increase the volatility of our share price in response to news in the market, could prevent investors from readily selling their shares and may otherwise negatively affect the market price and liquidity of our shares. In addition, in the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management from our business, which could significantly harm our profitability and reputation. If we are unable to regain compliance with the listing standards of Nasdaq, our common stock may become delisted, which could have a material adverse effect on our ability to raise funding, which could negatively impact our business, capital and financial condition. We are not in compliance with Nasdaq listing standards for our common stock and have been granted an exception through June 12, 2023 to meet a number of obligations before June 12, 2023 that have been imposed by Nasdaq and to meet all listing requirements no later than June 12, 2023. If we do not meet all of those obligations by the deadlines imposed, our common stock could be delisted by Nasdaq. If delisting occurs, it could be more difficult to buy or sell our securities and to obtain accurate quotations, and the price of our common stock could suffer a material decline. In addition, a delisting would impair our ability to raise capital through the public markets, could deter broker- dealers from making a market in or otherwise seeking or generating interest in our securities and might deter certain institutions and persons from investing in our securities. Any of these could negatively impact our financial condition or our ability to operate our business and maintain adequate capital. There may be no proceeds under the GEM Agreement or proceeds may be less than anticipated. The issuances of common stock pursuant to the GEM Agreement would result in dilution of existing stockholders and could have a negative impact on the market price of our common stock. Additionally, the negative covenants under the GEM Agreement are onerous and any breach by us thereunder may entitle GEM Global and GYBL to indemnification payments, reimbursements of legal and other expenses and other compensation thereby diverting our time and resources. While we have raised capital from other sources, we have not used the GEM Facility to date. Under a Share Purchase Agreement between us, GEM Global Yield LLC SCS (" GEM Global ") and GEM Yield Bahamas Limited (" GYBL "), dated as of December 29, 2020, including a Registration Rights Agreement between the same parties and dated as of the same date (the " GEM Agreement "), we are entitled to draw down up to $ 60 million of gross proceeds from GEM Global in exchange for shares of our common stock at a price equal to 90 % of the average closing bid price of the shares of our common stock on Nasdaq for a 30 day period, subject to meeting the terms and conditions of the GEM Agreement. This equity line facility is available for a period of 36 months from the closing date of the Merger. However, we have not been able to make use of the GEM Facility and we may not be able to do so before it expires. Please see the section entitled " Business " for additional information. The limitations on the amount and frequency of the draws that we can make pursuant to the GEM Agreement, which include the requirement that (i) there be an effective registration statement and (ii) size restrictions relating to our trading volume, may affect the ability to draw under the GEM Agreement and result in proceeds that are less than anticipated. In addition, the occurrence of the Merger triggered (i) payment of a commitment fee of $ 1. 2 million to GEM Global payable in either our common stock or cash, of which all has been satisfied with 46, 062 shares of common stock transferred from related parties in July 2022 and an additional 533, 334 shares of common stock issued in January 2023 and (ii) the issuance of a warrant granting GYBL the right to purchase 55, 306 shares of our common stock, at a strike price per share of $ 0. 7512 as of January 12, 2023. The number of shares underlying the warrant as well as the strike price is subject to adjustments for recapitalizations, reorganizations, change of control, stock split, stock dividend, reverse stock splits and certain issuances of additional shares of our common stock. The issuances of shares at discount under the GEM Agreement and the anti- dilution protection granted to GEM Global in connection with issuances of additional shares of our common stock, would result in dilution of existing stockholders and have a negative impact on the market price of our common stock and our ability to obtain equity financing. In addition, the negative covenants under the GEM Agreement are onerous and any breach thereof may trigger indemnification, reimbursement of losses and other liability for us thereby diverting our time and resources. To date, we have not used the GEM facility to raise capital. Our business is highly dependent on the success of our product candidates. If we are unable to successfully complete clinical development, obtain regulatory approval for or commercialize one or more of our product candidates, or if we experience delays in doing so, our business will be materially harmed. Our future success and ability to generate significant revenue from our product candidates, which we do not expect will occur for several years, is dependent on our ability to successfully develop, obtain regulatory approval for and commercialize one or more of our product candidates. A Phase 1b study of PF614 was initiated in 2021. Part A of the study completed enrollment in December 2021 and Part B was completed mid- year 2022. A Phase 1 trial was also initiated for PF614- MPAR ™ in December 2021 and the clinical portion of Part A of that trial was completed in December 2022. All of our other product candidates are in earlier stages of development and will require substantial additional investment for manufacturing, preclinical testing, clinical development, regulatory review and approval in one or more jurisdictions. If any of our product candidates encounter safety or efficacy problems, development

delays or regulatory issues or other problems, our development plans and business would be materially harmed. We may not have the financial resources to continue development of our product candidates. Even if clinical trials are completed, we may experience other issues that may delay or prevent regulatory approval of, or our ability to commercialize, our product candidates, including: ● inability to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective; ● insufficiency of our financial and other resources to complete the necessary clinical trials and preclinical studies; ● negative or inconclusive results from our clinical trials, preclinical studies or the clinical trials of others for product candidates that are similar to ours, leading to a decision or requirement to conduct additional clinical trials or preclinical studies or abandon a program; ● product- related adverse events experienced by subjects in our clinical trials, including unexpected toxicity results, or by individuals using drugs or therapeutic biologics similar to our product candidates; ● delays in submitting an Investigational New Drug application, or IND, or comparable foreign applications or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial or a suspension or termination, or hold, of a clinical trial once commenced; ● conditions imposed by the FDA, the European Medicines Agency, or EMA, or comparable foreign regulatory authorities regarding the scope or design of our clinical trials; ● poor effectiveness of our product candidates during clinical trials; ● better than expected performance of control arms, such as placebo groups, which could lead to negative or inconclusive results from our clinical trials; ● delays in enrolling subjects in clinical trials; ● high drop- out rates of subjects from clinical trials; ● inadequate supply or quality of product candidates or other materials necessary for the conduct of our clinical trials; ● greater than anticipated clinical trial or manufacturing costs; ● unfavorable FDA, EMA or comparable regulatory authority inspection and review of a clinical trial site; ● failure of our third- party contractors or investigators to comply with regulatory requirements or the clinical trial protocol or otherwise meet their contractual obligations in a timely manner, or at all; ● unfavorable FDA, EMA or comparable regulatory authority inspection and review of manufacturing facilities or inability of those facilities to maintain a compliance status acceptable to the FDA, EMA or comparable regulatory authorities; ● delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our therapies in particular; or ● varying interpretations of data by the FDA, EMA and comparable foreign regulatory authorities. Our product candidates will require additional, time- consuming development efforts prior to commercial sale, including preclinical studies, clinical trials and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that such product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot assure stockholders that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives. We depend heavily on the success of our lead product candidate PF614, which is currently in clinical trials. Our clinical trials of PF614 may not be successful. If we are unable to commercialize PF614 or experience significant delays in doing so, our business will be materially harmed. We have invested a significant portion of our efforts and financial resources in the research and development of our lead product candidate, PF614 and we expect to continue to do so. Our ability to generate revenues from the sale of abuse- deterrent opioid products, which may not occur at a significant level for several years, will depend heavily on the successful development, regulatory approval and eventual commercialization of PF614. We cannot commercialize product candidates in the United States without first obtaining regulatory approval for the product from the FDA; similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from similar regulatory authorities outside of the United States. Even if PF614 or another product candidate were to successfully obtain approval from the FDA and non- U. S. regulatory authorities, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post- approval study or risk management requirements. If we are unable to obtain regulatory approval for PF614 in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development, marketing and / or commercialization of PF614 or any other product candidate that we may discover, in- license, develop or acquire in the future. Furthermore, even if we obtain regulatory approval for PF614, we will still need to develop a commercial organization, or collaborate with third parties for the commercialization of PF614, establish commercially viable pricing and obtain approval for adequate reimbursement from third- party and government payors. If we or our commercialization collaborators are unable to successfully commercialize PF614, we may not be able to generate sufficient revenues to continue our business. Due to the significant resources required for the development of our product pipeline, and depending on our ability to access capital, we must prioritize the development of certain product candidates over others. Moreover, we may fail to expend our limited resources on product candidates or indications that may have been more profitable or for which there is a greater likelihood of success. We currently have three clinical- stage product candidates as well as certain other product candidates that are at various stages of preclinical development. We seek to maintain a process of prioritization and resource allocation to maintain an optimal balance between aggressively pursuing our more advanced clinical- stage product candidates, such [as nafamostat], PF614 and PF614- MPAR ™, and ensuring the development of additional potential product candidates. Due to the significant resources required for the development of our product candidates, we must focus on specific diseases and disease pathways and decide which product candidates to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial products and may divert resources away from better opportunities. If we make incorrect determinations regarding the viability or market potential of any of our product candidates or misinterpret trends in the pharmaceutical industry, in particular for opioid abuse and drug overdose, our business, financial condition, and results of operations could be materially adversely affected. As a result, we may (i) fail to capitalize on viable commercial products or profitable market opportunities, (ii) be required to forego or

delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or (iii) relinquish valuable rights to such product candidates through collaboration, licensing, or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights. Our PF614 and PF614- MPAR ™ product candidates may not be successful in limiting or impeding abuse, overdose or misuse or providing additional safety upon commercialization. We are committing a substantial majority of our resources to the development of products utilizing our TAAP and MPARTM. There can be no assurance that our products will perform as tested and limit or impede the actual abuse, overdose or misuse of such products or provide other benefits in commercial settings. Moreover, there can be no assurance that if our products are approved by the FDA, the post- approval epidemiological studies required by the FDA as a condition of any such approvals of the products will show a reduction in the consequences of abuse and misuse by patients for whom the applicable product is prescribed. The failure of our products to limit or impede actual abuse, overdose or misuse or provide other safety benefits in practice will have a material adverse impact on market acceptance for such products and on our financial condition and results of operations. If we fail to discover, develop and commercialize other product candidates, we may be unable to grow our business and our ability to achieve our strategic objectives would be impaired. In addition, we may also seek to commercialize certain treatments that may not be proprietary to us. Although the development and commercialization of our current product candidates are our initial focus, as part of our long- term growth strategy, we plan to develop other product candidates. We may also seek to commercialize treatments that may not be proprietary to us. We intend to evaluate internal opportunities from our existing product candidates or other potential product candidates. While our technology platforms have potential applicability to other uses, we have not conducted any clinical trials on these other uses and we may not be successful in developing product candidates for other uses. In addition, we intend to devote capital and resources for basic research to discover and identify additional product candidates. These research programs require technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following: ● the research methodology used may not be successful in identifying potential product candidates; ● competitors may develop alternatives that render our product candidates obsolete; ● product candidates that we develop may nevertheless be covered by third parties' patents or other exclusive rights; ● a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria; ● a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and ● a product candidate may not be accepted as safe and effective by patients, the medical community or third- party payors. In addition, future acquisitions may entail numerous operational and financial risks, including: ● exposure to unknown liabilities; ● disruption of our business and diversion of our management' s time and attention to develop acquired products or technologies; ● incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions; ● higher than expected acquisition and integration costs; ● difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel; ● increased amortization expenses; ● impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and ● inability to motivate key employees of any acquired businesses. If we are unsuccessful in identifying and developing additional product candidates, either through internal development or acquisition from third parties, our potential for growth and achieving our strategic objectives may be impaired. If we do not achieve our projected development and commercialization goals within the timeframes we expect, the development and commercialization of our product candidates may be delayed, and our business and results of operations may be harmed. For planning purposes, we seek to estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings, or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of marketing approval or a commercial launch of a product. The potential achievement of many of these milestones may be outside of our control. Each of these milestones is based on a variety of assumptions which, if not realized as expected, may cause the timing of such potential achievement of the respective milestones to vary considerably from our estimates, including: ● our available capital resources or capital constraints we experience; ● the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators; ● our ability to identify and enroll patients who meet clinical trial eligibility criteria; ● our receipt of approvals by the FDA and other regulatory authorities and the timing thereof; ● clinical outcomes; ● other actions, decisions or rules issued by regulators; ● our ability to access sufficient, reliable and affordable supplies of materials used in the manufacture of our product candidates; ● the efforts of our collaborators with respect to the commercialization of our product candidates; and ● the securing of, costs related to, and timing issues associated with, product manufacturing as well as sales and marketing activities. If we fail to achieve any announced milestones in the timeframes we expect, the development and commercialization of our product candidates may be delayed, and our business and results of operations may be harmed and it could negatively impact our share price performance. Please see " Business " for more information. Competitive products may reduce or eliminate commercial opportunity for our product candidates, if approved. If our competitors develop technologies or product candidates more rapidly than we do, or their technologies or product candidates are more effective or safer than any such technologies or product candidate of ours, our ability to develop and successfully commercialize our own technologies or product candidates may be adversely affected. The clinical and commercial landscapes for the solution of opioid abuse and drug overdose are highly competitive and subject to rapid and significant technological change. We face competition with respect to our indications for our product candidates and will face competition with respect to any other product candidates that we may seek to develop or

commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are several large pharmaceutical and biotechnology companies that currently market and sell drugs or are pursuing the development of product candidates for the treatment of the indications that we are pursuing. These companies include, but are not limited to, Purdue Pharma, LP, and Collegium Pharmaceutical, Inc. Potential competitors include companies developing novel non- opioid pain drug candidates such as pharmaceutical companies and academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. We believe that a significant number of product candidates are currently under development for the same indications that we are currently pursuing, and some or all may become commercially available in the future for the treatment of conditions for which we are trying or may try to develop product candidates. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. See the section entitled " Business — Competition " for examples of the competition that our product candidates face. Our competitors may have significantly greater financial resources, established presence in the market, expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than us. Accordingly, our competitors may be more successful than we may be in obtaining regulatory approval for therapies and achieving widespread market acceptance. Our competitors' products may be more effective, or more effectively marketed and sold, than any product candidate we may commercialize and may render our therapies obsolete or non- competitive before we can recover development and commercialization expenses. If any of our product candidates, including PF614, is approved, these product candidates could compete with a range of therapeutic treatments that are in development. In addition, our competitors may succeed in developing, acquiring or licensing technologies and products that are more effective or less costly than PF614, our other product candidates or any other product candidates that we may develop, which could render our product candidates obsolete and noncompetitive. If we obtain approval for any of our product candidates, we may face competition based on many different factors, including the efficacy, safety and tolerability of our products, the ease with which our products can be administered, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Existing and future competing products could present superior treatment alternatives, including being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or noncompetitive before we are able to recover the expense of developing and commercializing our product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan. In addition, our competitors may obtain patent protection, regulatory exclusivities or FDA approval and commercialize products more rapidly than we do, if we are successful at all, which may impact future approvals or sales of any of our product candidates that receive regulatory approval. If the FDA approves the commercial sale of PF614 or any other product candidate, we will also be competing with respect to marketing capabilities and manufacturing efficiency. We expect any such competition among products will be based on product efficacy and safety, the timing and scope of regulatory approvals, availability of supply, marketing and sales capabilities, product price, reimbursement coverage by government and private third- party payors, regulatory exclusivities and patent position. Our profitability and financial position will suffer if our product candidates receive regulatory approval but cannot compete effectively in the marketplace. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites, as well as in acquiring technologies complementary to, or necessary for, our programs. Our business could be harmed if we lose the services of our key personnel or if we are unable to hire additional highly qualified employees. Our business depends upon our ability to attract and retain highly qualified personnel, including managerial, sales and technical personnel. We compete for key personnel with other companies, healthcare institutions, academic institutions, government entities and other organizations. Our ability to maintain and expand our business may be impaired if we are unable to retain our current key personnel or hire or retain other qualified personnel in the future. We currently only have seven full- time employees and five consultants and we expect to add additional employees. Our future success also depends on our ability to identify, attract, hire or engage, retain and motivate other well- qualified managerial, technical, clinical and regulatory personnel. Competition for such individuals, particularly in the United States, is intense, and we may not be able to hire sufficient personnel to support our efforts. There can be no assurance that such professionals will be available in the market, or that we will be able to retain existing professionals or to meet or to continue to meet their compensation requirements. Furthermore, our cost base with respect to such compensation, which may include equity compensation, may increase significantly, which could have a material adverse effect on our financial results, including the potential for additional dilution to our stockholders. Failure to establish and maintain an effective management team and work force could adversely affect our ability to operate, grow and manage our business. Our employees, independent contractors, principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations. We are exposed to the risk that we and our contract research organizations' (" CROs ") employees and contractors, including principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and / or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies; manufacturing standards; federal and state healthcare fraud

and abuse and health regulatory laws and other similar foreign fraudulent misconduct laws; or laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained during clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter third- party misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations Some of our programs are partially supported by government grant awards, which may not be available to us in the future. We have received funding under grant award programs funded by governmental agencies, such as the NIH and NIDA. To fund a portion of our future research and development programs, we may apply for additional grant funding from these or similar governmental agencies in the future. However, funding by these, and other, governmental agencies may be significantly reduced or eliminated in the future for several reasons. For example, some programs are subject to a yearly appropriations process in Congress. In addition, we may not receive full funding under current or future grants because of budgeting constraints of the agency administering the program or unsatisfactory progress on the study being funded. Also, the continued spread of COVID- 19 could affect governmental priorities in the future or prospective funding for our product candidates. Therefore, we cannot provide any assurance that we will receive any future grant funding from any government agencies, or, that if received, we will receive the full amount of the particular grant award. Any such reductions could delay the development of our product candidates and the introduction of new products. Dependent on financing, we expect to expand our organization, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations. Dependent on financing, we expect to experience growth in the number of our employees and the scope of our operations. To manage these growth activities, 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. Our management may need to devote a significant amount of their attention to managing these growth activities. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations, retain key employees, or identify, recruit and train additional qualified personnel. Our inability to manage the expansion of our operations effectively may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could also require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced and we may not be able to implement our business strategy, including the successful commercialization of our product candidates. The failure of financial institutions or transactional counterparties could adversely affect our current and projected business operations and our financial condition and results of operations. On March 8, 2023, Silvergate Bank announced that it would self liquidate. On March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, with the Federal Deposit Insurance Corporation (" FDIC ") appointed as receiver. On March 12, 2023, Signature Bank was closed by the New York State Department of Financial Services, with the FDIC appointed as receiver. The standard deposit insurance amount is up to $ 250, 000 per depositor, per insured bank, for specified account categories. Although we do not have any funds deposited with the above- named banks, we regularly maintain cash balances with other financial institutions in excess of the FDIC insurance limit. A failure of a depository institution to return deposits could impact access to our invested cash or cash equivalents and could adversely impact our liquidity and financial performance. Risks Related to Our Dependence on Third- Party Providers We currently rely on, and expect to rely on in the future, third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for completing such trials, failing to satisfy legal or regulatory requirements or terminating the relationship. We currently rely on, and expect to rely on in the future, third- party CROs to conduct research and development activities and our clinical trials for our product candidates. Agreements with these CROs might terminate for a variety of reasons, including for their failure to perform. Entry into alternative arrangements, if necessary, could significantly delay our product development activities. Our reliance on these CROs for research and development activities and clinical trials will reduce our control over these activities but will not relieve us of any of our responsibilities. 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 good clinical practices, or 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 and confidentiality of trial participants are protected. If these CROs do not successfully carry out their contractual duties, meet expected deadlines or conduct the clinical trials in accordance with regulatory requirements or our stated protocols, it could adversely affect the development of our product candidates and it could result in us not being able to obtain, or being delayed in obtaining, marketing approvals for our product candidates and it could adversely affect our efforts to successfully commercialize our product candidates. We expect to be completely dependent on third parties to manufacture our product candidates, and our commercialization of our product candidates could be halted, delayed or made less profitable if those third parties fail to maintain a compliance status acceptable to the FDA or comparable foreign regulatory authorities, fail to provide to us with sufficient quantities of our product candidates or fail to do so at acceptable quality levels or prices. We do not currently have, nor do we plan to acquire, the capability or infrastructure to manufacture the ingredients in our product

