**Risk Factors Comparison 2024-03-26 to 2023-03-27 Form: 10-K**

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

An investment in our securities ~~involve~~ **involves** a high degree of risk. You should carefully consider the following risks, in conjunction with the financial and other information contained in this Annual Report on Form 10- K. As previously discussed, our actual results could differ materially from our forward- looking statements. These risks include those described below and may include additional risks and uncertainties not presently known to us or that we currently deem immaterial. If any of the events or circumstances described in the following risk factors occur, our business operations, performance, financial condition and prospects could be materially and adversely affected and the trading price of our common stock could decline, and you may lose all or part of your investment. We cannot assure you that any of the events discussed below will not occur. Risks Related to Our Business and Financial Condition Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern ~~as of December 31, 2022. We will be unable to continue to operate for the foreseeable future without additional capital~~ . Our independent registered public accounting firm issued a report dated March ~~27~~ **26** , ~~2023~~ **2024** in connection with the audit of our financial statements as of December 31, ~~2022~~ **2023** , which included an explanatory paragraph describing the existence of conditions that raise substantial doubt about our ability to continue as a going concern including our significant working capital deficiency, significant losses and need to raise additional funds to meet our obligations and sustain our operations. In addition, the notes to our financial statements for the year ended December 31, ~~2022~~ **2023** , included in this Annual Report on Form 10- K, contain a disclosure describing the existence of conditions that raise substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern ~~is~~ **was** dependent upon our ability to obtain substantial additional funding in connection with our continuing operations. ~~Adequate additional financing may not be available to us in the necessary timeframe, in the amounts we require, on terms that acceptable to us, or at all.~~ If we are unable to raise ~~additional~~ **sufficient** capital **or otherwise when needed,** our business ~~, prospectus~~ , financial condition and results of operations will be materially and adversely affected **,** and we ~~may be unable~~ **will need to significantly modify our operational plans** to continue as a going concern ~~. For example, we anticipate that our existing cash and cash equivalents will enable us to maintain our current operations through March 31, 2023, but not beyond~~ . If we are not able to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our consolidated financial statements and / or seek protection under federal bankruptcy law or enter into a receivership, and it is likely that holders of our common stock and holders of securities convertible into our common stock will lose all of their investment. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all. As such, there is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively, which raises substantial doubt about our ability to continue as a going concern. We will need additional capital to maintain our operations. If we cannot raise additional capital, our potential to generate future revenues will be significantly limited since we will not be able to further commercialize CHEMOSAT and HEPZATO, ~~complete our clinical trials~~ or conduct future product development ~~and~~ **, including** clinical trials **, if any** . **Developing and commercializing pharmaceutical products, including conducting** ~~Preclinical~~ **preclinical** testing and clinical trials **and preparing for and commencing commercial launch** are long, expensive, and highly uncertain processes and failure can unexpectedly occur at any stage of clinical development ~~. Drug development is very risky~~ , **including following commercial launch** ~~and it takes several years to complete clinical trials~~ . ~~The start or end of a clinical trial is often delayed or halted due~~ **Our expenses will increase, particularly as we commercialize HEPZATO in the United States, including expenses related** to ~~changing regulatory requirements~~ **product sales, marketing** , manufacturing **and distribution. If we** ~~challenges, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care~~ **are not able to generate significant revenue from either** ~~, availability, or prevalence of use of a comparator treatment or required prior therapy, clinical outcomes including insufficient efficacy, safety concerns, or our~~ **or** ~~own financial constraints. We~~ **both of HEPZATO and CHEMOSAT, we** will require additional substantial financing to **further commercialize** ~~complete our clinical trial program or our~~ ~~seek~~ **products in the United States and the European Union and any** other **jurisdictions where we may receive regulatory** ~~approvals~~ **approval for our products** , **and in order** to conduct future **product** development ~~and~~ **, if any, including** clinical trials **for new** ~~and to further commercialize our~~ product **candidates or for HEPZATO or CHEMOSAT** in **additional indications for which** ~~the EU and any other markets where~~ we ~~may receive~~ **do not currently have regulatory** approval ~~for our products~~ . ~~We anticipate that our existing~~ **In the absence of potential proceeds from** cash **exercises of** ~~and cash equivalents will enable us to maintain our current~~ **currently outstanding warrants and convertible** ~~operations through the first quarter of 2023, but not~~ **notes** ~~beyond. If~~ **and / or significant revenue from either or both of HEPZATO and CHEMOSAT,** we **may require substantial** ~~are unable to raise~~ additional **funding** ~~capital, our ability~~ to **continue the launch and commercialization of HEPZATO in the U. S.,** complete product development projects or clinical trials ~~will~~ **. If we are unable to raise additional capital or generate significant revenue from either or both of HEPZATO and CHEMOSAT, our ability to complete product development projects or clinical trials, including trials for HEPZATO and CHEMOSAT, in additional indications, may** be impaired **, which could have a material adverse effect on our business, financial condition and results of operations** . ~~We~~ **If we are not successful in generating product revenue, we** do not know if additional financing will be available on commercially reasonable terms or at all. In addition, we may not be able to access a portion of our existing cash, cash equivalents and investments due to market conditions ~~. For~~ **or** ~~example~~ **contractual**

**obligations** , **such** ~~on March 10, 2023, the Federal Deposit Insurance Corporation (FDIC), took control and was~~ - **as restrictive covenants that** ~~appointed receiver of Silicon Valley Bank (" SVB "). If other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash, cash equivalents and investments may be threatened and could have a material adverse effect on our business and financial condition. If we~~ are ~~unable to obtain additional~~ **sometimes included in debt** financing ~~in the near- term, we will not be able to further commercialize CHEMOSAT and HEPZATO, obtain regulatory approvals or complete our development projects or clinical trials, which would result in a complete loss of an investment in our securities~~ . Our liquidity and capital requirements will depend on numerous factors, including: • **our ability to successfully sell HEPZATO in the United States and CHEMOSAT in Europe; • the outcome of any of our future** clinical studies ~~, including closing our Phase 3 clinical trial in ocular melanoma liver metastases~~ ; • the timing and costs of our various United States and foreign regulatory filings, obtaining approvals and complying with regulations; • **our ability to secure the continuous supply of melphalan and other critical components of HEPZATO and CHEMOSAT from facilities in compliance with applicable manufacturing regulations; • our ability to secure commercially reasonable terms for the supply of melphalan and other critical components of HEPZATO and CHEMOSAT; •** the timing ~~and~~ **,** costs **and regulatory approval processes** associated with developing our **and / or our partners'** manufacturing operations; • the ~~timing~~ **cost and ability to effectively establish and maintain the commercial infrastructure and manufacturing capabilities required to support the commercialization** of **HEPZATO, CHEMOSAT and any other products for which we receive marketing approval including** product **sales** ~~commercialization activities~~ , ~~including~~ **medical affairs,** marketing **, manufacturing** and distribution ~~arrangements overseas~~ ; • market acceptance of any approved product candidates, including product pricing and product reimbursement by third- party payors; • **our need to implement additional internal systems and infrastructure, including financial and reporting systems; •** executive compensation, including the cost of attracting senior executives; • **our headcount growth and associated costs as we expand our research and development and further establish a commercial infrastructure; • our debt requirements, including contractual obligations under such agreements; •** the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; and • the impact of competing technological and market developments. Insufficient capital may require us to curtail or stop our commercialization activities, regulatory submissions or ongoing activities for regulatory approval, research and development and clinical trials, which will significantly limit our potential to generate future revenues. If we are not ~~able to raise additional capital~~ in **compliance with** the ~~near term~~ **terms** ~~, we may have to liquidate our assets~~ and **conditions of our existing debt agreement, our business and financial condition** may ~~receive less than the value at which~~ **be adversely affected. On August 6, 2021, we entered into** ~~those~~ -- **the** ~~assets are carried~~ **Loan and Security Agreement with Avenue Venture Opportunities Fund, L. P., as amended** on ~~our consolidated financial statements and / or seek protection under federal bankruptcy law or enter into a receivership, and it is likely that holders of our common stock and holders of securities convertible into our common stock will lose all of their investment. We will need additional capital to maintain our operations. If we cannot raise additional capital before~~ March 31, 2023 ~~, we may be unable to comply with the terms and conditions of our Loan and Security Agreement~~ (the " Avenue Loan Agreement ") ~~with Avenue Venture Opportunities Fund, L~~ . **The** ~~P. (the " Lender, " or " Avenue "). If we breach the~~ Avenue Loan Agreement **provides for a term loan in** ~~, this may have adversely impact our business and~~ - **an** ~~financial condition~~ **aggregate principal amount of up to $ 20** . **0 million** ~~On August 6, 2021, we entered into the Avenue Loan Agreement with Avenue~~ , pursuant to which, we have borrowed $ 15 million ~~as of the date hereof~~ . Pursuant to the Avenue Loan Agreement, we made monthly interest- only payments during the first fifteen months of the term of the Avenue Loan Agreement and began principal payments in December 2022. **On March 31** ~~We are now required to make equal monthly payments of principal~~ , **2023** ~~plus accrued 25 interest~~ , ~~until~~ **we reached an agreement to amend** the Avenue Loan Agreement ~~' s maturity date. If we prepay the Avenue Loan Agreement, we will be required~~ to **allow us to** ~~pay prepayment fee of 1 %. On the maturity date or on the date of the prepayment of the borrowed amount under the Avenue Loan Agreement, we must also~~ make **interest only payments until September 30, 2023, with** an ~~incremental final~~ **additional extension option upon FDA approval for the HEPZATO KIT and subsequent receipt of $ 10 million from the sale and issuance of equity securities. After the additional extension requirements were met, we elected to extend the interest only** payment ~~equal~~ **period** to **December 31** ~~4. 25 % of the aggregate funding. On March 15~~ , 2023 **and principal payments began** ~~, the Company returned to Avenue the $ 4. 0 million held~~ in **January 2024** ~~the restricted cash to paydown a portion of the outstanding loan balance~~ . The Avenue Loan Agreement bears interest at an annual rate equal to the greater of (a) the sum of 7. 7 % plus the prime rate as reported in The Wall Street Journal and (b) 10. 95 %. The interest rate ~~at~~ **pursuant to the Avenue Loan Agreement on** December 31, ~~2022~~ **2023** was ~~15~~ **16** . ~~2~~ **20** %. The Avenue Loan Agreement is secured by all of **our** ~~the Company' s~~ assets globally, including intellectual property. The amount borrowed pursuant to the Avenue Loan Agreement matures on August 1, 2024. The Avenue Loan Agreement contains customary events of default, including, among other things, our failure to fulfill certain of our obligations under the Avenue Loan Agreement and the occurrence of a material adverse change in our business, operations or condition (financial or otherwise), a material impairment of the prospect of repayment of any portion of the loan, the failure to deliver an unqualified audit report and board approved financial projections within time periods set forth in the Avenue Loan Agreement, or a material impairment in the perfection or priority of ~~lender~~ **Lender** ' s lien in the collateral or in the value of such collateral. In the event of default by us under the Avenue Loan Agreement, the ~~lender~~ **Lender** would be entitled to exercise its remedies thereunder, including the right to accelerate the debt, upon which we may be required to repay all amounts then outstanding under the Avenue Loan Agreement, which could harm our business, operations and financial condition. **If** ~~We anticipate that our existing cash and cash equivalents will enable us to maintain our current operations through March 31, 2023, but not beyond, and as a result, if~~ we do not make our required monthly ~~repayment~~ **repayments beginning** on ~~April~~ **January** 1, **2024, in accordance with the March** 2023 **amendment to the Avenue Loan Agreement** , we would be in default **of** the Avenue Loan Agreement. If we were to be

