Risk Factors Comparison 2024-03-21 to 2023-03-30 Form: 10-K

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Investing in our common stock involves a high degree of risk and there can be no assurance that **our** future results will meet expectations. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Annual Report on Form 10- K, before purchasing our common stock. ~~The risks and uncertainties described below are not the only ones facing our company. Additional risks and uncertainties may also impair our business operations.~~ If we are unable to successfully address these risks and challenges, our business, financial condition, results of operations, or prospects could be materially and adversely affected. If any of these risks actually occur, our business, financial condition or results of operations would likely suffer. In that case, the trading price of our common stock could fall, and you may lose all or part of the money you paid to buy our common stock **. It is not possible to predict or identify all such risks; our operations could also be affected by factors, events or uncertainties that are not presently known to us or that we currently do not consider to present significant risks to our operations. Therefore, you should not consider the following risks to be a complete statement of all the potential risks or uncertainties that we face** . RISK FACTOR SUMMARY • We have limited capital resources and will likely need additional funding ~~before we are able~~ to **operate and expand** ~~achieve profitability. • We may be unable to grow~~ our ~~concentrates~~ business ~~, either through acquisitions or organically, which could negatively impact our financial condition and prospects. • If we are unable to increase our revenue and decrease our expenses, we may need additional funding before we are able to achieve profitability~~ . If we are unable to raise additional capital on attractive terms, or at all, we may be unable to ~~sustain~~ **grow** our operations **. • Our A & R Loan Agreement with Innovatus contains certain covenants that could adversely affect our operations and, if an event of default were to occur, we could be forced to repay the outstanding indebtedness sooner than planned and possibly at a time when we do not have sufficient capital to meet this obligation. The occurrence of any of these events could cause a significant adverse impact on our business, prospects and share price. • Our existing capital resources may not be adequate to finance our operating cash requirements beyond the length of time that we have estimated and additional capital that we may need to operate or expand our business may not be available. • Our agreement with our largest customer in our concentrates business is set to expire on December 31, 2024 and our inability to negotiate a new agreement would have a material and adverse effect on our financial condition and results of operations. • Market dynamics in our concentrates business that have resulted in lower volumes could lead to the implementation of cost- saving measures that would have a material and adverse effect on our business** . • We ~~have been~~ **may fail to realize the anticipated benefits of the Evoqua Acquisition, including** ~~and~~ **an improved financial position, and those benefits** may ~~continue~~ **take longer** to ~~be affected~~ **realize than expected. • Our business is highly regulated, resulting in additional expense and risk of noncompliance that can** materially and adversely **affect** ~~by increases in raw material and transportation costs and may be unable to recover certain costs due to provisions in~~ our ~~contracts which provide for fixed prices~~ **business, results of operations, financial position and cash flows** . **•** Our **business** ~~Products Purchase Agreement with DaVita ends at the end of 2023. If we are unable to extend the relationship on favorable terms or at all, our financial condition and results of~~ operations ~~will be materially~~ **may subject us to numerous commercial disputes, claims, lawsuits** and **/ or investigations. • Our business could be** adversely affected ~~. • The ongoing COVID- 19 pandemic~~ **by economic downturns, inflation, increases in interest rates, natural disasters, public health crises, cybercrime, political crises, geopolitical events, such** ~~has~~ **as** ~~resulted~~ **the crisis** in ~~significant disruptions to Ukraine and the Middle East,~~ ~~our~~ **or** ~~business operations, including shortages or disruptions in labor and raw materials in our concentrates business and disruptions to the~~ **other macroeconomic conditions** ~~supply chain for pharmaceutical products in our clinical development programs~~ , which could have a material **and** adverse effect on our **results** ~~business. • If our international partners are unable to or choose not to move forward to obtain regulatory approval in their jurisdictions for Triferic, we will not realize the value~~ of **operations and financial condition** ~~these relationships. • If we are unable to develop, obtain regulatory approval for, or successfully commercialize new therapies leveraging our FPC platform, or if we experience significant delays in doing so, the long- term success of our drug portfolio could be harmed~~ . RISKS RELATED TO OUR FINANCIAL POSITION We have limited capital resources and will likely need additional funding ~~before we are able~~ to ~~achieve profitability~~ **operate and expand our business** . If we are unable to raise additional capital on attractive terms, or at all, we may be unable to sustain our operations. We have limited capital resources, a cumulative deficit of approximately $ ~~388~~ **397** . ~~8~~ **2** million since inception and we may incur further losses. As of December 31, ~~2022~~ **2023** , we had approximately $ ~~21~~ **10** . ~~5~~ **9** million of cash, cash equivalents and investments available- for- sale, and working capital of $ ~~17~~ **12** . ~~6~~ **1** million. Net cash used in operating activities for the year ended December 31, ~~2021~~ **2023** was approximately $ ~~17~~ **9** . 4 million. In March 2020, we entered into a Loan and Security Agreement (the" Loan Agreement") with Innovatus Life Sciences Lending Fund I, LP, (" Innovatus") to make certain term loans to the Company in the aggregate principal amount of up to $ 35 million. Net draw down proceeds at closing were approximately $ 21 million, net of estimated fees and expenses. As of December 31, ~~2022~~ **2023** , $ ~~10~~ **8** million remains drawn under the Loan Agreement. **While we expect to have sufficient capital through 12 months from the date of this filing, there is uncertainty beyond that period.** Our ability to fund our planned activities will be dependent upon our ability to restructure our ~~contract~~ **contracts** with **some of** our ~~largest customer in our concentrates business, enter into new distribution and purchase agreements with former Baxter~~ customers, ~~increase our revenue and lower our expenses in our concentrates business and to~~ raise additional ~~funds in a defined timeline~~ **capital, control our costs and maintain or increase our gross margin on sales** . These factors are subject to significant risks and uncertainties and there can be no assurance that

we will be successful in raising additional capital, **controlling costs and** restructuring our ~~contract with our largest~~ customer **relationships** ~~and entering into new contracts with former Baxter customers~~. If we are unable to achieve one or all of these objectives, we may be forced to implement **further** cost- saving measures that could have a negative impact on our activities. If we are unable to ~~restructure current or enter into new contracts in our concentrates business,~~ increase our revenues and decrease our expenses or raise **any** required capital, we may be forced to curtail our activities and, ultimately, cease **operations. In addition, our day- to- day operations depend in part on the amount of credit our suppliers will extend to us. If we are unable to maintain a favorable financial position, that credit may be curtailed, which could significantly impact our** operations. Even if we are able to raise sufficient capital, such financings may only be available on unattractive terms, or result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline. ~~Our Loan Agreement with Innovatus contains certain covenants that could adversely affect our operations and, if an event of default were to occur, we could be forced to repay the outstanding indebtedness sooner than planned and possibly at a time when we do not have sufficient capital to meet this obligation. The occurrence of any of these events could cause a significant adverse impact on our business, prospects and share price.~~ Pursuant to the **A & R** Loan Agreement, we have pledged substantially all of our assets and the assets of our subsidiary, Rockwell Transportation, Inc., and have agreed that we may not sell or assign rights to our patents and other intellectual property without the prior consent of Innovatus. Additionally, the Loan Agreement contains customary representations and warranties and affirmative covenants, subject to customary carve outs, and includes financial covenants related to liquidity and actual ~~concentrates~~ **hemodialysis products** revenue (measured on a ~~quarterly~~ **biannual** basis). The **A & R** Loan Agreement also contains negative covenants that, among other things, restrict our ability to: • incur additional indebtedness; • grant liens; • make distributions, including dividends; • enter into a merger or consolidation; • alter the business of the Company; or • sell all or a portion of the Company' s property, business or assets. These terms of the **A & R** Loan Agreement could prevent us from taking certain actions without the consent of our lenders, which may limit our flexibility in operating our business and our ability to take actions that might be advantageous to us and our stockholders, placing us at a competitive disadvantage compared to our competitors who have less leverage and who therefore may be able to take advantage of opportunities that our leverage prevents us from exploiting. These covenants could also limit our ability to make needed capital expenditures or otherwise conduct necessary or desirable business activities. If we cannot maintain compliance with the covenants under our **A & R** Loan Agreement, we may trigger an event of default. Our ability to comply with these covenants may be adversely affected by events beyond our control. For example, ~~in September 2021, we entered into an amendment to the Loan Agreement in which the Company, in exchange for Innovatus lowering the sales covenants (then based upon Triferic sales), agreed to (i) prepay an aggregate principal amount of $ 7. 5 million in ten installments commencing~~ on ~~December 1, 2021; (ii) pay an additional prepayment premium of 5 % on prepaid amounts if the Company elects to prepay all outstanding term loans on or before September 24, 2023 and (iii) maintain minimum liquidity of no less than $ 5 million if the aggregate principal amount of term loans is greater than $ 15 million pursuant to the liquidity covenant in the Loan Agreement. On~~ November 10, 2022, **we** ~~the Company~~ entered into the Second Amendment to Loan Agreement under which **we** ~~the Company~~ (i) prepaid an aggregate principal amount of $ 5. 0 million in outstanding term loans in one installment on November 14, 2022; (ii) agreed to make interest- only payments until September 2023 **(** at which time **we** ~~the Company will resume~~ **resumed** scheduled debt payments **)** in consideration for certain modifications to the financial covenants under the Loan Agreement. ~~As of December 31~~ **The A & R Loan Agreement provides for us to make interest- only payments for thirty months , or up to thirty- six months if certain conditions are met. The loan will mature on January 1,** ~~2022~~ **2029 , unless earlier repaid. The A & R Loan Agreement includes a financial covenant that requires actual consolidated revenue from the sale and supply of hemodialysis products for the trailing six- month period (ended on the date when tested), to be not less than 85. 