Risk Factors Comparison 2025-03-18 to 2024-02-28 Form: 10-K

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Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading " Risk Factors " and should be carefully considered, together with other information in this Form 10- K and our other filings with the SEC, before making an investment decision regarding our common stock. • ~~We have a history of losses and we may, in the future, need to raise additional capital to operate our business, which may not be available on favorable terms, if at all. •~~ Although we achieved net income on a ~~non-~~ GAAP basis ~~and generated positive cash flows~~ for the year ended December 31, ~~2023~~ **2024** for the first time, we may not be able to ~~achieve~~ **maintain** profitability and **continue to** generate positive cashflows in the future. • We contract with third parties for the filling, packaging, testing and labeling of the drug substance we manufacture **, and we also obtain source plasma from certain third parties** . This reliance on third parties carries the risk that the services **and raw materials** upon which we rely may not be performed in a timely manner **, in sufficient quantities** or according to our specifications, which could delay the availability of our finished drug product and could adversely affect our commercialization efforts and our revenues. • The estimates of market opportunity and forecasts of market and revenue growth included in our filings may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business could fail to grow at similar rates, if at all. • Both of our business segments and our facilities **, as well as our suppliers and contractors,** are subject to periodic inspections by the FDA **and other regulatory authorities** , which, depending on the outcome of such inspections, could result in certain ~~FDA~~ **regulatory** actions, including the issuance of observations, notices, citations, warning letters or other enforcement actions. • Business interruptions could adversely affect our business. • Although we have received approval from the FDA to market ASCENIV as a treatment for PIDD, our ability to market or seek approval for ASCENIV for alternative indications could be limited ~~and FDA could require clinical trials beyond what we may deem to be reasonable. Unless~~ **unless** additional clinical trials are **conducted** successfully ~~conducted~~ and the FDA approves a **Biologics License Application (" BLA ")** or other required submission for review ~~, we may not be authorized to market ASCENIV for any other indication~~ . • With the approval **of** ~~to market~~ ASCENIV ~~, BIVIGAM and Nabi- HB~~ , there can be no assurance that we will be successful in further developing and expanding commercial operations **, collecting and procuring an adequate supply of high- titer antibody RSV plasma** or balancing our research and development activities with our commercialization activities. • We depend on third- party researchers, developers and vendors to develop, manufacture, supply materials for or test our products and product candidates, **as well as for other pre- and post- approval services,** and such parties ~~are~~ **' performance is, to some extent,** outside of our control. • We may be unable to successfully expand our manufacturing processes to fulfill demand for our products or increase our production capabilities through the addition of new equipment, including if we do not obtain requisite approval from the FDA. • Our products, and any additional products for which we may obtain marketing approval in the future, could be subject to post- marketing restrictions or withdrawal from the market and we could be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products following approval. • Historically, a few customers have accounted for a significant amount of our total revenue and accounts receivable and the loss of any of these customers could have a material adverse effect on our business, results of operations and financial condition. • Issues with product quality and compliance could have a material adverse effect upon our business, subject us to regulatory actions and cause a loss of customer confidence in us or our products. • If physicians, payers and patients do not accept and use our current products or our future product candidates, our ability to generate revenue from these products will be materially impaired. • Our **accruals for U. S. Medicaid rebates and other liabilities related to the sale of our immunoglobulin products are estimates based on historical experience and other assumptions. These estimates are subject to change based on actual results and other factors. Any such change could have a material effect on our business, financial position and operating results. • Our** long- term success may depend on our ability to supplement our existing product portfolio through new product development or the in- license or acquisition of other new products, product candidates and label expansion of existing products, and if our business development efforts are not successful, our ability to ~~achieve~~ **maintain** profitability may be adversely impacted. • Our ADMA BioCenters operations collect information from donors in the **United States** ~~U. S.