in default of the Avenue Loan Agreement, our business and financial condition may be adversely impacted and result in us losing rights to certain or our assets, including intellectual property that is secured by the Avenue Loan Agreement. Furthermore, if we default on any installment under the Avenue Loan Agreement, we will not be eligible to use Form S- 3 registration statements for an extended period of time, which could further adversely impact our ability to raise additional financing. Drug development is an inherently uncertain process..... and may never obtain regulatory approval. Raising additional capital **, or the exercise or conversion of securities exercisable or convertible into shares of common stock,** may cause dilution to our existing stockholders and raising funds through lending and licensing arrangements may restrict our operations or require ~~it~~ **us** to relinquish proprietary rights. Significant additional capital will be needed in the future to continue our planned operations. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, **exercise of our outstanding warrants and conversion of outstanding preferred stock,** strategic alliances and license and development agreements in connection with any collaborations ~~. We do not currently have any committed external source of funds and we anticipate that our existing cash and cash equivalents will enable us to maintain our current operations through the first quarter of 2023, but not beyond~~ . To the extent that we raise additional capital by issuing equity securities, existing stockholders' ownership may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of a common stockholder. In addition, the exercise of outstanding warrants and options will also cause dilution. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, creating liens, redeeming its stock or making investments. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, or through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties on acceptable terms, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise develop and market. **We have incurred significant losses since inception, expect to incur significant and increasing losses for at least this year, and** ~~Continuing~~ **continuing** losses may exhaust our capital resources. As of December 31, ~~2022~~ **2023** , we had $ ~~11~~ **12. 7 million in cash and cash equivalents and $ 19** . 8 million in ~~cash and cash equivalents~~ **short- term investments** . We have had minimal revenue to date, and have a substantial accumulated deficit, recurring operating losses and negative cash flow. We are not profitable and have incurred losses in each year since commencing operations. For the years ended December 31, **2023, and** 2022 ~~and 2021~~ , we incurred net losses of approximately $ **47. 7 million and $** 36. 5 million ~~and $ 25. 6 million~~ , respectively **,** and expect ~~27~~ to continue to incur losses in ~~2023~~ **2024** . To date, we have funded operations through a combination of private placements and public offerings of our securities ~~,~~ **and** debt financing **,** including convertible notes. If we continue to incur losses, we may exhaust our capital resources, and as a result may be unable to ~~complete~~ **further commercialize our products in the United States and the European Union and any other jurisdictions where we may receive regulatory approval for our products** ~~our~~ **or conduct future product development, if any, including** clinical trials **for new** ~~, engage in~~ product ~~development and the~~ **candidates or for HEPZATO or CHEMOSAT in additional indications for which we do not currently have** regulatory approval ~~process and commercialization of CHEMOSAT and HEPZATO or any other versions of these products. If we are unable to raise capital or generate sufficient revenue, we may not be able to pay our debts when they become due and may have to seek protection under federal bankruptcy law or enter into a receivership~~ . Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. ~~In addition, we will not be able to generate product revenue unless and until one of our product candidates successfully completes clinical trials, receives regulatory approval and is successfully commercialized. In addition, we will not be able to generate product revenue unless and until one of our product candidates successfully completes clinical trials, receives regulatory approval and is successfully commercialized.~~ Our ability to generate any product revenue from ~~our current~~ **HEPZATO and CHEMOSAT** or future product candidates **, if any,** also depends on a number of additional factors, including our ability **to** : **• successfully commercialize and sell HEPZATO in the United States pursuant to our existing FDA approval;** • successfully complete research and clinical development of ~~current and~~ future product candidates **, if any, including clinical trials for new product candidates or for HEPZATO or CHEMOSAT in additional indications for which we do not currently have regulatory approval,** and obtain regulatory approval for those product candidates **and indications, as applicable** ; • establish and maintain supply and manufacturing relationships **, under commercially reasonable terms,** with third parties, and ensure adequate, scaled up and legally compliant manufacturing of **necessary components, including melphalan,** bulk drug substances and drug products to maintain sufficient supply; • launch and commercialize any product candidates for which ~~marketing~~ **FDA** approval is obtained ~~, if any, and, if launched independently by us without a partner, successfully establish a sales force and marketing and distribution infrastructure~~ ; • demonstrate the necessary safety data (and, if accelerated approval is obtained, verify the clinical benefit) post- approval to ensure continued regulatory approval; • obtain coverage and adequate product reimbursement from third- party payors, including government payors, for any approved products; • achieve market acceptance for any approved products; • establish, maintain, protect and enforce our intellectual property rights; and • attract, hire and retain qualified personnel. Because of the numerous risks and uncertainties associated with pharmaceutical product development, including that our product candidates may not advance through development or be approved for commercial sale, we are unable to predict if or when we will generate **significant** product revenue or achieve or maintain profitability. Even if we successfully complete development and regulatory processes for any product candidates that we take forward, we anticipate incurring significant costs associated with launching and commercializing any products. If we fail to become profitable or do not sustain profitability on a continuing basis, we may

be unable to continue our operations at planned levels and be forced to reduce or cease our operations. We have in the past, and may in the future, become subject to litigation or claims arising in or outside the ordinary course of business that could negatively affect our business operations and financial condition. We have in the past, and may in the future, become subject to litigation or claims arising in or outside the ordinary course of business (other than intellectual property infringement actions) that could negatively affect our business operations and financial condition, including securities class actions and shareholder derivative actions, both of which are typically expensive to defend. Such claims and litigation proceedings may be brought by third parties, including our competitors, advisors, service providers, partners or collaborators, employees, and governmental or regulatory bodies. For information on past legal proceedings, please see " Item 3. Legal ~~28~~ Proceedings. " Any claims and lawsuits, and the disposition of such claims and lawsuits, could be time- consuming and expensive to resolve, divert management attention and resources, and lead to attempts on the part of other parties to pursue similar claims. We may not be able to determine the amount of any potential losses and other costs we may incur due to the inherent uncertainties of litigation and settlement negotiations. In the event we are required or decide to pay amounts in connection with any claims or lawsuits, such amounts could be significant and could have a material adverse impact on our liquidity, business, financial condition and results of operations. In addition, depending on the nature and timing of any such dispute, a resolution of a legal matter could materially affect our future operating results, our cash flows or both. Additionally, we may be unable to maintain our existing directors' and officers' liability insurance in the future at satisfactory rates or adequate coverage amounts and may incur significant increases in insurance costs. **We may be the subject of product liability claims or product recalls, and we may be unable to maintain insurance adequate to cover potential liabilities. Our business exposes us to potential liability risks that may arise from clinical trials and the testing, manufacture, marketing, sale and use of CHEMOSAT and HEPZATO. In addition, because CHEMOSAT and HEPZATO are intended for use in patients with cancer, there is an increased risk of death among the patients treated with our product, which may increase the risk of product liability lawsuits related to clinical trials or commercial sales. We may be subject to claims against us even if the injury is due to the actions of others. For example, if the medical personnel that use our product on patients are not properly trained or are negligent in the use of the system, the patient may be injured, which may subject us to claims. Were such a claim asserted, we would likely incur substantial legal and related expenses even if we prevail on the merits. Claims for damages, whether or not successful, could result in the loss of physician endorsement, adverse publicity and / or limit our ability to market and sell our products, resulting in loss of revenue. In addition, it may be necessary for us to recall products that do not meet approved specifications, which would also result in adverse publicity and costs connected to the recall and loss of revenue. A successful products liability claim or product recall would have a material adverse effect on our business, financial condition, and results of operations. While we currently carry insurance, it may be insufficient to cover one or more large claims. Risks Related to Manufacturing, Commercialization and Market Acceptance of CHEMOSAT and HEPZATO We have only recently obtained regulatory approval for HEPZATO in the United States and commenced the commercial launch of HEPZATO. We have limited experience as a commercial company and generating revenue from product sales. If the commercial launch of HEPZATO is unsuccessful or any future approved products are unsuccessful, we may never be profitable. We received approval by the FDA for HEPZATO in the United States in August 2023 and began generating revenue from product sales during the first quarter of 2024. Our ability to become and remain profitable is heavily dependent on our ability to generate revenue from HEPZATO for the treatment of mUM.** The ~~Company~~ **success of our commercialization will depend on a number of factors, including, among others, the continued development of our commercial organization, including our internal sales and marketing team and distribution capabilities, our ability to navigate the significant expenses and risks involved with the development and management of such capabilities, satisfying any post- marketing regulatory requirements, our ability to secure adequate healthcare coverage and the acceptance of HEPZATO by patients and third- party payors. If HEPZATO, or any other future approved product,** does not **achieve** ~~.38 Risks Related to Manufacturing,Commercialization and~~ **an** ~~Market~~ **adequate level of** ~~Acceptance~~ **acceptance** ~~of CHEMOSAT~~ **,coverage,pricing or reimbursement,we may not generate significant revenue from product sales** and **we may not be profitable.Even if we successfully commercialize** HEPZATO ~~Manufacturers of melphalan~~ **in the United States,we** may be unable to ~~provide~~ **achieve or maintain profitability,unless HEPZATO is approved in other jurisdictions or for additional indications.Because of the uncertainties and risks associated with these activities,we are unable to accurately and precisely predict the timing and amount of revenues from product sales of HEPZATO,or any future approved products,or if or when we might achieve profitability.If we are unsuccessful in accomplishing our objectives,or if our commercialization efforts do not develop as planned,we may not be able to successfully commercialize HEPZATO or any future approved products,we may require significant additional capital and financial resources,we may not become profitable,and we may not be able to compete against more established companies in our industry.Even if we do achieve profitability,we may not be able to sustain or increase profitability on a quarterly or annual basis.We must maintain or enter into acceptable arrangements for the supply of melphalan and other critical components of HEPZATO and CHEMOSAT and we may not be able to ensure** adequate **supply impacting our ability to successfully commercialize HEPZATO in the United States and CHEMOSAT in the EU or complete any future clinical trials.Each manufacturer /** ~~supplies~~ **supplier** of **components for the production of HEPZATO and CHEMOSAT must be in compliance with cGMPs.Our supply of critical components of HEPZATO and CHEMOSAT includes the use of one contracted supplier.In order to successfully commercialize HEPZATO,we also must be able to enter into long- term supply agreements for critical components,including** melphalan **,under commercially reasonable terms** .Under the current regulatory scheme in the European Union,CHEMOSAT is approved for marketing as a device only,and doctors will separately obtain melphalan for use with CHEMOSAT.Although melphalan has been approved in the European Union for over a decade,we are aware that there are currently three approved manufacturers of melphalan in certain

countries ~~of~~ **in** the European Union.If any of these manufacturers fails to provide end- users with adequate supplies of melphalan or fails to comply with the requirements of regulatory authorities,we may be unable to successfully commercialize our product in the European Union.Additionally,melphalan is not available in certain foreign countries outside the European Union where we may seek to market CHEMOSAT.If supply of melphalan remains limited or unavailable,we will be unable to commercialize CHEMOSAT in these markets,thereby limiting future sales opportunities. ~~If~~ **FDA inspections of our suppliers / manufacturers,even for products other than those supplied to us,may result in the supplier / manufacturer being shut down or unable to deliver critical components to us in a timely manner.Such risks are increased for those components for which we have one contractual supplier.We currently have an agreement with one supplier of melphalan and,with the goal of minimizing the risk of a supply interruption,are in discussions with several melphalan ANDA holders who have indicated interest in supplying melphalan to us.We are aware that in 2023,the FDA issued our current melphalan manufacturer 483 observations as a result of an inspection unrelated to the HEPZATO and the manufacturer is working to address these observations.Although we are pursuing a variety of strategies to mitigate the risk of a supply interruption of commercial supply for our product,** we cannot **assure you that such shutdown** ~~maintain or enter into acceptable arrangements for the production of melphalan~~ and **related matters** ~~other chemotherapeutic agents,we~~ will **not result** ~~be unable to successfully commercialize HEPZATO~~ in **a loss of supply in** the ~~United States~~ **event the shutdown is longer than anticipated** or ~~complete~~ **in the event regulatory action is taken against the supplier.In** any ~~future clinical trials.We~~ **such situation,this could** have ~~entered into~~ a **material adverse impact on** ~~manufacturing and supply agreements with several suppliers for~~ our **business,operations and financial condition** ~~supply of melphalan for injection for our clinical trials~~.We may pursue agreements with additional contract manufacturers to produce melphalan and other ~~chemotherapeutic agents~~ **critical components** for use in ~~the future for~~ any future clinical trial programs and ~~commercialization~~ **for the production** of CHEMOSAT and HEPZATO,as well as for labeling and finishing services.We may not be able to enter into such arrangements on ~~acceptable~~ **commercially reasonable** terms or at all ~~.Every manufacturer is subject to inspection by the FDA and must meet all cGMP regulatory requirements~~.To manufacture melphalan or other chemotherapeutic agents on our own,we would have to develop a manufacturing facility that complies with FDA regulations for the production of melphalan and each other chemotherapeutic agent we choose to manufacture for use with our system.Developing these resources would be an expensive and lengthy process and would have a material adverse effect on our revenues and profitability.If we are unable to obtain sufficient melphalan and labeling services on acceptable terms or encounter delays or difficulties in our relationships with current and future suppliers or if current and future suppliers of melphalan do not comply with applicable regulations for the manufacturing and production of melphalan,our business,financial condition and results of operations may be materially harmed.If we cannot successfully manufacture CHEMOSAT and HEPZATO,our ability to develop and commercialize the system would be impaired.We manufacture certain components of our products,including our proprietary filter media,and assemble and package CHEMOSAT and HEPZATO at our facility in Queensbury,New York.We have established our European headquarters in Galway,Ireland and conduct finishing operations,assembly,packaging,labeling and distribution **for CHEMOSAT** at this facility.We currently utilize third parties to manufacture some components of CHEMOSAT and HEPZATO.We may have difficulty obtaining components for our products from our third- party suppliers in a timely manner or at all,which may adversely affect our ability to deliver CHEMOSAT and HEPZATO to purchasers.In addition to limiting sales opportunities,delays in manufacturing CHEMOSAT and HEPZATO may adversely affect our ability to obtain regulatory approval **for other indications** in the United States and other jurisdictions.Our ability to conduct timely clinical trials in the United States and abroad depends on our ability to manufacture the ~~system~~ **product** ,including sourcing the chemotherapeutic agents or other compounds through third parties in accordance with FDA and other regulatory requirements.If we are unable to manufacture CHEMOSAT and HEPZATO in a timely manner,we may not be able to conduct ~~the~~ **additional** clinical trials required to obtain regulatory approval and commercialize our product **for other indications** . ~~39~~ We have implemented quality systems throughout our organization designed to enable us to satisfy the various international quality system regulations,including those of the FDA with ~~respect to products sold in the United States and those established by the International Standards Organization,or ISO,with respect to products sold in the European Union.We are required to maintain ISO 13485 certification for medical devices to be sold in the European Union,which requires,among other items,an implemented quality system that applies to component quality,supplier control,product design and manufacturing operations.All of our facilities are presently ISO 13485:2016 certified.If our Queensbury,New York facility fails to maintain compliance with ISO 13485 and FDA cGMP or fails to pass facility inspection or audits,our ability to manufacture at the facility could be limited or terminated.In the future,we may manufacture and assemble CHEMOSAT and HEPZATO in our Galway,Ireland facility or elsewhere in the European Union,and any facilities in the European Union would have to obtain and maintain similar approvals or certifications of compliance.Although Deleath is not aware of any direct impacts of the war between the Ukraine and the Russian Federation on its supply chain,the war could adversely impact our ability to obtain components and / or significantly increase the cost of obtaining such components for the Company' s products from its third- party suppliers in a timely manner or at all.In addition,at this time,although the Company is not aware of any direct impacts,any increase in COVID cases and associated restrictions could adversely impact the Company' s ability to obtain components and / or significantly increase the cost of obtaining such components for the Company' s products from its third- party suppliers in a timely manner or at all.A rise in COVID cases and the associated absences from work of internal and external resources may also impact the Company' s ability to meet anticipated timelines.We do not have written contracts with all of our suppliers for the manufacture of components for CHEMOSAT and HEPZATO.While we have written contracts and supply agreements for key components for CHEMOSAT and HEPZATO,we do not have written contracts with all suppliers for the manufacture of components for CHEMOSAT and HEPZATO.If we are unable to obtain an adequate supply of the necessary components or negotiate acceptable terms,we may not be able to manufacture CHEMOSAT and HEPZATO in commercial quantities or in a cost-**

