

## Risk Factors Comparison 2024-04-10 to 2023-03-31 Form: 10-K

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

Investing in our common stock involves a high degree of risk. You should carefully consider the risk factors below together with the information contained elsewhere in this Annual Report on Form 10-K, including Part II, Item 8 “Financial Statements and Supplementary Data” and Part II, Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and in our other public filings in evaluating our business. Before you decide to invest in our common stock, you should consider carefully the risks described below, together with the other information contained in this Annual Report, including our financial statements and the related notes. We believe the risks described below are the risks that are material to us as of the date of this Annual Report. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and our stockholders may lose all or part of their investment. **Summary 23** ~~Summary~~ of the Material and Other Risks Associated with Our Business Our business is subject to numerous material and other risks and uncertainties that you should be aware of in evaluating our business. These risks include, but are not limited to, the following: · We have incurred significant net losses since inception, and we expect to continue to incur significant net losses for the foreseeable future. · We have a limited operating history, which may make it difficult to evaluate our prospects and likelihood of success. · Our business is tied directly to the **nuclear medicine diagnostic medical imaging** industry and is **dependent depends** on our ability to successfully introduce our Mo- 100 and ~~adapt~~ **other medical isotopes** to changing technology and a changing medical practice landscape. · **Our business is dependent on our ability to recognize the anticipated benefits of acquisitions, including our acquisition of assets of Molybdos (Pty) Limited in the “business rescue” auction, the assets and intellectual property we acquired from Klydon Proprietary Ltd, and our investment in PET Labs Pharmaceuticals;** · We currently have no sales **attributable to isotopes**, but we expect to be heavily dependent on a few large customers to generate a majority of our revenues ~~for from sales of our future isotopes Mo-100~~. Our operating results could be adversely affected by a reduction in business with our future significant customers. · We are **still conducting early in our** research and development efforts for **isotopes such as Mo- 100 and U-, Zinc - 235-68, Silicon- 28, Xenon- 129 / 136, Germanium- 70 / 72 / 74 and Chlorine- 37** using the ASP technology. If we are unable to advance our future isotopes in development, obtain applicable regulatory approval and ultimately commercialize our future isotopes, or experience significant delays in doing so, our business will be materially harmed. · We **are awaiting** ~~depend on our agreements with Klydon, the termination~~ **approvals necessary to conduct early research and development efforts for isotopes such as Uranium- 235 utilizing the Quantum Enrichment process. The necessary approvals may take a significant amount of which could time and may never fail to materialize. As a result in the loss of significant rights, which would harm we will not be able to enter into the nuclear energy space utilizing our business technology**. · Obtaining and maintaining our patent protection depends on compliance with various procedures, document submissions, fee payments and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements. · **Since our listing on the Nasdaq Capital Market in November 2022, There there** has been **no only a limited** prior public market for our ~~common Common stock Stock~~, the stock price of our ~~common Common stock Stock~~ may be volatile or may decline regardless of our operating performance and you may not be able to resell your shares **quickly or** at or above the ~~market~~ **initial public offering, or IPO, price if trading in shares of our common stock is not active**. · If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our ~~common Common stock Stock~~. · Our independent registered public accounting firm’s report contains an explanatory paragraph that expresses substantial doubt about our ability to continue as a “going concern.” The material and other risks summarized above should be read together with the text of the full risk factors below and in the other information set forth in this Annual Report, including our consolidated financial statements and the related notes, as well as in other documents that we file with the SEC. If any such material and other risks and uncertainties actually occur, our business, prospects, financial condition and results of operations could be materially and adversely affected. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not currently known to us, or that we currently deem to be immaterial may also materially adversely affect our business, prospects, financial condition and results of operations. **Risks 24** ~~Risks~~ Related to Our Limited Operating History, Financial Position and Need for Additional Capital We have a very limited operating history, and we have incurred losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future. We may never generate any revenue **attributable to sales of enriched isotopes** or become profitable or, if we achieve profitability, we may not be able to sustain it. We were incorporated in September 2021, and we have a very limited operating history upon which you can evaluate our business and prospects. Our operations to date have been primarily focused on acquiring the assets of Molybdos (after participating in and being declared the winner of a competitive auction process under Section 45 of the South Africa Consumer Protection Act, 2008 for ZAR 11, 000, 000, which at the then current exchange rate was approximately \$ 734, 000 ) and in- licensing intellectual property rights related to the production of Molybdenum- 100 (a non- radioactive isotope we believe may have applications primarily in the medical industry) and Uranium- 235 (an isotope of uranium we believe may have application in the clean, efficient and carbon- free energy industry) using the ASP technology, organizing and staffing our company, research and development activities, business planning, raising capital, and providing general and administrative support for these operations. In July 2022, we acquired assets comprising a

dormant Silicon- 28 aerodynamic separation processing plant from Klydon for ZAR 6, 000, 000 (which at the then current exchange rate was approximately \$ 364, 000), which will be payable to Klydon on the later of 180 days of the acquisition and the date on which the assets generate any revenues of any nature. We have not yet built a functioning Mo- 100 or U- 235 manufacturing plant **that is producing commercial quantities of isotopes** or even demonstrated the ability to produce **commercial quantities of isotopes Mo- 100 or U- 235** using the ASP **technology or quantum enrichment** technology. We have not yet demonstrated an ability to overcome many of the risks and uncertainties frequently encountered by companies in the medical, technology and energy industries, including an ability to obtain applicable regulatory approvals, manufacture any isotopes at commercial scale (or arrange for a third party to do so on our behalf), or conduct sales and marketing activities necessary for successful isotope commercialization. In addition, we have not yet sought any regulatory approval that may be necessary for application of Mo- 100 that we may **develop produce** using the ASP process in the medical industry **or the production of U- 235 that we may produce using quantum enrichment**. Consequently, any predictions about our future performance may not be as accurate as they would be if we had a history of successfully developing and commercializing isotopes. Investment in isotope enrichment technology is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential isotopes will fail to demonstrate adequate utility or effectiveness in the targeted application (or for medical indications, an acceptable safety profile), gain regulatory approval, if applicable, and become commercially viable. We have no products approved for commercial sale and have not generated any revenue to date **attributable to isotopes (and only limited revenues attributable to PET Labs)**, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses since our inception in September 2021. For the period from September 13, 2021 (inception) through December 31, 2021, we reported a net loss of \$ 2. 6 million. For the year **years** ended December 31, **2023 and** 2022, we reported a net loss of \$ **16. 3 million and** \$ 4. 9 million, **respectively**. As of December 31, **2022-2023**, we had an accumulated deficit of \$ **7-23. 6-8** million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we:

- continue to invest in our research and development activities;
- seek applicable regulatory approvals for any future isotopes that we may successfully develop;
- experience any delays or encounter any issues with any of the above, including but not limited to failed research and development activities, safety issues, or other regulatory challenges, **the risk of which in each case may be exacerbated by the ongoing COVID- 19 pandemic**;
- hire additional engineering and production personnel and build our internal resources, including those related to audit, patent, other legal, regulatory and tax- related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums and investor and public relations costs;
- obtain, expand, maintain, enforce and protect our intellectual property portfolio;
- establish a sales, marketing and distribution infrastructure and establish manufacturing capabilities, whether alone or with third parties, to commercialize future isotopes (assuming receipt of applicable regulatory approvals), if any; and
- operate as a public company. We expect limited commercial activity for our isotopes in the United States during the next two to three years and we anticipate that most of our initial revenues from future sales of our Mo- 100 will be derived from countries in Asia and EMEA (Europe, Middle East and Africa). To become and remain profitable, we must succeed in developing and eventually commercializing **enriched** isotopes that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing research and development activities relating to our ASP technology, obtaining applicable regulatory approval for future isotopes, if any, and manufacturing, marketing and selling any future isotopes (assuming receipt of applicable regulatory approvals). We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. Because of the numerous risks and uncertainties associated with chemical isotopes separation, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our future isotopes or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment. **Our 250ur** future prospects are tied directly to the end markets that use our isotopes including the diagnostic medical imaging industry and depend on our ability to successfully introduce our isotopes and adapt to a changing technology and medical practice landscape. The field of diagnostic medical imaging is dynamic, with new products, including equipment, software and products, continually being developed and existing products continually being refined. New hardware (scanners), software or agents in a given diagnostic modality may be developed that provide benefits superior to the then- dominant hardware, software and agents in that modality, resulting in commercial displacement of the existing radiotracers. For example, alternate scanners and radiotracers could be introduced. Similarly, changing perceptions about comparative efficacy and safety, as well as changing availability of supply may favor one agent over another or one modality over another. In addition, new or revised appropriate use criteria developed by professional societies, to assist physicians and other health care providers in making appropriate imaging decisions for specific clinical conditions, can and have reduced the frequency of and demand for certain imaging modalities and imaging agents. Technological obsolescence in any of the medical imaging products that would use the Mo- 100 that we plan to manufacture could have a material adverse effect on our business, results of operations, financial condition and cash flows. We may not realize the anticipated benefits of previous acquisitions. The success of the company will depend in large part on the success of our management in integrating the acquired assets into the company. In October 2021, our subsidiary in South Africa acquired the assets of Molybdos after participating in and being declared the winner of a competitive auction process under Section 45 of the South Africa Consumer Protection Act, 2008 for ZAR 11, 000, 000 (which at the then current exchange rate was approximately \$ 734, 000), plus value added tax (VAT) levied by the government of South Africa at the rate of 15 % and auctioneers' commission at the rate of 10 % **-We have not yet built a functioning Mo- 100 or U- 235 manufacturing plant or even demonstrated the ability to produce Mo- 100 or U- 235 using the**