~~ that subjects us to consumer and health privacy laws, which could create enforcement and litigation exposure if we fail to meet their requirements. • Our senior secured credit facility with Ares Capital Corporation and certain of its affiliates (" Ares ") is subject to acceleration in specified circumstances, which may result in Ares taking possession and disposing of any collateral. • If we are unable to protect our patents, trade secrets or other proprietary rights, if our patents are challenged or if our provisional patent applications do not get approved, our competitiveness and business prospects may be materially damaged. • Cyberattacks and other security breaches could compromise our proprietary and confidential information **or otherwise penetrate our network** , which could harm our business and reputation. • Our ability to continue to produce safe and effective products depends on the safety of our plasma supply, testing by third parties and the timing of receiving the testing results, and the manufacturing processes we have in place to counter transmittable diseases. • We could become supply- constrained and our financial performance would suffer if we cannot obtain adequate quantities of FDA- approved source **and high- titer** plasma with proper specifications or other necessary raw materials **. • Our ability to use our net operating loss carryforwards (" NOLs ") may be limited. • Fluctuations in our tax obligations and effective tax rate and realization of our net deferred tax assets may result in volatility of our operating results and materially impact our financial condition or financial results** . • The market price of

our common stock may be volatile and may fluctuate in a way that is disproportionate to our operating performance. Described below are various risks and uncertainties that may affect our business. These risks and uncertainties are not the only ones we face. You should recognize that other significant risks and uncertainties may arise in the future, which we cannot foresee at this time. Also, the risks that we now foresee might affect us to a greater or different degree than expected. Certain risks and uncertainties, including ones that we currently deem immaterial or that are similar to those faced by other companies in our industry or business in general, may also affect our business. If any of the risks described below actually occur, our business, financial condition or results of operations could be materially and adversely affected. You should carefully consider the following risk factors and the section entitled " Special Note Regarding Forward- Looking Statements " before you decide to invest in our securities. Risks Relating to our Business ~~To date, we have a history of losses and have historically needed to raise, and in the future may be required to raise, additional capital to operate our business. Our long- term liquidity depends upon our ability to grow our commercial programs, expand our commercial operations at the Boca Facility, improve our supply- chain capabilities, improve production yields, continue to build out our commercial infrastructure and meet our ongoing obligations. In addition, our end- to- end production cycle from procurement of raw materials to commercial release of finished product can take between seven and 12 months or potentially longer, requiring substantial investments in raw material plasma and other manufacturing materials. We currently anticipate, based upon our projected revenue and expenditures, that our current cash, cash equivalents and accounts receivable, along with our projected future operating cash flow, will be sufficient to fund our operations, as currently conducted, through the end of the first quarter of fiscal 2025. However, our current outlook on cash flows and profitability may change based upon how quickly we are able to execute on our commercialization efforts and operational initiatives and whether or not the assumptions underlying our projected revenues and expenses are correct.~~ Although we achieved net income on a ~~non-~~ GAAP basis ~~(see " Non- GAAP Financial Measures " within Management' s Discussion and Analysis of Financial Condition and Results of Operations) and positive cash flow from operations for the first time in our history~~ for the year ended December 31, ~~2023, at present we cannot be certain that we will be able to generate a sufficient amount of product revenue to maintain profitability through~~ 2024 ~~and beyond. If we are unable to generate sufficient positive cash flow throughout 2024 and cannot raise additional capital if needed, we may have to delay, curtail or~~ **for** ~~eliminate our commercialization efforts and product development activities. Even if we are able to raise additional capital, such equity or debt financings may only be available on unattractive terms, resulting in significant dilution of stockholders' interests and, in such event,~~ the **first time** ~~value and potential future market price of our common stock may decline. In addition~~ , ~~if~~ we ~~raise additional funds through license arrangements or through the disposition of any of our assets, it may be necessary to relinquish potentially valuable rights to our product candidates or assets or grant licenses on terms that are not favorable to us. Historically, the major source of our cash has been from proceeds from various public offerings of our common stock and debt transactions. The actual amount of additional cash that we may need, if any, is subject to many factors. There can be no assurances that additional financing will be available if needed or that management will be able to obtain financing on terms acceptable to us or that we will continue to be profitable and generate positive operating cash flow. We~~ may not be able to ~~achieve~~ **maintain** profitability **andcontinue to generate positive cash flows** in **the future** ~~2024 and beyond~~ . We have a history of losses through December 31, 2023, and we may not be able to ~~achieve~~ **maintain** profitability. ~~For~~ **Although we achieved net income of $ 197. 7 million for the year ended December 31, 2024, for** the years ended December 31, 2023 ~~,~~ **and** 2022 ~~and 2021~~ , we incurred net losses of $ 28. 