effective manner,and commercialization of CHEMOSAT and HEPZATO in the United States, expect respect to will separately obtain melphalan for use with CHEMOSAT.Although melphalan has been approved in the European Union for over a decade,we are aware that there are currently three approved manufacturers of melphalan in certain countries of the European Union.If any of these manufacturers fails to provide end- users with adequate supplies of melphalan or fails to comply with the requirements of regulatory authorities,we may be unable to successfully commercialize our product in the European Union.Additionally,melphalan is not available in certain foreign countries outside the European Union where we may seek to market CHEMOSAT.If supply of melphalan remains limited or unavailable,we will be unable to commercialize CHEMOSAT in these markets,thereby limiting future sales opportunities.If we cannot maintain or enter into acceptable arrangements for the production of melphalan and other chemotherapeutic agents,we will be unable to successfully commercialize HEPZATO in the United States or complete any future clinical trials.We have entered into a manufacturing and supply agreements with several suppliers for our supply of melphalan for injection for our clinical trials.We may pursue agreements with additional contract manufacturers to produce melphalan and other chemotherapeutic agents for use in the future for any future clinical trial programs and commercialization of CHEMOSAT and HEPZATO,as well as for labeling and finishing services.We may not be able to enter into such arrangements on acceptable terms or at all.Every manufacturer is subject to inspection by the FDA and must meet all cGMP regulatory requirements.To manufacture melphalan or other chemotherapeutic agents on our own,we would have to develop a manufacturing facility that complies with FDA regulations for the production of melphalan and each other chemotherapeutic agent we choose to manufacture for use with our system.Developing these resources would be an expensive and lengthy process and would have a material adverse effect on our revenues and profitability.If we are unable to obtain sufficient melphalan and labeling services on acceptable terms or encounter delays or difficulties in our relationships with current and future suppliers or if current and future suppliers of melphalan do not comply with applicable regulations for the manufacturing and production of melphalan,our business,financial condition and results of operations may be materially harmed.If we cannot successfully manufacture CHEMOSAT and HEPZATO,our ability to develop and commercialize the system would be impaired.We manufacture certain components of our products,including our proprietary filter media,and assemble and package CHEMOSAT and HEPZATO at our facility in Queensbury,New York.We have established our European headquarters in Galway,Ireland and conduct finishing operations,assembly,packaging,labeling and distribution at this facility.We currently utilize third parties to manufacture some components of CHEMOSAT and HEPZATO.We may have difficulty obtaining components for our products from our third- party suppliers in a timely manner or at all,which may adversely affect our ability to deliver CHEMOSAT and HEPZATO to purchasers.In addition to limiting sales opportunities,delays in manufacturing CHEMOSAT and HEPZATO may adversely affect our ability to obtain regulatory approval in the United States and other jurisdictions.Our ability to conduct timely clinical trials in the United States and abroad depends on our ability to manufacture the system,including sourcing the chemotherapeutic agents or other compounds through third parties in accordance with FDA and other regulatory requirements.If we are unable to manufacture CHEMOSAT and HEPZATO in a timely manner,we may not be able to conduct the clinical trials required to obtain regulatory approval and commercialize our product.39 We have implemented quality systems throughout our organization designed to enable us to satisfy the various international quality system regulations,including those of the FDA with respect to products sold in the United States and those established by the International Standards Organization ,or (“ ISO ,”) with respect to products sold in the European Union.We are required to maintain ISO 13485 certification for medical devices to be sold in the European Union,which requires,among other items,an implemented quality system that applies to component quality,supplier control,product design and manufacturing operations.All of our facilities are presently ISO 13485:2016 certified.If our Queensbury,New York facility fails to maintain compliance with ISO 13485 and FDA cGMP or fails to pass facility inspection or audits,our ability to manufacture at the facility could be limited or terminated.In the future,we may manufacture and assemble CHEMOSAT and HEPZATO in our Galway,Ireland facility or elsewhere in the European Union,and any facilities in the European Union would have to obtain and maintain similar approvals or certifications of compliance.Although Delcath is we are not aware of any direct impacts of the war between the Ukraine and the Russian Federation ,the conflicts in the Middle East,or any other global conflict on its our supply chain, the war such current or future conflicts could adversely impact our ability to obtain components and / or significantly increase the cost of obtaining such components for our the Company’ s products from its third- party suppliers in a timely manner or at all .In addition,at this time,although the Company is not aware of any direct impacts,any increase in COVID cases and associated restrictions could adversely impact the Company’ s ability to obtain components and / or significantly increase the cost of obtaining such components for the Company’ s products from its third- party suppliers in a timely manner or at all.A rise in COVID cases and the associated absences from work of internal and external resources may also impact the Company’ s ability to meet anticipated timelines .We do not have written contracts with all of our suppliers for the manufacture of components for CHEMOSAT and HEPZATO.While we have written contracts and supply agreements for key components for CHEMOSAT and HEPZATO,we do not have written contracts with all suppliers for the manufacture of components for CHEMOSAT and HEPZATO.If we are unable to obtain an adequate supply of the necessary components or negotiate acceptable terms,we may not be able to manufacture CHEMOSAT and HEPZATO in commercial quantities or in a cost- effective manner,and commercialization of CHEMOSAT and HEPZATO in the United States,the European Union and elsewhere may be delayed adversely impacted .In addition,certain components are available from only a limited number of sources.Components of CHEMOSAT and HEPZATO are currently manufactured for us in small quantities.We may require significantly greater quantities to further commercialize the product.We may not be able to find alternate sources of comparable components.If we are unable to obtain adequate supplies of components from existing suppliers or need to switch to an alternate supplier and obtain FDA or other regulatory agency approval of that supplier,commercialization of CHEMOSAT and HEPZATO may be delayed. We Even if we receive FDA or other foreign regulatory approvals,we may be unsuccessful in commercializing CHEMOSAT and HEPZATO in markets outside the European Union, because of inadequate

infrastructure or an ineffective commercialization strategy. **Our** ~~Even if we obtain regulatory approval from the FDA or other foreign regulatory agencies,our~~ ability to commercialize CHEMOSAT and HEPZATO may be limited due to our inexperience in developing a sales,marketing and distribution infrastructure.If we are unable to develop this infrastructure in the United States or elsewhere or to collaborate with an alliance partner to market our products in the United States or foreign countries,particularly in Asia,our efforts to commercialize CHEMOSAT and HEPZATO or any other product ~~outside~~ **may not succeed.We may not be successful in our efforts to expand the commercialization** of **CHEMOSAT in** the European Union ~~may be less successful.We may not be successful in our~~ **or United Kingdom** ~~efforts to expand the commercialization of CHEMOSAT in the European Union~~ ,and we may not be successful in commercializing HEPZATO in the United States and CHEMOSAT or HEPZATO in other foreign countries.Each country requires a different commercialization strategy ~~,so our European Union marketing strategy may not translate to other markets~~ .Without a successful commercialization strategy tailored for each market,our efforts to promote and market CHEMOSAT and HEPZATO in each of our target markets may fail in any or all of those markets. ~~40~~ **If we are unsuccessful in accomplishing our objectives,or if our commercialization efforts do not develop as planned,we may not be able to successfully commercialize HEPZATO or any future approved products,we may require significant additional capital and financial resources,we may not become profitable,and we may not be able to compete against more established companies in our industry.Even if we do achieve profitability,we may not be able to sustain or increase profitability on a quarterly or annual basis.If we are unable to establish,maintain and,if necessary,expand sales and marketing capabilities or enter into agreements with third parties to sell and market HEPZATO in the United States or other product candidates,we may not be successful in commercializing HEPZATO in the United States or any other of our product candidates if they are approved.We have limited experience in the sale,marketing and distribution of pharmaceutical products in the United States.To achieve commercial success for HEPZATO and any other product candidates,if approved,for which we retain sales and marketing responsibilities,we must either develop a sales and marketing organization or outsource these functions to other third parties.We have established sales and marketing capabilities to support our commercial launch of HEPZATO for the treatment of adult patients with unresectable hepatic- dominant metastatic uveal melanoma in the United States.We may need to further build our sales and marketing infrastructure,either directly or with third- party partners,to maintain our ongoing commercialization efforts and to commercialize HEPZATO in other indications or to commercialize any of our other product candidates for which we obtain marketing approval.There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services.For example,recruiting and training a sales force is expensive and time consuming.If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason,we would have prematurely or unnecessarily incurred these commercialization expenses.This may be costly,and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.Factors that may inhibit our efforts to commercialize HEPZATO and other product candidates on our own include:• our inability to recruit and retain adequate numbers of effective sales and marketing personnel;• the inability of sales personnel to obtain access to physicians or educate physicians on the benefits of our products;• the lack of complementary products to be offered by sales personnel,which may put us at a competitive disadvantage relative to companies with more extensive or integrated product offerings;and • unforeseen costs and expenses associated with creating an independent sales and marketing organization.If we enter into arrangements with third parties to perform sales,marketing and distribution services,our product revenue or the profitability of product revenue to us is likely to be lower than if we were to market and sell any products that we develop ourselves.In addition,we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us.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 do not establish sales and marketing capabilities successfully,either on our own or in collaboration with third parties,we will not be successful in commercializing HEPZATO in the United States or any of our product candidates for which we obtain marketing approval.** We may use collaborative arrangements with third parties to help finance and to market and sell CHEMOSAT and HEPZATO **,but it** may not be successful.We may be unable to enter into collaborative agreements without additional clinical data or unable to continue a collaborative agreement as a result of unsuccessful future clinical trials.Additionally,we may face competition in the search for alliances.As a result,we may not be able to enter into alliances on acceptable terms,if at all.Our collaborative relationships may never result in the successful development or commercialization of CHEMOSAT and HEPZATO or any other product.The success of any collaboration will depend upon our ability to perform our obligations under any agreements as well as factors beyond our control,such as the commitment of our collaborators and the timely performance of their obligations.The terms of any such collaboration may permit our collaborators to abandon the alliance at any time for any reason or prevent us from terminating arrangements with collaborators who do not perform in accordance with our expectations,or our collaborators may breach their agreements with us.In addition,any third parties with whom we collaborate may have significant control over important aspects of the development and commercialization of our products,including research and development,market identification,marketing methods,pricing,composition of sales force and promotional activities.We will not control the amount and timing of resources that any collaborator may devote to our research and development programs or the commercialization,marketing or distribution of our products.We may not be able to prevent any collaborators from pursuing alternative technologies or products that could result in the development of products that compete with CHEMOSAT and HEPZATO or the withdrawal of their support for our products.The failure of any such collaboration could have a material adverse effect on our business.If we fail to overcome the challenges inherent in international operations,our business and results of operations may be materially adversely affected.Currently we have only received authorization to market CHEMOSAT in the