candidates for use in our clinical trials or for commercial product, if any. We have entered into a Manufacturing Agreement (the " Recro Agreement ") with Recro Gainesville LLC (" Recro ") now known as Societal CDMO, (" Societal ") for the production of PF614 capsules and other materials and services with respect to our clinical studies. In addition, we do not have the capability to encapsulate any of our product candidates as a finished product for commercial distribution. As a result, we expect to be obligated to rely on contract manufacturers, like Societal, if and when any of our product candidates are approved for commercialization. In the event that Societal is unable to perform its obligations under the Recro Agreement, we may be unable to replace the Societal Agreement on terms as favorable to us. We have not entered into an agreement with any contract manufacturers for commercial supply and may not be able to engage a contract manufacturer for commercial supply of any of our product candidates on favorable terms to us, or at all. The processes used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or comparable foreign regulatory authorities and the facilities at which the product candidates are manufactured must maintain a compliance status acceptable to the FDA and foreign regulatory authorities. FDA and foreign regulatory authorities will conduct inspections after we submit a new drug application, or NDA, to the FDA or its equivalent to other relevant regulatory authorities. We will not control the manufacturing process of, and will be completely dependent on, its contract manufacturing partners for compliance with cGMPs for manufacture of both active drug substances and finished products. These cGMP regulations cover all aspects of the manufacturing, testing, quality control and record keeping relating to our product candidates. If our contract manufacturers, including Societal, do not successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, our product candidates may not be approved. If these facilities do not maintain a compliance status acceptable to the FDA, Drug Enforcement Agency, or DEA, or comparable regulatory authorities, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Our contract manufacturers, including Societal, will be subject to ongoing periodic unannounced inspections by the FDA, DEA and corresponding state and foreign agencies for compliance with cGMPs, security, recordkeeping and similar regulatory requirements. Although we will not have control over our contract manufacturers' compliance with these regulations and standards, we are nonetheless responsible for assuring such compliance. Failure by any of our contract manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure to grant approval to market any of our product candidates, delays, suspensions or withdrawals of approvals, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business and results of operations. Failure by our contract manufacturers to comply with or maintain any of these standards could adversely affect our ability to develop, obtain regulatory approval for or market any of our product candidates. If, for any reason, these third parties, including Societal, are unable or unwilling to perform, we may not be able to terminate our agreements with them, and we may not be able to locate alternative manufacturers or formulators or enter into favorable agreements with them and we cannot be certain that any such third parties will have the manufacturing capacity to meet future requirements. If these manufacturers or any alternate manufacturer of finished drug product experiences any significant difficulties in its respective manufacturing processes for our ingredients or finished products or should cease doing business with us, we could experience significant interruptions in the supply of any of our product candidates or may not be able to create a supply of our product candidates at all. Our inability to coordinate the efforts of our third- party manufacturing partners, or the lack of capacity available at our third-party manufacturing partners, could impair our ability to supply any of our product candidates at required levels. Because of the significant regulatory requirements that we would need to satisfy in order to qualify a new bulk or finished product manufacturer, if we face these or other difficulties with our current manufacturing partners, we could experience significant interruptions in the supply of any of our product candidates if we decide to transfer the manufacture of any of our product candidates to one or more alternative manufacturers in an effort to deal with the difficulties. Any manufacturing problem or the loss of a contract manufacturer, including Societal, could be disruptive to our operations and delay development of our investigational products. Additionally, we rely on third parties to supply the raw materials needed to manufacture our potential products. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to a future contract manufacturer caused by problems at suppliers could delay shipment of any of our investigational products and, if approved, product candidates. We cannot guarantee that our future manufacturing and supply partners will be able to reduce the costs of commercial scale manufacturing of any of our product candidates over time. If the commercial- scale manufacturing costs of any of our product candidates are higher than expected, these costs may significantly impact our operating results. In order to reduce costs, we may need to develop and implement process improvements. However, in order to do so, we will need, from time to time, to notify or make submissions with regulatory authorities, and the improvements may be subject to approval by such regulatory authorities. We cannot be sure that we will receive these necessary approvals or that these approvals will be granted in a timely fashion. We also cannot guarantee that we will be able to enhance and optimize output in our commercial manufacturing process. If we cannot enhance and optimize output, we may not be able to reduce our costs over time. If we are unable to develop our sales, marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing our product candidates. We currently have no marketing, sales or distribution capabilities. We intend to establish a sales and marketing organization, either on our own or in collaboration with third parties, with technical expertise and supporting distribution capabilities to commercialize PF614 or one or more of our other product candidates that may receive regulatory approval in key territories. These efforts will require substantial additional resources, some or all of which may be incurred in advance of any approval of the product candidate. Any failure or delay in the development of our or third parties' internal sales, marketing and distribution capabilities would adversely impact the commercialization of PF614, our other product candidates and other future product candidates. Factors that may inhibit our efforts to commercialize our product candidates on our own include: ● our inability to recruit and retain effective sales and

marketing personnel; ● the inability of sales personnel to obtain access to or persuade physicians to prescribe any future products; ● the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and ● unforeseen costs and expenses associated with creating an independent sales and marketing organization. With respect to our existing and future product candidates, we may choose to collaborate with third parties that have direct sales forces and established distribution systems to serve as an alternative to our own sales force and distribution systems. Our future product revenue may be lower than if we directly marketed or sold our product candidates, if approved. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third parties, which may not be successful and are generally not within our control. If we are not successful in commercializing any approved products, our future product revenue will suffer and we may incur significant additional losses. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates. Risks Related to Product Development, Regulatory Approval, Manufacturing and Commercialization The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time- consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed. We are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining regulatory approval from the FDA. Foreign regulatory authorities, such as the EMA, impose similar requirements. The time required to obtain approval by the FDA and comparable foreign authorities is inherently unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate' s clinical development and may vary among jurisdictions. To date, we have not submitted an NDA to the FDA or similar drug approval submissions to comparable foreign regulatory authorities for our most advanced product candidate, PF614, or any other product candidate. We must complete additional preclinical studies and clinical trials to demonstrate the safety and efficacy of our product candidates in humans before we will be able to obtain these approvals. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. The clinical development of our initial and potential additional product candidates is susceptible to the risk of failure inherent at any stage of development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of adverse events that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements, and determination by the FDA or any comparable foreign regulatory authority that a product candidate may not continue development or is not approvable. It is possible that even if any of our product candidates has a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of such product candidate that is greater than the actual positive effect, if any. Similarly, in our clinical trials, we may fail to detect toxicity of, or intolerability caused by, such product candidate, or mistakenly believe that our product candidates are toxic or not well tolerated when that is not in fact the case. Serious adverse events, or SAEs, or other adverse effects, as well as tolerability issues, could hinder or prevent market acceptance of the product candidate at issue. Our current and future product candidates could fail to receive regulatory approval for many reasons, including the following: ● the FDA or comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials; ● we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for our proposed indication; ● the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; ● we may be unable to demonstrate that a product candidate' s clinical and other benefits outweigh its safety risks; ● the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from clinical trials or preclinical studies; ● the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA to the FDA or other submission or to obtain regulatory approval in the United States, the European Union or elsewhere; ● the FDA or comparable foreign regulatory authorities may find deficiencies with the manufacturing processes of third- party manufacturers with which we contract for clinical and commercial supplies; and ● the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. This lengthy approval process as well as the unpredictability of clinical trial results may result in us failing to obtain regulatory approval to market any product candidate we develop, which would substantially harm our business, results of operations and prospects. The FDA and other comparable foreign authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be granted for any product candidate that we develop. Even if we believe the data collected from future clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or any other regulatory 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 labeling that does not include the 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. The FDA may recommend scheduling with respect to any of our current or future product candidates. In such event, prior to a product launch, the DEA will need to determine the controlled substance schedule of the product, taking into account the recommendation of the FDA. The timing of the scheduling process is uncertain and may delay our ability to market any product candidate that we successfully developed and approved. If our clinical trials fail to replicate positive results from earlier preclinical studies or clinical trials conducted by us or third parties, we may be unable to

successfully develop, obtain regulatory approval for, or commercialize our product candidates. The results observed from preclinical studies or early- stage clinical trials of our product candidates may not necessarily be predictive of the results of later-stage clinical trials that we conduct. Similarly, positive results from such preclinical studies or early- stage clinical trials may not be replicated in our subsequent preclinical studies or clinical trials. For example, preclinical studies showed that PF614 does not readily convert into oxycodone in the blood stream following direct injection, and the Phase 1 trial we have conducted with TAAP prodrug PF614 (" prodrug ": a medication or compound that, after administration, is metabolized, i. e., converted within the body into a pharmacologically active drug), demonstrated that, after oral administration, the corresponding opioid was measured in the subjects' blood. Furthermore, our product candidates may not be able to demonstrate similar activity or adverse event profiles as other product candidates that we believe may have similar profiles. There can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for drugs proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late- stage clinical trials after achieving positive results in early- stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA, EMA or comparable foreign regulatory authority approval. The FDA, EMA or comparable foreign regulatory authorities may disagree with our regulatory plan for our product candidates. We have submitted IND applications for PF614 and nafamostat and completed a Phase 1 trial for each product candidate. We have applied for and received fast track designation for PF614. However, fast track designation does not guaranty a faster development or regulatory review or approval process and does not assure FDA approval. We have received feedback from the FDA on requirements to achieve abuse deterrent labeling claims for PF614. We have submitted an IND for PF614- MPAR ™ and have received feedback on required pre- clinical, manufacturing and clinical studies that will be required for an NDA. Our clinical trial results may not support approval of our product candidates. The general approach for FDA approval of a new drug is dispositive data from two or more well- controlled Phase 3 clinical trials of the product candidate in the relevant patient population. Phase 3 clinical trials typically involve a large number of patients, have significant costs, and take years to complete. In addition, there is no assurance that the endpoints and trial designs that we intend to use for our planned clinical trials, including those that we have developed based on feedback from regulatory agencies or those that have been used for the approval of similar drugs, will be acceptable for future approvals. For example, while we have designed our Phase 2 clinical trials of nafamostat for coronaviral infections after receiving input and feedback from the FDA, there can be no assurance that the design of our planned clinical trials will be satisfactory to the FDA, the FDA will not require us to modify our trials, these trials will enable us to conduct the required Phase 3 studies or other testing or that completing these trials will result in regulatory approval. Interim topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publish interim topline or preliminary data from our clinical trials. Interim data from clinical trials that we may complete 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. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data is available. Adverse differences between preliminary or interim data and final data could significantly harm our reputation and business prospects. Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time- consuming and uncertain and may prevent us from obtaining approvals for the commercialization of our product candidates. Any product candidate we develop and the activities associated with such development and commercialization, including our design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of the product candidates we are developing or may seek to develop in the future will ever obtain regulatory approval. Ensysce has no experience in submitting and supporting the applications necessary to gain marketing approvals and we expect to rely on third-party CROs or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate' s safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us from obtaining marketing approval or prevent or limit commercial use. The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and requires additional preclinical,

clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Any marketing approval that we may ultimately obtain could be limited or subject to restrictions or post- approval commitments that render the approved product not commercially viable. For example, during the product approval process, the FDA will determine whether a REMS plan is necessary to assure the safe use of the product. All opioid analgesic products currently on the market in the United States are subject to a REMS. A REMS may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate health care providers of the risks, limitations on who may prescribe or dispense the drug or other measures that the FDA deems necessary to assure the safe use of the drug. In addition, the REMS plan must include a timetable to assess the strategy at eighteen months, three years and seven years after approval. We may be required to develop a REMS for the product, or participate in a REMS with other manufacturers, or to develop a similar strategy as required by a regulatory authority. Even if approved, our contract manufacturers will need to obtain quota from DEA to manufacture sufficient quantities and maintain inventories of product to be commercially distributed. If we experience delays in obtaining manufacturing approval or if we fail to obtain manufacturing approval of any product candidates we may develop, the commercial prospects for those product candidates may be harmed, and our ability to generate revenues will be materially impaired. We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the preclinical and clinical studies necessary for development and commercialization of our product candidates. To obtain the requisite regulatory approvals to commercialize any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans. We may experience delays in completing our clinical trials or preclinical studies and initiating or completing additional clinical trials or preclinical studies, including as a result of regulators not allowing or delay in allowing clinical trials to proceed under an IND, or not approving or delaying approval for any clinical trial grant or similar approval that we need to initiate a clinical trial. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize the product candidates we develop, including: ● regulators, or institutional review boards, or IRBs, or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site; ● we may not reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; ● we may experience challenges or delays in recruiting principal investigators or study sites to lead our clinical trials; ● the number of subjects or patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate; ● our third- party contractors, including those manufacturing our product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; ● we may have to amend clinical trial protocols submitted to regulatory authorities or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to resubmit to an IRB and regulatory authorities for re- examination; ● regulators or other reviewing bodies may find deficiencies with or subsequently find fault with the manufacturing processes or facilities of third- party manufacturers with which we enter into agreement for clinical and commercial supplies, or the supply or quality of any product candidate or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; and ● the potential for approval policies or regulations of the FDA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval. Regulators or IRBs of the institutions in which clinical trials are being conducted may suspend, limit or terminate a clinical trial, or data monitoring committees may recommend that we suspend or terminate a clinical trial, due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold (such as the clinical hold placed on PF614-MPAR in January 2021), safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions, or lack of adequate funding to continue the clinical trial. Negative or inconclusive results from our clinical trials or preclinical studies could mandate repeated or additional clinical trials and, to the extent we choose to conduct clinical trials in other indications, could result in changes to or delays in clinical trials of our product candidates in such other indications. We do not know whether any clinical trials that we conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates for the indications that we are pursuing. If later- stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for our product candidates will be adversely impacted. Our failure to successfully initiate and complete clinical trials and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates would significantly harm its business. The development costs of our product candidates will also increase if we experience delays in testing or regulatory approvals and we may be required to obtain additional funds to complete clinical trials. We cannot assure stockholders that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure or otherwise modify our trials after they have begun. Significant clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or 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 and results of operations. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected. The timely completion of clinical trials in accordance with our protocols depends on, among other things, our ability to enroll a sufficient number of patients who remain in the study

until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of factors, including: ● the patient eligibility criteria defined in the protocol; ● the size of the patient population required for analysis of the trial's primary endpoints; ● the proximity of patients to study sites; ● the design of the trial; ● our ability to recruit clinical trial investigators with the appropriate competencies and experience; ● competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications that we are investigating; ● our ability to obtain and maintain patient consents; and ● the risk that patients enrolled in clinical trials will drop out of the trials before completion. In addition, our clinical trials may compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. Furthermore, if significant adverse events or other side effects are observed in any of our clinical trials, we may have difficulty recruiting patients to our trials and patients may drop out of our trials. Our inability to enroll enough patients for our clinical trials would result in significant delays or might require us to abandon one or more clinical trials or our development efforts altogether. Delays in patient enrollment may result in increased costs, negatively affect the timing or outcome of the planned clinical trials, delay the product candidate development and approval process and jeopardize our ability to seek and obtain the regulatory approval required to commence product sales and generate revenue, which could cause our value to decline and limit our ability to obtain additional financing if needed. Fast track designation by the FDA for PF614 for chronic pain may not lead to a faster development or regulatory review or approval process and does not assure FDA approval. We have obtained fast track designation for PF614 for management of moderate to severe chronic pain when a continuous, around- the- clock analgesic is needed for an extended period of time. We believe that fast track designation will enable us to facilitate the development and expedite the review of PF614. Fast track designation does not ensure that PF614 will receive marketing approval or that approval will be granted within any particular timeframe. As a result, we may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast track designation does not guarantee that an NDA will obtain priority review designation. If any of these events occur, it could require us to conduct more extensive clinical trials and go through more extensive FDA review, which could substantially increase expenses and delay the time for commercializing our products. If the FDA does not conclude that certain of our product candidates satisfy the requirements for the Section 505 (b) (2) regulatory approval pathway, or if the requirements for such product candidates under Section 505 (b) (2) are not as we expect, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful. We may seek FDA approval through the Section 505 (b) (2) regulatory pathway for our product candidate PF614. Section 505 (b) (2) of the Federal Food, Drug and Cosmetic Act, or FDC Act, permits the submission of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505 (b) (2), if applicable to us under the FDC Act, would allow an NDA we submit to FDA to rely in part on data in the public domain or on the FDA's prior conclusions regarding the safety and effectiveness of an approved product, or listed drug, which could expedite the development program for our product candidates by potentially decreasing the amount of data that we would need to generate in order to obtain FDA approval. If the FDA does not agree that the 505 (b) (2) regulatory pathway is appropriate or scientifically justified for PF614, we may need to conduct additional preclinical and clinical trials, provide additional data and information, and meet additional standards for regulatory approval. For example, the FDA may not agree that we have provided a scientific bridge, through comparative bioavailability data, to demonstrate that reliance on the prior findings of safety or efficacy for a listed drug is justified. If this were to occur, the time and financial resources required to obtain FDA approval for this product candidate, and complications and risks associated with this product candidate, would likely substantially increase. We could need to obtain additional funding, which could result in significant dilution to the ownership interests of our then existing stockholders to the extent we issue equity securities or convertible debt. We cannot assure you that we would be able to obtain such additional financing on terms acceptable to us, if at all. Moreover, the inability to pursue the Section 505 (b) (2) regulatory pathway may result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact of our competitive position and prospects. Even if we are allowed to pursue the Section 505 (b) (2) regulatory pathway, we cannot assure our stockholders that our product candidates will receive the requisite approvals for commercialization. In addition, notwithstanding the approval of a number of products by the FDA under Section 505 (b) (2) over the last few years, certain brand- name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505 (b) (2). If the FDA's interpretation of Section 505 (b) (2) is successfully challenged, the FDA may change its 505 (b) (2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505 (b) (2). The pharmaceutical industry is highly competitive, and Section 505 (b) (2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505 (b) (2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. Even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505 (b) (2) regulatory pathway, there is no