2 million ~~,~~ **and** $ 65. 9 ~~million and $ 71. 6~~ million, respectively. From our inception in 2004 through December 31, ~~2023~~ **2024** , we have incurred an accumulated deficit of $ ~~506~~ **308** . ~~3~~ **6** million. We may not be able to **maintain** ~~generate a sufficient amount of product revenue to achieve~~ profitability ~~throughout~~ **in** ~~2024~~ **2025 or beyond** , and if we are unable to continue to ~~generate~~ **consistently achieve** positive cash ~~flow~~ **flows** we may need ~~to continue~~ to finance our operations through additional equity or debt financings or corporate collaboration and licensing agreements **. If, in the future, our operating or financial results for a particular period do not meet our guidance, analyst estimates or the expectations of investors, or if we reduce our guidance for future periods, our stock price may decline. Any sustained or increased profitability or financial performance may contribute to increased scrutiny from the investment community and applicable federal, state and foreign regulatory authorities and government bodies** . We also expect to continue to incur significant operating and capital expenditures and anticipate that as our business continues to grow our operating expenses will increase accordingly as we: • expand commercialization and marketing efforts **; • expand our research and development programs** ; • implement additional internal systems, controls and infrastructure; • hire additional personnel; and • expand production capacity at the Boca Facility. As a result, we will need **to continue** to generate significant revenues in order to maintain profitability. We may not be able to generate these revenues or maintain profitability in the future. Pandemics, or a resurgence of a pandemic, may adversely affect our business, financial condition, liquidity or results of operations. The COVID- 19 pandemic negatively impacted certain aspects of our business and operations. The resurgence of the COVID- 19 pandemic, or a future pandemic or health epidemic, could adversely affect our business, financial condition, liquidity or results of operations. These adverse effects include, but are not limited to, the potential adverse effects on the global economy, our manufacturing processes, including our supply chain, our submissions or applications to the FDA and our employees. The ultimate impact will depend on the severity and duration of the pandemic and actions taken by governmental authorities and other third parties in response, each of which is ~~uncertain~~ **unforeseeable** and difficult to predict. We contract with third parties for a portion of the filling, packaging, testing and labeling of the drug substance we manufacture, and also obtain plasma from certain third parties. This reliance on third parties carries the risk that the services **and raw materials** upon which we rely may not be performed in a timely manner, in sufficient quantities or according to our specifications, which could delay the availability of our finished drug product and could adversely affect our commercialization efforts and our revenues. Third parties may not perform as agreed or in accordance with FDA requirements. Any significant problem that our third- party providers experience could delay or interrupt our supply of finished drug product until the service provider cures the problem or

until we locate, negotiate for, validate and receive FDA approval for an alternative provider (when necessary), if one is available. Failure to obtain the needed services **, raw materials** and products meeting the necessary quality standards or at all could have a material and adverse effect on our products, business, financial condition and results from operations. Although we are utilizing our FDA- approved fill / finish suite that we built at the Boca Facility for a portion of our finished drug product and although we receive our raw material plasma from our ADMA BioCenters plasma collection facilities, we also intend to continue to utilize third parties to supplement our fill / finish process for final drug product and to supply raw material source and high- titer RSV plasma. Any failure by us, our contract fill / finishers, or other third parties involved in the process for producing our products or product candidates to comply with the applicable manufacturing and regulatory requirements, including quality requirements, could place us and them at risk of regulatory enforcement actions, recalls and other adverse consequences, could adversely impact our products, and could adversely impact patients receiving our products, which may negatively impact our business and our ability to produce and supply products to meet commercial and clinical needs. Our anticipated reliance on a limited number of third- party ~~manufacturers~~ **contractors** exposes us to the following risks: • we may be unable to identify contractors on acceptable terms or at all because the number of potential service providers is limited and the FDA must inspect and qualify any contract manufacturers for current cGMP compliance as part of our marketing application; • a new fill / finisher would have to be educated in, or develop substantially equivalent processes for, the production of our products and product candidates; • a pandemic, or the resurgence of a pandemic such as the COVID- 19 pandemic, **or a cyberattack or data breach,** could adversely affect our ~~contracted~~ **contractors** ~~fill / finishers~~ ' operations, supply chain or workforce; • our contracted fill / finishers' resources and level of expertise with plasma- derived biologics may be limited, therefore they may require a significant amount of support from us in order to implement and maintain the