European Union and ~~intend to~~ **the United Kingdom.If we** seek similar authorization or approvals in other foreign countries ~~.To accommodate our international sales~~ ,we will need to further invest financial and management resources to develop an international infrastructure that will meet the needs of our customers.Accordingly,we will face additional risks resulting from our international operations including:• difficulties in enforcing agreements and collecting receivables in a timely manner through the legal systems of many countries outside the United States;• the failure to satisfy foreign regulatory requirements to market our products on a timely basis or at all;• availability of,and changes in,reimbursement within prevailing foreign healthcare payment systems;• difficulties in managing foreign relationships and operations,including any relationships that we establish with foreign sales or marketing employees and agents;• limited protection for intellectual property rights in some countries;• fluctuations in currency exchange rates;• the possibility that foreign countries may impose additional withholding taxes or otherwise tax our foreign income,impose tariffs or adopt other restrictions on foreign trade;• the possibility of any material shipping delays;• significant changes in the political,regulatory,safety or economic conditions in a country or region;• protectionist laws and business practices that favor local competitors;and • trade restrictions,including the imposition of,or significant changes to,the level of tariffs,customs duties and export quotas. ~~If we fail to overcome the challenges inherent in international operations,our business and results of operations may be materially adversely affected.41~~ Rapid technological developments in treatment methods for liver cancer and competition with other forms of liver cancer treatments could affect our ability to achieve meaningful revenues or profit.Competition in the cancer treatment industry is intense.CHEMOSAT and HEPZATO compete with all forms of liver cancer treatments that are alternatives **to surgical resection.Many of our competitors have substantially greater resources and considerable experience in conducting clinical trials and obtaining regulatory approvals.If these competitors develop more effective or more affordable products or treatment methods,or achieve earlier product development,our revenues or profitability will be substantially reduced.If another company has orphan drug designations for the same drug and indication as us and receives marketing approval before we do,then we will be blocked from marketing approval for seven years from the date of its approval for the same indication of use unless we can make a showing of the clinical superiority of our drug.We may fail to achieve the degree of market acceptance by physicians,patients,third- party payors and others in the medical community necessary for the commercial success of CHEMOSAT or HEPZATO,in which case we may not** generate significant revenue for the foreseeable future. Our entire focus has been on developing, commercializing, and obtaining regulatory authorizations and approvals of CHEMOSAT and HEPZATO **. We may fail to gain sufficient market acceptance by physicians, patients, third- party payors** and **others in** ~~we have only developed these~~ -- **the medical community necessary for the commercial success of CHEMOSAT and HEPZATO. Physicians are often reluctant to switch their patients from existing therapies even when new and potentially more effective or convenient treatments enter the market. Further, patients often acclimate to the therapy that they are currently taking and do not want to switch unless their physicians recommend switching** products ~~for~~ **or** ~~the~~ **they are required** ~~treatment of cancers in the liver. If CHEMOSAT and HEPZATO for the treatment of cancers in the liver fail as commercial products, we have no other products~~ to ~~sell~~ **switch therapies due to lack of reimbursement for existing therapies** . In addition, since CHEMOSAT currently is approved for commercialization solely in the ~~European Union, or the~~ EU ~~,~~ and limited other jurisdictions (including the United Kingdom), **and HEPZATO is approved only in the United States,** if we are unsuccessful in commercializing the ~~product~~ **products** in the EU and ~~/ or if HEPZATO is not approved in~~ the United States ~~and elsewhere~~ , we will have no means of generating revenue. ~~Accordingly~~ **In addition** , **the potential market opportunity for CHEMOSAT and HEPZATO is difficult to precisely estimate. Our estimates of the potential market opportunity for CHEMOSAT and HEPZATO for their approved indications, or in other indications include several key assumptions based on our industry knowledge, industry publications, third- party research reports and other surveys. However, no independent source has verified such assumptions. If any of these assumptions proves to be inaccurate, then the actual market for CHEMOSAT and HEPZATO could be smaller than our estimates of potential market opportunity. If the actual market for CHEMOSAT and HEPZATO is smaller than** we **expect, our product revenue** may **be limited, and it may be more difficult for us to achieve or maintain profitability. The sizes of the market opportunities for our product or product candidates, particularly HEPZATO for the treatment of mUM and CHEMOSAT for the treatment of cancers of the liver, have** not ~~generate~~ **been established with precision and may be smaller than we estimate, possibly** ~~material~~ **materially . If our estimates of the sizes overestimate these markets, our sales growth may be adversely affected. We may also not be able to grow the markets for our product candidates as intended or at all. Our assessment of the potential market opportunity for HEPZATO and other product candidates that we develop is based on industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties and our own internal market research studies. Industry publications and third- party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third- party research, surveys and studies are reliable, we have not independently verified such data. Similarly, although the studies we have conducted are based on information that we believe to be complete and reliable, we cannot guarantee that such information is accurate or complete. Therefore, our estimates of the potential market opportunities for our product candidates include several key assumptions based on our industry knowledge, industry publications, third- party research and our own studies and market research, which may be based on a small sample size and fail to accurately reflect market opportunities. While we believe that our internal assumptions and the bases of the studies and research, we have conducted are reasonable, no independent source has verified such assumptions or bases. If any of our assumptions or estimates, or these publications, research, surveys or studies prove to be inaccurate, then the actual market for HEPZATO, CHEMOSAT or any of our other product candidates may be smaller than we expect, and as a result our** ~~revenues~~ **revenue** from product sales **may be** ~~in the United States in the next year, if at all. As a result, our revenue~~

sources are, and will remain, extremely limited unless and until our product candidates are approved by the FDA or other additional foreign regulatory agencies and successfully marketed. CHEMOSAT and HEPZATO may not be approved by the FDA or other additional foreign regulatory agency or marketed at any time in the foreseeable future or at all. Our business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises such as the COVID- 19 pandemic, political crises, geopolitical events, such as the crisis in Ukraine, or other macroeconomic conditions, which have in the past and may in the future negatively impact our business and financial performance. The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, severely diminished liquidity and credit availability, declines in economic growth, supply chain shortages and disruptions, increases in inflation rates, higher interest rates and uncertainty about economic stability. The COVID- 19 pandemic has had, and may continue to have, an **and** impact on various aspects of our business and that of third parties on which we rely. There remains a high level of uncertainty due to the potential spread of new variants and surges in COVID- 19 cases, and this could continue to harm and / or delay our research, development and commercialization efforts, increase our costs and have a material effect on our operations, including by impacting regulatory authorities' ability to review and / or inspect required facilities or submissions. In addition, the COVID- 19 pandemic has impacted the global supply chain making it **may be** more difficult and / or impossible for us to **achieve** obtain a sufficient supply of critical materials for - **or maintain** our operations. The COVID- 19 pandemic has affected many countries, including the United States and several European countries, where we conducted our FOCUS Trial. In response to the pandemic, hospitals participating in the trials in affected countries took a number of actions, including restricting elective and other procedures that were not deemed to be life- threatening, suspending clinical trial activities and limiting access to data monitoring. As a result, patients enrolled in our clinical trials had the start of their treatments postponed and ongoing treatment regimens were delayed. In addition, we did not have sufficient access to monitor trial data on a timely basis. These restrictions had a materially adverse effect on our clinical operations. 29 The extent to which the COVID- 19 pandemic may affect our clinical trial operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, the spread and severity of new variants of COVID- 19, and the effectiveness of governmental actions in response to the pandemic. The Federal Reserve has raised interest rates multiple times in response to concerns about inflation and it may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets may increase economic uncertainty and affect consumer spending. Similarly, the ongoing military conflict between Russia and Ukraine has created extreme volatility in the global capital markets and is expected to have further global economic consequences, including disruptions of the global supply chain and energy markets. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, or do not improve, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Further downgrades of the U. S. credit rating, automatic spending cuts, or a government shutdown could negatively impact our liquidity, financial condition and earnings. U. S. debt ceiling and budget deficit concerns have increased the possibility **profitability** of credit- rating downgrades and economic slowdowns, or a recession in the United States. Although U. S. lawmakers have previously passed legislation to raise the federal debt ceiling on multiple occasions, there is a history of ratings agencies lowering or threatening to lower the long- term sovereign credit rating on the United States given such uncertainty. The impact of this or any further downgrades to the U. S. government' s sovereign credit rating or its perceived creditworthiness could adversely affect the U. S. and global financial markets and economic conditions. Moreover, these developments could cause interest rates and borrowing costs to rise, which may negatively impact our ability to access the debt markets on favorable terms. In addition, disagreement over the federal budget has caused the U. S. federal government to shut down for periods of time. Continued adverse political and economic conditions could have a material adverse effect on our business, financial condition and results of operations . Risks Related to FDA and Foreign Regulatory Approvals and Regulatory Matters The development and approval process in the United States **and abroad** could take many years, require substantial resources and may never lead to the approval of HEPZATO **our product candidates** by the FDA for use in the United States **or by foreign regulators in their respective jurisdictions** . We cannot **commercialize,** sell or market **any products** HEPZATO with melphalan or other chemotherapeutic agents in the United States without prior FDA approval of a NDA for HEPZATO . Although melphalan and **Foreign regulatory authorities, such as** other -- **the** drugs **European Medicines Agency (the " EMA "), impose similar requirements. We** have **received** been approved by the FDA for use as chemotherapeutic agents, regulatory approval is required in the United States for the combined medical device component and drug component and the specific indication, dose and route of administration of melphalan or **for** other chemotherapeutic agents or compounds used in our system. We are seeking approval of HEPZATO for a substantially higher dose of melphalan than prior approved doses of melphalan and such other chemotherapeutic agents or other compounds. We must obtain separate regulatory approvals for HEPZATO with melphalan, and every other chemotherapeutic agent or other compound used with the system that we intend to market, and all the manufacturing facilities used to manufacture components or assemble our system must be inspected and meet legal requirements. Securing regulatory approval requires the submission of extensive pre- clinical and clinical data and other supporting information for each proposed therapeutic indication in order to establish to the FDA' s satisfaction the product' s safety, efficacy, potency and purity for each intended use. The pre- clinical testing and clinical trials of HEPZATO with melphalan or any other chemotherapeutic agent or compound we use in its system must comply with the regulations of the FDA and other federal, state and local government authorities in the United States. Clinical development is a long, expensive and uncertain process and is subject to delays. We may encounter delays or rejections for various reasons. Moreover, approval policies or regulations may change. If we do not obtain and maintain regulatory approval for HEPZATO and the use of 30 melphalan or other chemotherapeutic agents, our business, results of operations, financial condition and prospects would be materially and adversely affected. In August 2012, we submitted an NDA seeking an indication for ocular

~~melanoma liver metastases for HEPZATO. In September 2013, the FDA issued a complete response letter or CRL indicating that we must perform additional well- controlled randomized trial (s) to establish the safety and efficacy of HEPZATO using overall survival as the primary efficacy outcome measure and which demonstrates that the clinical benefits of HEPZATO outweigh its risks. Our Phase 3 trial in ocular melanoma liver metastases, the FOCUS Trial, was not randomized and used a different primary efficacy outcome measure. Failure to obtain FDA approval for HEPZATO will have a material adverse effect on our business, financial condition, and results of operations and prospects. On February 14, 2023, the Company completed a NDA resubmission to the FDA for the HEPZATO Kit (melphalan hydrochloride for Injection / Hepatic Delivery System) seeking approval for~~ the treatment of **adult** patients with unresectable hepatic- dominant **mUM in the United States** ~~metastatic ocular melanoma (mOM). On March 20~~ , ~~2023~~ **but there is no assurance that we will receive regulatory approvals for HEPZATO for the treatment in other jurisdictions** , **or for other indications in any jurisdiction. Similarly, we have received approval for CHEMOSAT in Europe, but there is no assurance that we will receive regulatory approvals for CHEMOSAT in other jurisdictions. Securing regulatory approval requires the submission of extensive pre- clinical and clinical data and other supporting information for each proposed therapeutic indication in order to establish to** the FDA ~~determined~~ **' s satisfaction** the ~~resubmission constituted~~ **product' s safety, efficacy, potency and purity for each intended use. Clinical development is** a ~~Response Letter.Preclinical testing and clinical trials are~~ long,expensive ~~,~~ and ~~highly~~ uncertain ~~processes~~ -- **process** and ~~failure can unexpectedly occur at any stage of clinical development.Drug development~~ is **subject** ~~very risky,and it takes several years~~ to **delays** ~~complete clinical trials~~ .The start or end of a clinical trial is often delayed or halted due to changing regulatory requirements,manufacturing challenges,required clinical trial administrative actions,slower than anticipated patient enrollment,changing standards of care,availability,or prevalence of use of a comparator treatment or required prior therapy,clinical outcomes including insufficient efficacy,safety concerns,or our own financial constraints. ~~In response to our NDA~~ **If we commence additional clinical trials in the future** , ~~which~~ we ~~submitted to the FDA in August 2012 seeking~~ **may encounter delays or rejections for various reasons.If we do not maintain regulatory** approval for ~~use~~ **HEPZATO,our business,results** of **operations,financial condition and prospects would be materially and adversely affected.In addition,** our ~~HEPZATO~~ **failure to successfully** complete **clinical trials** ~~response and set a Prescription Drug User Fee Act target action date~~ of ~~August 14, 2023. The resubmission is in response to the September 12, 2013 CRL from the FDA. The NDA resubmission contains comprehensive data and information relating to the matters identified in the CRL. FDA may find~~ our **product candidates** ~~attempt to address the issues in the 2013 CRL insufficient to support approval~~ and **to demonstrate the efficacy and safety necessary to** ~~we may receive another CRL, which would have significant adverse effects on our business operations. Even if we~~ obtain regulatory approval **to market any of** ~~for HEPZATO in the United States,~~ our **product candidates would significantly harm our business. Our** ability to market HEPZATO **is** ~~would be~~ limited to those uses that are approved. The FDA closely regulates the post- approval marketing and promotion of drugs, including standards and regulations for direct- to- consumer advertising, dissemination of off- label information, industry- sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. **Our** ~~If the FDA approves a NDA for HEPZATO, our~~ ability to market and promote HEPZATO **is** ~~would be~~ limited to the approved indication ~~, so even with FDA approval, HEPZATO may only be promoted in this limited market~~ . Physicians may prescribe legally available drugs for uses that are not described in the product' s labeling and that differ from those tested by us and approved by the FDA **within their own medical judgment** . The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off- label use ~~, and FDA approval may otherwise limit our sales practices and our ability to promote, sell and distribute the product~~ . Thus, we may only market HEPZATO ~~, if approved by the FDA,~~ for its approved indication and could be subject to enforcement action for off- label marketing. Further, if there are any modifications to the product, including changes ~~in indications~~ **to product** , labeling or manufacturing processes or facilities, we may be required to submit and obtain **prior** FDA approval ~~of a new or supplemental NDA~~ , which may require us to develop additional data or conduct additional ~~preclinical~~ studies ~~and clinical trials~~ . Failure to comply with these requirements can result in adverse publicity, FDA warning letters, corrective advertising and potential civil and criminal penalties. If future clinical trials are unsuccessful, significantly delayed or not completed, we may not be able to market HEPZATO for other indications.