0 % of the projections for the same period and, beginning with the quarter ending September 30, 2024, actual consolidated revenue from the sale and supply of hemodialysis products for the trailing six- month period (ended on the date when tested), to be not less than 80. 0 % of the projections for the same period. The A & R Loan Agreement also includes a liquidity covenant that requires that us to maintain minimum liquidity of the greater of (x) our** ~~the~~ **three** ~~Company was~~ **- month cash burn or (y) the sum of $ 1. 5 million and the aggregate amount of capital lease payments required to be made during the succeeding 12 months (or during a continuing event of default, the aggregate amount of capital lease payments required to be made during the entire term of such capital leases). Although we are currently** in compliance with all reporting and financial covenants, ~~but~~ there can be no assurance that we will be able to **continue to** maintain compliance in the future. The **A & R** Loan Agreement also includes customary events of default, including, among other things, a change of control or a failure to comply with certain of the covenants in the **A & R** Loan Agreement. Upon the occurrence and continuation of an event of default, all amounts due under the **A & R** Loan Agreement become (in the case of a bankruptcy event), or may become (in the case of all other events of default and at the option of Innovatus), immediately due and payable. If an event of default under the **A & R** Loan Agreement should occur, we could be required to immediately repay the outstanding indebtedness. If we are unable to repay this debt, the lenders would be able to foreclose on the secured collateral, including our cash accounts, and take other remedies permitted under the **A & R** Loan Agreement. Even if we are able to repay the indebtedness on an event of default, the repayment of these sums may significantly reduce our working capital and impair our ability to operate as planned. The occurrence of any of these events could cause a significant adverse impact on our business and financial condition. Our existing capital resources may not be adequate to finance our operating cash requirements for the length of time that we have estimated and additional capital that we may need to operate or expand our business may not be available. Our forecast of the period of time through which our existing capital resources will be adequate to support our current operations is a forward- looking statement that involves risks and uncertainties. The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include, but are not limited to: • the **extension** ~~timing of any restructuring~~ of the contract with our largest customer in our concentrates business;

• our ability to enter into new contracts and negotiate favorable terms with **our** ~~former Baxter~~ customers; • our ability to increase our prices to keep up with inflation; • whether we experience significant input costs for, or disruptions to, the manufacturing or distribution of our products; ~~and~~ • ~~our international partners' commitment~~ **whether we expand into new territories;** and **• whether we develop and launch new product offerings** ~~ability to obtain regulatory approval for Triferic in their countries~~ . If we are required to raise additional capital to fund our operations, such equity financings may be dilutive to our stockholders and newly issued securities may have rights, preferences or privileges senior to those of holders of our common stock. Any debt financing is limited by the terms of our Securities Purchase Agreement with DaVita, dated as of April 6, 2022, pursuant to which they invested in our convertible preferred stock. Specifically, until DaVita owns less than 50 % of its investment, the Company may only incur additional debt in the form of a purchase money loan, a working capital line of up to $ 5 million or to refinance existing debt, unless DaVita consents. Debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate as a business. If our operations ~~or development activities~~ require substantial cash resources in the future in excess of our liquid resources on hand and if our cash flows are not sufficient to support financing through unsecured indebtedness, we may not be able to obtain debt financing and our capital financing options may become limited. Regardless of whether we seek to raise additional working capital through the sale of equity securities or the incurrence of indebtedness, if we do not have sufficient funds available to run our concentrates business and pursue business opportunities, our business, results of operations, financial position and cash flows could be materially adversely affected. Our revenue growth and profitability projections are based on various assumptions that may not come to fruition. Our revenue growth and profitability projections are subject to many assumptions regarding our future operations, including that we are successful in expanding to new territories, that we successfully develop and launch new product offerings, that we are able to increase our prices to keep up with inflation, and that we do not experience significant disruptions to the manufacturing or distribution of our products, among other assumptions. If we are unsuccessful in one or more of those efforts, we may not be able to achieve our projected growth and profitability. RISKS RELATED TO OUR BUSINESS Our **Amended and Restated Products Purchase** ~~agreement~~ **Agreement (the " Products Purchase Agreement ")** with **DaVita** ~~our largest customer in our concentrates business~~ is set to expire on December 31, **2024. The Products Purchase Agreement is a fixed price agreement. In September** 2023 **, we amended the original** ~~and our inability to negotiate a new agreement would have a material and adverse effect on our financial condition and results of operations. Our~~ Products Purchase Agreement with DaVita ~~is set~~ to ~~expire on December 31, 2023~~ **raise our prices in light of inflationary pressures and to remove certain provisions** . The Products Purchase Agreement **may be extended by DaVita for** ~~is a fixed price agreement that contains a number of limitations on~~ **one** ~~our ability to raise prices~~ **year in its sole discretion** . **When the** ~~In April 2022, we amended our~~ Products Purchase Agreement **is again up for** ~~to raise our prices in light of inflationary pressures. However, rising costs and declining volumes ordered by DaVita since April 2022 have had and could continue to have a negative impact on our business. The Products Purchase Agreement requires ninety (90) days' notice of non-~~ renewal **,** ~~upon expiration. If~~ we ~~are~~ **may be** unable to reach an agreement with DaVita on new terms that make economic sense for us **. In that case** , we ~~do~~ **would** not expect to enter into a new agreement. This would result in the loss of approximately one- half of our current volume of concentrates products and would have a material and adverse effect on our financial condition and results of operations and would likely lead to the implementation of cost saving measures that would negatively impact our activities. Market dynamics in our concentrates business ~~that~~ have resulted in ~~lower~~ **fluctuating** volumes **that** could lead to the implementation of cost **-** saving measures that would have a material and adverse effect on our business. Volumes have **fluctuated** ~~been decreasing~~ in our concentrates business, due to the reduction in patient census caused by COVID- 19 and cost saving measures by our customers **, including switching to single use bicarbonate canisters** . If these volumes decrease ~~further~~ **substantially** , we may be forced to consolidate our operations and curtail our activities to lower our fixed costs. While our fixed costs would be reduced by such actions, we may not be able to realize the full amount of that reduction if our variable costs (such as transportation) increase and we are unable to pass along those increases to our customers. In addition, a consolidation or restructuring of our business could lead to significant one- time costs related to exiting operations. Such a consolidation could have a material and adverse effect **on** our business, financial condition and results of operations. **On July 10, 2023, we completed our acquisition of the hemodialysis concentrates assets (the " Evoqua Acquisition ") from Evoqua.** Our **synergistic goals with regard to the** ~~reacquisition~~ -- **acquisition include an improved financial position, expanded geographic footprint, customer base and product offerings, and increased manufacturing capacity. While we have completed the integration** of ~~distribution rights~~ **Evoqua' s former assets, there can be no assurance that we will be able to operate Evoqua' s former product line profitably. In addition, many of the former Evoqua customers that we inherited as a result of the Evoqua Acquisition are not subject to contractual purchasing commitments and may discontinue their business with us as a result of the transition of ownership. Following the Evoqua Acquisition, the number of our customers is significantly larger than prior to the Evoqua Acquisition. The Company' s future success depends, in part, upon our ability to manage this expanded business, which will pose substantial challenges** for our **management, including challenges related to the management and monitoring of new operations and associated increased costs and complexity. The dedication of management resources to this portion of our business could detract attention from our current day- to- day operations. Because we have limited financial resources, by investing in the Evoqua Acquisition, we may forgo or delay pursuit of other future opportunities that may have proven to have greater commercial potential. Also, we now possess certain liabilities and obligations, including contractual liabilities and obligations, that were assumed by us upon closing of the Evoqua Acquisition. Further, it is possible that undisclosed, contingent, or other liabilities, problems or obligations may arise in the future of which we were previously unaware. These disclosed and undisclosed liabilities could have an adverse effect on our business, financial condition and results of operations. These factors, including the failure of the expanded business to perform as expected, could decrease or delay the expected accretive effect of the Evoqua Acquisition, negatively affect our stock price, result in impairment of our**

intangible assets, and harm our financial condition, results of operations or business prospects. As a result, it cannot be assured that the Evoqua Acquisition will result in the full realization of the benefits anticipated from the Evoqua Acquisition or in the anticipated time frames or at all. We depend on a third party to manufacture products for the business that was the subject of the Evoqua Acquisition. If this organization is unable or unwilling to manufacture our newly acquired concentrates products **,** ~~from Baxter through the termination of our~~ **or** ~~Exclusive Distribution Agreement has many attendant risks~~ **if the organization fails to comply with applicable regulations or otherwise fails to meet our requirements, our business will be harmed. We rely on a contract manufacturing organization (" CMO") to manufacture the concentrates products that were the subject of the Evoqua Acquisition. If that CMO is unable to manufacture those products in sufficient quantities** and **on a consistent basis, or if it becomes unwilling to produce the products for us, we** may not ~~result in~~ **be able to fulfill our contractual requirements or sell** ~~the~~ **those products while we look for an alternative. We currently have a single- source supplier, and our supply contract expires at the end of 2024. If we were to experience a supply disruption, it could take an extended period of time to take over the manufacturing ourselves. The manufacturing facilities and processes used by our CMO must be approved by the FDA before the products manufactured by such CMO can be sold. After approval, our CMO must meet certain ongoing regulatory requirements for product testing and stability of commercially marketed products. We do not control the manufacturing processes of our CMO and depend on it to comply with current good manufacturing practices (“ cGMP ”) and obtain and