infrastructure and processes required to deliver our finished drug product; • our third- party contractors might be unable to timely provide finished drug product or raw material plasma in sufficient quantity **or in accordance with our specifications** to meet our commercial needs; • contractors may not be able to execute our inspection procedures and required tests appropriately; • contractors are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations, and we do not have control over third- party providers' compliance with these regulations; • contractors may fail to comply with applicable regulatory requirements, placing them and us at risk of regulatory enforcement actions, recalls and other adverse consequences, and which place our patients at risk, which may negatively impact our business and their ability to supply products to meet our development, clinical and commercial needs; • our third parties could breach or terminate their agreements with us; and • our contract fill / finishers may have unacceptable or inconsistent drug product quality success rates and yields, and we have no direct control over our contract fill / finishers' ability to maintain adequate quality control, quality assurance and qualified personnel. Each of these risks could delay or prevent **production,** the completion of our finished drug product and the release of finished drug product by us or the FDA, which could result in higher costs or adversely impact our revenues. These risks could also result in the delay in obtaining clinical supplies, which would delay our development programs. In addition, our contract fill / finishers and our other third- party vendors may source their materials and supplies globally and are therefore subject to supply disruptions in the event of fire, weather related events such as hurricanes, wind and rain, international conflicts, **strikes, embargoes,** trade and sanction requirements and limits, other acts of God or force majeure events or global health occurrences and emergencies. The estimates of market opportunity and forecasts of market and revenue growth included in our filings may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business could fail to grow at similar rates, if at all. Market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates that may not prove to be accurate. In particular, the size and growth of the overall U. S. IVIG and source plasma markets and the potential market opportunity for an S. ~~pneumonia~~ **pneumoniae** hyperimmune globulin are subject to significant variables that can be difficult to measure, estimate or quantify. **Additionally, we anticipate receiving FDA approval by mid- 2025 for the PAS for our innovative yield enhancement production process, which has demonstrated an ability to increase production yields by approximately 20 % from the same starting plasma volume, potentially driving significant increases to financial targets beginning in the second half of 2025, if approved. Although our financial targets for 2025 and 2026 described in Part 1, Item 1. Business- Overview do not account for the potential FDA approval of our innovative yield enhancement production process, in the event that the FDA does not approve the PAS, or in the event that such approval occurs after mid- 2025, our growth rate may be materially impacted.** Our business depends on, among other things, successful commercialization of our existing products, market acceptance of such products and ensuring that our products are safe and effective. Further, there can be no assurance that we will be able to generate the revenue that we believe our products and plasma collection facilities are capable of generating. As a result, we may not be able to accurately forecast or predict revenue. For these reasons, the estimates and forecasts in our filings relating to revenue generation and growth may prove to be inaccurate. Even if the markets in which we compete meet our size estimates and forecasted growth, our business could fail to grow at similar rates, if at all. Geopolitical **and economic** conditions, war, terrorism or other military actions may have a material adverse effect on our business. Geopolitical conflicts, war or other military action or international acts of terrorism may cause significant disruption to commerce throughout the world. To the extent that such disruptions result in disruptions to our supply chain, delays or cancellations of customer orders, a general decrease in consumer spending, our inability to effectively market and distribute our products and / or our inability to access the capital markets, our business and results of operations could be materially and adversely affected. For example, in response to the ongoing conflict between Russia and Ukraine, the United States has imposed and may further impose, and other countries may additionally impose, broad sanctions or other restrictive actions against governmental and other entities in Russia. Additionally, further escalation of geopolitical tensions, such as ongoing conflicts in the Middle East and the surrounding areas could have a broader impact that extends into other markets where we do business. **Additionally, rapid changes in U. S. trade policy, such as the imposition of additional tariffs and trade barriers, as well as**