**HEPZATO is now approved for the treatment of adult patients with unresectable hepatic- dominant metastatic uveal melanoma.** The ~~clinical trial data~~ **approval was based primarily** on **the results** ~~our product was limited to specific types~~ of **the FOCUS Trial** ~~liver cancer. In 2010~~ , ~~we concluded~~ a Phase 3 ~~clinical trial~~ **, single arm, multicenter, open label study. We plan to begin the study** of HEPZATO ~~with a prior version of the medical device and procedure in patients with metastatic ocular and cutaneous melanoma to the liver and also completed a multi- arm Phase 2 clinical trial of that same version of HEPZATO in patients with primary and metastatic melanoma stratified into four~~ -- **for** ~~arms. We have completed the~~ **other indications** ~~dosing phase and analysis of the primary endpoint of an open- label Phase 3 clinical trial~~ in ~~ocular melanoma liver metastases called~~ the **future** ~~FOCUS Trial. 31 It may take several years if the FDA or foreign regulatory authorities requests additional clinical trials of HEPZATO relating to our NDA submission,~~ and failure can occur at any stage of development, for many reasons, including: • any pre- clinical or clinical test may fail to produce results satisfactory to the FDA or foreign regulatory authorities **; • we may not be able to establish and maintain the supply of necessary components, including melphalan, bulk drug substances and drug products to maintain sufficient supply to conduct such clinical studies** ; • pre- clinical or clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval; • negative or inconclusive results from a pre- clinical study or clinical trial or adverse medical events during a clinical trial could cause a pre- clinical study or clinical trial to be repeated or a program to be terminated, even if other studies or trials relating to the program are successful; • the FDA or foreign regulatory authorities can place a clinical hold on a trial if, among other reasons, it finds that patients enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury; • we

may encounter delays or rejections based on changes in regulatory agency policies during the period in which we are developing a system, or the period required for review of any application for regulatory agency approval; • enrollment in any additional clinical trials may proceed more slowly than expected; ~~• any other clinical trials may not demonstrate the safety~~ and ~~efficacy of any system or result in marketable products;~~ • the FDA or a foreign regulatory authority may change its approval policies or adopt new regulations that may negatively affect or delay our ability to bring a ~~system~~ **product** to market or require additional clinical trials; ~~and • a system may not be approved for all the requested indications.~~ The failure or delay of clinical trials could cause an increase in the cost of product development, delay filing of ~~a~~ **an** NDA for marketing approval or cause us to cease the development of HEPZATO for other indications. If we are unable to develop HEPZATO for other indications, the future growth of our business could be negatively impacted ~~. In addition, we have limited clinical data relating to the effectiveness of HEPZATO in certain types of cancer. Such limited data could slow the adoption of CHEMOSAT and HEPZATO and significantly reduce our ability to commercialize CHEMOSAT and HEPZATO~~ . We have obtained the right to affix the CE Mark for the CHEMOSAT Hepatic Delivery System as a medical device for the delivery of melphalan **in the EU** . Since we may only promote the device within this specific indication, if physicians are **unable or** unwilling to obtain melphalan separately for use with CHEMOSAT, our ability to commercialize CHEMOSAT in the EU will be significantly limited. In the EU, CHEMOSAT is regulated as a Class III medical device indicated for the intra- arterial administration of a chemotherapeutic agent, melphalan hydrochloride, to the liver with additional extracorporeal filtration of the venous blood return. Our ability to market and promote CHEMOSAT is limited to this approved indication. To the extent that our promotion of CHEMOSAT is found to be outside the scope of its approved indication, we may be subject to fines or other regulatory action, limiting our ability to commercialize CHEMOSAT in the EU. ~~We are limited to marketing CHEMOSAT in the EU as a medical device for the delivery of melphalan.~~ If physicians are **unable or** unwilling to obtain melphalan separately for use with CHEMOSAT, our ability to commercialize CHEMOSAT in the EU will be significantly limited. Our product instructions and indication reference the chemotherapeutic agent melphalan. However, no melphalan labels in the EU reference our product, and the labels vary from country to country with respect to the approved indication of the drug and its mode of ~~32~~ administration. As a result, the delivery of melphalan with our device may not be within the applicable label with respect to some indications in some Member States of the EU where the drugs are authorized for marketing. Physicians intending to use CHEMOSAT must obtain melphalan separately for use with CHEMOSAT and must use melphalan independently at their discretion. If physicians are **unable or** unwilling to obtain melphalan separately from CHEMOSAT and / or to prescribe the use of melphalan independently, our sales opportunities in the EU will be significantly limited. We are subject to significant ongoing regulatory obligations and oversight in the EU and ~~will be subject to such obligations in~~ the United States and **will be in** any other country where we receive marketing authorization or approval. **We** ~~In April 2012, we obtained the required certification from a designated EU Notified Body, enabling us to complete an EC Declaration of Conformity with the essential requirements of the EU Medical Device Directive and affix the CE Mark to the Generation Two version of CHEMOSAT. More recently, on February 28, 2022, we obtained Medical Device Regulation certification under the new European Medical Devices Regulation [ 2017 / 745 / EU ]. In order to maintain the right to affix the CE Mark in the EU, we~~ are subject to ~~compliance obligations, and any material changes to the approved product, such as manufacturing changes, product improvements or revised labeling, may require further regulatory review. Additionally, we are subject to ongoing audits by the European Notified Body, and the right to affix the CE Mark to the Generation Two version of CHEMOSAT may be withdrawn for a number of reasons, including the later discovery of previously unknown problems with the product. To the extent that HEPZATO is approved by the FDA or CHEMOSAT by any other regulatory agency, we will be subject to similar~~ ongoing regulatory obligations and oversight in ~~those~~ -- **the** countries where **HEPZATO and CHEMOSAT have been** ~~approval~~ **approved** ~~is obtained~~ . For example, we may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or requirements for potentially costly post- marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. **With HEPZATO' s** ~~In addition, if the FDA approves~~ **approval** ~~a product candidate~~ , the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product **are** ~~will be~~ subject to extensive and ongoing regulatory requirements ~~. These requirements include submissions of safety and other post- marketing information and reports, registration, as well as continued compliance with current good manufacturing practice, or cGMPs, good clinical practices, or GCPs, and good laboratory practices, which are regulations and guidelines enforced by the FDA for all products in clinical development, for any pre- clinical or clinical trials that we conduct post- approval~~ . In addition, post- marketing requirements for HEPZATO ~~may~~ include implementation of a ~~risk evaluation and mitigation strategies, or~~ REMS ~~,~~ program to ensure that the benefits of the product outweigh its risks. ~~A typical~~ **We must implement and ensure compliance with the HEPZATO** REMS ~~may include a medication guide, a patient package insert, a communication plan to healthcare professionals, restrictions on distribution or use and / or other elements to assure safe use of the product. However, our discussions with the FDA have indicated that a medication guide or communication plan will not be required~~ . Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third- party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things: • ~~refusals or delays in the approval of NDAs or supplements to approved NDAs; • refusal of a regulatory authority to review pending market approval applications or supplements to approved NDAs; •~~ restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls or seizures; • fines, FDA warning letters or untitled letters, or holds on clinical trials; ~~33~~ • import or export restrictions; • injunctions or the imposition of civil or criminal penalties; • restrictions on product administration, requirements for additional clinical trials or changes to product labeling or REMS programs; or • recommendations by regulatory authorities against entering into governmental contracts with us. If we are not able to maintain regulatory compliance, we may lose any marketing approval that we ~~may have~~ obtained and may not achieve

or sustain profitability, which would have a material adverse effect on our business, results of operations, financial condition and prospects. We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates. The FDA has granted us six orphan drug designations and we may seek additional orphan drug designations in the future. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 individuals in the United States. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the ~~European Medicines Agency, or~~ EMA, from approving another marketing application for the same indication for that drug during that time period. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. We cannot assure you that any future application for orphan drug designation with respect to any product candidate will be granted. If we are unable to obtain **or maintain** orphan drug designation in the United States, we will not be eligible to obtain the period of market exclusivity that could result from orphan drug designation or be afforded the financial incentives associated with orphan drug designation. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. We **relied and may continue to** rely on third parties to conduct certain elements of ~~the~~ clinical trials for CHEMOSAT and HEPZATO, ~~and~~ **should we seek to obtain regulatory approval for use of these products to treat additional indications for which we do not currently have regulatory approval, or for any future product candidates,** if ~~they~~ **any, and if these third parties** do not perform their obligations to us, we may not be able to obtain **the necessary** regulatory ~~approvals~~ **approval for our products** ~~for~~ **or** ~~our system~~ **product candidates, as applicable** . We design the clinical trials for our products, but rely on academic institutions, corporate partners, contract research organizations and other third parties to assist in managing, monitoring and otherwise carrying out these trials. We ~~rely~~ **also plan on relying** heavily on these parties for the execution of our clinical studies and control only certain aspects of their activities. Accordingly, we may have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own. We **intend to** rely on third parties to conduct monitoring and data collection of our future clinical trials **, however** ~~. Although we rely on these third parties to manage the data from these clinical trials~~ , we are **ultimately** responsible for confirming that each of our clinical trials is conducted in accordance with ~~34~~ our general investigational plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the trial participants are adequately protected. The FDA enforces these GCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. Our reliance on third parties does not relieve us of these responsibilities and requirements and if we or the third parties upon whom we rely for our clinical trials fail to comply with the applicable GCPs, the data generated in our clinical trials may be deemed unreliable and the FDA or other foreign regulatory agencies may require us to perform additional trials before approving our marketing application. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply or complied with GCPs. In addition, our clinical trials must be conducted with product that complies with the FDA' s cGMP requirements **and we are dependent on third- party manufacturing and supply of critical components necessary for such clinical trial supply. To the extent a critical component relies on a single- sourced manufacture / supplier our ability to mitigate this risk decreases** . Our failure **, or any failure by such third- party partners,** to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process, and may result in a failure to obtain regulatory approval for **product candidates then being studied** ~~HEPZATO if these requirements are not met~~ . Purchasers of CHEMOSAT in Europe may not receive third- party reimbursement or such reimbursement may be inadequate. Without adequate reimbursement, commercialization of CHEMOSAT in Europe may not be successful. We have obtained the right to affix the CE Mark for CHEMOSAT, and we intend to seek third- party or government reimbursement within those countries in ~~the~~ Europe where we expect to market and sell CHEMOSAT. In Germany, we had received a ZE diagnostic- related group code ~~, or~~ **(“** ZE Code ~~,~~ **”)** which, beginning in 2016, permits hospitals in Germany to obtain reimbursement for CHEMOSAT procedures. Negotiations on the amount of reimbursement to be received under the ZE Code were concluded in 2016 and the procedure was reimbursed under the ZE Code in 2017. Reimbursement negotiations under the ZE system are conducted annually. Consequently, reimbursement obtained may not be for the full amount sought. In countries where we are able to obtain reimbursement, local policy could limit our ability to obtain adequate and consistent reimbursement and limit other sales opportunities in those countries. In other countries, until we obtain government reimbursement, we will rely on private payors or local pre- approved funds where available. There are also no assurances that third- party payors or government health agencies in Europe will reimburse use of CHEMOSAT in the long term or at all. Further, each country has its own protocols regarding reimbursement, so successfully obtaining third party or government health agency reimbursement in one country does not necessarily translate to similar reimbursement in another European country. Physicians, hospitals and other health care providers may be reluctant to purchase CHEMOSAT if they do not receive substantial reimbursement for the cost of using the product from third- party payors or government entities. The lack of adequate reimbursement may significantly limit sales opportunities in Europe. The success of our products may be harmed if the government, private health insurers or other third- party ~~payers~~ **payors** do not provide sufficient coverage or reimbursement.