maintain regulatory approval. If approval for a CMO is not received or ongoing testing does not continue to meet approved standards and approval is withdrawn, the CMO’ s production would be delayed or suspended, which could adversely affect our business. If that was to happen, we may be forced to find another capable CMO or take over production ourselves. Any such circumstance could significantly hamper our ability to supply our customers in a timely manner, which may have a material adverse effect on our** financial ~~outcome we expect~~ **condition and results of operations** . ~~In 2022~~ **We have been and may continue to be materially and adversely affected by increases in raw material** , ~~we terminated~~ **labor and transportation costs and may be unable to recover certain costs due to provisions in** our ~~Exclusive Distribution~~ **largest customer contract and other fixed price contracts and we may lose other customers due to price sensitivity. A significant portion of our costs relates to chemicals and other raw materials and transportation, which such costs are out of our control, and we may not be able to recover a portion of such costs due to provisions in the Products Purchase** Agreement with ~~Baxter~~ **DaVita** and ~~reacquired the~~ **other fixed price** ~~distribution rights related to our concentrates~~ **contracts . The costs of chemicals and other raw materials are subject to price volatility based on supply and demand and are highly influenced by the overall level of economic activity in the United States and abroad. In addition, labor costs have been steadily rising and our manufacturing process is labor intensive, which increases our costs to produce our** products ~~price volatility based on supply and demand and are highly influenced by the overall level of economic activity in the United States and abroad~~ .These costs have tended to rise from year to year and are likely to continue to rise in the future.In the past year,raw materials costs have increased significantly,due to short supply and excess demand **.In addition,in many areas,we have a single source of raw materials,which makes us particularly sensitive to cost increases** .Transportation also comprises a significant portion of our costs.We have been adversely affected by a general shortage in commercial truckers in the United States and significant increases in labor and fuel costs.In addition, ~~as mentioned above,~~ there has **,in the past,** been a nationwide shortage of diesel fuel in the United States,which we use to run our delivery trucks.Such a shortage,has and in the future may result in an increase in the cost of diesel fuel or lack of availability of diesel fuel and we would need to find another way to deliver our products to clinics.If we are unable to do so,we could be in breach of our contracts.In addition,any increase in the use of third- party freight would significantly increase our costs,which we may not be able to pass on to our customers.Our Product Purchase Agreement with DaVita provides ~~for a~~ for ~~Baxter~~ **a fixed** price to DaVita,with limited increases from year to year that must be agreed to by the parties,regardless of the increases in raw materials costs and transportation costs.As a result,we have in the past been unable to fully recover our costs for the products we sell to DaVita (including transportation costs). ~~This has had and could in the future have a material and adverse impact on our financial position.On April 6,2022,we entered into an amendment to the Products Purchase Agreement under which we agreed to a price increase,effective May 1,2022,as well as the pass- through of certain costs (subject to a cap),which are determined on a quarterly basis.~~ Continued rising costs and declining volumes have had and could continue to have a negative impact on our business. ~~In addition,if our costs exceed an overall cap,the Products Purchase Agreement may be subject to termination by DaVita.~~ We expect that if we continue to be subject to the limitations in the Products Purchase Agreement **and other fixed price contracts** ,the increasing costs and decreasing volumes may continue to negatively impact our profit margins and materially and adversely affect our financial position. **Some of our customers buy products from us on a purchase order basis or pursuant to contracts that allow for price increases at least once per year.In situations where we are able to increase prices to keep up with our costs,we may lose customers if such customers are unwilling to pay higher prices.That would result in lost revenue for the Company and may negatively impact our financial position and results of operations.** A few customers account for a substantial portion of the end user sales of our concentrate products.The loss of any of these customers could ~~have a material~~ **materially** and ~~adverse~~ **adversely** ~~effect~~ **affect** ~~on~~ our business,results of operations,financial position and cash flows.Sales of our medical device products are highly concentrated ~~in~~ **among** a few customers.One customer accounted for nearly half of our sales in each of the last three years and for **a substantial number of the clinics we serve.Due to the composition of Evoqua** ’ s **customer** portfolio **, we experienced further concentration** ~~of clinics. Our Distribution Agreement~~ with **regard** ~~Baxter enabled us~~ to ~~charge Baxter~~ **that customer and** an **additional customer through** ~~amount above cost for our concentrates products, while limiting us to a capped percentage of sales for~~ the ~~transportation costs associated with delivering~~ **Evoqua Acquisition. The loss of any of** ~~those~~ **these significant** ~~products. Now that we have assumed full responsibility for selling and delivering our concentrates products to former Baxter~~ customers **could materially** and **adversely affect our business** ~~any other~~

~~customers we may add~~ , ~~we bear all~~ **results of operations,** financial **position** and **cash flows** ~~other risk associated with the business. We may lose former Baxter customers if we need to increase the prices of our concentrates products due to rising costs or for other reasons. In addition, since we agreed to charge certain customers a fixed cost through March 31, 2023, we may lose money if those fixed costs do not cover our actual costs. We also may be unable to renegotiate unprofitable contracts with certain customers. In addition, because we do not have access to all of the distribution channels Baxter utilized for our products, we may lose certain customers if we cannot find a suitable alternative channel by which to serve them. Each of these scenarios could result in the business we reacquired generating less revenue or less profit than we expect and could adversely impact our financial condition or results of operations~~ . Unfavorable weather, economic conditions or supply shortages could **materially and** adversely affect our business, financial condition or results of operations. Our results of operations could be **materially and** adversely affected by general weather conditions, as well as conditions in the United States and global economy and in the global financial markets. A severe weather or other geological event in our locations or those of our suppliers, or prolonged economic downturn or persistent inflation have and could continue to result in a variety of risks to our business, including our ability to recover our costs or to raise additional capital when needed on acceptable terms, if at all. In addition, weather- related events may jeopardize our ability to deliver our products as required by our contracts. For example, **in 2023** ~~after Hurricane Ian severely damaged parts of the Florida Gulf Coast~~ , ~~many~~ **winter storms led to delays in our operations, particularly in the transportation division as equipment froze and** roads **became impassible** ~~and bridges were destroyed. While we were able to make our deliveries after the storm, that may not always be the case~~ . A weak or declining United States or global economy could also strain our suppliers, possibly resulting in supply disruption. In addition, due to macro- economic conditions in the global economy **(including inflation)** , there have been shortages in raw materials, parts and fuel that we need to run our business. ~~Rceently~~ **For example, from time to time** , our suppliers have experienced shortages in bicarbonate and acid, which are components of our dialysis concentrates, and parts needed for our equipment to make certain of our products. Diesel fuel has also been in short supply in the United States **at times** and our delivery trucks run on diesel. While we have been able to minimize the impact of these disruptions to date, there can be no assurance that will continue. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business. We have been and may continue to be..... financial position and cash flows. We face competition in the ~~concentrate~~ **concentrates** market and have a large competitor with substantial resources. The primary competitor in the market for our ~~concentrate~~ **concentrates** products is Fresenius, a large **,** diversified company which has financial, technical, manufacturing, marketing, research and management resources substantially greater than ours. We may not be able to successfully compete with Fresenius. Fresenius has historically used product bundling and low pricing as a competitive strategy to capture market share of ~~concentrate~~ **concentrates** products. We may be at a disadvantage in competing against these strategies to sell ~~concentrate~~ **concentrates** products. Furthermore, Fresenius is vertically integrated and is the largest provider of dialysis services in the United States, treating approximately 37 % of all U. S. in- center hemodialysis patients through its clinics. Fresenius has routinely acquired our customers, and it may acquire more of our customers in the future. In addition to Fresenius, we are aware of other large manufacturers potentially looking to increase their market share of the domestic concentrates market, which, if successful, could have an impact upon our profitability. Our **production and other processes are largely manual, which introduces risk of error and may result in rising production costs. The production of our hemodialysis concentrates products is largely manual and involves considerable unskilled labor. The manual nature of production can introduce the risk of error. In addition, manual processes involving high amounts of labor can result in significant production costs. Many of our products are " made to order, " which can further increase production costs as we have to frequently change production runs. Unless we are able to automate our production processes, our costs may continue to increase and we may be unable to recover those rising costs or may lose customers altogether, which could negatively impact on our financial position. Our** business depends on government funding of health care, and changes could impact our ability to be paid in full for our products, increase prices or cause consolidation in the dialysis provider market. Medicare and Medicaid fund the majority of dialysis costs in the United States. Many dialysis providers receive **most** ~~the majority~~ of their funding from the government and are supplemented by payments from private health care insurers. These providers depend on Medicare and Medicaid funding to be viable businesses. Changes to health insurance and reimbursement by Congress may have a negative impact on Medicare and Medicaid funding and on reimbursement protocols. If Medicare and Medicaid funding were to ~~be~~ materially ~~decreased~~ **decrease** , dialysis providers would be severely impacted, increasing our risk of not being paid in full. An increase in our exposure to uncollectible accounts could have a material adverse effect on our business, results of operations, financial position and cash flows. Since 2011, CMS has continued to modify reimbursement policies for dialysis under the end- stage renal disease (" ESRD") prospective payment system generally falling short of covering the increasing cost of dialysis care resulting in economic pressure of dialysis providers. We anticipate that dialysis providers will continue to seek ways to reduce their costs per treatment due to these reimbursement policies, which could reduce our sales and profitability and have a material adverse effect on our business, results of operations, financial position and cash flows. Federal and state healthcare reform measures could be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, or change the methods used by Medicare and Medicaid to reimburse providers, including the " bundled " payment model. Any such reforms could potentially impact reimbursement by Medicare and Medicaid programs for dialysis and could negatively affect the ability of certain individuals to obtain coverage. As a result of these changes to Medicare and Medicaid reimbursement, the dialysis provider industry may continue to consolidate. This may result in increased purchasing leverage for providers across all dialysis product categories and increased pricing pressure on all suppliers to the industry. **Our medical device products are life sustaining and any failure to supply them to our customers and resulting scrutiny related to such circumstances could negatively impact our reputation and stock price. Our hemodialysis concentrates products are**