potential retaliatory measures taken by other governments, could increase the price of and / or affect the availability of imported raw materials used in the production of our products. We are unable to predict **whether** geopolitical **or economic** conditions, ~~whether~~ acts of international terrorism or the involvement in a war or other military actions will result in any long-term commercial disruptions or if such involvement or responses will have any long- term material adverse effect on our business, results of operations, or financial condition. Both of our business segments and our facilities, as well as our suppliers and contractors, are subject to periodic inspections by the FDA and other regulatory authorities, which, depending on the outcome of such inspections, could result in certain regulatory actions, including the issuance of observations, notices, citations ~~or~~ **,** warning letters **or other enforcement actions** . We and our suppliers and contractors may be unable to comply with our specifications, cGMP requirements and with other FDA, state, and foreign regulatory requirements for commercial and clinical supply. The FDA and other regulatory authorities are authorized to perform inspections and remote regulatory assessments of our and our suppliers' facilities, including the Boca Facility. The FDA and other regulatory authorities also may inspect and approve our and our third- parties' facilities before they may be used for commercial production. If we or our suppliers are not able to comply with the applicable regulatory requirements, we or they may be subject to regulatory enforcement actions, which can materially impact our business. For instance, at the end of such an inspection, the FDA could issue a Form 483 Notice of Inspectional Observations, which could cause the FDA to not approve the use of the facility and cause us to modify certain activities identified during the inspection. Following such inspections, the FDA may issue an untitled letter as an initial correspondence that cites violations that do not meet the threshold of regulatory significance of a warning letter. FDA guidelines also provide for the issuance of warning letters for violations of " regulatory significance " for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action. FDA also may issue warning letters and untitled letters in connection with events or circumstances unrelated to an FDA inspection. Depending on the seriousness of any findings, we or our suppliers may be subject to additional significant enforcement actions which could have a material impact on our business. In the event of any enforcement actions, we and our third- party contractors would need to implement remedial actions which may be time- intensive or costly. We may not be able to timely resolve concerns raised by the applicable regulator as a result of an inspection or without expending significant resources. We are unable to control the timing of inspections, communications and actions, and will be required to respond to the regulator and make certain submissions within certain timeframes. We also do not know whether or not the regulator will change its requirements, guidance or expectations. If the regulator determines that we have not remediated the issues identified in a warning letter or any other inspection issues and deficiencies, any failure of ours to address or provide requested documentation of corrections for these issues could disrupt our business operations and the timing of our commercialization efforts and could have a material adverse effect on our financial condition and operating results. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our commercial manufacturing and any research and development activities involve the use of biological and hazardous materials and produce hazardous waste products. We generally contract with third parties for the disposal of these materials. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption to our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean- up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized internally and by our third- party manufacturers and service providers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and / or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our commercial manufacturing, research and development, or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties, or other sanctions. **Business interruptions could adversely affect our business.** Our operations, including our headquarters located in Ramsey, NJ, the Boca Facility and our plasma collection facilities, are vulnerable to interruption by fire, weather related events such as hurricanes, wind and rain, other acts of God or force majeure events, electric power loss, telecommunications failure, equipment failure **and breakdown** , cyberattacks on our operations and information technology systems **as well as the systems of our customers, suppliers** and ~~breakdown~~ **related entities** , human error, employee issues, global health occurrences such as **a** ~~the COVID- 19~~ pandemic, global and economic uncertainty, war **, terrorism** , geopolitical conditions and emergencies, product liability claims and events beyond our control. While we maintain several insurance policies with reputable carriers that provide partial coverage for a variety of these risks, including replacing or rebuilding a part of our facilities, these policies are subject to the insurance carriers' final determination of compensation to us and we may not have adequate coverage if we need to rebuild or replace our inventory, infrastructure, business income or our entire facility. In addition, our disaster recovery plans for our facilities may not be adequate and we do not have an alternative manufacturing facility or contractual arrangements with other manufacturers in the event of a casualty to or destruction of any of our facilities. If we are required to rebuild or relocate any of our facilities, a substantial investment in improvements and equipment would be necessary. We carry only a limited amount of business interruption insurance, which may not sufficiently compensate us for losses that may occur. As a result, any significant business interruption could adversely affect our business and results of operations. If we are unsuccessful in obtaining regulatory