Our ability to commercialize CHEMOSAT and HEPZATO successfully will depend in part on the extent to which reimbursement for the costs of such products and related treatments will be available from government health administration authorities, private health insurers and other third- party payors **. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such products. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization** . We will seek reimbursement by third- party payors of the cost of HEPZATO ~~after its use is approved~~ , but there are no assurances that adequate third- party coverage will be **adequate** ~~available to establish and maintain price levels sufficient~~ for us to realize an appropriate return on our investment in developing new therapies. Government, private health insurers and other third- party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new therapeutic products approved for marketing. Accordingly, even if coverage and reimbursement are provided by government, private health insurers and third- party payors for uses of our products, market acceptance of these products would be adversely affected if the reimbursement available proves to be unprofitable for healthcare providers. **Even if favorable coverage and reimbursement status is attained for any of our products or product candidates that receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. In the United States, decisions about reimbursement for new medicines under Medicare are made by CMS, as the administrator for the Medicare program. On January 30, 2024, CMS announced an established permanent and product- specific J- Code for HEPTAZO. The J- Code (J9248) will become effective on April 1, 2024. J- Codes are part of the Healthcare Common Procedure Coding System, or HCPCS, as maintained by CMS. However, there is no guarantee that these billing codes, or the payment amounts, if any, associated with such codes will not change in the future.** Further implementation of healthcare reforms in the United States and in significant overseas markets may limit the ability to commercialize CHEMOSAT and HEPZATO and the demand for CHEMOSAT and HEPZATO. ~~35~~ Healthcare providers may respond to such cost- containment pressures by choosing lower cost products or other therapies. CHEMOSAT and HEPZATO may not achieve sufficient acceptance by the medical community to sustain our business. The commercial success of CHEMOSAT and HEPZATO ~~, if approved,~~ will depend upon their acceptance by the medical community and third- party ~~payers~~ **payors** as clinically useful, cost effective and safe. Acceptance by the medical community may depend on the extent to which leaders in the scientific and medical communities publish scientific papers in reputable academic journals. If testing and clinical practice do not confirm the safety and efficacy of CHEMOSAT and HEPZATO or even if further testing and clinical practice produce positive results but the medical community does not view these favorably, our efforts to market CHEMOSAT and HEPZATO may fail, which would cause us to cease operation. We may be subject, directly or indirectly, to federal and state health care fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties. **Our** ~~If we obtain FDA approval for any of our drug candidates and begin commercializing those products in the United States, our~~ operations **are** ~~will be~~ directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws. These laws may affect, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include, but are not limited to: • the federal Anti- Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal health care program, such as Medicare and Medicaid programs; • federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third- party payors that are false or fraudulent; • ~~the~~ **The** federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third- party ~~payers~~ **payors** and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services; • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which impose certain requirements **on covered entities, their respective business associates and covered subcontractors, and others** relating to the privacy, security and transmission of individually identifiable health information **; • Washington' s My Health My Data Act, or MHMD, which broadly defines consumer health data, places restrictions on processing consumer health data (including imposing stringent requirements for consents), provides consumers certain rights with respect to their health data, and creates a private right of action to allow individuals to sue for violations of the law. Other states are considering and may adopt similar laws** ; • the federal transparency requirements under the Patient Protection and Affordable Care Act of 2010, which requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to certain payments and other transfers of value provided to physicians, (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physicians assistants and nurse practitioners), and teaching hospitals, as well as certain ownership and investment interests held by physicians and their immediate family members; and • state law and foreign law equivalents of each of the above federal laws, such as anti- kickback and false claims laws which may apply to items or services reimbursed by any third- party payor, including ~~36~~ commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. If our operations are found to be in violation of any of the laws described above or

any other governmental regulations that apply to us, we may be subject to **significant** penalties, including exclusion from payment by federal health care programs, civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly. ~~Compliance with laws and regulations pertaining to the privacy and security of health information may be time consuming, difficult and costly, particularly in light of increased focus on privacy issues in countries around the world, including the United States and the European Union.~~ We are subject to **stringent and evolving U. S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to information privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences. In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, " process ") personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property and data. Our data processing is subject to numerous domestic and foreign information privacy and security obligations such as** various ~~domestic~~ **laws, regulations, guidance, industry standards, external** and ~~international~~ ----- **internal information** privacy and security ~~regulations~~ **policies, contractual requirements, and other obligations relating to information privacy and security** . The confidentiality, collection, use and disclosure of personal data, including clinical trial patient- specific information, are subject to governmental regulation generally in the country where the personal data were collected or used. In the United States we are subject to various state and federal **information** privacy and ~~data~~ security regulations, including but not limited to, HIPAA as amended by HITECH ~~. HIPAA~~ **, which** mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common health care transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. **For more information regarding risks associated with HIPAA, please refer to the section above that discusses risks associated with federal and state healthcare laws and regulations. Moreover, in the United States, federal, state, and local governments have enacted numerous information privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e. g., Section 5 of the Federal Trade Commission Act), and other similar laws (e. g., wiretapping laws).** In **the past few years, numerous U. S. states- including California, Virginia, Colorado, Connecticut, and Utah- have enacted comprehensive information privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020, (collectively, " CCPA ") applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines of up to $ 7, 500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. These developments further complicate compliance efforts, and increase legal risk and compliance costs for us, and the third parties upon whom we rely. Outside the United States, an increasing number of laws, regulations, and industry standards govern information privacy and security. For example, both** the European Union ~~, personal data includes any information that relates to an identified or identifiable natural person with health information carrying additional obligations, including obtaining the explicit consent from the individual for collection, use or disclosure of the information. In addition, we are subject to EU regulation with respect to protection of and cross- border transfers of such data out of the European Union, and this regulation became more stringent in May 2018 when the EU~~ ' s General Data Protection Regulation ( **" EU** GDPR **" ) and the United Kingdom' s GDPR (" UK GDPR ") define personal data to include any information that relates to an identified or identifiable natural person with identifiable health information carrying additional obligations, including obtaining the explicit consent from the individual for collection, use or disclosure of their information. Under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17. 5 million pounds sterling under the UK GDPR or, in each ~~came~~ case ~~into effect~~ , 4 % of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. In addition, we may transfer personal data from Europe and other jurisdictions to the United States or other countries and may be subject to EU regulation with respect to limiting the cross- border transfers of such data out of the European Economic Area (" EEA ") to the United States or other countries. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK' s International Data Transfer Agreement / Addendum, and the EU- U. S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U. S.- based organizations who self- certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally- compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other**

**jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. We are also bound by contractual obligations related to information privacy and security, and our efforts to comply with such obligations may not be successful. We publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self- regulatory principles, regarding information privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences** . Furthermore, the legislative and regulatory landscape for **information** privacy and **security** ~~data protection~~ continues to evolve, and there has been an increasing amount of focus on privacy and **security** ~~data protection~~ issues. The United States and the European Union and its member states continue to issue new privacy and data protection rules and regulations that relate to personal data ~~and health~~ **. Obligations related to** information **privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions** . Compliance with ~~these~~ **information privacy and security** laws may be time consuming, difficult and ~~costly~~ **/ or require us to devote significant resources** . If we **or the third parties on which we rely** fail **, or are perceived to have failed,** to comply with applicable laws, regulations or duties relating to the use, privacy or security of personal data we could be subject to ~~the imposition of~~ significant ~~civil and criminal~~ **consequences including: government enforcement actions (e. g., investigations, fines,** penalties, **audits, inspections, and similar); litigation (including class- action claims) and mass arbitration demands; additional reporting requirements and / or oversight; bans on processing personal data; orders to destroy or not use personal data; reputational harm; or** be forced to alter our business practices ~~and suffer~~ **or change our business model. Any of these events could have a material adverse effect on our** ~~reputational~~ **reputation** ~~harm~~ **, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations; inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations** . Changes in health care law and implementing regulations, including government restrictions on pricing and reimbursement, as well as health care policy and other health care payor cost- containment initiatives, may have a material adverse effect on us. In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the health care system and efforts to control health care costs, including drug prices, that could have a significant negative impact on our business, including preventing, limiting or delaying regulatory approval of our drug candidates and reducing the sales and profits derived from our products once they are approved. For example, in the United States, the Patient Protection and Affordable Care Act of 2010, or ACA, substantially changed the way health care is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. The ACA, among other things, subjected manufacturers to new annual fees and taxes ~~37~~ for specified branded prescription drugs, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, expanded health care fraud and abuse laws, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs under the Medicaid Drug Rebate Program are calculated, imposed an additional rebate similar to an inflation penalty on new formulations of drugs, extended the Medicaid Drug Rebate Program to Medicaid managed care organizations, expanded the 340B program, which caps the price at which manufacturers can sell covered outpatient pharmaceuticals to specified hospitals, clinics and community health centers, and provided incentives to programs that increase the federal government' s comparative effectiveness research. Since its enactment, there have been judicial and Congressional challenges and amendments to certain aspects of ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 ~~, or~~ **(the "** Tax Act ~~,~~ **")** includes a provision repealing, effective January 1, 2019, the tax- based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the " individual mandate. " On June 17, 2021, the ~~United States~~ **U. S.** Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the " individual mandate " was repealed by Congress. Congressional actions to repeal and replace provisions of the law and litigation and legislation over the ACA is likely to continue with unpredictable and uncertain results. More recently, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA ~~,~~ was signed into law by President Biden. The new legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare ( **and the maximum price as a result of the negotiations becoming effective** beginning ~~in~~ **on January 1,** 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D **for** ~~to penalize~~ price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Department of Health and Human Services **, or HHS,** to implement many of these provisions through guidance, as opposed to regulation, for the initial years **These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges** . Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated " maximum fair price " under the law or for taking price increases that exceed inflation. The legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The new law

also caps Medicare out- of- pocket drug costs at an estimated $ 4, 000 a year in 2024 and, thereafter beginning in 2025, at $ 2, 000 a year. **In response to the Biden administration' s October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march- in rights under the Bayh- Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March- In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march- in rights. While march- in rights have not previously been exercised, it is uncertain if that will continue under the new framework.** At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Consolidation in the healthcare industry could lead to demands for price concessions. The cost of healthcare has risen significantly over the past decade and numerous initiatives and reforms initiated by legislators, regulators and third- party payors to curb these costs have resulted in a consolidation trend in the medical device industry. Group purchasing organizations, independent delivery networks and large single accounts in the United States and foreign markets may result in a consolidation of purchasing decisions for potential healthcare provider customers. We expect that market demand, government regulation, third- party reimbursement policies and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances which may exert further downward pressure on the price of CHEMOSAT and HEPZATO and adversely impact our business, financial condition and results of operations . 38 Risks Related to Manufacturing,..... of the clinical superiority of our drug . Risks Related to our Intellectual Property Intellectual property rights may not provide adequate protection, which may permit third parties to compete against us more effectively. Our success depends significantly on our ability to maintain and protect our proprietary rights in the technologies and inventions used in or embodied by our products. To protect our proprietary technology, we rely on patent protection, as well as a combination of copyright, trade secret and trademark laws, as well as nondisclosure, confidentiality, license and other contractual restrictions in our employment, manufacturing, consulting and other third- party agreements. These legal means may afford only limited protection, however, and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We have not and may not be able to adequately protect our intellectual property rights throughout the world. Filing, prosecuting and defending patents on our products and technologies in all countries throughout the world could be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some foreign countries may not protect our intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from copying our inventions in foreign countries to the extent we can in the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection that covers the commercial products to develop their own competing products that are the same or substantially the same as our commercial product and, further, may export otherwise infringing products to territories where we have patent protection, but judicial systems do not adequately enforce patents to cause infringing activities to be ceased. We do not have patent rights in certain foreign countries in which a market for our product and technologies exists or may exist in the future. Moreover, in foreign jurisdictions where we do have patent rights, proceedings to enforce such rights could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. **The complexity and uncertainty of European patent laws have increased in recent years. In Europe, the new unitary patent system that came into effect in June of 2023, would significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications will have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (UPC). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC- based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long- term effects of any potential changes.** We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Thus, we may not be able to stop a competitor from marketing and selling in foreign countries products that are the same as or similar to our product and technologies. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. The ~~United States Patent and Trademark Office (~~USPTO ~~)~~, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during ~~42~~ the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non- compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non- payment of

fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our product or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our product and technologies. Our success depends in part on our ability to obtain patents, which can be an expensive, time consuming, and uncertain process, and the value of the patents is dependent in part on the breadth of coverage and the relationship between the coverage and the commercial product. The patent position of medical drug and device companies is generally highly uncertain. The degree of patent protection we require may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us sufficient exclusivity, or to gain or keep our competitive advantage. For example: • we might not have been the first to invent or the first to file patent applications on the inventions covered by each of our pending patent applications and issued patents; • others may independently develop similar or alternative technologies or duplicate any of our technologies; • the patents of others may have an adverse effect on our business; • any patents we obtain or license from others in the future may not encompass commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties; and • any patents we obtain or license from others in the future may not be valid or enforceable. The process of applying for patent protection itself is time consuming and expensive and we cannot assure you that we have prepared or will be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is possible that innovation over the course of development and commercialization may lead to changes in CHEMOSAT and HEPZATO methods and / or devices that cause such methods and / or devices to fall outside the scope of the patent protection we have obtained and the patent protection we have obtained may become less valuable. It is also possible that we will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. In addition, our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example, with respect to proper priority claims, inventorship, claim scope or patent term adjustments. Moreover, we cannot assure you that all of our pending patent applications will issue as patents or that, if issued, they will issue in a form that will be advantageous to us. Our success depends in part on our ability to commercialize CHEMOSAT and HEPZATO prior to the expiration of our patent protection. Our patent protection for CHEMOSAT and HEPZATO is primarily in the United States and the EU. We currently have patents in the United States and the EU directed to our product, system, components, procedure, and method of treatment, with additional design patent protection in Argentina, Canada, Europe, the UK, and Japan. Our patents provide patent protection for our CHEMOSAT hepatic delivery system, HEPZATO, ~~43~~ hemofiltration cartridge apparatus, hemofiltration cartridge design, methods of treatment of a subject with cancer in accordance with various embodiments of our system, embodiments of our system for delivering a high concentration of a small molecule chemotherapeutic agent to a subject while minimizing systemic exposure to the small molecule chemotherapeutic agent, and methods of setting up a filter apparatus for hemofiltration in accordance with our procedures using our proprietary hepatic deliver system. However, patents have a limited lifespan. In the United States and the EU, the ordinary statutory natural expiration of a utility patent is generally 20 years from its filing date. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. We may in the future become involved in lawsuits to protect or enforce our intellectual property, or to defend our products against assertion of intellectual property rights by a third party, which could be expensive, time consuming and unsuccessful. Competitors may infringe our patents or misappropriate or otherwise violate our intellectual property rights. To stop any such infringement or unauthorized use, litigation may be necessary. Our intellectual property has not been tested in litigation. There is no assurance that any of our issued patents will be upheld if later challenged or will provide significant protection or commercial advantage. A court may declare our patents invalid or unenforceable, may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question, or may interpret the claims of our patents narrowly, thereby substantially narrowing the scope of patent protection they afford. Because of the length of time and expense associated with bringing new medical drugs and devices to the market, the healthcare industry has traditionally placed considerable emphasis on patent and trade secret protection for significant new technologies. Other parties may challenge patents, patent claims or patent applications licensed or issued to us, or may design around technologies we have patented, licensed or developed. In addition, third parties may initiate legal or administrative proceedings against us to challenge the validity or scope of our intellectual property rights, such as inter partes review, post- grant review, re- examination or opposition proceedings before the USPTO, the European Patent Office or other foreign counterparts. Third parties may also allege an ownership right in our patents, as a result of their past employment or consultancy with us. Many of our current and potential competitors have the ability to dedicate substantially greater resources to defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Competing products may also be sold in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, alleging our infringement of a competitor' s patents, we could be prevented from marketing our product in one or more foreign countries. Our competitors or other patent holders may assert that our products and the methods employed in our products are covered by their patents. Although we have performed a search for third- party patents and believe we have adequate defenses available if faced with any allegations that we infringe these third- party patents, it is possible that CHEMOSAT and HEPZATO could be found to infringe these patents. It is also possible that our competitors or potential competitors may have patents, or have applied for, will apply for, or will obtain patents that will prevent, limit or interfere with our ability to make, have made, use, sell, offer for sale, import or export our product. If our products or methods are found to infringe, we could be prevented from manufacturing or marketing our product. Companies in the medical drug / device industry may use intellectual property infringement litigation to gain a competitive advantage. In the United States, patent applications filed in recent years are confidential for 18 months, while older applications are not publicly available until the patent issues. As a result, there may be some uncertainties associated with avoiding patent infringement. Litigation may be necessary to enforce