assets acquired at the business rescue auction. We will not know whether the assets that we acquired will work according to our expectations until we have completed construction of the Molybdenum plant. In July 2022, we acquired assets comprising a dormant Silicon-28 aerodynamic separation processing plant from Klydon located in Pretoria, South Africa for ZAR 6,000,000 (which at the then current exchange rate was approximately \$364,000). **In addition, in April 2023, we perfected our interest under the Acknowledgement of Debt Agreement, under which we acquired specific intellectual property from Klydon. To date, we have completed the construction of one isotope enrichment facility, but we have not yet produced any commercial quantities of isotopes and we have not yet demonstrated the ability to produce any isotope in commercial quantities using ASP technology. We intend will not know whether the assets that we acquired will work according to explore our expectations until we have produced commercial quantities of opportunities for Silicon-28 and other light isotopes at our enrichment facilities that may be produced using these assets.** Our failure to achieve the integration of the acquired assets into the company and to commercialize the assets could result in our failure to realize the anticipated benefits of those acquisitions and could impair our results of operations, profitability and financial results. **The acquisition of a controlling interest in Pet Labs Pharmaceuticals may fail to result in anticipated benefits but has involved significant investment of financial and other resources. In October 2023, we entered into a Share Purchase Agreement with Nucleonics Imaging Proprietary Limited, a company incorporated in South Africa, to purchase 51% of the ordinary shares (the "initial shares") in Nucleonics' wholly-owned subsidiary, Pet Labs Pharmaceuticals Proprietary Limited, a company incorporated in South Africa and dedicated to nuclear medicine and the science of radiopharmaceutical production. We agreed to pay a total of \$2,000,000 for the initial shares in two installments. The first installment of \$500,000 was paid in November 2023. The remaining balance of \$1,500,000 is due upon demand any time after October 31, 2024 and is expected to be paid in November 2024. In addition, we have an option to purchase the remaining 49% of the ordinary shares (the "option shares"). If we exercise our option to purchase the option shares (which option is exercisable until January 31, 2027, provided that the initial shares have been paid for in full), we have agreed to pay \$2,200,000 for the option shares. Acquisitions generally create risks such as (i) the need to integrate and manage the businesses and products acquired with our own business and products; (ii) additional demands on our resources, systems, procedures and controls; (iii) disruption of our ongoing business; (iv) potential unknown or unquantifiable liabilities associated with the target company; and (v) diversion of management's attention from other business concerns. Moreover, this acquisition involves substantial investment of funds. This acquisition may not be successful in generating material revenue, income or other returns, and any resources we committed will not be available to us for other purposes. Our inability to take advantage of growth opportunities or address risks associated with this acquisition and investment may negatively affect our operating results. This acquisition may not result in its anticipated benefits, and we may not be able to properly integrate the business with our future products and operations or successfully combine personnel and cultures. Failure to do so could deprive us of the intended benefits of this acquisition.** 26We currently have no sales **attributable to enriched isotopes**, but we expect to be heavily dependent on a few large customers to generate a majority of our revenues. Our operating results could be adversely affected by a reduction in business with our future significant customers. We currently have no sales **attributable to enriched isotopes**. However, we expect to rely on a limited number of customers **outside of the United States** to purchase any isotopes that we **develop-produce** using the ASP technology **or quantum enrichment** under long-term contracts. Our future key customers may stop ordering our isotopes at any time or may become bankrupt or otherwise unable to pay. The loss of any of our future key customers could result in lower revenues than we anticipate and could harm our business, financial condition or results of operations. We **incurred a net loss of generated an accumulated deficit totaling approximately \$2.23-6.8 million for the period from September 13, 2021 (inception) through December 31, 2021-2023 and a net loss of \$4. As of 9 million for the year ended December 31, 2022. As of December 31, 2022 and March 31, 2023, we had approximately \$2.7-4.9 million and \$5.2 million in cash, respectively. We have Prior to our acquisition of 51% of PET Labs Pharmaceuticals, we had** yet to generate any revenues, and we anticipate that our losses will continue for the foreseeable future. We cannot assure you that our plans to commercialize **enriched** isotopes that we may **develop-produce** will be successful. These factors, among others, raise substantial doubt about our ability to continue as a going concern. The financial statements contained elsewhere in this report do not include any adjustments that might result from our inability to continue as a going concern. Unless we can begin to generate material revenue **from production and sale of enriched isotopes** or raise capital **through from** equity offerings, we may not be able to remain in business. We cannot assure you that we will raise enough money or generate sufficient sales to meet our future working capital needs. We will require substantial additional capital to finance our operations, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate certain of our product development efforts or other operations. We expect our expenses to increase substantially in connection with our ongoing and planned activities, particularly as we continue our research and development activities, seek applicable regulatory approvals for any future isotopes that we may successfully develop, and expand our organization by hiring additional personnel. In addition, we expect to **incur additional-continue incurring significant** costs associated with operating as a public company. As of December 31, **2022-2023**, our cash was approximately \$2.7-4.9 million. **Subsequent to the end of 2023, in March 2024, QLE sold unsecured promissory notes for aggregate cash consideration of approximately \$20.5 million. In March-addition, in April 2023-2024, we-the Company** received **approximately gross proceeds of \$5.0-5 million through from** the issuance of 3,164,557 shares of our common stock **and-upon the exercise of** warrants to purchase up to an aggregate of 3,164,557 shares of our common stock with an exercise price of \$1.75 per share. We believe, based on our current operating plan, that **the net proceeds from our IPO, private placements completed in March 2023, October 2023, promissory notes issued in March 2024, and the exercise of warrants in April 2024 together with** our existing cash and cash equivalents, will not be sufficient to fund our operations for at least the next 12 months from the date the financial statements are issued. Therefore, we **plan-may need to**

seek additional funds through public or private equity or debt financings, third- party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. In any event, we will require substantial additional capital to support our business operations as we pursue additional research and development activities related to our ASP technology and seek applicable regulatory approval of our any future isotopes, and otherwise to support our continuing operations. In addition, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution (assuming receipt of applicable regulatory approvals for our future isotopes). Even if we believe we have sufficient capital for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. Any additional capital raising efforts may divert our management from their day- to- day activities, which may adversely affect our ability to develop and commercialize our future isotopes (assuming receipt of applicable regulatory approvals). Additionally, as a result of **severely diminished liquidity** ~~the COVID-19 pandemic and actions taken to slow its spread~~ **credit availability, increased interest rates, inflationary pressures, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability**, the global credit and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability. **The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict.** If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly or more dilutive. If we do not raise additional capital in sufficient amounts, we may be prevented from pursuing development and commercialization efforts, which will harm our business, operating results and prospects. ~~We~~ **27** ~~We~~ are subject to credit counterparty risk **which could have a material adverse effect on our business, results of operations, financial condition and cash flows**. The Company maintains cash balances at many financial institutions in multiple geographies. While the majority of cash balances are currently held in ~~US-USD \$~~ at U. S. financial institutions, our cash balances at those institutions may exceed the Federal Deposit Insurance Corporation (“ FDIC ”) insurance limit of \$ 250, 000 per depositor, per insured bank for each account ownership category. Our non- US banking counterparties might not have protections offered to their customers that are considered standard in the U. S. and even if such deposit insurances do exist, there is no guarantee that the insurer will honor those insurance policies. Although the Company currently believes that the financial institutions with whom it does business, will be able to fulfill their commitments to the Company, there is no assurance that those institutions will be able to continue to do so. Any credit losses that may occur could have a material adverse effect on our business, results of operations, financial condition and cash flows. Raising additional capital or acquiring or licensing assets by issuing equity or debt securities may cause dilution to our stockholders, and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights. We **may** plan to seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional capital through future collaborations, strategic alliances or third- party licensing arrangements, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or future isotopes, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional capital 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 our future isotopes (assuming receipt of applicable regulatory approvals for our future isotopes) that we would otherwise develop and market ourselves. Risks Related to the Development and Commercialization of Our Future Isotopes We are early in our research and development efforts for isotopes using the ASP technology **and the quantum enrichment process**. If we are unable to advance our future isotopes in development, obtain applicable regulatory approval and ultimately commercialize our future isotopes, or experience significant delays in doing so, our business will be materially harmed. We are **still conducting early-in** ~~our~~ research and development efforts **using ASP technology to produce a wide array of isotopes**, and have not yet produced ~~even experimental samples of any finished~~ **isotope at commercial scale**. It is possible that the research and development, proof- of- concept, construction of a plant and commercialization will take longer than anticipated due to unexpected delays. We also plan to begin researching the enrichment of uranium, which is a chemical element we believe may have application in the clean, efficient and carbon- free energy industry, using **quantum enrichment. Quantum enrichment has never been used to produce isotopes at a commercial scale and** ~~the ASP-research that has been conducted using this technique has never been published. The IAEA has never inspected any facility that leverages this~~ **technology and there is no proof that this technology has ever been used to enrich uranium. There are significant regulatory hurdles associated with enabling our research and development efforts to enter the nuclear energy market. Multiple regulatory agencies need to provide approvals to allow us to proceed with the research and development necessary to show proof of concept to the market. If we demonstrate proof of concept, we anticipate that there will be further approvals needed to expand to a larger footprint to support commercial demand**. ~~We are in~~ **may not ever obtain** ~~the these approvals~~ **planning stage of research and development activities for enriched uranium**. If we are unable to advance our future isotopes in development, obtain applicable regulatory approval and ultimately commercialize our future isotopes (assuming receipt of applicable regulatory approvals), or experience significant delays in doing so, our business will be materially harmed. Our ability to generate product revenues will depend heavily on the success of our research and development activities, receipt of applicable regulatory approvals, and eventual commercialization of our future isotopes (assuming receipt of applicable regulatory approvals and compliance with all applicable regulatory authorities). The success of our business, including our ability to finance our company

and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of our currently planned future isotopes, which may never occur. We will have to be successful in a range of challenging activities, including completing research and development activities relating to our ASP technology, obtaining applicable regulatory approval for future isotopes, if any, and manufacturing, marketing and selling any future isotopes (assuming receipt of applicable regulatory approvals). We are only in the preliminary stages of most of these activities. If we are unable to succeed in these activities, we may not be able to generate sufficient revenue to continue our business. We 28 We rely on a limited number of suppliers to provide us components and a material interruption in supply could prevent or limit our ability to execute our strategic plan and development programs in the expected timeframe. We depend upon a limited number of third- party suppliers located for certain components required to construct the centrifuges and other equipment for the enrichment plant plants that is are being constructed in South Africa. To date, we have been able to obtain the required components for our centrifuges without any significant delays or interruptions, except for certain delays related to COVID- 19. If we lose any of these suppliers, we may be required to find and enter into supply arrangements with one or more replacement suppliers. Obtaining alternative sources of supply could involve significant delays and other costs, and these supply sources may not be available to us on reasonable terms or at all. Any disruption of supplies could delay completion of the enrichment plant in South Africa, which could adversely affect our ability to execute our strategic plan and development programs in the expected timeframe. Our business, financial and operating performance could be adversely affected by epidemics and other health related issues including but not limited to the coronavirus disease 2019 (“ COVID- 19 ”) pandemic. The global outbreak of COVID- 19 has negatively affected global economies, disrupted supply chains, and has resulted in significant travel, transport, and other restrictions. The COVID- 19 outbreak has disrupted the supply chains and our day- to- day operations (and the operations of our suppliers and contractors (including Klydon), which could materially adversely affect our operations). In this regard, global supply chains and the timely availability of components imported to South Africa from the United States, countries in Europe or other nations could be materially disrupted by quarantines, slowdowns or shutdowns, border closings, and travel restrictions resulting from the global COVID- 19 pandemic or other global pandemic or health crises. Further, impacts of COVID- 19 infections and other COVID- 19 pandemic related impacts on our management and workforce, or our suppliers and contractors (including Klydon), could adversely impact our business. While we have taken steps to protect our workforce and carry- on operations, we may not be able to mitigate all of the potential impacts. We anticipate increased costs related to, or resulting from, the COVID- 19 pandemic due to, among other things, delays in supplier deliveries, impacts of travel restrictions, site access and quarantine requirements. In the event that the COVID- 19 pandemic prevents our employees or our contractors from working in person at our facility in South Africa or our suppliers are unable to provide goods and services on the schedule we anticipated, the impacts on our schedule and costs could be material. The ultimate impact of the COVID- 19 pandemic on our operations, including our ability to execute our strategic plan and development programs in the expected timeframe, remains uncertain and will depend on future pandemic- related developments, including the duration of the pandemic and any potential subsequent variants of COVID- 19 and related government actions to prevent and manage disease spread, all of which are uncertain and cannot be predicted. The long- term impacts of the COVID- 19 pandemic on us, our contractors and suppliers that could impact our business are also difficult to predict but could adversely affect our business, results of operations, and prospects. Development activities at our facility in South Africa could be disrupted for a variety of reasons, which could prevent us from completing our development activities. A disruption in development activities at our facility in South Africa could have a material adverse effect on our business. Disruptions could occur for many reasons, including power outages, fire, natural disasters, weather, unplanned maintenance or other manufacturing problems, public health crises (including, but not limited to, the COVID- 19 pandemic), disease, strikes or other labor unrest, transportation interruption, government regulation, political unrest or terrorism. Alternative facilities with sufficient capacity or capabilities may not be available, may cost substantially more or may take a significant time to start production, each of which could negatively affect our business and financial performance. South Africa struggles with limited electricity supply and regions of the country regularly undergo load- shedding, during which electricity is not available. This uncertain supply of electricity could impact our ability to operate and produce commercial products and could negatively affect the financial position of the Company. Risks associated with the development in-licensing of the ASP technology for development enrichment of isotopes could cause substantial delays in production the development of our future isotopes. Prior to October 2021, as a company, we had no involvement with or control over the research and development of the ASP technology. We have relied and continue to rely on Klydon to conduct such research and development in accordance with the applicable legal, regulatory and scientific standards prior to the in-licensing of the ASP technology for development of isotopes. If the research and development processes or the results of the development programs associated with prior to the in-licensing of the ASP technology for development of isotopes prove to be unreliable, this could result in increased costs and delays in the development of our future isotopes, which could adversely affect any future revenue from these future isotopes (assuming receipt of applicable regulatory approvals). Regulatory approval for production and distribution of radiopharmaceuticals used for medical imaging and therapeutic treatments may involve a lengthy and expensive process with an uncertain outcome. Currently, the sale or use of Mo- 100 is not regulated by a healthcare regulator, such as the FDA, European Medicines Agency (EMA) or comparable foreign regulatory authorities. However, products such as Mo- 99 and Tc- 99m that are produced from Mo- 100 in a cyclotron or a linear accelerator are regulated by healthcare regulators. We expect radiopharmacies, hospitals, clinics and others in the medical community to produce the widely used medical radioisotope technetium- 99m (Tc- 99m) from the Mo- 100 that we may produce using our ASP technology. Tc- 99m is a diagnostic agent that is used by health care professionals with FDA- approved imaging devices to detect potential diseases like coronary artery disease and cancer, as well as evaluate lung, liver, kidney and brain function. When used with the appropriate diagnostic scanner device, such as a SPECT imaging system, the Tc- 99m emits signals that are captured and produces an image of internal organs to detect various medical problems and contribute to diagnosis and treatment decisions. Our future customers who may use Mo-