approval for any of our product candidates or if any of our product candidates do not provide positive results, we may be required to delay or abandon development of such product, which would have a material adverse impact on our business. Product candidates require extensive clinical data analysis and regulatory review and may require additional testing. Clinical trials and data analysis can be very expensive, time- consuming and difficult to design and implement. The conduct of preclinical studies and clinical trials is subject to numerous risks and results of the studies and trials are highly uncertain. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time- consuming. Furthermore, delays or setbacks can occur at any stage of the process, and we could encounter problems that cause us to abandon our product development programs and related ~~INDs~~ **IND applications** or BLAs, or to repeat clinical trials. The commencement and completion of clinical trials or ultimate product approval for any current or future development product candidate may be delayed by several factors, including: • unforeseen safety issues; • determination of dosing issues; • lack of safety or effectiveness, or other adverse study results during clinical trials; • slower than expected rates of patient recruitment or noncompliance with clinical trial requirements; • inability to monitor patients adequately during or after treatment; and • inability or unwillingness of medical investigators to follow our clinical protocols. We cannot be certain as to what type and how many clinical trials the FDA, or equivalent foreign regulatory agencies, will require us to conduct before we may successfully gain approval to market any of our product candidates that still require FDA approval. Prior to approving a new drug or biologic, the FDA generally requires that the effectiveness of the product candidate (which is not typically fully investigated until Phase III) be demonstrated in two adequate and well- controlled clinical trials. However, if the FDA or an equivalent foreign regulatory authority determines that our Phase III clinical trial results do not demonstrate a statistically significant, clinically meaningful benefit with an acceptable safety profile, or if a relevant regulator requires us to conduct additional Phase III clinical trials in order to gain approval, we will incur significant additional development costs and commercialization of these products would be prevented or delayed and our business could be adversely affected. In addition, the FDA or an IRB may not permit us to commence a clinical trial, may require amendments to our clinical trial protocols, or may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA or IRB finds deficiencies in our IND submissions or the conduct of these trials. Regulatory authorities may also not accept data from clinical trials if the trials are not conducted in accordance with the applicable regulatory requirements. Failure to comply with the applicable regulatory requirements may also result in enforcement actions. Therefore, we cannot provide any assurance or predict with certainty the schedule for future clinical trials. In the event we do not ultimately receive regulatory approval for our product candidates, we may be required to terminate development of such product candidates. If we fail to obtain regulatory approval to market and sell our product candidates, or if approval is delayed, we will be unable to generate revenue from the sale of these products, our potential for generating positive cash flow will be diminished and the capital necessary to fund our operations will increase. If the results of our clinical trials do not support our product candidate claims, completing the development of such product candidate may be significantly delayed or we may be forced to abandon development of such product candidate altogether. We cannot be certain that the clinical trial results of our product candidates will support our product candidates' claims. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. This failure would cause us to abandon a product candidate and may delay **the** development of other product candidates. Any delay in, or termination of, our clinical trials will delay our ability to commercialize our product candidates and generate product revenues. Other issues that may impact our clinical trials and that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, include: • Delays in reaching, or failure to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and our **contract research organizations (“** CROs **”)** ; • Regulators requiring us to perform additional or unanticipated clinical trials to obtain approval or becoming subject to additional post- marketing testing, surveillance, or ~~REMS~~ **Risk Evaluation and Mitigation Strategies** requirements to maintain regulatory approval; • Failure by our third- party contractors to comply with regulatory requirements or the clinical trial protocol, or meet their contractual obligations to us in a timely manner, or at all, or our being required to engage in additional clinical trial site monitoring; • The cost of clinical trials of our product candidates being greater than we anticipate ~~or our having insufficient funds for a clinical trial or to pay the substantial user fees required by FDA upon the filing of a marketing application~~ ; • Insufficient supply or inadequate quality of our product candidates or other materials necessary to conduct clinical trials; • Inability to achieve sufficient study enrollment, subjects dropping out or withdrawing from our studies, delays in