critical to sustain the lives of patients who need them. Routine business actions we take under our contractual arrangements with purchasers or individual clinics, such as price increases or discontinuation of supply to customers who fail to pay us on time or at all, could mean that our customers may need to find alternative sources of supply and may not be able to serve their patients. This may result in increased governmental or other scrutiny on our business. Such actions could also result in reputational harm to us and have a negative impact on our stock price. We may not be successful in expanding our ~~concentrates~~ business ~~or our drug product portfolio~~ or in our business development efforts related to in- licensing, acquisitions or other business collaborations. Even if we are able to enter into business development arrangements, they could have a negative impact on our business and our profitability. ~~We~~ **In addition to the Evoqua Acquisition, we** may seek to make **further** acquisitions or enter into business development arrangements in our concentrates business to expand our customer base or geographic footprint. In addition, as part of our business strategy ~~to expand our drug product portfolio~~, we may seek to acquire or in- license ~~other drug~~ products or product candidates that we believe are a complementary fit with our **business** ~~current product candidate portfolio~~, as well as other product or product candidates that we believe have substantial development potential. We may not be able to identify such opportunities. If we do, the negotiation of such arrangements can be a lengthy, complex and expensive process and there can be no assurance that any such negotiations will be completed on a timely basis or at all ~~,~~ or result in an arrangement that will enable us to effectively integrate, develop and launch such products or product candidates effectively. In addition, the market potential for new ~~drug~~ products or product candidates is highly uncertain and evaluation of such potential requires significant judgment and assumptions. There is a significant risk that any new ~~drug~~ product may not be able to be brought to market as profitably as expected or at all. If the results of any new ~~drug~~ product initiative are materially worse than expected, it could have a material adverse effect on our business, results of operations, financial position and cash flows. **Our international partnerships for Triferic involve risks that may materially impact those international relationships or our business generally.** We **have international partnerships** ~~rely on third party suppliers~~ for ~~raw materials and packaging components of our~~ **Triferic that require us to supply the** drug ~~products~~ **product** ~~that we supply and will supply~~ to ~~our international partners. We may not~~ be **marketed** ~~able to obtain the raw materials~~ and **sold in foreign countries** ~~proper components we need, or the cost of the materials or components may be higher than expected, any of which could impair our production or commercialization of drug products for our international partners and have a material adverse effect on our relationships with our international partners~~. We may not be able to obtain the raw materials or packaging components we need to supply our international partners, or the price of such materials or components may rise significantly, for a variety of reasons, including but not limited to ~~: • a~~ business interruption, **increased costs** ~~including a force majeure, cyber-attack, labor strike at a supplier, a COVID- related halt or slowdown of supply~~ of raw materials ~~or production of components; • global supply chain delays or disruptions; • regulatory requirements or action by regulatory agencies or others against a supplier~~ , **a** ~~including delays in receiving necessary approvals ; •~~ failure of a supplier to comply with cGMP standards, which could result in quality or product failures, adulteration, contamination and / or recall **and** ~~; • adverse financial or~~ other **factors beyond** ~~strategic developments at or~~ **our control** ~~affecting a supplier; • termination or disagreement over the terms and conditions of the supply contract by a supplier or our inability to comply with the minimums in such an agreement; • unexpected demand for or shortage of raw materials or packaging components; and • unexpected increases in our product demand. Some of the suppliers for our raw materials or packaging components are single- source suppliers. If those suppliers were unable to supply us for any reason, including the reasons mentioned above, we could experience cost increases or supply interruptions. Finding an alternative source can be expensive and take a substantial amount of time, especially when regulatory approval is required to qualify the supplier~~. If we are unable to obtain our raw materials and packaging components and are not able to establish alternative supply sources, or if the prices for such items increase substantially, our CMOs may not be able to produce the desired quantities of our drug products for our international partners and our relationships may be materially adversely affected. ~~We~~ **In addition, the third parties that we** depend on ~~third parties~~ to manufacture Triferic for our international partners **may be** ~~. If these organizations are~~ unable or unwilling to manufacture our drug products, **which could also harm** ~~or~~ **our** ~~if these organizations fail to comply with applicable regulations or otherwise fail to meet our requirements, our business~~ relationships with **those** ~~our international~~ partners ~~will be harmed. We rely on CMOs to manufacture Triferic for our international partners. If a CMO is unable to manufacture Triferic in sufficient quantities and on a consistent basis, or if it becomes unwilling to produce Triferic for us, we may not be able to supply our international partners in a timely or cost- effective manner~~. For Triferic (dialysate) and Triferic AVNU, we have a single- source finished goods supplier and do not have a long- term supply contract. If we were to experience a supply disruption, it could take an extended period of time to find and qualify an alternate supplier. The manufacturing facilities and processes used by our CMOs must be approved by the FDA and foreign regulators, where applicable, before the drug products manufactured by such CMOs can be sold. After approval, CMOs must meet certain ongoing regulatory requirements for product testing and stability of commercially marketed products. We do not control the manufacturing processes of our CMOs and depend on them to comply with ~~current good manufacturing practices (“~~ cGMP ~~”)~~, and obtain and maintain regulatory approval. If approval for a CMO is not received or ongoing testing does not continue to meet approved standards and approval is withdrawn, the CMO’ s production would be delayed or suspended, which could adversely affect our international ~~partner~~ **partners** ’ ~~s~~ Triferic commercialization efforts. **Finally** ~~If that was to happen~~, we ~~may be forced to find another capable CMO or shift production to another CMO that is already approved and under contract with us. Any such circumstance could significantly hamper our ability to supply our customers with our drug products in a timely manner, which may have a material adverse effect on our international business relationships. We may not be successful in arranging out-licensing partners capable of obtaining the approvals needed to effectively commercialize Triferic (dialysate), Triferic AVNU or any other drug product candidates outside of the United States. Even if our international partners are successful in obtaining the required regulatory approvals, they may not be effective at marketing our drug products in certain markets or at all. The regulatory procedures for obtaining marketing approval of drug products and product candidates, including Triferic (dialysate)~~

~~and Triferic AVNU, outside the United States vary from country to country and such approvals can be difficult to obtain. Our strategy is to out- license the rights to our drug products in markets outside the United States to partners who we believe will have the necessary resources and expertise to obtain regulatory approval and ultimately commercialize our out- licensed drug products. However, we may not be successful in finding new partners who will be willing to invest in our drug products outside the United States and even if we are able to find new partners, they may not be able to obtain the necessary foreign regulatory approvals. Our international partners may decide not to move forward with clinical trials or other steps necessary for foreign regulatory approval, which could result in their failure to meet milestones and the loss of potential revenue to us. If we are not successful in out- licensing our drug products outside of the United States or entering into other arrangements with partners capable of obtaining the necessary regulatory approvals to commercialize our drug products or if our current international partners delay or cease their efforts, we may decide to delay or abandon development efforts in certain markets. Any such delay or abandonment, or any failure to receive one or more foreign approvals, may have an adverse effect on the benefits otherwise expected from marketing in foreign countries and may result in the violation of our license agreements. If we are successful in obtaining partners to develop and commercialize our drug products in foreign markets, we will be dependent upon their effectiveness in selling and marketing our drug products in those foreign markets. These partners may face stiff competition, government price regulations, generic versions of our drug products, violations of our intellectual property rights and other negative events or may otherwise be ineffective in commercializing our drug products, any of which could reduce the market potential for our drug products and our success in those markets. If Triferic or any other drug product candidates are approved and marketed outside of the United States, a variety of risks associated with international operations could materially adversely affect our business. We~~ may be subject to additional risks due to Triferic ~~or any other drug product candidates~~ being approved and marketed outside of the United States, including: • increased cost or resource requirements associated with measures required to support the registration and / or sale of the product or products, such as labeling changes, product changes, testing, provision of documents or production requirements; • unexpected changes in the safety profile; • reduced protection for intellectual property rights; • additional risk of litigation; • unexpected changes in tariffs, trade barriers and regulatory requirements; • economic weakness, including inflation, or political instability in particular foreign economies and markets; • **compliance with** anti- corruption laws, including the Foreign Corrupt Practices Act (the " FCPA "); • foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country; and • business interruptions resulting from disease outbreaks, including **pandemics** ~~the recent coronavirus disease epidemic~~ , geopolitical actions, including war and terrorism, or natural disasters, including earthquakes, typhoons, floods and fires. If we do not successfully manage these risks, our prospects related to marketing **Triferic** ~~products or product candidates~~ outside the United States **by our international partners** could suffer ~~.