100 to produce radiopharmaceuticals will likely require regulatory approval for their products. To date, only one healthcare regulator (Canada) has approved the use of Tc- 99m produced from Mo- 100 via a cyclotron. Obtaining regulatory approval is expensive and can take many years to complete, and its outcome is inherently uncertain. Our customers' regulatory approval process may not be conducted as planned or completed on schedule, if at all, and failure can occur at any time during the process. In the future, we may need to obtain approval from the FDA, EMA or comparable foreign regulatory authorities prior to the sale of Mo- 100 that we may produce using our ASP technology for use in medical imaging and therapeutic treatments. If we require FDA, EMA or other comparable foreign regulatory authorities to approve the sale of Mo- 100 that we may produce using our ASP technology for medical imaging and therapeutic treatments, we must demonstrate the safety and utility or efficacy of our Mo- 100. Obtaining regulatory approval is expensive and can take many years to complete, and its outcome is inherently uncertain. Our regulatory approval process may not be conducted as planned or completed on schedule, if at all, and failure can occur at any time during the process. Other isotopes that we intend to produce in the future may also require approvals from healthcare regulators such as FDA, EMA or comparable foreign regulatory authorities. Our 29 Our success depends on our future customers' ability to successfully commercialize products that are produced from our isotopes. Our customers operate in a competitive environment. If our customers are unable to successfully commercialize products that they produce from our isotopes, our business will be negatively impacted. Our customers may fail for a number of reasons, including but not limited to pricing pressure from competing products and failure to gain regulatory approval for the production of their products from healthcare regulators. Our success depends on our ability to adapt to a rapidly changing competitive environment in the nuclear industry. The nuclear industry in general, and the nuclear fuel industry in particular, is in a period of significant change, which could significantly transform the competitive landscape we face. The uranium and isotope enrichment sector is competitive. Changes in the competitive landscape may adversely affect pricing trends, change customer spending patterns, or create uncertainty. To address these changes, we may seek to adjust our cost structure and efficiency of operations and evaluate opportunities to grow our business organically or through acquisitions and other strategic transactions. We are actively considering, and expect to consider from time to time in the future, potential strategic transactions, which could involve, without limitation, changes in our capital structure, acquisitions and / or dispositions of businesses or assets, joint ventures or investments in businesses, products or technologies. In connection with any such transaction, we may seek additional debt or equity financing, contribute or dispose of assets, assume additional indebtedness, or partner with other parties to consummate a transaction. Any such transaction may not result in the intended benefits and could involve significant commitments of our financial and other resources. Legal and consulting costs incurred in connection with debt or equity financing transactions in development are deferred and subject to immediate expensing if such a transaction becomes less likely to occur. If the actions we take in response to industry changes are not successful, our business, results of operations and financial condition may be adversely affected. We may explore strategic collaborations that may never materialize or may fail. We intend to accelerate the development of our enriched uranium program by selectively collaborating with energy companies in the United States. We intend to retain significant technology, economic and commercial rights to our programs in key geographic areas that are core to our long- term strategy. As a result, we intend to periodically explore a variety of possible additional strategic collaborations in an effort to gain access to additional resources. At the current time, we cannot predict what form such a strategic collaboration might take. We are likely to face significant competition in seeking appropriate strategic collaborators, and negotiations are difficult strategic collaborations can be complicated and time- consuming to negotiate and document. We may not be able to negotiate strategic collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional strategic collaborations because of the numerous risks and uncertainties associated with establishing them. If the market opportunities for our future enriched isotopes are smaller than we estimate (even assuming receipt of any required regulatory approval), our business may suffer. We are currently focused on producing enriched isotopes using our ASP technology to meet critical needs in society. We also plan to research the production of enriched uranium using quantum enrichment to meet the future needs of developers of U. S. advanced reactor technologies requiring HALEU. Our projections of the potential markets are based on estimates that have been derived from a variety of sources, including scientific literature and market research, and which may prove to be incorrect. We must be able to successfully acquire a significant market share in our potential markets to achieve profitability and growth. Customers may become difficult to gain access to, which would adversely affect our results of operations and our business. We face substantial competition, which may result in others discovering, developing or commercializing enriched isotopes before or more successfully than us. The development and commercialization of radioisotopes and chemical elements is highly competitive. We face competition with respect to all the enriched isotopes that we may produce using our ASP technology from established biotechnology and nuclear medicine technology companies and will face competition with respect to enriched uranium that we may seek to develop or commercialize in the future from innovative technology and energy companies. There are a number of large biotechnology and nuclear medicine technology companies that currently market and sell radioisotopes to radiopharmacies, hospitals, clinics and others in the medical community (Mo- 99 is the active ingredient for Tc- 99m- based radiopharmaceuticals used in nuclear medicine procedures). There are also a number of technology and energy companies that are currently seeking to develop HALEU. Potential competitors also include 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. More 30 More established companies may have a competitive advantage over us due to their greater size, resources and institutional experience. In particular, these companies have greater experience and expertise in securing reimbursement, government contracts, relationships with key opinion leaders, obtaining and maintaining regulatory approvals and distribution relationships to market products. These companies also have significantly greater research and marketing capabilities than we do. If we are not able to compete effectively against existing and potential competitors, our business and financial condition may be harmed. As a result of these factors, our competitors may complete development of isotopes before

we are able to, which may limit our ability to develop or commercialize our future isotopes. Our competitors may also develop radioisotopes or technologies that are safer, more effective, more widely accepted and cheaper than ours, and may also be more successful than us in manufacturing and marketing their isotopes. These appreciable advantages could render our future isotopes obsolete or non-competitive before we can recover the expenses of their development and commercialization. Mergers and acquisitions in the technology and energy 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, management and commercial personnel, as well as in acquiring technologies complementary to, or necessary for, our programs. Even if the products that we or our customers may produce using the ASP technology receives regulatory approval, it may fail to achieve market acceptance by radiopharmacies, hospitals, clinics or others in the medical community necessary for commercial success. Even if the **isotopes Mo-100** that we may produce using the ASP technology ; ~~or for Tc-99m~~ **the medical industry**, or **the radioisotopes Mo-99** that we expect our future customers to produce using the **stable isotopes Mo-100** that we plan to offer, receives regulatory approval, the isotopes may fail to gain sufficient market acceptance by radiopharmacies, hospitals, clinics and others in the medical community. If it does not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of **isotopes Mo-100** that we may produce using the ASP technology, or the **radioisotopes Tc-99m or Mo-99** that our future customers may produce, will depend on a number of factors, including but not limited to: · the potential advantages compared to alternative radioisotopes; · the timing of market introduction of the product as well as competitive products; · effectiveness of sales and marketing efforts; · the strength of our relationships with radiopharmacies, hospitals, clinics and others in the medical community; · the cost in relation to alternative radioisotopes; · our ability to offer **isotopes Mo-100** that we may produce using the ASP technology for sale at competitive prices; · the convenience and ease of use compared to alternative radioisotopes; · the willingness of radiopharmacies, hospitals, clinics and others in the medical community to try an innovative radioisotope; and · the strength of marketing and distribution support. Our efforts to educate radiopharmacies, hospitals, clinics and others in the medical community on the benefits of **our isotopes Mo-100** that we may produce using the ASP technology may require significant resources and may never be successful. Because we expect sales of **isotopes Mo-100** that we may produce using the ASP technology (assuming receipt of applicable regulatory approvals for commercial sale) to generate substantially all of our revenues for the foreseeable future, the failure of **these isotopes Mo-100** that we may produce using the ASP technology (assuming receipt of applicable regulatory approvals for commercial sale) to find market acceptance would harm our business and could require us to seek additional financing. ~~We~~<sup>31</sup>**We** currently have no marketing and sales organization **for our future isotopes** and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate product revenue. We have no internal sales, marketing or distribution capabilities **for our future isotopes**, nor have we commercialized ~~a product~~ **any isotopes**. If the isotopes that we may produce using our ASP technology gains market acceptance and our customers receive regulatory approval for the isotopes they produce, we must build a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize such product in the markets that we target, which will be expensive and time-consuming, or collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. We currently plan to independently commercialize the isotopes that we may produce using our ASP technology (assuming receipt of applicable regulatory approvals) in the United States by establishing a focused sales force and marketing infrastructure. We may opportunistically seek additional strategic collaborations to maximize the commercial opportunities for our medical isotopes business outside of the United States. We have no prior experience as a company in the marketing, sale and distribution of isotopes and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing our isotopes, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses. Obtaining regulatory approval for either the Mo- 100 that we may produce using the ASP technology, or the Tc- 99m or Mo- 99 that our future customers may produce using the Mo- 100 that we plan to offer, in one jurisdiction does not mean that we or they will be successful in obtaining regulatory approval of such future products in other jurisdictions. Currently, the production and distribution of Mo- 100 does not require any regulatory licenses from healthcare regulators. Healthcare regulators frequently change such requirements, and it is possible that in the future Mo- 100 may be regulated as a healthcare product. Obtaining such regulatory licenses, if required, may be a timely and costly process and could materially impact our ability to commercialize the Mo- 100 that we plan to offer. Obtaining regulatory approval of the Mo- 100 that we may produce using the ASP technology in one jurisdiction does not guarantee that we will be able to obtain regulatory approval in any other jurisdiction. For example, even if the FDA grants regulatory approval of the Mo- 100 that we may produce using the ASP technology, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of such future product in those countries. However, a

failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States. Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of the Mo- 100 that we may produce using the ASP technology. Products such as Tc- 99m and Mo- 99 that may be produced by our future customers using the Mo- 100 that we plan to offer will likely require regulatory licenses in most regions. Healthcare regulators frequently change such requirements and it is unclear what each healthcare regulator will require. To date, only one region (Canada) has approved the use of Tc- 99m that has been produced from Mo- 100 in a cyclotron. Obtaining such regulatory licenses, if required, may be a timely and costly process and could materially impact the ability of our future customers to operate and use the Mo- 100 that we plan to offer. Obtaining regulatory approval in one jurisdiction does not guarantee that we or they will be able to obtain regulatory approval in any other jurisdiction. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of the Mo- 100 that we may produce using the ASP technology will be harmed. Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any isotopes that we may **develop-produce**. We face an inherent risk of product liability exposure if we commercialize any isotopes that we may **develop-produce**. If we cannot successfully defend ourselves against claims that any such isotopes caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: · decreased demand for any isotopes that we may **develop-produce**; · loss of revenue; · substantial monetary awards to patients; · significant time and costs to defend the related litigation; · a diversion of management's time and our resources; · initiation of investigations by regulators; · the inability to commercialize any isotopes that we may **develop-produce**; · **injury to our reputation and significant negative media attention; and** · a decline in our share price.

**Any 32**Any product liability insurance coverage that we obtain and maintain may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any isotopes. Insurance coverage is increasingly expensive. We may not be able to obtain or maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

**Risks Related to Regulatory Compliance** Our business is and could become subject to a wide variety of extensive and evolving laws and regulations. Failure to comply with such laws and regulations and failure to obtain licenses, approvals and permits that may be required to execute on our strategy and develop our company's business could have a material adverse effect on our business. We are subject to a wide variety of laws and regulations relating to various aspects of our business, including with respect to the development of the ASP technology and our future isotopes, employment and labor, health care, tax, privacy and data security, health and safety, and environmental issues. Laws and regulations at the South African and foreign, federal, state and local levels frequently change, especially in relation to new and emerging industries, and we cannot always reasonably predict the impact of, or the ultimate cost of compliance with, current or future regulatory or administrative changes. In South Africa, our **isotope Mo-100-enrichment facility-facilities is are** heavily regulated. South Africa is a signatory to the International Atomic Energy Agency ("IAEA") conventions and has adopted safety standards from the IAEA. The design, construction and operation of the isotope enrichment plants are highly regulated and require government licenses, approvals and permits, and may be subject to the imposition of conditions. In some cases, these licenses, approvals and permits entail periodic review and inspections. While we and Klydon have received all licenses, approvals and permits required to build and operate our isotope enrichment facilities in South Africa, we cannot predict whether the conditions associated with such licenses, approvals and permits will be maintained. For example, each of Klydon and ASP Isotopes South Africa (Proprietary) Limited has received from the South African Council for The Non- Proliferation of Weapons of Mass Destruction (1) a registration certificate (which are valid for two years from the date of issuance) and (2) a Manufacturing and Services Permit. The permits provide that the Non- Proliferation Secretariat will conduct at least two industry visits in June and November (or as arranged) of every year. Each of the permits includes numerous conditions, including, for example, the obligation to keep the Council updated or informed on all separation projects at all times and at least through biannual declarations, which must be done through correspondence to the Council at the end of April and September every year. The permit issued to ASP Isotopes South Africa (Proprietary) Limited includes additional specific information requirements related to (i) the progress on the design and construction of the **isotope Mo-100** separation plant, (ii) the progress on the manufacturing of **Molybdenum isotope** separation elements, and (iii) the commissioning of the plant. Each of the permits further provides that (i) any potential export of controlled goods and technology should be requested at an early stage through a Provisional Export Guidance Request, (ii) all isotope separation applications remain controlled regardless of the isotope atomic mass and will be dealt with on a case- by- case basis, and (iii) any ultimate transfer of these controlled goods and technology will be subject to the issuance of a permit by the Council as required in terms of the Non- Proliferation Act and related Government Notices and Regulations. In addition, we cannot assure you that we will be able to obtain, on a timely basis or at all, any additional licenses, approvals and permits that may be required to execute on our strategy and develop our company's business, including any such licenses, approvals and permits that may be required to introduce isotopes produced using ASP technology into the market and to begin the enrichment of uranium to demonstrate our capability to produce HALEU using the **ASP-Quantum Enrichment** technology. Changes in law or the imposition of new or additional regulations or permit requirements that impact our business could negatively impact our performance in various ways, including by limiting our ability to collaborate with partners or customers or by increasing our costs and the time necessary to obtain required authorization. We monitor new developments and devote a significant amount of management's time and external resources to compliance with these laws and regulations. We cannot assure you, however, that we are and will remain in compliance with all such requirements and, even when we believe we are in compliance, a regulatory agency may determine that we are not. In addition, we cannot assure you that we will be able to obtain all licenses, approvals



and permits that may be required to execute on our strategy and develop our company's business as currently contemplated. Failure by us, our employees, affiliates, partners or others with whom we work to comply with applicable laws and regulations or to obtain or comply with necessary licenses, approvals and permits could result in administrative, civil, commercial or criminal liabilities, including suspension or debarment from government contracts or suspension of our export / import privileges. Failure by us, our employees, affiliates, partners or others with whom we work to comply with the permits issued to us by the South African Council for The Non- Proliferation of Weapons of Mass Destruction could result in disruption of our development activities at our facility in South Africa, which could prevent us from completing our development activities. **¶ 33**If technology developed for the purposes of enriching isotopes can be applied to the creation or development of weapons-grade materials, then our technology may be considered " dual use " technology and be subject to limitations on public disclosure or export. Our research and development of isotope enrichment is dedicated not only to producing **enriched** isotopes for use in nuclear medical diagnostic procedures and concentrating uranium in the isotope uranium- 235 for use in nuclear energy, but also to safeguarding any information with broad, dual- use potential that could be inappropriately applied. Enrichment is among the most sensitive nuclear technologies because it can produce weapon- grade materials. The ASP technology **and the Quantum Enrichment technology** may be considered dual use and could be subject to export control, for example, under the Wassenaar Arrangement.

**Risks Related to Our Intellectual Property** Our intellectual property is not protected through patents or formal copyright registration. As a result, we do not have the full benefit of patent or copyright laws to prevent others from replicating the ASP technology. ~~We Neither we nor Klydon have not yet protected our respective~~ intellectual property rights through patents or formal copyright registration, and ~~neither we nor Klydon~~ currently have **any no** patent applications pending. To date, we ~~and Klydon~~ have relied exclusively on trade secrets and other intellectual property laws, non- disclosure agreements with our respective employees, consultants, vendors, potential customers and other relevant persons and other measures to protect our intellectual property, and intend to continue to rely on these and other means. As we intend to transition into the commercialization of **isotopes Mo-100**, we envision our intellectual property and its security becoming more vital to our future. Until we protect our intellectual property through patent, trademarks and registered copyrights, we may not be able to protect our intellectual property and trade secrets or prevent others from independently developing substantially equivalent proprietary information and techniques or from otherwise gaining access to our intellectual property or trade secrets. In such an instance, our competitors could produce products that are nearly identical to ours, resulting in us selling less products or generating less revenue from our sales. We may be unable to adequately protect our intellectual property and proprietary rights and prevent others from making unauthorized use of our products and technology. Our success and competitiveness depend, in significant part, on our ability to protect our intellectual property rights, including the ASP technology and **the Quantum Enrichment technology and** certain other practices, tools, technologies and technical expertise we utilize in designing, developing, implementing and maintaining processes used in the development of our future isotopes. To date, we ~~and Klydon~~ have relied exclusively on trade secrets and other intellectual property laws, non- disclosure agreements with our respective employees, consultants, vendors, potential customers and other relevant persons and other measures to protect our intellectual property, and intend to continue to rely on these and other means. For strategic reasons, ~~neither we nor Klydon~~ have **not** yet protected our intellectual property by filing patent applications related to our technology, inventions and improvements. Even if we ~~or Klydon~~ filed patent applications and patents were granted, we cannot assure you we would be fully protected against third parties as those patents may not be sufficiently broad in their coverage, may not be economically significant, or may not provide us with any competitive advantage. Competitors may be able to design around any patents and develop isotope production techniques comparable or superior to the ASP technology **or the Quantum Enrichment technology** . Furthermore, the filing of a patent would entail the disclosure of our know- how, and breaches of patent rights related to a wrongful use of this know- how would be difficult to enforce in the international landscape. We believe that our intellectual property strategy differs significantly from the strategies of others involved in the medical isotope industry, many of whom have extensive patent portfolios and rely heavily on intellectual property registrations to enforce their intellectual property rights. As a result of this discrepancy in strategy, we may be at a competitive disadvantage with respect to the strength of our intellectual property protection. Unlike others involved in the medical isotope industry, who generally have patents providing exclusive control over their innovations, we have no recourse against any entity that independently creates the same technology as ours or legitimately reverse- engineers our technology. We generally enter into non- disclosure agreements with our employees, consultants and other parties with whom we have strategic relationships and business alliances. We cannot, however, assure you that these agreements will be effective in controlling access to and distribution of our technology and proprietary information. Since we do not protect our intellectual property by filing patent applications, we rely on our personnel to protect our trade secrets, know- how and other proprietary information to a greater degree than we would if we had patent protection for our intellectual property. In any jurisdiction in which our research and development is not protected by similar agreements, there is no protection against the manufacture and marketing of identical or comparable research and development by third parties, who are generally free to use, independently develop, and sell our developments and technologies without paying license or royalty fees. Furthermore, our former employees may perform work for our competitors and use our know- how in performing this work. In the event we scale our business by hiring additional personnel and entering into contracts with third parties, the risks associated with breaches of non- disclosure agreements, confidentiality agreements and other agreements pertaining to our technology and proprietary information will increase, and such breaches could have an adverse effect on our business and competitive position. ~~We~~ **34**~~We~~ may come to believe that third parties are infringing on, or otherwise violating, our intellectual property or other proprietary rights. To prevent infringement or unauthorized use, we may need to file infringement and / or misappropriation suits, which are expensive and time- consuming, could result in meritorious counterclaims against us and would distract management's attention. In addition, in an infringement or misappropriation proceeding, a court may decide that one or more of our intellectual property rights is invalid, unenforceable, or both, in which case third parties may be able to use