guarantee this would ultimately lead to accelerated product development or earlier approval. Moreover, even if our product candidates are approved under Section 505 (b) (2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post- marketing testing and surveillance to monitor the safety or efficacy of the products. If we submit a 505 (b) (2) application that references a third-party product, we may be subject to a patent infringement suit and the approval of our product may be delayed. If we submit a 505 (b) (2) application that relies in whole or in FDA' s findings for a listed drug, we will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA' s publication Approved Drug Products with Therapeutic Equivalence Evaluations, which we refer to as the Orange Book, with respect to the listed drug; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of our product. A certification that our new drug will not infringe the Orange Book- listed patents for the applicable listed drug, or that such patents are invalid, is called a paragraph IV certification. If we submit a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to the NDA holder once our 505 (b) (2) application is filed by the FDA. The third party may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving our 505 (b) (2) application until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in our favor. If the third party does not file a patent infringement lawsuit within the required 45- day period, our 505 (b) (2) application will not be subject to the 30- month stay of FDA approval. Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay. As product candidates proceed through preclinical studies to late- stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay or prevent completion of clinical trials, require conducting bridging clinical trials or repeating one or more clinical trials, increase clinical trial costs, delay or prevent approval of our product candidates and jeopardize our ability to commence sales and generate revenue. Our product candidates may cause undesirable side effects or have other properties **Properties** that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if obtained. Undesirable side effects caused by any of our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in restrictive warnings or contraindication or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. In our planned and future clinical trials of our product candidates, we may observe a less favorable safety and tolerability profile than was observed in earlier- stage testing of these candidates. Undesirable side effects have been observed in our product candidates to date. For example, in clinical trials of PF614, opioid side effects were observed. Many compounds that initially showed promise in clinical or earlier- stage testing are later found to cause undesirable or unexpected side effects that prevented further development of the compound. Results of future clinical trials of our product candidates could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics, despite a favorable tolerability profile observed in earlier- stage testing. If unacceptable side effects arise in the development of our product candidates, we, the FDA or comparable foreign regulatory authorities, the IRBs, or independent ethics committees at the institutions in which its trials are conducted, could suspend, limit or terminate our clinical trials, or the independent safety monitoring committee could recommend that we suspend, limit or terminate our trials, or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment- emergent side effects that are deemed to be drug- related could delay recruitment of clinical trial subjects or may cause subjects that enroll in our clinical trials to discontinue participation in our clinical trials. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We may need to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in harm to patients that are administered our product candidates. Any of these occurrences may adversely affect our business, financial condition and prospects significantly. Moreover, clinical trials of our product candidates are conducted in carefully defined sets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. FDA' s evolving standards for the approval of opioid products may delay or prevent approval of our product candidates. FDA has identified addressing misuse and abuse of opioid drugs as one of its highest priorities. As part of its plan, the agency has established new standards for the development of prescription opioids with abuse- deterrent formulations and has published two sets of guidance. Since the publication of the second guidance in November 2017, FDA has not approved any new abuse – deterrent opioid drugs. If we are unable to meet FDA' s new and evolving standards for approving opioid products, we will not be able to market our products. Product liability lawsuits against us or any of our future collaborators could divert our resources and attention, cause us to incur substantial liabilities and limit commercialization of our product candidates. We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. Currently, we have no products that have been approved for commercial sale; however, the use of our product candidates by us and any collaborators in clinical trials, and the sale of these product candidates, if approved, in the future, may expose us to liability claims. We face an inherent risk of product liability lawsuits related to the use of our product candidates in patients and

will face an even greater risk if product candidates are approved by regulatory authorities and introduced commercially. Product liability claims may be brought against us by participants enrolled in our clinical trials, patients, health care providers, pharmaceutical companies, our collaborators or others using, administering or selling any of our future approved products. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Regardless of the merits or eventual outcome, liability claims may result in: ● decreased demand for any of our future approved products; ● injury to our reputation; ● withdrawal of clinical trial participants; ● termination of clinical trial sites or entire trial programs; ● significant litigation costs; ● substantial monetary awards to, or costly settlements with, patients or other claimants; ● product recalls or a change in the indications for which they may be used; ● loss of revenue; ● diversion of management and scientific resources from our business operations; and ● the inability to commercialize our product candidates. Although the clinical trial process is designed to identify and assess potential side effects, clinical development does not always fully characterize the safety and efficacy profile of a new medicine, and it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If our product candidates were to cause adverse side effects during clinical trials or after approval, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies. Although we maintain product liability insurance coverage consistent with industry norms, including clinical trial liability, this insurance may not fully cover potential liabilities that we may incur. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. We will need to increase our insurance coverage if we commercialize any product that receives regulatory approval. In addition, insurance coverage is becoming increasingly expensive. If we are unable to maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of our product candidates, which could harm our business, financial condition, results of operations and prospects. Oxycodone is a Schedule II controlled substance under the federal CSA, and any failure to comply with the CSA or its state equivalents would have a negative impact on our business. Oxycodone, the ingredient in PF614, is classified as a Schedule II controlled substance under the Controlled Substances Act, or CSA and regulations promulgated by the DEA. The law and regulations classify substances as Schedule I, II, III, IV or V controlled substances, with Schedule I controlled substances considered to present the highest risk of substance abuse and Schedule V controlled substances the lowest risk. Scheduled controlled substances are subject to DEA regulations relating to supply, procurement, manufacturing, storage, shipment, sale, use, distribution and physician prescription procedures. For example, Schedule II controlled substances are subject to various restrictions, including, but not limited to, mandatory written prescriptions and the prohibition of refills. In addition to federal scheduling, oxycodone is subject to state- controlled substance laws and regulations, and in some cases, with additional requirements than those imposed by federal law and regulations. Though state controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may schedule products separately. Entities must register annually with the DEA to manufacture, distribute, dispense, import, export and conduct research using controlled substances. In addition, the DEA requires entities handling controlled substances to maintain complete and accurate records and file reports, including reports related to thefts or losses of any controlled substances, and to obtain authorization to destroy any controlled substances. Registered entities also must follow specific labeling and packaging requirements. Facilities must maintain appropriate security measures to control against diversion of controlled substances. Security requirements vary by controlled substance schedule with the most stringent requirements applying to Schedule I and Schedule II controlled substances. Required security measures include background checks on employees and physical control of inventory through measures such as vaults and inventory reconciliations. Our contract manufacturing organizations, or CMOs, who manufacture and distribute PF614 are required to be registered with DEA and relevant state authorities and comply with all security, recordkeeping and reporting requirements. Manufacturers and distributors are subject to routine inspections and audits by the DEA related to compliance with security, recordkeeping and reporting requirements. Failure to maintain the required registrations or to comply and follow these requirements can lead to significant civil and / or criminal penalties and possibly even lead to a revocation of a DEA registration to manufacture or distribute such products. Manufacturing of oxycodone is subject to annual quotas that limit the amount of API and dosage forms that can be produced in any given year; the failure of our CMOs to obtain the necessary manufacturing and / or procurement quota would have a negative impact on our business. The CSA and DEA regulations establish an annual aggregate production quota for Schedule I and II controlled substances, including oxycodone and other narcotic drugs. In addition, each manufacturer of active pharmaceutical ingredient, or API or dosage forms must obtain an individual manufacturing or production quota that limits the amount of product that a company can produce and / or distribute each year. The DEA allocates manufacturing quota issued to companies so as to not exceed the aggregate quota established for a given year. Moreover, companies must demonstrate the need for procurement quota based on expected demand and sales of the controlled substance the DEA requires the submission of substantial evidence of expected legitimate medical and scientific need for the drug product before assigning its aggregate production quotas, or manufacturing and procurement quotas to manufacturers. The DEA has decreased the aggregate quota for certain narcotic drugs, including oxycodone over the last five years. Also, in October 2018, Congress passed the SUPPORT Act which requires the DEA to consider potential diversion in establishing quotas for narcotic drugs which could lead to continued decreases in quota available to API manufacturers and dosage form manufacturers of these substances. In future years, we may need greater amounts of controlled substances that are subject to the DEA' s quota system to sustain our development program. We may also need significantly greater amounts to implement our commercialization plans if the FDA approves our proposed formulations. If any of our manufacturers of API or

dosage forms are unable to obtain the necessary annual quota to meet the research and development or commercial demand for PF614, our business would be negatively impacted. Any delay or refusal by the DEA in establishing a quota, a reduction in quota, or a failure to increase quota over time could delay or stop the clinical development or commercial sale of some of our products or product candidates. This could have a material adverse effect on our business, results of operations, financial condition and prospects. Risks Related to our Intellectual Property If we are unable to obtain and maintain patent protection for our products candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize product candidates that are similar or identical to our product candidates, and our ability to successfully commercialize our product candidates may be adversely affected. Our commercial success will depend, in part, on our ability to obtain and maintain patent protection in the United States and other countries with significant commercial markets with respect to our product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates that are important to our business, as appropriate. We cannot be certain that patents will be issued or granted with respect to applications that are currently pending or that we may apply for in the future with respect to one or more of our product candidates, or that issued or granted patents will not later be found to be invalid and / or unenforceable. The patent prosecution process is expensive and time- consuming, and we may not be able to file and prosecute 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. Although we may enter into non- disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, distribution partners, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. The patent position of pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued, and even if issued, the patents may not meaningfully protect our product candidates, effectively prevent competitors and third parties from commercializing competitive products or otherwise provide us with any competitive advantage. Even if the patent applications that we own or licenses 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. For product candidates for which we do not hold or do not obtain composition of matter patents, competitors who obtain the requisite regulatory approval can offer products with the same composition as our product candidate so long as the competitors do not infringe any method patents that we may hold. Method patents protect the product when used or sold for the specified method. However, this type of patent protection can be more difficult to enforce and does not limit a competitor from making and marketing a product that is identical to our product candidate that is either labeled or marketed for an indication that is outside of the patented method, or for which there is a substantial use in commerce outside the patented method. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative products in a non- infringing manner. Changes in either the patent laws, implementing regulations or interpretation of the patent laws in the United States and other countries may also diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States, and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. We cannot be certain that our patents and patent rights will be effective in protecting our product candidates and technologies. Failure to protect such assets may have a material adverse effect on our business, operations, financial condition and prospects. We may face litigation from third parties claiming that our products or business infringe, misappropriate, or otherwise violate their intellectual property rights, or seeking to challenge the validity of our patents. Our future success is also dependent in part on the strength of our intellectual property, trade secrets and know- how, which have been developed from years of research and development, and on our ability, and the ability of our future collaborators, to develop, manufacture, market and sell our product candidates, if approved, and use our proprietary technologies without alleged or actual infringement, misappropriation or other violation of the patents and other intellectual property rights of third parties. We may be exposed to, or be threatened with, adversarial proceedings or additional future litigation by third parties regarding intellectual property rights with respect to our current and any future product candidates and technology, including interference or derivation proceedings, post grant review and inter partes review before the United States Patent and Trademark Office, or USPTO, or similar adversarial proceedings or litigation in other jurisdictions seeking to challenge the validity of our intellectual property rights, claiming that we have misappropriated the trade secrets of others, or claiming that our technologies, products or activities infringe the intellectual property rights of others. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, post grant review, inter partes review and reexamination proceedings before the USPTO, and corresponding foreign patent offices. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the intellectual property rights of third parties. We are aware of patents owned by third parties, including potential competitors, that are directed to compositions comprising a chemically modified opioid, such as oxycodone, which decreases the potential of the opioid to be abused or cause overdose and related methods of use. Third parties, including potential competitors, may assert infringement claims against us based on existing patents or patents that may be granted in the future including, perhaps, the aforementioned patents, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third- party patents are valid, enforceable and infringed, and the holders of any such