any patents issued or assigned to us or to determine the scope and validity of third- party proprietary rights. Litigation could be costly and could divert our attention from our business. There are no guarantees that we will receive a ~~44~~ favorable outcome in any such litigation. If a third- party claims that we infringed its patents, any of the following may occur: • we may become liable for substantial damages for past infringement if a court decides that our technologies infringe upon a competitor' s patent; • we may become prohibited from selling or licensing our product without a license from the patent holder, which may not be available on commercially acceptable terms or at all, or which may require us to pay substantial royalties or grant cross- licenses to our patents; and • we may have to redesign our product so that it does not infringe upon others' patent rights, which may not be possible or could require substantial funds or time. Litigation related to infringement and other intellectual property claims such as trade secrets, with or without merit, is unpredictable, can be expensive and time- consuming, and can divert management' s attention from our core business. If we lose this kind of litigation, a court could require us to pay substantial damages, treble damages, and attorneys' fees, and could prohibit us from using technologies essential to our product, any of which would have a material adverse effect on our business, results of operations, and financial condition. If relevant third- party patents are upheld as valid and enforceable and we are found to infringe, we could be prevented from selling our product unless we can obtain licenses to use technology covered by such patents. We do not know whether any necessary licenses would be available to us on satisfactory terms, if at all. If we cannot obtain these licenses, we could be forced to design around those patents at additional cost or abandon the product altogether. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could cause the price of our common stock to decline. If others have filed patent applications with respect to inventions for which we already have patents issued to us or have patent applications pending, we may be forced to participate in interference or derivation proceedings declared by the USPTO to determine priority of invention, which could also be costly and could divert our attention from our business. If the USPTO declares an interference and determines that our patent or application is not entitled to a priority date earlier than that of the other patent application, our ability to maintain or obtain those patent rights will be curtailed. Similarly, if the USPTO declares a derivation proceeding and determines that the invention covered by our patent application was derived from another, we will not be able to obtain patent coverage of that invention. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before CHEMOSAT and HEPZATO or any other product can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantages of the patent. Not all of our ~~United States~~ **U. S.** patent rights have corresponding patent rights effective in European or other foreign jurisdictions. Similar considerations apply in any other country where we are prosecuting patent applications, have been issued patents, or have decided not to pursue patent protection relating to our technology. The laws of foreign countries may not protect our intellectual property rights to the same extent as do laws of the United States. Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product and our technologies. Patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement, and defense of our patents and applications. Furthermore, the ~~United States~~ **U. S.** Supreme Court and the ~~United States~~ **U. S.** Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign ~~45~~ courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by United States and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain and enforce or defend additional patent protection in the future. Our trademarks may be infringed or successfully challenged, resulting in harm to our business. We rely on our trademarks as one means to distinguish for our customers our products from the products of our competitors, and we have registered or applied to register many of these trademarks. The USPTO or foreign trademark offices may deny our trademark applications, however, and even if published or registered, these trademarks may be ineffective in protecting our brand and goodwill and may be successfully opposed or challenged. Third parties may oppose our trademark applications, or otherwise challenge our use of our trademarks ~~. For example, even if FDA approves our NDA resubmission, it may not approve use of the proprietary name HEPZATO, in which case any goodwill we have built up with that tradename in the U. S. would be extinguished~~ . In addition, third parties may use marks that are confusingly similar to our own, which could result in confusion or a likelihood of confusion among our customers, thereby weakening the strength of our brand or allowing such third parties to capitalize on our goodwill. In such an event, or if our trademarks are successfully challenged, we could be forced to rebrand our product, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademark rights in the face of any such infringement. We may rely primarily on trade secret protection for important proprietary technologies. In addition to patent and trademark protection, we also rely on trade secrets, including unpatented know- how, technology, and other proprietary information, to maintain our competitive position. Unlike patents, trade secrets are only recognized under applicable law if they are kept secret by restricting their disclosure to third parties. We protect our trade secrets and proprietary knowledge in part through confidentiality agreements with employees, consultants and other parties. However, certain consultants and third parties with whom we have business relationships, and to whom in some cases we have disclosed trade secrets and other proprietary knowledge, may also provide services to other parties in the medical device **/ pharmaceutical** industry, including companies, universities and research organizations that are developing competing products. In addition, some of our former employees who were exposed to certain of our trade secrets and other proprietary knowledge in the course of their employment may seek employment with, and become employed by, our competitors. We cannot be assured that consultants, employees and other third

parties with whom we have entered into confidentiality agreements will not breach the terms of such agreements by improperly using or disclosing our trade secrets or other proprietary knowledge. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Trade secret protection does not prevent independent discovery of the technology or proprietary information or use of the same. Competitors may independently duplicate or exceed our technology in whole or in part. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us in countries where we do not have patent protection. Similar considerations apply in foreign countries where we receive approval and do not have issued patents for the current version of CHEMOSAT and HEPZATO. In these countries, our ability to successfully commercialize CHEMOSAT and HEPZATO will depend on our ability to maintain trade secret protection in these markets. ~~46~~ We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non- competition or non- solicitation agreements with our competitors. We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of former employers, competitors, or other third parties. Although we endeavor to ensure that our employees and consultants do not use the intellectual property, proprietary information, know- how or trade secrets of others in their work for us, we may in the future be subject to claims that we caused an employee to breach the terms of his or her non- competition or non- solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our product, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers or other third parties. An inability to incorporate technologies or features that are important or essential to our product may prevent us from selling our product. In addition, we may lose valuable intellectual property rights or personnel. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our product. Risks Related to Our Common Stock The market price of our common stock has been, and may continue to be volatile and fluctuate significantly, which could result in substantial losses for investors. The trading price of our common stock has been, and we expect it to continue to be, volatile. For example, the **closing** trading price of our common stock has varied between a high of $ 7. ~~95~~ **96** on ~~January 3~~ **May 31** , ~~2022~~ **2023** and a low of $ 2. ~~34~~ **25** on ~~October 13~~ **November 14** , ~~2022~~ **2023** . The price at which our common stock trades depends upon a number of factors, including historical and anticipated operating results, our financial situation, announcements of technological innovations or new products by us or our competitors, our ability or inability to raise the additional capital needed and the terms on which it may be raised, and general market and economic conditions. Some of these factors are beyond our control. Broad market fluctuations may lower the market price of our common stock and affect the volume of trading, regardless of our financial condition, results of operations, business or prospects. Among the factors that may cause the market price of our common stock to fluctuate are the risks described elsewhere in this " Risk Factors " section and other factors, including: • fluctuations in our quarterly operating results or the operating results of competitors; • variance in financial performance from the expectations of investors; • changes in the estimation of the future size and growth rate of our markets; • changes in accounting principles or changes in interpretations of existing principles, which could affect financial results; • conditions and trends in the markets served; • changes in general economic, industry and market conditions; • success of competitive products and services; • changes in market valuations or earnings of competitors; • changes in pricing policies or the pricing policies of competitors; • announcements of significant new products, contracts, acquisitions or strategic alliances by us or our competitors; ~~47~~ • potentially negative announcements, such as a review of any of our filings by the SEC, changes in accounting treatment or restatements of previously reported financial results or delays in our filings with the SEC; • the commencement or outcome of litigation involving us, our general industry or both; • our filing for protection under federal bankruptcy laws; • changes in capital structure, such as future issuances of securities or the incurrence of additional debt; • actual or expected sales of common stock by stockholders; and • the trading volume of our common stock. In addition, the stock markets and the market for pharmaceutical companies in particular, may experience a loss of investor confidence. Such loss of investor confidence may result in extreme price and volume fluctuations in our common stock that are unrelated or disproportionate to the operating performance of our business, financial condition or results of operations. These broad market and industry factors may materially harm the market price of our common stock and expose **us** ~~the Company~~ to securities class action litigation. Such litigation, even if unsuccessful, could be costly to defend and divert management' s attention and resources, which could further materially harm our financial condition and results of operations. Because of volatility in our trading price and trading volume, we may incur significant costs from class action securities litigation. Holders of stock in companies that have a volatile stock price frequently bring securities class action litigation against the company that issued the stock. We may be the target of this type of litigation in the future. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit is without merit, we could incur substantial costs defending the lawsuit and the time and attention of our management could be diverted from other business concerns, either of which could seriously harm our business. Sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock and could impair our ability to raise additional equity capital. **As of December 31, 2023, 22, 761,**

**554 shares of common stock are issued and outstanding, and we have reserved 20, 510, 737 shares of our common stock for future issuance pursuant to our stock option and equity incentive plans, outstanding warrants and preferred stock. Future** ~~Sales~~ **sales** of a substantial number of shares of our common stock in the public market ~~,~~ or the perception that such sales may occur **, or the issuance of our common stock pursuant to outstanding warrants or convertible preferred stock, could cause immediate dilution and adversely affect the market price of our common stock. The sale or issuance of our common stock, as well as the existence of outstanding stock options and shares of common stock reserved for issuance under our equity incentive plans and outstanding warrants and convertible preferred stock** , could cause the market price of our common stock to decline and could impair our ability to raise capital through the sale of additional equity securities. We cannot predict the effect that future sales of shares of our common stock or other equity- related securities would have on the market price of our common stock. We have a history of reverse splits, which have severely impacted our common stock price. Since our initial public offering in 2000, we have effected five reverse stock splits ~~, for a cumulative ratio since our IPO of 1: 31, 360, 000, 000~~ . Each such reverse split has resulted in an effective decline in the price of our common stock. There can be no assurance that we will not be required to effect one or more additional reverse stock splits which could further impact the market price and liquidity of our common stock. Anti- takeover provisions in our Amended and Restated Certificate of Incorporation and By- laws may reduce the likelihood of a potential change of control or make it more difficult for our stockholders to replace management. Certain provisions of our Amended and Restated Certificate of Incorporation and By- laws could have the effect of making it more difficult for our stockholders to replace management at a time when a substantial number of ~~48~~ stockholders might favor a change in management. These provisions include providing for a staggered board of directors and authorizing the board of directors to fill vacant directorships or increase the size of the board of directors. Furthermore, our ~~board~~ **Board** ~~of directors~~ has the authority to issue up to 10, 000, 000 shares of preferred stock in one or more series and to determine the rights and preferences of the shares of any such series without stockholder approval. **To date, we have designated the following series of preferred stock: Series A (4, 200 shares), Series B (2, 360 shares), Series C (590 shares), Series D (10, 000 shares), Series E (40, 000 shares), Series E- 1 (12, 960 shares), Series F- 1 (24, 900 shares), Series F- 2 (24, 900 shares), Series F- 3 (34, 860 shares) and Series F- 4 (24, 900 shares).** Any series of preferred stock is likely to be senior to the common stock with respect to dividends, liquidation rights and, possibly, voting rights. The ~~board~~ **Board** ' s ability to issue preferred stock may have the effect of discouraging unsolicited acquisition proposals, thus adversely affecting the market price of our common stock. We have never declared or paid any dividends to the holders of our common stock and we do not expect to pay cash dividends in the foreseeable future. We intend to retain all earnings for use in connection with the expansion of our business and for general corporate purposes. The ~~board~~ **Board** ~~of directors~~ will have the sole discretion in determining whether to declare and pay dividends in the future. The declaration of dividends will depend on profitability, financial condition, cash requirements, future prospects and other factors deemed relevant by our ~~board~~ **Board** ~~of directors~~ . Our ability to pay cash dividends in the future could be limited or prohibited by the terms of financing agreements that we may enter into or by the terms of any preferred stock that may be authorized and issued **. For example, the terms of the Avenue Loan Agreement contain negative covenants prohibiting us from issuing cash dividends** . We do not expect to pay dividends in the foreseeable future. As a result, holders of our common stock must rely on stock appreciation for any return on their investment. If we engage in acquisitions, reorganizations or business combinations, we will incur a variety of risks that could adversely affect our business operations or our stockholders. From time to time, we may consider strategic alternatives, such as acquiring businesses, technologies or products or entering into a business combination with another company. If we do pursue such a strategy, we could, among other things: • issue equity securities that would dilute current stockholders' percentage ownership; • incur substantial debt that may place strains on our operations; • spend substantial operational, financial and management resources in integrating new businesses, personnel, intellectual property, technologies and products; • assume substantial actual or contingent liabilities; • reprioritize our programs and even cease development and commercialization of CHEMOSAT and HEPZATO; • suffer the loss of key personnel ~~,~~ **;** or • merge with, or otherwise enter into a business combination with, another company in which our stockholders would receive cash or shares of the other company or a combination of both on terms that certain of our stockholders may not deem desirable. Although we intend to evaluate and consider different strategic alternatives, we have no agreements or understandings with respect to any acquisition, reorganization, or business combination at this time. If securities or industry analysts do not publish or cease publishing research or reports about us, our business, or our market, or if they change their recommendations regarding our securities adversely, the price and trading volume of our securities could decline. The trading market for our securities will be influenced by the research and reports that industry or securities analysts may publish about us, our business, market or competitors. Securities and industry analysts do not ~~49~~ currently, and may never, publish research on us. If no securities or industry analysts commence coverage of us, the price and trading volume of our securities would likely be negatively impacted. If any of the analysts who may cover us change their recommendation regarding our shares of ~~Common~~ **common** ~~Stock~~ **stock** adversely, or provide more favorable relative recommendations about our competitors, the price of our shares of ~~Common~~ **common** ~~Stock~~ **stock** would likely decline. If any analyst who may cover us were to cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our share price or trading volume to decline. ~~We have identified material weaknesses in our internal control over financial reporting. 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 stock. Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes- Oxley Act of 2002, or the Sarbanes- Oxley Act, or any~~