our technology without paying license fees or royalties. If we are unable to protect our intellectual property and proprietary rights, we may be unable to prevent competitors from using our own inventions and intellectual property to compete against us, and our business may be harmed. **Our ASP** We depend on intellectual property licensed from Klydon, the termination of which could result in the loss of significant rights, which would harm our business. We are dependent on technology, know-how, and proprietary materials licensed from Klydon. We have an exclusive license from Klydon to use, develop, modify, improve, subcontract and sublicense certain intellectual property rights relating to **Third parties may in the future assert claims or initiate litigation related to their intellectual property rights in technology that is important to us, including** the ASP technology for the production, distribution, marketing and sale of all isotopes produced using the ASP technology (the “Klydon license agreement”). **For example** The Klydon license agreement is royalty-free, has a term of 999 years, and the license is worldwide for the development of the ASP technology and the distribution, marketing and sale of isotopes. Future production of isotopes is limited to member countries of the Nuclear Suppliers Group. Klydon has the right to terminate the exclusivity of the Klydon license agreement in the event that the licensee ceases to carry on activities related to isotope enrichment for a period longer than 24 consecutive months. Any termination of exclusivity under the Klydon license agreement will result in the loss of significant rights and will restrict our ability to develop and commercialize our planned isotopes. If we or Klydon fails to adequately protect this intellectual property, our ability to commercialize the isotopes, such as Mo-100 or uranium, that we may produce using ASP technology could suffer. In addition, agreements under which we license intellectual property or technology to or from third parties may be complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our 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. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected future isotopes. Our business also would suffer if our licensor fails to abide by the terms of the license, or if we are unable to enter into necessary licenses on acceptable terms. Moreover, our licensor may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor’s rights. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including those relating to: – the scope of rights granted under the license 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 license agreement; – our right to sublicense rights to third parties under collaborative development relationships; – whether we are complying with our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our future isotopes, and what activities satisfy those diligence obligations; – the priority of invention of patented technology; – the amount and timing of payments owed under license agreements; and – the allocation of ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensor and by us and our partners. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected future isotopes. We are generally also subject to all of the same risks with respect to protection of intellectual property that we license as we are for intellectual property that we own, which are described below. If we or our licensor fail to adequately protect this intellectual property, our ability to commercialize our future isotopes could suffer. We have received a letter asserting that the license for the ASP technology granted to us from Klydon, which is critical to our business, may be invalid because these rights were already granted to a third party, Radfarma. On October 25, 2022, we received a letter (the “NMS Letter”) from a law firm acting on behalf of Norsk Medisinsk Syklotronsenter AS (“NMS”), asserting, among other things, that the grant of a **the former** license to the ASP technology to us by Klydon **violates** a pre-existing exclusive sub-license to the ASP technology granted to Radfarma. **In November 2023, we** The NMS Letter makes reference to: (1) a license agreement entered into on October 25, 2013 by Klydon and API Labs Pharmaceuticals (Proprietary) Limited (“API Labs”) to license the ASP technology for enriching certain isotopes of the element Molybdenum (“2013 API Labs License”); and (2) an exclusive sub-license to the ASP technology granted on October 1, 2019 to Radfarma, as licensee, by API Labs and SaPhotonica Limited (“SaPhotonica”), as licensors (the “2019 Radfarma Sub-License”). The NMS Letter states that Radfarma is a **mutual release** joint venture that is 45% owned by NMS and 45% owned by SaPhotonica. The NMS Letter also states that Klydon, SaPhotonica and ASP Isotopes Inc. are under common control by Dr. Hendrik Strydom and Einar Ronander. The NMS Letter asserts, among other things, that the grant of a license to the ASP technology to us by Klydon (pursuant to license agreements entered into subsequent to the Radfarma Sub-License) violates a covenant in the 2019 Radfarma Sub-License that the licensors shall not be entitled, directly or indirectly, to use, grant or otherwise give the rights, or any similar rights, which were granted to Radfarma under the 2019 Radfarma Sub-License to any other person for use in the territory. “Territory” is defined in the 2019 Radfarma Sub-License as “the Kingdom of Norway for the construction of the 20-kilogram capacity plants; and means the international market where distribution agreements can be produced.” The NMS Letter asserts that while Klydon purported to give to us a license to market the ASP technology globally, these rights were already granted to Radfarma. The NMS Letter includes a request for us to enter into discussions and an agreement with NMS based on terms proposed, **Radfarma, and certain board members and shareholders of Radfarma related to the claims asserted in the previous correspondence from NMS which outlined a letter and other matters, without any payment or license of any rights by any party to the release. Any** future collaboration on technology and product development. The NMS Letter does not include a threat of litigation against us or any parties to the 2013 API Labs License or

2019 Radfarma Sub-License. However, if the licensed rights granted to us are found to be invalid or unenforceable (in whole or in part), or if our exclusive license agreement with Klydon is terminated or Klydon, as licensor, fails to abide by the terms of our exclusive license agreement, our ability to commercialize our future isotopes would suffer and our business, results of operations and financial condition may be adversely affected. Our license for the ASP technology with Klydon may be found to infringe third party intellectual property rights. Third parties may in the future assert claims or initiate litigation related to their intellectual property rights in technology that is important to us, including the ASP technology. For example, on October 25, 2022, we received a letter (the “NMS Letter”) from a law firm acting on behalf of Norsk medisinsk syklotronsenter AS (“NMS”), asserting, among other things, that the grant of a license to the ASP technology to us by Klydon violates a pre-existing exclusive sub-license to the ASP technology granted to Radfarma, as more fully described in the risk factor above. The asserted claims, arbitration and / or litigation could include claims against us, our licensor (Klydon), or Klydon’s present or former sub-licensors alleging infringement of intellectual property rights with respect to the ASP technology on which our company relies. Regardless of the merit of the claims, they could be time consuming, resulting in costly arbitration or litigation and diversion of technical and management personnel, or require us to develop non-infringing technology or enter into license agreements. We cannot assure you that licenses will be available on acceptable terms, if at all. Furthermore, because of the potential for significant damage awards, which are not necessarily predictable, it is not unusual to find even arguably unmeritorious claims resulting in large settlements. If any infringement or other intellectual property claim made against us by any third party (including NMS or Radfarma) is successful, or if we fail to develop non-infringing technology or license the proprietary rights on commercially reasonable terms and conditions, our business, operating results and financial condition could be materially adversely affected. If the ASP technology that we license from Klydon infringes the proprietary rights of other parties (including NMS or Radfarma), we could incur substantial costs, and we may have to take certain actions, including the following: · obtain licenses, which may not be available on commercially reasonable terms, if at all; · redesign our technology or processes to avoid infringement; · stop using the subject matter claimed to be held by others; · pay damages; or · defend arbitration, litigation or administrative proceedings which may be costly whether we win or lose (and may be prohibitively expensive, particularly for a company of our size), and which could result in a substantial diversion of our financial and management resources. In addition, in an infringement proceeding, a court or tribunal may decide that our asserted intellectual property is not valid or is unenforceable. An adverse determination in any litigation, arbitration or defense proceedings could put our licensed intellectual property at risk of being invalidated or interpreted narrowly. If the licensed our intellectual property rights granted to us are found to be invalid or unenforceable (in whole or in part), or if our exclusive license agreement with Klydon is terminated or Klydon, as licensor, fails to abide by the terms of our exclusive license agreement, our ability to commercialize our future isotopes would suffer and our business, results of operations and financial condition may be adversely affected. We may enter into collaboration agreements and strategic alliances, and we may not realize the anticipated benefits of such collaborations or alliances. We may wish to form collaborations in the future with respect to our future isotopes but may not be able to do so or to realize the potential benefits of such transactions, which may cause us to alter or delay our development and commercialization plans. Research and development collaborations are subject to numerous risks, which may include the following: · collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration and may not commit sufficient efforts and resources or may misapply those efforts and resources; · collaborators may not pursue development and commercialization of future isotopes or may elect not to continue or renew development or commercialization programs; · collaborators may delay, provide insufficient resources to, or modify or stop development activities for future isotopes; · collaborators could develop or acquire products outside of the collaboration that compete directly or indirectly with our future isotopes; 35 · collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability; · disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our future isotopes, or that result in costly litigation or arbitration that diverts management attention and resources; · collaborations may be terminated and, if terminated, may result in a need for additional capital and personnel to pursue further development or commercialization of the applicable future isotopes; and · collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property. The development and potential commercialization of our future isotopes will require substantial additional capital to fund expenses. We may form or seek further strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our future isotopes, including in territories outside the United States or for certain indications. These transactions can entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management’s time and attention in order to manage a collaboration or develop acquired products or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. As a result, if we enter into acquisition or in-license agreements or strategic partnerships, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, or if there are materially adverse impacts on our or the counterparty’s operations resulting from COVID-19, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction or such other benefits that led us to enter into the

arrangement. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our future isotopes because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our future isotopes as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third-party for development and commercialization of a future isotope, we can expect to relinquish some or all of the control over the future success of that future isotope to the third-party. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of our technologies, future isotopes and market opportunities. The collaborator may also consider alternative isotopes or technologies for similar applications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our future isotope. We may also be restricted under any license agreements from entering into agreements on certain terms or at all with potential collaborators. As a result of these risks, we may not be able to realize the benefit of our existing collaborations or any future collaborations or licensing agreements we may enter into. In addition, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such future isotope, reduce or delay one or more of our other development programs, delay the potential commercialization or reduce the scope of any planned sales or marketing activities for such future isotope, or increase our expenditures and undertake development, manufacturing or commercialization activities at our own expense. If we elect to increase our expenditures to fund development, manufacturing or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our future isotopes or bring them to market and generate product revenue. We may be dependent on intellectual property licensed or sublicensed to us from, or for which development was funded or otherwise assisted by, government agencies, for development of our technology and future isotopes. Failure to meet our own obligations to our any licensor or upstream licensors, including such government agencies, may result in the loss of our rights to such intellectual property, which could harm our business. Government agencies may provide funding, facilities, personnel or other assistance in connection with the development of the intellectual property rights owned by or licensed to us. Such government agencies may have retained rights in such intellectual property, including the right to grant or require us to grant mandatory licenses or sublicenses to such intellectual property to third parties under certain specified circumstances, including if it is necessary to meet health and safety needs that we are not reasonably satisfying or if it is necessary to meet requirements for public use specified by federal regulations, or to manufacture products in the United States. Any exercise of such rights, including with respect to any such required sublicense of these licenses could result in the loss of significant rights and could harm our ability to commercialize licensed products. If we are unable to obtain patent protection for our future isotopes, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets. We anticipate that we may either Klydon or ourselves will file patent applications both in the United States and in other countries, as appropriate. However, we cannot predict: · if and when any patents will issue; · the degree and scope of protection any issued patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents; · whether others will apply for or obtain patents claiming aspects similar to those covered by our patents and patent applications; · whether we will need to initiate litigation or administrative proceedings to defend our patent rights, which may be costly whether we win or lose; or · whether the patent applications that we own or in-license will result in issued patents with claims that cover our future isotopes or uses thereof in the United States or in foreign countries. We currently rely upon a combination of trade secret protection and confidentiality agreements to protect the intellectual property related to our isotope development techniques and future isotopes. Our success will depend in large part on our (or Klydon, as our licensor) ability to obtain and maintain patent protection in the United States and other countries with respect to the ASP technology and the Quantum Enrichment technology. We may expect Klydon to seek to protect its our proprietary position by filing patent applications in the United States and abroad related to its current and future development programs and future isotopes to the extent permitted by applicable law. Our exclusive license agreement with Klydon provides that additional patents, knowhow and improvements in the ASP technology that may be developed in the future will be considered part of the intellectual property rights granted under the license. 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, including as a result of the COVID-19 pandemic impacting our or our licensors' operations. It is possible that we (or Klydon, as our licensor) will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our future isotopes in the United States or in foreign countries. There is no assurance that all of the potentially relevant prior art relating to our (or Klydon's) patents and patent applications has been found, which can invalidate a patent or prevent a patent from being issued from a pending patent application. Even if patents are successfully issued and even if such patents cover the ASP technology and the Quantum Enrichment technology, third parties may challenge their scope, validity, or enforceability, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any future isotopes using the ASP technology or the Quantum Enrichment technology. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a future isotope could be reduced. If the patent applications we hold or have in-licensed with respect to our development programs fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for the ASP technology or the Quantum Enrichment technology, it could dissuade companies from collaborating with us, and threaten our ability to commercialize, isotopes produced using the ASP technology or the Quantum Enrichment technology. Any such outcome could have a negative effect on our business. Even if we obtain