patents may be able to block our ability to commercialize such product candidate unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third- party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, or methods of treatment, prevention or use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtain a license or until such patent expires or is finally determined to be invalid or unenforceable. In either case, such a license may not be available 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. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or to enable the commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In such an event, we would be unable to further practice our technologies or develop and commercialize any of our product candidates at issue, which could harm our business and financial condition significantly. Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates, if approved. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and employee time and resources from our business. Third parties making such claims may have the ability to dedicate substantially greater resources to these legal actions than us or our licensors or collaborators can. In the event of a successful claim of infringement, misappropriation or other violation against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. Patent litigation and other proceedings may also absorb significant management time. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. During the course of any patent or other intellectual property litigation or other proceeding, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings or developments and if securities analysts or investors regard these announcements as negative, the perceived value of our product candidates or intellectual property could be diminished. Accordingly, the market price of our common stock may decline. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business, ability to compete in the marketplace, financial condition, results of operations and growth prospects. We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful. Competitors may infringe, misappropriate or otherwise violate our patents, trademarks, copyrights or other intellectual property, or those of our licensors. To counter infringement, misappropriation, unauthorized use or other violations, we may be required to file legal claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. There can be no assurances that we will be successful with respect to any litigation matters which may arise in the ordinary course of our business. Such a failure may have a material impact on our business, results of operations and financial condition in the future. We may not be able to prevent, alone or with any future licensors, infringement, misappropriation or other violations of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. 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, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patents do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. In any infringement, misappropriation or other intellectual property litigation, any award of monetary damages we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. The expiration or loss of patent protection may adversely affect our future revenues and operating earnings. We rely on patent, trademark, trade secret and other intellectual property protection in the discovery, development, manufacturing and sale of our product candidates. In particular, patent protection is important in the development and eventual commercialization of our product candidates. Patents covering our product candidates normally provide market exclusivity, which is important in order to improve the probability that our product candidates are able to become profitable. Certain of our patents relating to PF614 will expire in 2030. In addition, certain of our patents relating to the use of nafamostat for treating respiratory diseases will expire in 2028. While we are seeking additional patent coverage which may protect the technology underlying these patents, there can be no assurances that such additional patent protection will be granted, or if granted, that these patents will not be infringed upon or otherwise held enforceable. Even

if we are successful in obtaining a patent, patents have a limited lifespan. In the United States, the natural expiration of a utility patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection of our product candidates, we may be open to competition from generic versions of such methods and compositions. If we do not obtain protection under the Hatch- Waxman Amendments by extending the patent term, our business may be harmed. Our commercial success will largely depend on our ability to obtain and maintain patent and other intellectual property in the United States and other countries with respect to our product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after such candidates begin to be commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one or more of our United States patents may be eligible for limited patent term extension, or PTE, under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch- Waxman Amendments. The Hatch- Waxman Amendments permit a patent restoration term of up to five years beyond the normal expiration of the patent as compensation for patent term lost during development and the FDA regulatory review process, which is limited to the approved indication (and potentially additional indications approved during the period of extension) covered by the patent. This extension is limited to only one patent that covers the approved product, the approved use of the product, or a method of manufacturing the product. If we are unable to extend the expiration date of our existing patents or obtain new patents with longer expiry dates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to obtain approval of competing products following our patent expiration and launch their product earlier than might otherwise be the case. We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business. Filing, prosecuting and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Further, licensing partners may not prosecute patents in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop our own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, 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 such 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. Additionally, the requirements for patentability may differ in certain countries, particularly developing countries. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In India, unlike the United States, there is no link between regulatory approval of a drug and our patent status. Furthermore, generic or biosimilar drug manufacturers or other competitors may challenge the scope, validity or enforceability of us or our licensors' patents, requiring us or our licensees or any future licensors to engage in complex, lengthy and costly litigation or other proceedings. In addition, certain countries in Europe and developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, We and our licensees or any future licensors may have limited remedies if patents are infringed or if we or our licensees or any future licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, we and our licensees' or any future licensors' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Changes in European law have caused uncertainty about our European patent portfolio and may result in additional costs to us. In 2012, the European Patent Package, or EU Patent Package, regulations were passed with the goal of providing for a single pan- European Unitary Patent, and a new European Unified Patent Court, or UPC, for litigation of European patents. The EU Patent Package was ratified in February 2023 and currently covers 17 member states. On June 1, 2023, all European patents, including those issued prior to ratification, will by default automatically fall under the jurisdiction of the UPC and allow for the possibility of obtaining pan- European injunctions, and further will be at risk of a central revocation proceeding at the UPC in participating UPC states. Under the EU Patent Package,

patent holders are permitted to " opt out " of the UPC on a patent- by- patent basis during an initial seven year period after the EU Patent Package is ratified, with the proviso that an " opt- out " is no longer available for EP patents for which a revocation has been initiated before the UPC. Owners of European patent applications who receive notice of grant after the EU Patent Package is ratified could, for the UPC contracting states, either obtain a Unitary Patent or validate the patent nationally and file an opt- out demand. The EU Patent Package may increase the uncertainties and costs surrounding the enforcement or defense of our issued European patents and pending applications. The full impact on future European patent filing strategy and the enforcement or defense of our issued European patents in member states and / or the UPC is not known. We may be subject to claims that we or our employees, consultants, contractors or advisors have infringed, misappropriated or otherwise violated the intellectual property of a third party, or claiming ownership of what we regard as our own intellectual property. Many of the contributors to our intellectual property, including patents and applications, were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the intellectual property and other proprietary information, know- how or trade secrets of others in their work for us, we may be subject to claims that we or these employees have used or disclosed such intellectual property or other proprietary information. Litigation may be necessary to defend against these claims. In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. For example, we have not obtained assignments for certain patent applications relating to abuse- resistant amphetamines. To the extent that we fail to obtain such assignments, such assignments do not contain a self- executing assignment of intellectual property rights or such assignments are breached, 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. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed and if we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed. In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know- how, technology and other proprietary information, in seeking to develop and maintain a competitive position. Because we expect to rely on third parties to manufacture our product candidates and we expect to collaborate with third parties on the development of our product candidates, we must, at times, share trade secrets with them. 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, consultants, independent contractors, advisors, corporate collaborators, outside scientific collaborators, contract manufacturers, suppliers and other third parties. We also enter into confidentiality and invention or patent assignment agreements with employees and certain consultants. We also seek to preserve the integrity and confidentiality of our data, trade secrets and know- how by maintaining physical security of our premises and physical and electronic security of our information technology systems. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Since our inception, we have sought to contract with manufacturers to supply commercial quantities of pharmaceutical formulations and products. As a result, we have disclosed, under confidentiality agreements, various aspects of our technology with potential manufacturers and suppliers. We believe that these disclosures, while necessary for our business, may have resulted and may result in the attempt by potential manufacturers and suppliers to improperly assert ownership claims to our technology in an attempt to gain an advantage in negotiating manufacturing and supplier rights. We cannot guarantee that our trade secrets and other proprietary and confidential information will not be disclosed or that competitors will not otherwise gain access to our trade secrets. Any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. Further, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, 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 business and competitive position could be harmed. Trade secrets and know- how can be difficult to protect as trade secrets and know- how will over time be disseminated within the industry through independent development, the publication of journal articles, and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. If we fail to prevent material disclosure of the know- how, trade secrets and other intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition. Even if we are able to adequately protect our trade secrets and proprietary information, our trade secrets could otherwise become known or could be independently discovered by our competitors. For example, we are aware that certain of our former employees founded Elysium Therapeutics, which appears to be developing orally administered abuse deterrent opioids. Additionally, competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade

secrets were to be lawfully obtained or independently developed by a competitor, in the absence of patent protection, we would have no right to prevent them, or those to whom they communicate, from using that technology or information to compete with us. We may not be able to prevent misappropriation of our intellectual property, trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property. We may be subject to claims that former employees, collaborators or other third parties have an ownership interest in the patents and intellectual property that we own or that we may own or license in the future. While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own; our licensors may face similar obstacles. In addition, we have not updated the records in the patent offices to reflect our ownership of our patent filings relating to PF614 and other technologies. Failure to update such ownership may result in an innocent purchaser potentially acquiring rights in such patents that are adverse to our interests. Furthermore, as noted above, we have not obtained assignments for certain patent applications relating to abuse- resistant amphetamines. We could be subject to ownership disputes arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against any claims challenging inventorship or ownership. If we fail in defending any such claims, we may have to pay monetary damages and may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property, which could adversely impact our business, results of operations and financial condition. We may not identify relevant third- party patents or may incorrectly interpret the relevance, scope or expiration of a third- party patent, which might adversely affect our ability to develop and market our product candidates. To the extent undertaken, we cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third- party patent and pending application in the United States and abroad that is or may be relevant to or necessary for the commercialization of our product candidates in any jurisdiction. Patent applications in the United States and elsewhere are not published until approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. In addition, certain United States patent applications can remain confidential until patents issue. Therefore, patent applications covering our products could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent' s prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third- party patent or may incorrectly predict whether a third party' s pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates. If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates or services so that we no longer infringe the third- party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors. Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. Disputes may arise between us and any of these counterparties regarding intellectual property rights that are subject to such agreements, including, but not limited to: ● the scope of rights granted under the agreement and other interpretation- related issues; ● whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the agreement; ● our right to sublicense patent and other rights to third parties; ● our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; ● the ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; ● our right to transfer or assign our license; and ● the effects of termination. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. If we fail to comply with our obligations under any agreements, we may be required to pay damages and could lose intellectual property rights that are necessary or useful for developing and protecting our product candidates. We have acquired all intellectual property rights from Signature and Mucokinetica, Ltd. (" Mucokinetica "), with the exception of our pending application directed to the use of orally administered nafamostat to treat coronaviruses. Any future collaboration agreements or license agreements we enter into are likely to impose various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. If we breach any such material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to

terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology, or having to negotiate new or reinstated licenses on less favorable terms, or enable a competitor to gain access to the licensed technology. Intellectual property rights do not necessarily address all potential threats to our business. Once granted, patents may remain open to opposition, interference, re- examination, post- grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked or may lose the allowed or granted claims altogether. In addition, the degree of future protection afforded by our intellectual property rights is uncertain because even granted intellectual property rights have limitations and may not adequately protect our business. The following examples are illustrative: ● others may be able to make formulations that are similar to our product candidates or other formulations but that are not covered by the claims of our patent rights; ● the patents of third parties may have an adverse effect on our business; ● we or any future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patent or pending patent application that we own; ● we or any future strategic partners might not have been the first to file patent applications covering certain of our inventions; ● others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; ● it is possible that our pending patent applications will not lead to issued patents; ● issued patents that we may own or that we exclusively license in the future may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors; ● our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; ● third parties performing manufacturing or testing for us using our product candidates or technologies could use the intellectual property of others without obtaining a proper license; ● we may not develop additional proprietary technologies that are patentable; and ● the patents of others may have an adverse effect on our business. Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects. The validity, scope and enforceability of any patents listed in the Orange Book that cover our product candidates can be challenged by third parties. If one of our product candidates is approved by the FDA, one or more third parties may challenge the current patents, or patents that may issue in the future, within our portfolio which could result in the invalidation of, or render unenforceable, some or all of the relevant patent claims or a finding of non- infringement. For example, if a third party submits an application under Section 505 (b) (2) or an abbreviated new drug application, or ANDA, for a generic drug containing any of our product candidates, and relies in whole or in part on studies conducted by or for us, the third party will be required to certify to the FDA that either: (1) there is no patent information listed in the Orange Book with respect to our NDA for the applicable approved drug candidate; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of the third party' s generic drug. A certification that the new drug will not infringe the Orange Book- listed patents for the applicable approved drug candidate, or that such patents are invalid, is called a paragraph IV certification. If the third party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us once the third party' s ANDA is accepted for filing by the FDA. We may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the third party' s ANDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of the third party. If we do not file a patent infringement lawsuit within the required 45- day period, the third party' s ANDA will not be subject to the 30- month stay of FDA approval. Moreover, a third party may challenge the current patents, or patents that may be issued in the future, within our portfolio which could result in the invalidation of some or all the patents that might otherwise be eligible for listing in the Orange Book for one of our products. If a third party successfully challenges all of the patents that might otherwise be eligible for listing in the Orange Book for one of our products, we will not be entitled to the 30- month stay of FDA approval upon the filing of an ANDA for a generic drug containing any of our product candidates, and relies in whole or in part on studies conducted by or for us. Litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be very expensive and time- consuming, may divert our management' s attention from our core business, and may result in unfavorable results that could limit our ability to prevent third parties from competing with our product candidates. Cyber- attacks or other failures in our telecommunications or information technology systems, or those of our collaborators, CROs, third- party logistics providers, distributors or other contractors or consultants, could result in information theft, data corruption and significant disruption of our business operations. We, our collaborators, CROs, third- party logistics providers, distributors and other contractors and consultants utilize information technology, or IT, systems and networks to process, transmit and store electronic information in connection with our business activities. As use of digital technologies has increased, cyber incidents, including third parties gaining access to employee accounts using stolen or inferred credentials, computer malware, viruses, spamming, phishing attacks or other means, and deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of us, our collaborators', CROs', third- party logistics providers', distributors' and other contractors' and consultants' systems and networks, and the confidentiality, availability and integrity of our data. There can be no assurance that we will be successful in preventing cyber- attacks or successfully mitigating their effects. Similarly, there can be no assurance that our collaborators, CROs, third- party logistics providers, distributors and other contractors and consultants will be successful in protecting our clinical and other data that is stored on their systems. Like other companies, we have on occasion experienced, and will continue to experience, threats to our data and systems, including malicious codes and viruses, phishing, business email compromise attacks or other cyber- attacks. Any cyber- attack, data breach or destruction or loss of data could

result in a violation of applicable United States and international privacy, data protection and other laws and subject us to litigation and governmental investigations and proceedings by federal, state and local regulatory entities in the United States and by international regulatory entities, resulting in exposure to material civil and / or criminal liability. Further, our general liability insurance and corporate risk program may not cover all potential claims to which we are exposed and may not be adequate to indemnify us for all liability that may be imposed, which could have a material adverse effect on our business and prospects. For example, the loss of clinical trial data from completed or ongoing clinical trials for any of our product candidates could result in delays in our development and regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyber- attacks or other data security breaches and may incur significant additional expense to implement further data protection measures. Risks Related to the Ownership of Common Stock and Financial Reporting Raising additional capital has caused, and may in the future cause, dilution to our stockholders, adversely affect the market price of our common stock, restrict our operations or require us to relinquish rights to our technologies or product candidates. We expect our expenses to increase in connection with our planned operations. Unless and until we can generate a substantial amount of revenue from our product candidates, we expect to finance our future cash needs through public or private equity offerings, debt financings, collaborations, licensing arrangements or other sources, or any combination of the foregoing. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities as we have done in the past, our stockholders' ownership interest has been, and may in the future be, diluted. In addition, debt financing, if available, may result in fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming stock or declaring dividends, that could adversely impact our ability to conduct our business. In addition, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day- to- day activities, which may adversely affect our management' s ability to oversee the development of our product candidates. The possible issuance of additional shares of common stock at lower conversion prices in repayment of the 2022 Notes or obligations arising under the 2022 Notes could have a negative impact on the price of our common stock. Also, we will receive reduced proceeds if the exercise price of the Prior Warrants is reduced. The conversion price of the 2022 Notes and exercise price of the Prior Warrants issued in 2022 were reset to a price of $ 2. 006 and we have, from time to time, temporarily lowered the conversion price such that a greater amount of principal on the 2022 Notes could be extinguished for shares. The conversion price of the 2022 Notes is $ 0. 7512 for the period from January 12, 2023 until May 12, 2023. In the future, to conserve cash necessary for us to conduct operations, we may do similarly for amounts owed in connection with the 2022 Notes or other notes. The exercise price of the Prior Warrants issued in 2021 were reset to a price of $ 15. 60. Because of a decline in the price of our common stock since issuance of the 2022 Notes and the ability of holders of the 2022 Notes to convert amounts payable under the 2022 Notes into additional shares of our common stock, we are required to register for resale with the SEC additional shares of common stock. We are obligated to register a sufficient number of shares of common stock for resale and our failure to timely register sufficient additional shares of common stock could cause us to default in our payments and result in our payment of additional shares and / or cash to the holders of the 2022 Notes. In addition, we may sell securities in the public or private equity markets if and when conditions are favorable, or at prices per share below the current market price of our common stock, even if we do not have an immediate need for additional capital at that time. Sales of substantial amounts of shares of our common stock, or the perception that such sales could occur, could adversely affect the prevailing market price of our shares and our ability to raise capital. We may issue additional shares of common stock in future financing transactions or as incentive compensation for our executive management and other key personnel, consultants and advisors. Moreover, sales of substantial amounts of shares in the public market, or the perception that such sales could occur, may adversely affect the prevailing market price of our common stock and make it more difficult for us to raise additional capital. 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, engaging in acquisition, merger or collaboration transactions, selling or licensing our assets, making capital expenditures, redeeming our stock, making certain investments, declaring dividends or encumbering our assets to secure future indebtedness. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan. The Investor Notes contain such restrictions. If we raise additional funds through upfront payments or milestone payments pursuant to strategic collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or intellectual property, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. In addition, any issuances of common stock pursuant to the GEM Agreement would result in dilution of the ownership interest of our shareholders. Any such issuances may also have a negative impact on the market price of our common stock because of the discount at issuance. Strike price resets of the GEM Warrants would also dilute our shareholders. See " — We require substantial additional funding. If we are unable raise capital when needed, we could be forced to delay, reduce or terminate our product discovery and development programs or commercialization efforts " for description of risks related to additional funding. Our internal controls over financial reporting currently do not meet all of the standards contemplated by Section 404 of Sarbanes- Oxley Act, and failure to achieve and maintain effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes- Oxley Act could impair our ability to produce timely and accurate financial statements or comply with applicable regulations and have a material adverse effect on our business. We