~~ Our business and operations would suffer in the event of a security breach,system failure,invasion,corruption,destruction or interruption of our or our business partners' critical information technology systems or infrastructure.In the ordinary course of business,we and our business partners store sensitive data,including intellectual property and proprietary information related to our business,our customers and our business partners,on our information technology systems.Despite the implementation of security measures,these systems are vulnerable to damage from computer viruses,unauthorized access,cyber- attacks,natural disasters,terrorism,war and telecommunication,electrical and other system failures due to employee error,malfeasance or other disruptions.We could experience a business interruption,monetary loss,intentional theft of confidential information or reputational damage,including damage to key customer and partner relationships,from system failures,espionage attacks,malware,ransomware or other cyber-attacks.Such cyber- security breaches may compromise our system infrastructure or lead to data leakage,either internally or at our contractors or consultants. **In particular,system failures or cyber- security breaches could result in the loss of nonclinical or clinical trial data from completed,ongoing or planned trials,which could cause delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.** The risk of a security breach or disruption,particularly through cyber- attacks,has generally increased as the number,intensity and sophistication of attempted attacks and intrusions from around the world have increased. ~~From time to time,we are subject to phishing attempts.In the fourth quarter of 2023,we discovered a business email compromise caused by phishing.We do not believe that it had a material adverse effect on our business.We implemented remedial measures promptly following this incident;however,we cannot guarantee that those remedial measures will prevent additional related,as well as unrelated,incidents.~~ To the extent that any disruption or security breach were to result in a loss of,or damage to,our data or applications,or inappropriate disclosure of confidential or proprietary information,including protected health information or personal data of employees or former employees,we could be subject to legal claims or proceedings,liability under laws and regulations governing the protection of health and other personally identifiable information and related regulatory **penalties.In any such event,our business,results of operations,financial position and cash flows could be materially adversely affected.** . Our future success depends on our ability to retain executives and key employees and to attract, retain and motivate qualified personnel in the future. We are highly dependent on the operations, product development, clinical and business development expertise of the principal members of our management, operations and clinical team. We have hired executive- level employees who are leading Company initiatives, including its operational initiatives. Although we have entered into employment agreements with our executives and key employees, each of them may terminate their employment with us at any time. We do not maintain " key person " insurance for any of our executives or other employees. Recruiting and retaining qualified manufacturing, sales and marketing, scientific, and clinical personnel is critical to our success. The loss of the services of our executive officers or other key employees could seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time due to the overall state of the labor pool and the difficulty finding the specialized skills we require. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous medical device,

pharmaceutical and biotechnology companies for similar personnel. Finding production associates for our manufacturing facilities and truck drivers for our transportation division has also presented challenges for us. There is similarly a great deal of competition for these workers. This competition has resulted in increasing compensation costs as we attempt to attract and retain workers. Our business and operations would suffer in..... flows could be materially adversely affected. We use hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly. We use hazardous materials, which could be dangerous to human health and safety or the environment. Our operations also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair **the operation of** our ~~pharmaceutical~~ **business and any** development **or expansion** efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. If one of our employees was accidentally injured from the use, storage, handling or disposal of these materials or wastes, the medical costs related to his or her treatment would be covered by our workers' compensation insurance policy. However, we do not carry specific hazardous waste insurance coverage and our property and casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, or operations otherwise affected. RISKS RELATED TO ~~OUR PRODUCT CANDIDATES The long- term success of our drug product portfolio depends on our ability to leverage the FPC platform to develop new therapies in disease states that currently have an unmet need for management of iron deficiency or iron deficiency anemia. If we are unable to develop, obtain regulatory approval for or successfully commercialize these new therapies, or if we experience significant delays in doing so, our business prospects could be harmed. Successful development and ultimate regulatory approval of new therapies based on our FPC platform in disease states outside of ESRD where iron replacement is required is important to our business prospects. We conducted an evaluation of the potential utility of FPC in certain disease states and believe that, based on the results of this analysis, FPC would be viable. However, there is no assurance that our findings regarding the clinical and commercial viability of FPC are accurate or provide a complete portrayal of the medical and commercial challenges FPC will face. Furthermore, new legislation, reimbursement guidance, regulatory requirements or medical developments may negatively impact our conclusion that FPC is economically and clinically viable. The development of new therapies is lengthy, time- consuming and expensive. We expect to incur substantial expense for both preclinical studies and clinical trials with no guarantee that these efforts would either be completed in a timely manner or that they would result in a positive outcome. Completion of clinical trials may take several years or more. The length of time can vary substantially with the type, complexity, novelty and intended use of the product. Factors that can influence and affect the rate of completion of clinical trials include the potential delay by a partner in beginning a clinical trial, the failure of third- party contract research organizations (" CROs ") and other third- party service providers and independent clinical investigators to manage and conduct the trials properly, to perform their oversight of the trials or to meet expected deadlines, the inability to recruit clinical trial participants at the expected rate, the inability to follow patients adequately after treatment, unforeseen safety issues and unforeseen governmental or regulatory issues or concerns, including those of the FDA, DEA and other regulatory agencies. For example, we submitted an IND for FPC to be used in the home infusion setting and based upon the feedback we received from the FDA, we determined to put the program on hold due to the time and expense that would be required to satisfy the FDA' s concerns. We expect that we will need to raise additional funds to develop new therapies based on our FPC platform. We may not be able to obtain or secure the funding necessary to complete such development or initiate or complete the necessary clinical trials. In addition, there is no assurance that such funding will be available to us or that it will be obtained on terms favorable to us or will provide us with sufficient funds to meet our objectives. Any failure to raise capital as and when needed could have a negative impact on our ability to pursue our business plans and strategies related to our FPC platform. If we are unable to obtain and maintain adequate protection for our data, intellectual property and other proprietary rights, our FPC asset may be harmed. The value of our FPC platform depends in part on our ability to obtain and defend patent and other intellectual property rights that are important to the commercialization of our drug products and product candidates. The degree of patent protection that will be afforded to our drug products and processes in the United States and in other important markets remains uncertain and is dependent upon the scope of protection afforded to us by the patent offices, courts, administrative bodies and lawmakers in the relevant jurisdictions. We can provide no assurance that we will successfully obtain or preserve patent protection for the technologies incorporated into our drug products and processes, or that the protection obtained will be of sufficient breadth and degree to protect our commercial interests in all countries where we conduct business. If we cannot prevent others from exploiting our inventions, we will not derive the benefit from them that we currently expect. While we have an issued patent in the United States and certain other major markets, including Europe and Japan, that covers the I. V. and Dialysate formulations of Triferic, these patents expire in 2028 in Europe and Japan and 2029 in the United States. The previously issued foundational composition- of- matter patents for Triferic expired in 2016. In light of the current patent protection that we have for Triferic, it is possible that a competitor could seek to manufacture a generic version of Triferic using product specifications and manufacturing methods that do not infringe our issued patent. Further, it is possible that a competitor could seek to invalidate our issued Triferic patent. We also rely on regulatory exclusivity for protection of our drug products, which includes regulatory data protection and market protection. Implementation and enforcement of regulatory exclusivity varies widely from country to country. The failure of our international partners to qualify for regulatory exclusivity, or failure to obtain or maintain the necessary extent or duration of such protections for our drug products could affect our decision on whether to seek a partner to market our drug products in a particular country. Litigation, interferences, oppositions, inter partes reviews, administrative challenges or other similar types of proceedings are, have been and may in the future be necessary to determine the validity and scope of certain of our proprietary~~