patents covering the ASP **technology or the Quantum Enrichment** technology or our methods, we may still be barred from making, using and selling such technology or methods because of the patent rights of others. Others may have filed, and in the future may file, patent applications covering technology or methods that are similar or identical to ours, which could materially affect our ability to successfully develop our technology or to successfully commercialize any isotopes alone or with collaborators. Patent applications in the United States and elsewhere are generally published 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. Therefore, patent applications covering our platform technologies and methods could have been filed by others without our knowledge. Additionally, pending claims in patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies. These patent applications may have priority over patent applications filed by us. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements. **Periodic 37Periodic** maintenance fees, renewal fees, annuity fees and various other government fees on patents and / or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned and licensed patents and / or applications and any patent rights we may own or license in the future. We will rely on our outside counsel, patent annuity service providers, or our licensing partners to pay these fees due to non- U. S. patent agencies. The USPTO and various non- U. S. government patent agencies require compliance with several procedural, documentary, and other similar provisions during the patent application process. We will employ reputable law firms and other professionals to help us comply ~~and we will also be dependent on Klydon (as our licensor) to take the necessary action to comply with these requirements with respect to our licensed intellectual property~~. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could harm our business. Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business. Our commercial success depends, in part, upon our ability and the ability of our current or future collaborators to develop, manufacture, market and sell our future isotopes and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. The technology industry is characterized by extensive and complex litigation regarding patents and other intellectual property rights. Our future isotopes and other proprietary technologies we may develop may infringe existing or future patents owned by third parties. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our future isotopes and technology, including interference proceedings, post- grant review and inter partes review before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, 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, which could have a negative impact on our ability to commercialize our future isotopes. In order to successfully challenge the validity of any such U. S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U. S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U. S. patent. If we are found to infringe a third party' s valid and enforceable intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing our future isotope (s) and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non- exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or future isotope. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from manufacturing and commercializing our future isotopes or force us to cease some or all of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects. Third parties asserting their patent or other intellectual property rights against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our future isotopes or force us to cease some of our business operations. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, cause development delays, and may impact our reputation. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties, or redesign our infringing products, which may be impossible on a cost- effective basis or require substantial time and monetary expenditure. In that event, we would be unable to further develop and commercialize our future isotopes, which could harm our business significantly. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property. Certain of our employees, consultants or advisors are currently, or were previously, employed at universities or other technology companies, ~~including Klydon~~. Although we try to ensure that our employees, consultants and

advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. **In 38**In addition, while it is our policy to require our employees and contractors who may be involved in the conception or 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, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. 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. If we rely on third parties to manufacture or commercialize our future isotopes, or if we collaborate with additional third parties for the development of our future isotopes, we must, at times, share trade secrets with them. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, services agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business and results of operations. In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any third-party collaborators. A competitor's discovery of our trade secrets could harm our business. Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information. In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce, and any other elements of our future isotopes, technology and product discovery and development processes that involve proprietary know-how, information, or technology that is not covered by patents. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Because we expect to rely on third parties in the development and manufacture of our future isotopes, we must, at times, share trade secrets with them. 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. Trade secrets and confidential information, however, may be difficult to protect. We seek to protect our trade secrets, know-how and confidential information, including our proprietary processes, in part, by entering into confidentiality agreements with our employees, consultants, outside scientific advisors, contractors, and collaborators. With our consultants, contractors, and outside scientific collaborators, these agreements typically include invention assignment obligations. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, outside scientific advisors, contractors, and collaborators might intentionally or inadvertently disclose our trade secret information to competitors. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, we would have no right to prevent them from using that technology or information to compete with us. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, or misappropriation of our intellectual property by third parties, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results, and financial condition. **39****If Risks Related to Our Dependence on Third Parties If** we use hazardous and chemical materials in a manner that causes injury or violates applicable law, we may be liable for damages. Our research and development activities involve the controlled use of potentially hazardous substances, including chemical materials. **Klydon is We are** subject to international and local laws and regulations in South Africa governing the use, manufacture, storage, handling and disposal of radioactive and hazardous materials. Although we believe that **our Klydon's** procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards,

we cannot completely eliminate the risk of contamination or injury resulting from radioactive or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from radioactive or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development, and production efforts, which could harm our business, prospects, financial condition, or results of operations.

**Risks Related to Our Business Operations, Employee Matters and Managing Growth** We are highly dependent on the services of our senior management team, and if we are not able to retain these members of our management team and recruit and retain additional management, clinical and scientific personnel, our business will be harmed. We are highly dependent on our senior management team. The employment agreements we have with these officers do not prevent such persons from terminating their employment with us at any time. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives. In addition, we will need to attract, retain and motivate highly qualified additional management and scientific personnel. If we are not able to retain our management and to attract, on acceptable terms, additional qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow. We may not be able to attract or retain qualified personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. Many of the other pharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high- quality candidates and consultants than what we have to offer. If we are unable to continue to attract, retain and motivate high- quality personnel and consultants to accomplish our business objectives, the rate and success at which we can develop future isotopes and our business will be limited, and we may experience constraints on our development objectives. Our future performance will also depend, in part, on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management. Our failure to integrate these individuals and create effective working relationships among them and other members of management could result in inefficiencies in the development and commercialization of our future isotopes, harming future regulatory approvals, sales of our future isotopes and our results of operations. Additionally, we do not currently maintain “key person” life insurance on the lives of our executives or any of our employees. We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations. As of December 31, 2022, we had ~~four full-time employees and we presently employ~~ **employed 76** approximately 31 people on a full-time basis, ~~27~~ **69** of whom are located in South Africa. We rely on service providers for certain general administrative, financial, accounting, tax, intellectual property and other legal services, and we will need to expand our organization to hire qualified personnel to perform these functions internally. Our management may need to divert significant attention and time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational inefficiencies, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our future isotopes. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance, our ability to commercialize future isotopes, develop a scalable infrastructure and compete effectively will depend, in part, on our ability to effectively manage any future growth. ~~Our 40~~ **Our** employees, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading. We are exposed to the risk of fraud or other misconduct by our employees, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in other jurisdictions, provide accurate information to the FDA and other regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. It is not always possible to identify and deter employee 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 government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a negative impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions. **We and our contractors are highly dependent on the performance of sub-contractors and other third parties. We and our contractors are highly dependent on the performance of sub-contractors and other third parties. If these contractors, sub-contractors and third parties are unable to deliver the results that we require, our operating results could be adversely affected and our business could be materially harmed.** Significant disruptions of our information technology systems or data security incidents could result in significant financial, legal, regulatory, business and reputational harm to us. We are dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store, process and transmit large amounts of sensitive information, including intellectual property, proprietary business information, personal information and other confidential information. It is critical that we do so in a secure manner to maintain the confidentiality, integrity and availability of such sensitive information. We have also outsourced elements of our operations (including elements of our information technology infrastructure) to third parties, and as a result, we manage a number of third-party vendors who may or could have access to our computer networks or our confidential information. In addition, many of those third parties, in turn, subcontract or outsource some of their responsibilities to third parties. While all information technology operations are

inherently vulnerable to inadvertent or intentional security breaches, incidents, attacks and exposures, the accessibility and distributed nature of our information technology systems, and the sensitive information stored on those systems, make such systems potentially vulnerable to unintentional or malicious, internal and external attacks on our technology environment. In addition, some of our employees work remotely, which may make us more vulnerable to cyberattacks. Potential vulnerabilities can be exploited from inadvertent or intentional actions of our employees, third- party vendors, business partners, or by malicious third parties. Attacks of this nature are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, “hacktivists,” nation states and others. In addition to the extraction of sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial- of- service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. In addition, the prevalent use of mobile devices increases the risk of data security incidents. Significant disruptions of our, our third- party vendors’ and / or our business partners’ information technology systems or other similar data security incidents could adversely affect our business operations and / or result in the loss, misappropriation, and / or unauthorized access, use or disclosure of, or the prevention of access to, sensitive information, which could result in financial, legal, regulatory, business and reputational harm to us. In addition, information technology system disruptions, whether from attacks on our technology environment or from computer viruses, natural disasters, terrorism, war and telecommunication and electrical failures, could result in a material disruption of our development programs and our business operations. Additionally, theft of our intellectual property or proprietary business information could require substantial expenditures to remedy. If we or our third- party collaborators, consultants, contractors, suppliers, or service providers were to suffer an attack or breach, for example, that resulted in the unauthorized access to or use or disclosure of personal or health information, we may have to notify consumers, partners, collaborators, government authorities, and the media, and may be subject to investigations, civil penalties, administrative and enforcement actions, and litigation, any of which could harm our business and reputation. **There-41There** is no way of knowing with certainty whether we have experienced any data security incidents that have not been discovered. While we have no reason to believe this to be the case, attackers have become very sophisticated in the way they conceal access to systems, and many companies that have been attacked are not aware that they have been attacked. Any event that leads to unauthorized access, use or disclosure of personal information, including but not limited to personal information regarding our patients or employees, could disrupt our business, harm our reputation, compel us to comply with applicable federal and / or state breach notification laws and foreign law equivalents, subject us to time-consuming, distracting and expensive litigation, regulatory investigation and oversight, mandatory corrective action, require us to verify the correctness of database contents, or otherwise subject us to liability under laws, regulations and contractual obligations, including those that protect the privacy and security of personal information. This could result in increased costs to us, and result in significant legal and financial exposure and / or reputational harm. In addition, any failure or perceived failure by us or our vendors or business partners to comply with our privacy, confidentiality or data security- related legal or other obligations to third parties, or any further security incidents or other inappropriate access events that result in the unauthorized access, release or transfer of sensitive information, which could include personally identifiable information, may result in governmental investigations, enforcement actions, regulatory fines, litigation, or public statements against us by advocacy groups or others, and could cause third parties, including clinical sites, regulators or current and potential partners, to lose trust in us or we could be subject to claims by third parties that we have breached our privacy- or confidentiality- related obligations, which could materially and adversely affect our business and prospects. Moreover, data security incidents and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. While we have implemented security measures intended to protect our information technology systems and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or security incidents. Our international operations subject us to risks of doing business in foreign countries, which could adversely affect our business, financial condition and results of operations. Our primary operations are located outside the U. S. (primarily the construction of **the-isotope enrichment plant-plants** in South Africa), and we plan to sell our isotopes to customers outside the U. S. Accordingly, our business is subject to risks related to the differing legal, political, social and regulatory requirements and economic conditions of non- U. S. jurisdictions. Risks inherent in international operations include the following: · fluctuations in foreign currency exchange rates may affect product demand and may adversely affect the profitability in U. S. dollars of products and services we provide in international markets where payment for our products and services is made in the local currency; · transportation and other shipping costs may increase, or transportation may be inhibited; · increased cost or decreased availability of raw materials; · changes in foreign laws and tax rates or U. S. laws and tax rates with respect to foreign income may unexpectedly increase the rate at which our income is taxed, impose new and additional taxes on remittances, repatriation or other payments by subsidiaries, or cause the loss of previously recorded tax benefits; · foreign countries in which we do business may adopt other restrictions on foreign trade or investment, including currency exchange controls; · trade sanctions by or against these countries could result in our losing access to customers and suppliers in those countries; · unexpected adverse changes in foreign laws or regulatory requirements may occur; · our agreements with counterparties in foreign countries may be difficult for us to enforce and related receivables may be difficult for us to collect; · compliance with the variety of foreign laws and regulations may be unduly burdensome; · compliance with anti- bribery and anti- corruption laws (such as the Foreign Corrupt Practices Act) as well as anti- money- laundering laws may be costly; · unexpected adverse changes in export duties, quotas and tariffs and difficulties in obtaining export licenses may occur; · general economic conditions in the countries in which we operate could have an adverse effect on our earnings from operations in those countries; · our foreign operations may experience staffing difficulties and labor disputes; · termination or substantial modification of international trade agreements may adversely affect our access to raw materials and to markets for our products outside the U.