previously operated as a private company. In connection with the preparation of our consolidated financial statements for the years ended December 31, 2020 and 2019, we concluded that there were material weaknesses in our internal controls over financial reporting. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal controls over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses identified are insufficient internal controls because of inadequate technical accounting expertise and inappropriate level of supervision and review due to the limited number of accounting personnel. While we are taking steps to remediate the material weaknesses in our internal controls over financial reporting, including hiring a Chief Financial Officer in February 2021, we may not be successful in remediating such weaknesses. Following the Business Combination, our management has significant requirements for enhanced financial reporting and internal controls as a public company. The process of designing and implementing effective internal controls is a continuous effort that will require us to anticipate and react to changes in our business and the economic and regulatory environments and to expend significant resources to maintain a system of internal controls that is adequate to satisfy our reporting obligations as a public company. If we are unable to establish or maintain appropriate internal financial reporting controls and procedures, it could cause us to fail to meet our reporting obligations on a timely basis or result in material misstatements in our consolidated financial statements, which could harm our operating results. In addition, we are required, pursuant to Section 404 of the Sarbanes- Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal controls over financial reporting. This assessment needs to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation. Testing and maintaining internal controls may divert management' s attention from other matters that are important to our business. Our independent registered public accounting firm is required to attest to the effectiveness of our internal control over financial reporting on an annual basis. However, while we remain an emerging growth company, we are not required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. If we are not able to complete an initial assessment of our internal controls and otherwise implement the requirements of Section 404 of the Sarbanes- Oxley Act in a timely manner or with adequate compliance, our independent registered public accounting firm may not be able to certify as to the adequacy of our internal controls over financial reporting. Matters impacting our internal controls may cause us to be unable to report our financial information on a timely basis and thereby subject us to adverse regulatory consequences, including sanctions by the Securities and Exchange Commission, or SEC, or violations of applicable stock exchange listing rules, which may result in a breach of the covenants under existing or future financing arrangements. There also could be a negative reaction in the financial markets due to a loss of investor confidence in us and the reliability of our financial statements. Confidence in the reliability of our financial statements also could suffer if we or our independent registered public accounting firm continue to report a material weakness in our internal controls over financial reporting. This could materially adversely affect us and lead to a decline in the market price of our common stock. We are an emerging growth company and a smaller reporting company within the meaning of the Securities Act, and if we take advantage of certain exemptions from disclosure requirements available to " emerging growth companies " or " smaller reporting companies, " this could make our securities less attractive to investors and may make it more difficult to compare our performance with other public companies. We are an " emerging growth company " within the meaning of the Securities Act, as modified by the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, our stockholders may not have access to certain information they may deem important. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non- affiliates exceeds $ 700 million as of the end of any second quarter of a fiscal year, in which case we would no longer be an emerging growth company as of the last day of such fiscal year. We cannot predict whether investors will find our securities less attractive because we will rely on these exemptions. If some investors find our securities less attractive as a result of our reliance on these exemptions, the trading prices of our securities may be lower than they otherwise would be, there may be a less active trading market for our securities and the trading prices of our securities may be more volatile. Further, Section 102 (b) (1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a registration statement under the Securities Act declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non- emerging growth companies but any such election to opt out is irrevocable. We have elected not to opt out of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of our financial statements with another public company that is not an emerging growth company or is an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used. Additionally, we are a " smaller reporting company " as defined in Item 10 (f) (1) of Regulation S- K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (i) the market value of our common

stock held by non- affiliates is greater than or equal to $ 250 million as of the end of that fiscal year' s second fiscal quarter, and (ii) our annual revenues are greater than or equal to $ 100 million during the last completed fiscal year and the market value of our common stock held by non- affiliates exceeds $ 700 million as of the end of that fiscal year' s second fiscal quarter. To the extent we take advantage of such reduced disclosure obligations, it may also make comparison of our financial statements with other public companies difficult or impossible. The amount of our future losses is uncertain and our quarterly and annual operating results may fluctuate significantly or fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline. Our quarterly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following: ● the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, ● our ability to successfully recruit and retain subjects for clinical trials, and any delays caused by difficulties in such efforts, including as a result of COVID- 19; ● the risk / benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future therapeutics that compete with our product candidates; ● our ability to obtain marketing approval for our product candidates and the timing and scope of any such approvals we may receive; ● the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time; ● the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with manufacturers; ● our ability to attract, hire and retain qualified personnel; ● expenditures that we will or may incur to develop additional product candidates; ● the level of demand for our product candidates should they receive approval, which may vary significantly; ● the changing and volatile U. S. and global economic environments; and ● future accounting pronouncements or changes in our accounting policies. The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period- to- period basis may not be meaningful. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our operating results or revenue fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide, if any. Warrants for shares of our common stock, if exercised, will increase the number of shares eligible for future resale in the public market and result in dilution to our stockholders. There are Public Warrants exercisable for an aggregate of approximately 500, 000 shares of our common stock with an exercise price of $ 230. 00 per share. There are LACQ Warrants exercisable for an aggregate of approximately 351, 663 shares of our common stock with a weighted average exercise price of $ 227. 87 per share. In addition, there are GEM Warrants exercisable for 55, 306 shares of our common stock (subject to possible adjustment for anti- dilution events) with an exercise price of $ 0. 7512 per share as of January 12, 2023. There are also Prior Warrants from 2021 exercisable for an aggregate of 54, 174 shares of our common stock (subject to possible adjustment for anti- dilution events) with an exercise price of $ 15. 60 per share. In addition, Prior Warrants from 2022 are exercisable for an aggregate of 466, 788 shares of our common stock (subject to possible adjustment for anti- dilution events) with an exercise price of $ 14. 17 per share. The exercise price of the Prior Warrants issued in 2022 were reset to a price of $ 2. 006. To the extent such warrants are exercised, additional shares of our common stock will be issued, which will result in dilution to the holders of shares of our common stock and increase the number of shares of common stock eligible for resale in the public market. Sales of substantial numbers of such shares of common stock in the public market or the fact that such Warrants may be exercised could adversely affect the market price of our common stock. Substantial blocks of our total outstanding shares may be sold into the market. If there are substantial sales of shares of our common stock, the price of our common stock could decline. The price of our common stock could decline if there are substantial sales of shares of our common stock by our directors, executive officers, or significant stockholders, if there is a large number of shares of our common stock available for sale, or if there is the perception that these sales could occur. Immediately after the Merger, a significant portion of our shares of common stock or Warrants exercisable for our shares of common stock were held by persons who had been affiliated with LACQ prior to the Merger but did not remain so with respect to us after the Merger. In addition, we have registered shares of common stock that we may issue under our 2021 Omnibus Incentive Plan. Shares held by our directors, executive officers and other affiliates are subject to restrictions on resale under the Securities Act, lock- up agreements and may be subject to various vesting agreements. In addition, the rights of holders of the 2022 Notes to convert amounts payable under the 2022 Notes into shares of our common stock has required us to register a substantial number of shares of common stock and we are required to register an additional substantial amount of shares of common stock for possible resale by holders of those 2022 Notes. The market price of the shares of our common stock could decline as a result of the sale of a substantial number of our shares of common stock in the public market or the perception in the market that the holders of a large number of such shares intend to sell their shares. Our issuance of additional capital stock in connection with financings, acquisitions, investments, our 2021 Omnibus Incentive Plan and to repay interest or principal on the Investor Notes or otherwise will dilute all other stockholders. We expect to issue additional capital stock in the future that will result in dilution to all other stockholders. We have granted equity awards to employees, directors, and consultants under our 2021 Omnibus Incentive Plan and plan to do so in the future. We have used, and may in the future use, our common stock to make repayment of some or all of the principal and interest on the Investor Notes. We may also raise capital through equity financings in the future. As part of our business strategy, we may acquire or make investments in complementary companies, products, or technologies and issue equity securities to pay for any such acquisition or investment. Any such issuances of additional capital stock may cause stockholders to experience significant dilution of their ownership interests and the per share value of our common stock to decline. Trading on the OTC Pink Open Market is volatile and sporadic, which could depress the market price of the Public Warrants and make it difficult for the Public Warrant holders to resell their Public Warrants. The Public Warrants are quoted on

~~the OTC Pink Open Market. Trading in securities quoted on the OTC Pink Open Market is often thin and characterized by wide fluctuations in trading prices, due to many factors, some of which may have little to do with our operations or business prospects. This volatility could depress the market price of the Public Warrants for reasons unrelated to operating performance. Moreover, the OTC Pink Open Market is not a stock exchange, and trading of securities on the OTC Pink Open Market is often more sporadic than the trading of securities listed on Nasdaq. These factors may result in investors having difficulty reselling any Public Warrants. If we are unable to regain compliance with the listing standards of Nasdaq, our common stock could be delisted and may become subject to " penny stock " rules, which could have a material adverse effect on the liquidity of our common stock, the ability of investors to sell their shares and our ability to raise funding. On January 27, 2023, we received a notice in the form of a letter (the " Deficiency Letter ") from the listing qualifications department staff of The Nasdaq Stock Market (" Nasdaq ") stating that the Company was not in compliance with Nasdaq Listing Rule 5550 (a) (2) because the bid price for the Company' s common stock had closed below $ 1. 00 per share (the Minimum Bid Price ") for the previous 30 consecutive business days. The Company' s Minimum Value of Listed Securities (" MVLS ") is below the minimum of $ 35 million required for continued listing on Nasdaq. Because we did not regain compliance by the deadline set forth in a June 16, 2022 Notice we received from Nasdaq we requested a hearing before a Nasdaq Hearings Panel (the " Panel "). That hearing was held on January 26, 2023 and on February 14, 2023, our request for continued listing by means of exception was granted through June 12, 2023, subject to, at various dates in the interim, obtaining shareholder approval for a reverse split, eliminating outstanding convertible notes, meeting the Minimum Bid Price requirement for at least 10 consecutive trading days, filing a registration statement with the SEC for a public offering to raise additional capital and regaining compliance with the MVLS. There can be no assurance that the Company will be able to meet these requirements or be able to maintain compliance thereafter with Nasdaq listing standards. The de- listing of our common stock on Nasdaq could have a material adverse effect on us, including on our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities. Upon any delisting, our common stock could become subject to the regulations of the SEC relating to the market for penny stocks. Penny stocks are securities with a price of less than $ 5. 00 per share unless (i) the securities are traded on a " recognized " national exchange or (ii) the issuer has net tangible assets less than $ 2, 000, 000 (if the issuer has been in continuous operation for at least three years) or $ 5, 000, 000 (if in continuous operation for less than three years), or with average annual revenues of less than $ 6, 000, 000 for the last three years. The procedures applicable to penny stocks requires a broker- dealer to (i) obtain from the investor information concerning his financial situation, investment experience and investment objectives; (ii) reasonably determine, based on that information, that transactions in penny stocks are suitable for the investor and that the investor has sufficient knowledge and experience as to be reasonably capable of evaluating the risks of penny stock transactions; (iii) provide the investor with a written statement setting forth the basis on which the broker- dealer made the determination in (ii) above; and (iv) receive a signed and dated copy of such statement from the investor, confirming that it accurately reflects the investor' s financial situation, investment experience and investment objectives. The regulations applicable to penny stocks may severely affect the market liquidity for our common stock and could limit the ability of stockholders to sell their common stock in the secondary market. Item 1B. Unresolved Staff Comments~~