~~subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. 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 our consolidated financial statements would not be prevented or detected on a timely basis. Inadequate internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock. Management determined there was material weaknesses that existed at December 31, 2022. The material weaknesses relate to detection and application of the Company' s expense policy on its share- based compensation under the accelerated method. We have commenced measures to remediate this material weaknesses and will design additional key controls in order to ensure the Company' s share- based compensation is calculated under the accelerated method. We will continue to assess our finance and accounting staffing needs to ensure remediation of this material weakness. The material weakness will not be considered remediated until the applicable remedial controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. If not remediated, this material weakness could result in further material misstatements to our annual or interim consolidated financial statements that might not be prevented or detected on a timely basis, or in delayed filing of required periodic reports. If we are unable to assert that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of the stock could be adversely affected, and we could become subject to litigation or investigations by Nasdaq, the SEC, or other regulatory authorities, which could require additional financial and management resources. Management will be required to assess the effectiveness of our internal controls annually. However, for as long as we are a non- accelerated filer, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404 of the Sarbanes- Oxley Act. An independent assessment of the effectiveness of our internal controls could detect problems that our management' s assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements requiring us to incur the expense of remediation and could also result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. 50~~ General Risk Factors The loss of key personnel could adversely affect our business. Our success depends upon the efforts of our employees. The loss of any of our senior executives or other key employees could harm ~~its~~ **our** business. Competition for experienced personnel is intense and, if key individuals leave us, we could be adversely affected if suitable replacement personnel are not quickly identified and hired. Competition for qualified individuals exists in all functional areas, which makes it difficult to attract and retain the qualified employees we need to operate our business. Our success also depends in part on our ability to attract and retain highly qualified scientific, technical, commercial and administrative personnel. If we are unable to attract new employees and retain our current key employees, our ability to compete could be adversely affected and the development and commercialization of our products could be delayed or negatively impacted. We **and the third parties that support us** rely on the proper function, availability and security of information technology systems to operate our business and a cyber- attack or other breach of these systems could have a material adverse effect on our business, ~~financial condition~~ **including by not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of** ~~or~~ **our business** ~~results of~~ operations **; reputational harm; loss of revenue or profits; and other adverse consequences** . We **and the third parties upon which we** rely ~~on~~ **collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, processing) proprietary, confidential, and sensitive data, including personal data (such as health- related data), intellectual property and trade secrets (collectively, sensitive** information **)** ~~technology systems to process, transmit, and store electronic information~~ in our day- to- day operations. Similar to other companies, the size and complexity of our information technology systems makes them vulnerable to a **variety of evolving threats, including** cyber- attack, malicious intrusion, breakdown, destruction, loss of ~~data~~ **information** privacy, or other significant disruption **that threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer " hackers, " threat actors, " hacktivists, " organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation- state- supported actors. Some actors now engage and are expected to continue to engage in cyber- attacks, including without limitation nation- state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, the third parties upon which we rely, may be vulnerable to a heightened risk of these attacks, including retaliatory cyber- attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to social- engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial- of- service attacks, credential stuffing attacks, credential harvesting, personnel misconduct or error, ransomware attacks, supply- chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, attacks enhanced or facilitated by artificial intelligence (" AI "), and other similar threats. Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and**

**technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program. We rely on third- party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud- based infrastructure, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third- party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third- party service providers fail to satisfy their privacy or security- related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply- chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third- party partners' supply chains have not been compromised. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems. We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Unremediated high risk or critical vulnerabilities pose material risks to our business. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities** . Our information systems require an ongoing commitment of significant resources to maintain, protect, and enhance existing systems and develop new systems to keep pace with continuing changes in information processing technology, evolving systems and regulatory standards. **We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents.** Any failure by us to maintain or protect our information technology systems and data integrity, including from cyber- attacks, intrusions or other breaches, could result in the unauthorized access to **sensitive** ~~personally identifiable~~ information ~~, theft of intellectual property or other misappropriation of assets~~ , or otherwise compromise our confidential or proprietary information and disrupt our operations. ~~Any~~ **Applicable information privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, customers, regulators, and investors,** of **security incidents. Such disclosures are costly, and** ~~these -- the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and / or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may events -- prevent~~ ~~may~~ **or** cause **customers to stop using our services, deter new customers from using our services, and negatively impact our ability to grow and operate our business. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect** us **from liabilities** ~~to have difficulty preventing , detecting~~ **damages , or** ~~and controlling fraud, be subject to legal~~ claims **related to** ~~and liability, have regulatory sanctions or~~ **our** ~~penalties imposed, have increases in operating expenses, incur expenses or lose revenues as a result of a~~ data privacy ~~breach~~ **and security obligations. We cannot be sure that** ~~or~~ **our** ~~theft~~ **insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out** of ~~intellectual property, or~~ **our** ~~suffer other adverse consequences~~ **privacy and security practices , that such coverage will continue to be available** ~~any of which could have a material adverse effect~~ on **commercially reasonable terms** ~~our -- or business~~ **at all** , ~~financial condition~~ or **that such coverage will pay future** ~~results of operations. We may be the subject of product liability~~ claims ~~or product recalls, and we may be unable to maintain insurance adequate to cover potential liabilities. Our business exposes us to potential liability risks that may arise from clinical trials and the testing, manufacture, marketing, sale and use of CHEMOSAT and HEPZATO~~ . In addition **to experiencing a security incident , third** ~~because CHEMOSAT and HEPZATO are intended for use in patients --~~ **parties** ~~with cancer~~ **may gather , collect,** ~~there is an increased risk of death among the patients treated with our -~~ **or infer sensitive information about** ~~system, which may increase the risk of product liability lawsuits related to clinical trials or commercial sales. We may be subject to claims against~~ us **from public sources, data brokers, or** ~~even if the injury is due to the actions of others --~~ **other means** ~~. For example, if the medical personnel~~ that **reveals competitively sensitive details about** ~~use our system on patients are not properly trained or~~ **our organization** ~~are negligent in the use of the system, the patient may be injured, which may subject us to claims. Were such a claim asserted, we would likely incur substantial legal~~ and ~~related expenses even if we prevail on the merits. Claims for damages, whether or not successful,~~ could **be used to undermine** ~~cause delays in clinical trials and result in the loss of physician endorsement, adverse publicity and / or~~ **our** ~~limit~~ **competitive advantage** ~~our -~~ **or** ~~ability to~~ market **position** ~~and sell the system, resulting in loss of revenue . In addition, it may be necessary for us to recall products that do not meet approved specifications, which would also result in adverse publicity and costs connected to the recall and loss of revenue. A successful products liability claim or product recall would have a material adverse effect on our business, financial condition, and results of operations. While we currently carry product liability and clinical trial insurance coverage, it may be insufficient to cover one or more large claims. 51~~ We will continue to incur significant costs as a result of operating as a public company, and our management will continue to devote substantial time to compliance initiatives. As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses. As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes- Oxley Act ~~of 2002 (the " Sarbanes- Oxley Act ")~~ , the Dodd- Frank Wall Street Reform and Consumer Protection Act, as well as rules adopted, and to be adopted, by the SEC and Nasdaq. Our management

and other personnel need to continue to devote a substantial amount of time to comply with these requirements. Moreover, these rules and regulations have increased, and will continue to increase, our legal and financial compliance costs and make some activities more time ~~-~~consuming and costly. The increased costs may increase our net loss ~~. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be forced to accept reduced policy limits or incur substantially higher costs to maintain the same or similar coverage as we did prior to becoming a public company~~ . These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in future uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our Board, our ~~board~~ **Board** committees or as our executive officers. We are a " smaller reporting company " and have elected to comply with reduced public company reporting requirements, which could make our ~~Common~~ **common** ~~Stock~~ **stock** less attractive to investors. Because our annual revenue was less than $ 100. 0 million during the most recently completed fiscal year and the market value of our voting and non- voting ~~Common~~ **common** ~~Stock~~ **stock** held by non- affiliates was less than $ ~~560~~ **700** . 0 million measured on the last business day of our second fiscal quarter, we qualify again as a " smaller reporting company " as defined in the Exchange Act. Accordingly, we may provide less public disclosure than larger public companies, including, the inclusion of only two years of audited financial statements and only two years of related selected financial data and management' s discussion and analysis of financial condition and results of operations disclosure. We are also ~~no~~ **not** ~~longer~~ required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests. We cannot predict if investors will find our ~~Common~~ **common** ~~Stock~~ **stock** less attractive as a result of our reliance on these exemptions. If some investors find our ~~Common~~ **common** ~~Stock~~ **stock** less attractive as a result of any choice we make to reduce disclosure, there may be a less active trading market for our ~~Common~~ **common** ~~Stock~~ **stock** and the market price for our ~~Common~~ **common** ~~Stock~~ **stock** may be more volatile. ~~52~~ **Our business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises, political crises, global geopolitical conflicts, or other macroeconomic conditions, which have in the past and may in the future negatively impact our business and financial performance. The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, severely diminished liquidity and credit availability, declines in economic growth, supply chain shortages and disruptions, increases in inflation rates, higher interest rates and uncertainty about economic stability. The Federal Reserve has raised interest rates multiple times in response to concerns about inflation and it may raise them again. Higher interest rates, coupled with the risk of government shutdowns reduced government spending and volatility in financial markets may increase economic uncertainty and affect consumer spending. Similarly, public health crises and ongoing global geopolitical conflict has created extreme volatility in the global capital markets and is expected to have further global economic consequences, including disruptions of the global supply chain and energy markets. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, or do not improve, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Further downgrades of the U. S. credit rating, automatic spending cuts, or a government shutdown could negatively impact our liquidity, financial condition and earnings. The U. S. debt ceiling and budget deficit concerns have increased the possibility of credit- rating downgrades and economic slowdowns, or a recession in the United States. Although U. S. lawmakers have previously passed legislation to raise the federal debt ceiling on multiple occasions, there is a history of ratings agencies lowering or threatening to lower the long- term sovereign credit rating on the United States given such uncertainty. On August 1, 2023, Fitch Ratings downgraded the U. S.' long- term foreign currency issuer default rating to AA from AAA as a result of these repeated debt ceiling and budget deficit concerns. The impact of this or any further downgrades to the U. S. government' s sovereign credit rating or its perceived creditworthiness could adversely affect the United States and global financial markets and economic conditions. Moreover, these developments could cause interest rates and borrowing costs to rise, which may negatively impact our ability to access the debt markets on favorable terms. In addition, disagreement over the federal budget has caused the U. S. federal government to shut down for periods of time. Continued adverse political and economic conditions could have a material adverse effect on our business, financial condition and results of operations. Environmental, social and governance matters and any related reporting obligations may impact our business. U. S. and international regulators, investors and other stakeholders are increasingly focused on environmental, social and governance matters. For example, new domestic and international laws and regulations relating to environmental, social and governance matters, including environmental sustainability and climate change, human capital management and cybersecurity, are under consideration or being adopted, which may include specific, target- driven disclosure requirements or obligations. Our response could require additional investments and implementation of new practices and reporting processes, all entailing additional compliance risk.**