S.; · foreign governments may nationalize or expropriate private enterprises; · increased sovereign risk (such as default by or deterioration in the economies and creditworthiness of local governments) may occur; and · political or economic repercussions from terrorist activities, including the possibility of hyperinflationary conditions and political instability, may occur in certain countries in which we do business. Unanticipated events, such as geopolitical changes, could result in a write-down of our investment in the affected joint venture or a delay or cause cancellation of those capital projects, which could negatively impact our future growth and profitability. Our success as a global business will depend, in part, upon our ability to succeed in differing legal, regulatory, economic, social and political conditions by developing, implementing and maintaining policies and strategies that are effective in each location where we and our joint ventures do business. ~~Furthermore~~ **42Furthermore**, we will be subject to rules and regulations related to anti-bribery and anti-trust prohibitions of the U. S. and other countries, as well as export controls and economic embargoes, violations of which may carry substantial penalties. For example, export control and economic embargo regulations limit the ability of our subsidiaries to market, sell, distribute or otherwise transfer their products or technology to prohibited countries or persons. Failure to comply with these regulations could subject our subsidiaries to fines, enforcement actions and / or have an adverse effect on our reputation and the value of our ~~common~~ **Common stock Stock**. Our tangible assets may be subject to defects in title. We have investigated our rights to the assets we have purchased and developed, and, to the best of our knowledge, those rights are in good standing. However, no assurance can be given that such rights will not be revoked, or significantly altered, to our detriment. There can also be no assurance that our rights will not be challenged or impugned by third parties, including by governments and non-governmental organizations. We are subject to foreign currency risks. Our operations are subject to foreign currency fluctuations. Our ~~current~~ **current** operating expenses ~~and revenues~~ are primarily transacted in U. S. dollars, while ~~our current revenues and~~ some of our cash balances and expenses are measured in other currencies. **As our business expands internationally, the U. S. dollar may or may not be our primary current for operating expenses**. Any strengthening or weakening of the U. S. dollar in relation to the currencies of other countries or vice versa can have a material impact on our cash flows and profitability and affect the value of our assets and shareholders' equity.

**Risks Related to Ownership of Our Common Stock** We do not know whether an active, liquid and orderly trading market will develop for our ~~common~~ **Common stock Stock** or what the market price of our ~~common~~ **Common stock Stock** will be and as a result it may be difficult for you to sell your shares of our ~~common~~ **Common stock Stock**. Prior to our IPO in November of 2022, there was no public market for shares of our ~~common~~ **Common stock Stock**. Although our ~~common~~ **Common stock Stock** is listed on the Nasdaq Capital Market (Nasdaq), ~~an active~~ **only a limited** trading market for our shares has ~~not yet~~ developed, and ~~an active market~~ may never develop or if developed be sustained in the future. You may not be able to sell your shares quickly or at the market price if trading in shares of our ~~common~~ **Common stock Stock** is not active. ~~The initial public offering price for our common stock was determined through negotiations with the underwriters, and the negotiated price is not indicative of the market price of our common stock as of the date of this Form 10-K. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price.~~ Further, an inactive market may also impair our ability to raise capital by selling shares of our ~~common~~ **Common stock Stock** and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of ~~common~~ **Common stock Stock** as consideration. The price of our stock may be volatile, and you could lose all or part of your investment. The trading price of our ~~common~~ **Common stock Stock** is highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this **Annual Report on** Form 10-K, these factors include: · adverse results or delays in our development activities; · adverse regulatory decisions, including failure to receive regulatory approval for our future isotopes; · changes in laws or regulations applicable to our future isotopes, including but not limited to requirements for approvals; · any changes to our relationship with any manufacturers, suppliers, licensors, future collaborators or other strategic partners; · our inability to obtain adequate product supply for any future isotope or inability to do so at acceptable prices; · our inability to establish collaborations if needed; · our failure to commercialize our future isotopes; · additions or departures of key scientific or management personnel; · unanticipated serious safety concerns related to the use of our future isotopes; · introduction of new products or services offered by us or our competitors; · announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors; · our ability to effectively manage our growth; · actual or anticipated variations in quarterly operating results; · our cash position; · our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public; **43** · publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts; · changes in the market valuations of similar companies; · overall performance of the equity markets; · issuances of debt or equity securities; · sales of our ~~common~~ **Common stock Stock** by us or our stockholders in the future or the perception that such sales may occur; · trading volume of our ~~common~~ **Common stock Stock**; · changes in accounting practices; · ineffectiveness of our internal controls; · disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies; · significant lawsuits, including patent or stockholder litigation; · general political and economic conditions, including **military conflict or** the COVID- 19 pandemic; and · other events or factors, many of which are beyond our control. In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our ~~common~~ **Common stock Stock**, regardless of our actual operating performance, and you may not realize any return on your investment in us and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition. We do not intend to pay dividends on our ~~common~~ **Common stock Stock**, so any

returns will be limited to the value of our stock. We have never declared or paid any cash dividend on our ~~common~~ **Common Stock**. We currently anticipate that we will retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders would therefore be limited to the appreciation, if any, of their stock. Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval. Our executive officers, current directors, greater than 5 % holders, and their affiliates beneficially own, in the aggregate, approximately ~~53-43~~ **73** % of our ~~common~~ **Common Stock** as of December 31, ~~2022~~ **2023**. Therefore, these stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our ~~common~~ **Common Stock** that you may feel are in your best interest as one of our stockholders. Sales of a substantial number of shares of our ~~common~~ **Common Stock** by our existing stockholders in the public market, or the perception that such sales could occur, could cause our stock price to fall. **As of April 1, 2024, we had a total of 48,923,276 shares of Common Stock outstanding.** If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our ~~common~~ **Common Stock** in the public market ~~after the lock-up and other legal restrictions on resale lapse~~, the trading price of our ~~common~~ **Common Stock** could decline. **Of our** ~~As of March 29, 2023, we had a total of 37,385,684 shares of common stock outstanding~~ **As of March 29, 2023, we had a total of 37,385,684 shares of common stock outstanding** ~~Of these shares, the shares of common~~ **Common Stock** sold in our IPO by us, any shares sold upon exercise of the underwriters' option to purchase additional shares and 8,702,500 shares eligible for resale under Rule 144 of the Securities Act are freely tradable without restriction in the public market. Subject to the restrictions described in the paragraph below, future sales in the public market of shares will be subject to the volume and other restrictions of Rule 144 under the Securities Act if held by a person that is deemed to be our affiliate, unless the shares to be sold are registered with the SEC. The sale of a substantial number of shares pursuant to Rule 144 or other exemption from registration under the Securities Act, or a perception that such sales could occur, could significantly reduce the market price of our common stock. Of our outstanding common stock, shares held by our management are subject to lock-up agreements pertaining to our IPO that we expect will expire on May 15, 2023. ~~After the lock-up agreements expire~~, the shares held by directors, executive officers, and other affiliates **are and will be** subject to volume limitations under Rule 144 under the Securities Act. In addition, ~~2-3~~ **949-254**, ~~611-606~~ **611-606** shares of ~~common~~ **Common Stock** that are either subject to outstanding options or reserved for future issuance under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, ~~the lock-up agreements~~, and Rule 144 and Rule 701 under the Securities Act. If these additional shares of ~~common~~ **Common Stock** are sold, or if it is perceived that they will be sold ~~in the public market~~, the trading price of our ~~common~~ **Common Stock** could decline. ~~We have an aggregate of 8,702,500 shares which are freely tradable without restriction under the Securities Act. Up to 28,683,184 shares are held by our affiliates and are subject to limitations imposed by Rule 144 and /or lock-up agreements which expire on May 15, 2023. Any sales of these securities by our stockholders could have a material adverse effect on the trading price of our common~~ **Common Stock** or rights to purchase ~~common~~ **Common Stock**, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall. We expect that we will need significant additional capital in the future to continue our planned operations, including development activities, commercialization efforts if we are able to obtain marketing approval of future isotopes, research and development activities, and costs associated with operating a public company. To raise capital, we may sell ~~common~~ **Common Stock**, convertible securities or other equity securities in one or more transactions at prices and in a manner that we determine from time to time. If we sell ~~common~~ **Common Stock**, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our ~~common~~ **Common Stock**, ~~including shares of common stock sold in our IPO~~. Pursuant to our 2022 Plan, our management is authorized to grant stock options to our employees, directors and consultants. Additionally, the number of shares of our ~~common~~ **Common Stock** reserved for issuance under our 2022 Plan will automatically increase on January 1 of each year, beginning on January 1, 2023 and continuing through and including January 1, 2032, by 5 % of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year (determined on an as- converted to voting ~~common~~ **Common Stock** basis, without regard to any limitations on the conversion of the non- voting ~~common~~ **Common Stock**), or a lesser number of shares determined by our board of directors. Such issuances will result in dilution to our stockholders. We have broad discretion in the use of our existing cash and cash equivalents and may not use them effectively. Our management has broad discretion in the application of our existing cash and cash equivalents. Because of the number and variability of factors that will determine our use of our existing cash and cash equivalents, their ultimate use may vary substantially from their currently intended use. Our management might not apply our existing cash and cash equivalents in ways that ultimately increase the value of our ~~common~~ **Common Stock**. The failure by our management to apply these funds effectively could harm our business. We intend to invest our existing cash and cash equivalents that are not used as described above in short- and medium- term, investment- grade, interest- bearing instruments, certificates of deposit or direct or guaranteed obligations of the U. S. government. These investments may not yield a favorable return to our stockholders. If we do not invest or apply our existing cash and cash equivalents in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline. We are an emerging growth company and a smaller reporting company, and the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies may make our ~~common~~ **Common Stock** less attractive to investors. We are an emerging growth company, as defined in the JOBS Act. For as long