rights. Such proceedings may also be necessary to determine the validity, scope or non- infringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our drug products. We may also face challenges to our patent and regulatory protections covering our product candidates by third parties. Litigation, interference, oppositions, inter partes reviews, administrative challenges or other similar types of proceedings are unpredictable and may be protracted, expensive and distracting to management. The outcome of such proceedings could adversely affect the validity and scope of our patent or other proprietary rights, hinder our ability to manufacture and market our drug products, require us to seek a license for the infringed product or technology or result in the assessment of significant monetary damages against us that may exceed amounts, if any, accrued in our financial statements. An adverse determination in a judicial or administrative proceeding or a failure to obtain necessary licenses could prevent us from developing, manufacturing or selling our product candidates. Furthermore, payments under any licenses that we are able to obtain would reduce our profits derived from the covered products and services. We have in- licensed rights to certain patents that cover our FPC products. If we fail to remain in compliance with these license agreements, we could forfeit the rights to these patents, which could negatively impact our partners' ability to commercialize our products and our ability product candidates. We have acquired rights to certain patents under license agreements, including from an affiliate of Dr. Ajay Gupta, our former Chief Scientific Officer. These in- licensed patents, if granted, cover Triferic AVNU and have other claims that could cover Triferic and other product candidates. If we fail to remain in compliance with the terms of these license agreements, including due diligence obligations relating to our efforts to develop and commercialize licensed products in certain markets, we could be found to be in breach of these license agreements. If this was to happen, the licensor could terminate the license agreement in certain circumstances, causing us to forfeit our rights to the licensed patents. This could cause us to lose the ability to sell certain products, including Triferic and Triferic AVNU, and could potentially subject us to expensive and protracted litigation. Any of these occurrences could significantly harm our results of operations and future prospects. RISKS RELATED TO REGULATORY APPROVALS Current and future legislation may increase the difficulty and cost for us, and any collaborators, to obtain marketing approval of and commercialize our drug candidates and affect the prices we, or they, may obtain. Heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. We expect that additional state and federal healthcare reform measures will be adopted in the future, particularly in light of the new presidential administration, any of which could limit the amounts that federal and state governments will pay for healthcare therapies, which could result in reduced demand for our product candidates or additional pricing pressures. Most recently, on August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022 (" IRA "), which, among other provisions, included several measures intended to lower the cost of prescription drugs and related healthcare reforms. We cannot be sure whether additional legislation or rule making related to the IRA will be issued or enacted, or what impact, if any, such changes will have on the profitability of any of our drug candidates, if approved for commercial use, in the future. The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time- consuming and inherently unpredictable. Our inability to obtain regulatory approval for our FPC pipeline product candidates would limit our prospects and harm the long term viability of our drug portfolio. We do not expect our FPC pipeline product candidates to be commercially available for several years, if at all. Our future product candidates will be subject to strict regulation by regulatory authorities in the United States and in other countries. The time required to obtain approval from the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities, which may, among other things, interpret data differently. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate' s development and may vary among jurisdictions. It is possible that none of our FPC pipeline product candidates will ever obtain regulatory approval. Our future product candidates could fail to receive regulatory approval from the FDA or comparable foreign regulatory authorities for many reasons. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post- marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of the product candidate. Even if we obtain regulatory approval for one of our FPC pipeline product candidates, it would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post- market information. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP, regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall, withdrawal of the product from the market, suspension of manufacturing or other actions. Even if our FPC pipeline product candidates receive regulatory approval, they may still face future reimbursement challenges. If approved, reimbursement of our FPC pipeline product candidates by Medicare and commercial payers will be integral to their ability to be a commercial success. While we attempt to incorporate factors such as marketing strategy and payer reimbursement into our clinical trial decision making, these decisions must be balanced against the time and resources required to demonstrate a benefit, the increased complexity of development and manufacturing and the potential delays to approval of the lead indication. While we try to plan clinical trials appropriately to foresee such challenges, there is no guarantee that unexpected or unforeseen issues will not arise. Furthermore, pricing and reimbursement of pharmaceutical products is subject to intense political scrutiny

~~and the reimbursement understandings that we currently have now may be modified or rendered obsolete by the time the FPC pipeline product candidate could potentially receive regulatory approval. Such modifications could change the commercial viability of marketing the FPC pipeline product candidate which would have an effect upon the value of our drug product portfolio. There is also a risk our FPC pipeline product candidates, even if successfully developed, approved and reimbursed, will not be acceptable to or adopted by the market. Factors that may impact market adoption may include competition, health economic value of FPC versus alternative therapeutic approaches, usability, or suitability of the product for providers. RISKS RELATED TO CLINICAL TRIALS Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes, and the results of prior preclinical or clinical trials are not necessarily predictive of our future results. Future FPC pipeline product candidates will be subject to rigorous and extensive clinical trials and extensive regulatory approval processes implemented by the FDA and comparable foreign regulatory authorities before obtaining marketing approval from these regulatory authorities. The drug development and approval process is lengthy and expensive, and approval is never certain. Investigational new drugs may not prove to be safe and effective in clinical trials. We have no direct experience as a company in conducting later stage clinical trials required to obtain regulatory approval in the disease states in which we are currently investigating FPC pipeline product candidates. We may be unable to conduct clinical trials at preferred sites, enlist clinical investigators, enroll sufficient numbers of participants or begin or successfully complete clinical trials in a timely fashion, if at all. We may experience delays in clinical trials due to FDA requirements or otherwise, and may face administrative challenges or limitations when conducting clinical trials. In addition, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and execute a clinical trial to support regulatory approval. Even if a current clinical trial is successful, participants may experience undesirable side effects or the candidate may demonstrate a lack of efficacy, so that the clinical trial may be insufficient to demonstrate that our product candidates are safe or effective for registration purposes. There is a high failure rate for drugs and biologic products proceeding through clinical trials. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of FPC pipeline product candidates may not be predictive of the results of later- stage clinical studies or trials and the results of studies or trials in one set of patients or line of treatment may not be predictive of those obtained in another. In fact, many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late- stage clinical trials even after achieving promising results in preclinical studies and earlier stage clinical trials. In addition, data obtained from preclinical and clinical activities is subject to varying interpretations, which may delay, limit or prevent regulatory approval. It is impossible to predict when or if our future product candidates will prove effective or safe in humans in the disease states that we will be conducting the clinical trials or that they will receive regulatory approval. FPC pipeline product candidates may not demonstrate in patients the biochemical and pharmacological properties we anticipate based on laboratory studies or earlier stage clinical trials, and they may interact with human biological systems or other drugs in unforeseen, ineffective or harmful ways. The number of patients exposed to product candidates and the average exposure time in the clinical development programs may be inadequate to detect rare adverse events or findings that may only be detected once a product candidate is administered to more patients and for greater periods of time. If we are unable to successfully demonstrate the safety and efficacy of FPC pipeline product candidates in these disease states and are unable to receive the necessary regulatory approvals, our drug product portfolio could be harmed. RISKS RELATED TO~~ LEGAL AND REGULATORY Our ~~drug and concentrate businesses are highly regulated, resulting in additional expense and risk of noncompliance that can materially and adversely affect our~~ business **is** ~~, results of operations, financial position and cash flows. Our businesses are~~ highly regulated. The testing, manufacture, sale and delivery of the products we manufacture directly or through third party CMOs are subject to extensive regulation by the FDA and by other federal, state and foreign authorities, including, with respect to our transportation operations, the U. S. Department of Transportation. Before ~~drug product candidates or~~ medical devices, such as our concentrate products, can be commercially marketed in the United States, the FDA must give either premarket approval or 510 (k) clearance. After a product is approved, regulatory authorities may impose significant restrictions on a product' s indicated uses or marketing or requirements for potentially costly post- marketing studies. In addition, manufacturers and their facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to current cGMP and applicable state laws. As such, we and our CMOs are subject to continual review and periodic inspections to assess compliance with cGMP and state laws. For example, **in 2023,** the FDA conducted a routine GMP inspection of one of our manufacturing facilities and issued Form FDA- 483 report with ~~four~~ **one** ~~observations~~ **observation** ~~, for which the inspector classified Voluntary Action Indicated~~. The Company **performed** ~~submitted a voluntary~~ corrective ~~action~~ **actions and resolved** ~~plan, to which~~ the **issue** ~~FDA replied~~. While ~~none of~~ the ~~findings~~ **finding** ~~were~~ **was not** serious, management time and effort **was expended** ~~will be necessary~~ for the correction ~~and the FDA response~~. Accordingly, we and our partners must continue to expend time, money and effort in all areas to achieve and maintain regulatory compliance. We are also required to report certain adverse reactions and production problems, if any, to applicable regulatory authorities ~~and to comply with requirements concerning advertising and promotion for our drug products or product candidates~~. If non- compliant inventory is sold or if a regulatory agency determines that we are not compliant with any applicable regulatory requirements, we may be subject to warnings from, or enforcement action by, state and federal government authorities, which may include penalties, fines, injunctions, recall or seizure of products, suspension of production, denial of future regulatory approvals, withdrawal or suspension of existing regulatory approvals, operating restrictions, injunctions and criminal prosecution. If regulatory sanctions are applied, the value of our Company and our operating results could be materially and adversely affected. For example, such actions could cause our customers to doubt the safety or efficacy of our products, which could adversely impact our business. Even a voluntary Class III recall, which is a recall of products for a defect that is unlikely to result in adverse health consequences, can have an adverse impact on the Company due to the costs of the recall or the reactions of customers. ~~We~~