as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including 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 nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company until December 31, 2027, although circumstances could cause us to lose that status earlier, including if we become a “ large accelerated filer ” as defined in Rule 12b- 2 under the Exchange Act or if we have total annual gross revenue of \$ 1. 235 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31 or, if we issue more than \$ 1. 0 billion in non- convertible debt during any three year period before that time, we would cease to be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we may still qualify as a “ smaller reporting company ” which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. Investors may find our ~~common~~ **Common stock Stock** less attractive because we may rely on these exemptions. If some investors find our ~~common~~ **Common stock Stock** less attractive as a result, there may be a less active trading market for our ~~common~~ **Common stock Stock** and our stock price may be more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of accounting standards that have different effective dates for public and private companies until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards, and therefore we will not be subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies. We are also a “ smaller reporting company ” as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non- voting common stock held by non- affiliates is less than \$ 250. 0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than \$ 100. 0 million during the most recently completed fiscal year and our voting and non- voting common stock held by non- affiliates is less than \$ 700. 0 million measured on the last business day of our second fiscal quarter. ~~Delaware~~ **45Delaware** law and provisions in our ~~certificate of incorporation and bylaws, as amended, and restated certificate of incorporation and amended and restated bylaws~~ **certificate of incorporation and bylaws, as amended, and restated certificate of incorporation and amended and restated bylaws** could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock. Provisions of our ~~our~~ **certificate of incorporation and bylaws as amended and restated certificate of incorporation and amended and restated bylaws, which became effective upon the closing of our IPO,** may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws: · permit our board of directors to issue up to 10, 000, 000 shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change in our control); · provide that the authorized number of directors may be changed only by resolution of the board of directors; · provide that our board of directors or any individual director may only be removed with cause and the affirmative vote of the holders of at least 66- 2 / 3 % of the voting power of all of our then- outstanding shares of the capital stock entitled to vote generally in the election of directors, voting together as a single class; · provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum; · divide our board of directors into three classes; · require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent; · provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder’ s notice; · do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose); · provide that special meetings of our stockholders may be called only by the chair of our board of directors, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and · provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under state, statutory and common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders; (iii) any action asserting a claim pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws; (iv) any action as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; and ( ~~v~~ **v** ) any action governed by the internal affairs doctrine, in all cases subject to the court’ s having personal jurisdiction over the indispensable parties named as defendants; provided these provisions of our amended and restated certificate of incorporation and amended and restated bylaws will not apply to suits brought to enforce a duty or liability created by the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction; and provided that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended (Securities Act), including all causes of action asserted against any defendant to

such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional or entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. ~~The amendment of any of these~~ **These** provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require approval by the holders of at least 66- 2 / 3 % of our then- outstanding common stock. In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15 % or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision. ~~These~~ **46These** and other provisions in our **certificate of incorporation and bylaws, as amended and restated certificate of incorporation, amended and restated bylaws** and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then- current board of directors, including delay or impede a merger, tender offer or proxy contest involving our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for you to realize value in a corporate transaction. ~~For information regarding these and other provisions, see “Description of Capital Stock.”~~ Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for certain disputes between us and our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees. Our amended and restated certificate of incorporation provides that, subject to the court’ s having personal jurisdiction over the indispensable parties named as defendants, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings: · any derivative action or proceeding brought on our behalf; · any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders; · any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or bylaws; · any action as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; and · any action asserting a claim that is governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions. These exclusive forum provisions may limit a stockholder’ s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business. **We are currently listed on The Nasdaq Capital Market. If we are unable to maintain listing of our securities on Nasdaq or any stock exchange, our stock price could be adversely affected and the liquidity of our stock and our ability to obtain financing could be impaired and it may be more difficult for our shareholders to sell their securities. Although our Common Stock is currently listed on The Nasdaq Capital Market, we may not be able to continue to meet the exchange’ s minimum listing requirements or those of any other national exchange. If we are unable to maintain listing on Nasdaq or if a liquid market for our Common Stock does not develop or is sustained, our Common Stock may remain thinly traded. The Listing Rules of Nasdaq require listing issuers to comply with certain standards in order to remain listed on its exchange. If, for any reason, we should fail to maintain compliance with these listing standards and Nasdaq should delist our securities from trading on its exchange and we are unable to obtain listing on another national securities exchange, a reduction in some or all of the following may occur, each of which could have a material adverse effect on our shareholders: · the liquidity of our Common Stock; · the market price of our Common Stock; · our ability to obtain financing for the continuation of our operations; · the number of investors that will consider investing in our Common Stock; · the number of market makers in our Common Stock; · the availability of information concerning the trading prices and volume of our Common Stock; and · the number of broker- dealers willing to execute trades in shares of our Common Stock.** ~~General~~ **47General** Risk Factors We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives. ~~As~~ **We became** a public company **in November of 2022**, and as a **public company** we will incur significant legal, accounting, and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC annual, quarterly, and current reports with respect to our business and financial condition. In addition, the Sarbanes- Oxley Act, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes- Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and

financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd- Frank Wall Street Reform and Consumer Protection Act (Dodd- Frank Act) was enacted. There are significant corporate governance and executive compensation- related provisions in the Dodd- Frank Act that require the SEC to adopt additional rules and regulations in these areas such as “ say on pay ” and proxy access. Emerging growth companies and smaller reporting companies are exempted from certain of these requirements, but we may be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time- consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, and results of operations. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. We have identified a material weakness in our internal control over financial reporting. If our remediation of this material weakness is not effective, or if we experience material weaknesses in the future or otherwise fail to implement and maintain an effective system of internal controls in the future, we may not be able to accurately report our financial condition or results of operations which may adversely affect investor confidence in us, and as a result, the value of our ~~common~~ **Common stock**. Our ~~common~~ **Common stock** was ~~only recently~~ listed on the ~~NASDAQ~~ **Nasdaq** Stock Exchange on November 10, 2022. Prior to listing, we were a privately- held company, we were not required to evaluate our internal control over financial reporting in a manner that meets the standards of publicly traded companies required by Section 404 (a) of the Sarbanes- Oxley Act, or Section 404. As a public company, we are subject to significant requirements for enhanced financial reporting and internal controls. The process of designing and implementing effective internal controls is a continuous effort that requires 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. In addition, we are required, pursuant to Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting in the ~~second~~ annual report. This assessment ~~will need to include~~ **includes** disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company’ s annual and interim financial statements will not be detected or prevented on a timely basis. 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. Once we are no longer an “ emerging growth company, ” or a “ smaller reporting company ”, our auditors will be required to issue an attestation report on the effectiveness of our internal controls on an annual basis. ~~In 48~~ **In** the course of preparing the financial statements that are included in this **Annual Report on** Form 10- K, management has determined that a material weakness exists within the internal controls over financial reporting. The material weakness identified relates to **the lack of formal control documentation and consistent execution of control procedures, and** the lack of a sufficient complement of personnel within the finance and accounting function with an appropriate degree of knowledge, experience and training. We also noted a material weakness related to logical security and privileged access in the area of information technology. We concluded that the material ~~weakness~~ **weaknesses** in our internal control over financial reporting **information technology** occurred because, prior to our IPO, we were a private company and did not have the necessary business processes, systems, personnel, and related internal controls necessary to satisfy the accounting and financial reporting requirements of a public company. In order to remediate the material ~~weakness~~ **weaknesses**, we expect to **enhance our formal documentation over internal control procedures and management controls infrastructure to allow for more consistent execution of control procedures and** hire additional accounting, finance and **information technology** resources or consultants with public company experience. We may not be able to fully remediate the identified material weakness until the steps described above have been completed and our internal controls have been operating effectively for a sufficient period of time. We believe we have already and will continue to make progress in our remediation plan ~~during the year ending December 31, 2022,~~ but cannot assure you that we will be able to fully remediate the material weakness by such time. If the steps we take do not correct the material weakness in a timely manner, we will be unable to conclude that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis. We also may incur significant costs to execute various aspects of our remediation plan but cannot provide a reasonable estimate of such costs at this time. In accordance with the provisions of the JOBS Act, we and our independent registered public accounting firm were not required to, and did not, perform an evaluation of our internal control over financial reporting as of December 31, ~~2022~~ **2023** nor any period subsequent in accordance with the provisions of the Sarbanes- Oxley Act. Accordingly, we cannot assure you that we have identified all material weaknesses. Material weaknesses may still exist when we report on the effectiveness of our internal control over financial reporting as required under Section 404 of the Sarbanes- Oxley Act ~~after the completion of our IPO.~~ In the future, it is possible that additional material weaknesses or significant deficiencies may be identified that we may be unable to remedy before the requisite deadline for these

reports. Our ability to comply with the annual internal control reporting requirements will depend on the effectiveness of our financial reporting and data systems and controls across our company. Any weaknesses or deficiencies or any failure to implement new or improved controls, or difficulties encountered in the implementation or operation of these controls, could harm our operating results and cause us to fail to meet our financial reporting obligations, or result in material misstatements in our consolidated financial statements, which could adversely affect our business and reduce our stock price. If we are unable to conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404, our independent registered public accounting firm may not issue an unqualified opinion. If we are unable to conclude that we have effective internal control over financial reporting, investors could lose confidence in our reported financial information, which could have a material adverse effect on the trading price of our ~~common~~ **Common stock** ~~Stock~~. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets. We could be subject to securities class action litigation. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business. Our failure to meet Nasdaq's continued listing requirements could result in a delisting of our ~~common~~ **Common stock** ~~Stock~~. If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our ~~common~~ **Common stock** ~~Stock~~. Such a delisting would likely have a negative effect on the price of our ~~common~~ **Common stock** ~~Stock~~ and would impair your ability to sell or purchase our ~~common~~ **Common stock** ~~Stock~~ when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our ~~common~~ **Common stock** ~~Stock~~ to become listed again, stabilize the market price or improve the liquidity of our ~~common~~ **Common stock** ~~Stock~~, prevent our ~~common~~ **Common stock** ~~Stock~~ from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with the listing requirements of Nasdaq. **If 491f** securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline. The trading market for our ~~common~~ **Common stock** ~~Stock~~ depends in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.