~~recently conducted a Class III recall in our concentrates business due to the degradation of secondary seals on some of our bottles of concentrates, which consumed management time and effort. Further, in our discussions with the FDA, the FDA has indicated that it believes our recall, though completed, should be recharacterized as a Class II recall. Our business could also be adversely affected by delays in obtaining necessary regulatory approvals and any restrictions placed by the FDA on our intended marketing or the use of our drug product candidates.~~ Our failure to comply with applicable regulations could also result in product liability litigation against us. In addition, our failure to comply with applicable regulations with respect to our ~~concentrate~~ **concentrates** products could constitute a breach of our Products Purchase Agreement, providing DaVita with various remedies that would be material and adverse to us. Moreover, changes in applicable regulatory requirements could significantly increase the costs of our operations, which **we may not be able to recover under** ~~numerous commercial disputes,claims,lawsuits and / or~~ **our** ~~investigations~~ **fixed price contracts** .Operating in the medical device and pharmaceutical industries involves numerous commercial relationships,complex contractual arrangements,uncertain intellectual property rights,potential product liability and other aspects that create heightened risks of disputes,claims,lawsuits and investigations.In particular,we may face claims related to the safety of our products,intellectual property matters,employment matters,tax matters,commercial disputes,competition,sales and marketing practices,environmental matters,personal injury,insurance coverage and acquisition or divestiture - related matters.A counterparty may assert claims that we do not believe are meritorious,but we nonetheless need to defend.In addition,any commercial dispute,claim,lawsuit or investigation may divert our management' s attention away from our business,we may incur significant expenses in addressing or defending any commercial dispute,claim or lawsuit or responding to any investigation,and we may be required to pay damage awards or settlements or become subject to equitable remedies that could adversely affect our operations and financial results.We may become the target of litigation,which is costly and time- consuming to defend.We have in the past been subject to litigation and it is possible that legal proceedings could be brought against us in the future based upon decisions we make regarding our strategy or otherwise.Litigation can be costly and time- consuming **,** and the results of complex legal proceedings are difficult to predict.These lawsuits assert types of claims that ~~,if~~ , if **resolved against us** ~~such higher costs result in cost increases that we cannot recoup or that price increases exceed the thresholds specified in the Products Purchase Agreement~~ , could give ~~DaVita~~ **rise to substantial damages, and an unfavorable outcome or settlement of** ~~the~~ **these** ~~right~~ **lawsuits, or any future lawsuits, could have a material adverse effect on our business, financial condition, results of operations and / or stock price. Even if any future lawsuits are not resolved against us, the costs of defending such lawsuits may be material** to ~~terminate~~ **our business and our operations. Moreover, these lawsuits may divert our Board and our management' s attention from the operation of our business** . Our ~~product candidates and drug~~ products may have **or have had** undesirable side effects **,** and our product liability insurance may not be sufficient to protect us from material liability or harm to our business. **We sell hemodialysis concentrates that are used in dialysis procedures in the United States and foreign countries. In addition, prior to its discontinuation, we marketed and sold Triferic in the United States for four years and prior to that, engaged in clinical trials to support the submission of the NDA for approval. Our international partners continue to market and sell Triferic in foreign countries.** If **patients experience** ~~concerns are raised regarding the safety of a product candidate as a result of undesirable~~ side effects **from** ~~identified during clinical testing,~~ the **use** ~~FDA may decline to approve the product candidate at the end~~ of ~~the NDA review period or~~ **our hemodialysis concentrates** ~~issue a letter requesting additional data~~ or ~~information prior to making a final decision regarding whether or~~ **from Triferic and the statutes of limitation and repose have** not **expired** ~~to approve the product candidate. Following FDA approval~~ , **such** ~~if we or others later identify previously unknown undesirable~~ side effects ~~caused by our product candidate or concentrate products, if known side effects are more frequent or severe than in the past, or if we or others detect unexpected safety signals for such products or any products perceived to be similar to such products, the FDA or other applicable regulatory authorities~~ may ~~require the addition of unfavorable labeling statements, specific warnings or contraindications, may suspend or withdraw their approval of the product, may require it to be removed from the market or may impose restrictions on the distribution or use of the product. Such side effects may also~~ result in litigation against us by private litigants. ~~We~~ **Although we** maintain product liability insurance ~~. We~~ **, we** cannot be sure that such insurance would be sufficient to protect us against liabilities associated with any of these events in view of our expanding business **or otherwise,** or that such insurance will remain available at economical levels. We may have significant legal expenses that are not covered by insurance. In addition, our reputation could be damaged by such sanctions or product liability litigation and that could harm our business reputation and marketing ability. Any such sanctions or litigation could also hurt our ability to retain product liability insurance or make such insurance more expensive. In any such event, our business, results of operations, financial position and cash flows could be materially adversely affected. We could be found to be infringing intellectual property rights of third parties, which could prevent us from selling products and could require us to pay significant damages and compel us to defend against litigation. We may be subject to claims that our employees or directors have wrongfully used or disclosed alleged trade secrets of their former employers. It is possible that we may infringe on intellectual property rights of others without being aware of the infringement. If a third party believes that one of our ~~drug~~ products ~~or product candidates~~ infringes on the third party' s patent, it may sue us even if we have received our own patent protection for the technology. If we infringe the rights of a third party, we could be prevented from manufacturing and selling products, forced to pay damages, compelled to license technology from the party claiming infringement and lose the opportunity to license our technology to others and collect royalty payments, any of which could have a material adverse effect on our business. If we are prevented from selling any of our concentrate or ancillary products due to a patent infringement or if our ability to sell any of our concentrate or ancillary products due to a patent infringement is materially and adversely affected, DaVita may be entitled to terminate our Products Purchase Agreement. As is common in the medical device, biotechnology and pharmaceutical industry, we engage the services of consultants to assist us in the development of our ~~drug~~ products ~~and product candidates~~ . Many of these consultants were previously employed at, may have previously been, or are currently providing

consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. As such, the Company advises consultants not to disclose, or use trade secrets, or proprietary information of their former employers or their former or current customers. Although no claims against us are currently pending, we may be subject to claims that these consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. 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 be a distraction to management and day- to- day business operations. Many of our employees and certain of our directors were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and directors do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or these employees or directors have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee' s or director' s former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. Our business operations may subject us to numerous commercial..... operation of our business. Our business could be impacted as a result of actions by activist stockholders, including as a result of a potential proxy contest for the election of directors at our annual meeting. **We were** ~~The Company was~~ subjected to a proxy contest at ~~the~~ **our** 2017 Annual Meeting of Stockholders, which resulted in the negotiation of changes to the Board and the incurrence of substantial costs. A future proxy contest would require us to incur significant legal fees and proxy solicitation expenses and require significant time and attention by management and the Board. The potential of a proxy contest could interfere with our ability to execute our strategic plan, give rise to perceived uncertainties as to our future direction, adversely affect our relationships with customers, suppliers, investors, prospective and current team members and others, result in the loss of potential business opportunities or make it more difficult to attract and retain qualified personnel, any of which could materially and adversely affect our business and operating results. We may also be subject, from time to time, to other legal and business challenges in the operation of our company due to actions instituted by activist stockholders. Responding to such actions, which may include publicity campaigns and, potentially, litigation, could be costly and time-consuming, divert the time and attention of our Board and management from our business, interfere with our ability to execute our strategic plan, give rise to perceived uncertainties as to our future direction, adversely impact our lobbying efforts, adversely affect our relationships with customers, suppliers, prospective and current team members and others, result in the loss of potential business opportunities or make it more difficult to attract and retain qualified personnel, any of which could materially and adversely affect our business and operating results. We cannot predict, and no assurances can be given as to, the outcome or timing of any matters relating to actions by activist stockholders or the ultimate impact on our business, results of operations, financial position and cash flows. RISKS RELATED TO OUR COMMON STOCK The market price of our common stock has fluctuated in the past, and is likely to continue to be volatile, which could subject us to litigation. The market price of our common stock has fluctuated and is likely to be subject to further wide fluctuations in response to numerous factors, many of which are beyond our control, such as those in this " Risk Factors " section and others including: • the reporting of sales, operating results and cash resources; • announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments; • the entry into, or termination of, key agreements, including key commercial partner agreements; • changes in the structure of healthcare payment systems; • the loss of key employees; • changes in estimates or recommendations by securities analysts, if any, who cover our common stock; • ~~our ability to obtain regulatory approvals for our product candidates, and delays or failures to obtain such approvals; • failure of any of our product candidates, if approved, to achieve commercial success; •~~ issues in manufacturing our ~~device~~ products ~~or product candidates; • the results of any future clinical trials of our product candidates~~; • the initiation of, material developments in, or conclusion of litigation to enforce or defend any of our intellectual property rights or defend against the intellectual property rights of others; and • the introduction of technological innovations or new therapies that compete with our products ~~or product candidates~~. In addition, third parties may engage in trading strategies that result in intentional volatility to and control over our stock price. Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. In the past, following periods of volatility in the market price of a company' s securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation. Shares eligible for future sale may affect the market price of our common stock. Any future sales by us of substantial amounts of our common stock, or the possibility of such sales, could adversely affect the market price of our common stock and also impair our ability to raise capital through an offering of our equity securities in the future. In the future, we may issue additional shares or warrants in connection with investments or for other purposes considered advisable by our Board ~~of Directors~~. Any substantial sale of our common stock may have an adverse effect on the market price of our common stock and may dilute the economic value and voting rights of existing stockholders. In addition, as of December 31, ~~2022~~ **2023**, there were ~~243~~ **361**, ~~088~~ **531** shares issuable upon the exercise of then- outstanding and exercisable stock options, ~~963~~ **967**, ~~817~~ **090** shares issuable upon the exercise of then- outstanding stock options that were not yet exercisable, and ~~16~~ **3**, ~~200~~ **793**, ~~990~~ **000** shares issuable upon the exercise of then- outstanding and exercisable warrants. The market price of the common stock may be depressed by the potential exercise of these options **and warrants and the sale of the underlying common stock**. The holders of these options **and warrants** are likely to exercise them when we would otherwise be able to obtain additional capital on more favorable terms than those provided by the options **and warrants**. We may fail to qualify for continued listing on Nasdaq, which could make it more difficult for our stockholders to sell their shares. We are required to satisfy the continued

listing requirements of Nasdaq to maintain such listing, including, among other things, the maintenance of a minimum closing bid price of $ 1. 00 per share. **In** ~~On June 11,~~ 2021, we received a notice from Nasdaq that we were not in compliance with the minimum bid price requirements set forth in Nasdaq Listing Rule 5450 (a) (1) for continued listing on The Nasdaq Global Market and were unable to regain compliance in the time allotted by Nasdaq. As a result, we moved our listing to The Nasdaq Capital Market and effected an 11- for- 1 reverse stock split in May 2022 to regain compliance. While we have been in compliance with the minimum closing bid price requirement since that time, there can be no assurance that we will be able to maintain compliance with the minimum bid price requirement going forward. If our common stock were delisted by Nasdaq, we could face significant material adverse consequences, including: • a limited availability of market quotations for our common stock; • reduced liquidity with respect to our common stock; • a determination that our shares are " penny stock, " which will require brokers trading in our shares to adhere to more stringent shares, and which may limit demand for our common stock among certain investors; • a limited amount of news and analyst coverage for our company; and • a decreased ability to issue additional securities or obtain additional financing in the future. Our ability to use our net operating loss carryforwards to offset potential taxable income and related income taxes that would otherwise be due may be limited. We have substantial net operating loss carryforwards (" NOLs") available to reduce future taxable income. Our ability to use our NOLs to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income before the expiration dates of the NOLs. In addition to uncertainty regarding our future profitability, our use of the NOLs may be subject to annual limitations under the " ownership change " provisions of Section 382 of the Internal Revenue Code of 1986, as amended, which may result in the expiration of some or all of the NOLs before they can be used. In general, an " ownership change " occurs if, during a rolling three- year period, there is a greater than 50 % change in the percentage ownership of the corporation by 5 % owners (and persons treated as 5 % owners), as defined in Section 382 and related regulations. We may experience an ownership change in the future as a result of future changes in our stock ownership. The inability to use our NOLs to reduce federal taxable income could result in increased future tax liability to us and reduce the cash that would otherwise be available to our business. We do not anticipate paying dividends in the foreseeable future. Since inception, we have not paid any cash dividend on our common stock and do not anticipate paying such dividends in the foreseeable future. The payment of dividends is within the discretion of our Board of Directors and depends upon our earnings, capital requirements, financial condition and requirements, future prospects, restrictions in future financing agreements, business conditions and other factors deemed relevant by the Board. We intend to retain earnings and any cash resources to finance our operations. Therefore, it is highly unlikely we will pay cash dividends. If securities analysts do not publish research or reports about our business, or if they publish negative evaluations, the price of our common stock could decline. The trading market for our common stock may be impacted by the availability or lack of research and reports that third- party industry or financial analysts publish about **us** ~~the Company~~. There are many large, publicly traded companies active in the medical device and biopharmaceutical industry, which may mean it will be less likely that we receive widespread analyst coverage. Furthermore, if one or more of the analysts who do cover **us** ~~the Company~~ downgrade our stock, our stock price would likely decline. If we do not receive adequate coverage by reputable analysts that have an understanding of our business and industry, we could fail to achieve visibility in the market, which in turn could cause our stock price to decline. GENERAL RISK FACTORS Our business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises **, political crises, geopolitical events,** such as the ~~COVID- 19 pandemic, political crises, geopolitical events, such as the~~ crisis in Ukraine **and the Middle East** , or other macroeconomic conditions, which could have a material and adverse effect on our results of operations and financial condition. The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates, and uncertainty about economic stability ~~. For example, the COVID- 19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets~~. 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~~ **and the conflict in the Middle East have** created extreme volatility in the global capital markets and may have further global economic consequences, including disruptions of the global supply chain. 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, including as a result of political unrest or war, it may make any necessary debt or equity financing more costly, more dilutive, or more difficult to obtain in a timely manner or on favorable terms, if at all. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs. We have experienced and may in the future experience disruptions as a result of such macroeconomic conditions **and the occurrence of natural disasters and public health crises** , including delays or difficulties in manufacturing sufficient quantities of materials. If we fail to maintain inventory or deliver product as a result of such delays or difficulties, we could breach the requirement in our Products Purchase Agreement with DaVita to maintain safety stock and maintain transportation and other services, which would allow DaVita to exercise various remedies under such agreement. Any one or a combination of these events could have a material and adverse effect on our results of operations and financial condition. Our certificate of incorporation, bylaws and Delaware law could prevent a third party from acquiring us (even if an acquisition would benefit our stockholders), may limit the ability of our stockholders to replace our management and limit the price that investors might be willing to pay for shares of our common stock. Our certificate of incorporation and bylaws could have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, control of us. These provisions could delay or prevent a change in control of the company and could limit the price that investors might be willing to pay in the future for shares of our common stock. These provisions, among other things: • establish a staggered ~~board~~ **Board of directors** ~~of directors~~ divided into three classes serving

staggered three- year terms, such that not all members of the board will be elected at one time; • authorize our ~~board~~ **Board** ~~of directors~~ to issue new series of preferred stock without stockholder approval and create, subject to applicable law, a series of preferred stock with preferential rights to dividends or our assets upon liquidation, or with superior voting rights to our existing common stock; • disallow our stockholders to fill vacancies on our board ~~of directors~~; • establish advance notice requirements for nominations for election to our ~~board~~ **Board** ~~of directors~~ or for proposing matters that can be acted upon by stockholders at our annual stockholder meetings; • permit our ~~board~~ **Board** ~~of directors~~ to establish the number of directors between three and fifteen; • provide that stockholders can remove directors only for cause and only upon the approval of not less than a majority of all outstanding shares of our voting stock; • require the approval of not less than a majority of all outstanding shares of our voting stock to amend our bylaws and specific provisions of our certificate of incorporation; and • limit the jurisdictions in which certain stockholder litigation may be brought. We are not subject to the provisions of Section 203 of the Delaware General Corporation Law, which could negatively affect your investment. We elected in our certificate of incorporation to not be subject to the provisions of Section 203 of the Delaware General Corporation Law (" Section 203 "). In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a " business combination " with an " interested stockholder " for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. A " business combination " includes a merger, asset sale or other transaction resulting in a financial benefit to the interested stockholder. An " interested stockholder " is a person who, together with affiliates and associates, owns (or, in certain cases, within three years prior, did own) 15 % or more of the corporation' s voting stock. This may make us more vulnerable to takeovers that are completed without the approval of our Board ~~of Directors~~ and / or without giving us the ability to prohibit or delay such takeovers as effectively. Our certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our certificate of incorporation provides that the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another state court or a federal court located within the State of Delaware) is the exclusive forum for any claims that are based upon a violation of a duty by a current or former director, officer, employee or stockholder in such capacity, or as to which the Delaware General Corporation Law confers jurisdiction upon the Court of Chancery. This provision would not apply to claims brought to enforce a duty or liability created by the Exchange Act or any have exclusive jurisdiction. This choice of forum provisions may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees. If a court were to find the choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business.