adding new investigators or clinical trial sites or a withdrawal of clinical trial sites; • Flaws in our clinical trial design that are not discoverable until the clinical trial has progressed; • Disagreement by the FDA or comparable foreign regulatory authorities with our intended indications or study design, including endpoints, or our interpretation of data from preclinical studies and clinical trials, finding that a product candidate' s benefits do not outweigh its safety risks or requiring that we conduct additional development or study work; • The need to make changes to our product candidates that require additional testing or that cause our product candidates to perform differently than expected; • Global trade policies that may impact our ability to obtain raw materials and / or finished product for commercialization; • FDA or comparable regulatory authorities taking longer than we anticipate to make decisions on our products or product candidates; and • Potential inability to demonstrate that a product or product candidate provides an advantage over current standards of care or current or future competitive therapies in development. In addition, our clinical trials involve a relatively small patient population. Because of the small sample size, the results of these clinical trials may not be indicative of future results. In addition, certain portions of our clinical trials and product testing for our product candidates may be performed outside of the **United States** ~~U. S.~~ , and therefore, may not be performed in accordance with standards normally required by the FDA and other regulatory agencies. If we do not obtain and maintain the necessary U. S. or international regulatory approvals to

commercialize a product candidate, we will not be able to sell that product candidate, which would make it difficult for us to recover the costs of researching and developing such product candidate. If we are not able to generate revenue from our products and product candidates, our sources of revenue may continue to be from a product mix consisting only of plasma collection and sales revenues, revenues generated from sales of our FDA- approved commercial products ~~,~~ **and** revenues generated from new contract manufacturing arrangements with third parties ~~and revenues generated from the sales of manufacturing intermediates~~ . We cannot assure you that we will receive the approvals necessary to commercialize any product candidate we may acquire or develop in the future or that we will be able to maintain our current approvals. In order to obtain FDA approval of any product candidate requiring FDA approval, our clinical development must demonstrate that the product candidate is safe for humans and effective for its intended use, and we must successfully complete an FDA BLA review. Obtaining FDA approval of a product candidate generally requires significant research and testing, referred to as preclinical studies, as well as human tests, referred to as clinical trials. Satisfaction of the FDA' s regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in products that the FDA considers safe for humans and effective for indicated uses. The FDA has substantial discretion in the product approval process and may require us to conduct additional preclinical and clinical testing or to perform post- marketing studies or may require additional CMC or other data and information, and the development and provision of this data and information may be time- consuming and expensive. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may: • delay commercialization of, and our ability to derive revenues from, our product candidates; • impose costly procedures on us; and • diminish any competitive advantages that we may otherwise enjoy. Even if we comply with all FDA requests, the FDA may ultimately reject our product candidate' s BLA. In addition, the FDA could determine that we must test additional subjects and / or require that we conduct further studies with more subjects. We may never obtain regulatory approval for any future potential product candidate or label expansion activity. Failure to obtain FDA approval ~~of~~ **for** any of our product candidates will severely undermine our business by leaving us without the ability to generate additional accretive revenues. There is no guarantee that we will ever be able to develop or acquire other product candidates. In foreign jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize any products or product candidates outside the U. S. Foreign regulatory approval processes generally include all of the risks and uncertainties associated with the FDA review, inspection and approval procedures described above. We cannot assure you that we will receive the approvals necessary to commercialize any product candidate for sale outside the **United States** ~~U. S~~ . Although we have received approval from the FDA to market ASCENIV as a treatment for PIDD, our ability to market or seek approval for ASCENIV for alternative indications could be limited, unless additional clinical trials are conducted successfully and the FDA approves a BLA or other required submission for review. The FDA and other governmental authorities strictly regulate and monitor marketing, labeling and the advertising and promotion of prescription drugs. These regulations include standards and restrictions for direct- to- consumer advertising, industry- sponsored scientific and educational activities, promotional activities involving the Internet and off- label promotion. The FDA does not allow drugs to be promoted for " off- label " uses ~~—~~ **-** that is, uses that are not described in the product' s labeling and that differ from those that were approved by the FDA. The FDA limits approved uses to those studied by a company in its clinical trials. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. Although we have received approval from the FDA to market ASCENIV as a treatment for PIDD, we cannot be sure whether we will be able to obtain FDA approval for any desired future indications for ASCENIV. While physicians in the **United States** ~~U. S.~~ may choose, and are generally permitted, to prescribe drugs for uses that are not described in the product' s labeling, and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote our products is narrowly limited to those indications that are specifically approved by the FDA. " Off- label " uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the **United States** ~~U. S.~~ generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off- label use. If the FDA determines that our promotional activities fail to comply with the FDA' s regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines related to promotion and advertising may cause the FDA to issue warning letters or untitled letters, bring an enforcement action against us, suspend or withdraw an approved product from the market, require a recall, require payment of civil fines or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, among other consequences, any of which could harm our reputation and our business. With the approval of ASCENIV, there can be no assurance that we will be successful in further developing and expanding commercial operations, collecting and procuring an adequate supply of high- titer antibody RSV plasma or balancing our research and development activities with our commercialization activities. Since receiving FDA approval for ASCENIV, we have been commercializing this product while also continuing our research and development activities. There can be no assurance that we will be able to successfully manage the balance of our research and development operations with our commercialization activities. Potential investors and stockholders should be aware of the problems, delays, expenses and difficulties frequently encountered by companies balancing development of product candidates, which can include problems such as unanticipated issues related to clinical trials and receipt of approvals from the FDA and foreign regulatory bodies, with commercialization efforts, which can include problems related to managing manufacturing and supply, including supply chain constraints, reimbursement, marketing challenges, development of a comprehensive compliance program, and other related and additional costs. For example, the raw material plasma we collect and procure to manufacture ASCENIV using our patented proprietary microneutralization assay is comprised of plasma collected from donors which contains high- titer

antibodies to RSV. This high - titer – plasma which meets our internal specifications for the manufacture of ASCENIV that we are able to identify with our patented testing assay amounts to less than 10 % of the total donor collection samples we test. As a result, we may experience an insufficient supply of this plasma. Our product candidates will require significant additional research and clinical trials, and we will need to overcome significant regulatory burdens prior to commercialization in the **United States** ~~U. S.~~ and other countries. In addition, we may be required to spend significant funds on building out our commercial operations. There can be no assurance that after the expenditure of substantial funds and efforts, we will successfully develop and commercialize any of our product candidates, generate any significant revenues or ever achieve and maintain a substantial level of sales of our products. We depend on third- party researchers, developers and vendors to develop, manufacture **, supply materials for** or test **our** products and product candidates, as well as for other pre **and post** - ~~and- post~~ approval services, and such parties' performance is, to some extent, outside of our control. We depend on independent investigators and collaborators, such as universities and medical institutions, contract laboratories, CROs, contract manufacturers, contract fill / finishers, third- party plasma centers and consultants to conduct our preclinical activities, clinical trials, CMC testing and other activities under agreements with us. **We also depend on third- party suppliers for materials used in our operations.** These collaborators are not our employees and we cannot control the amount or timing of resources that they devote to our programs. These third parties may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. **Additionally, certain of our third- party suppliers may be single- sourced or may not be able to supply sufficient materials for our operations, and it may be time- consuming, expensive or otherwise not feasible to locate an alternative supplier.** If outside collaborators fail to devote sufficient time and resources to our products and / or development programs, or if their performance is substandard or does not comply with the applicable regulatory standards, our trials may be repeated, extended, delayed, or terminated, the approval of our FDA application (s), if any, and our introduction of new products, if any, will be delayed, and we may not be able to maintain existing approvals or meet our regulatory requirements **or we may not be able to produce forecasted amounts of product** . We or they may also be subject to regulatory enforcement actions, may need to take corrective actions, including initiating recalls, and we may not be able to meet commercial demand. These collaborators may also have relationships with other commercial entities, some of whom may compete with us. If our collaborators assist our competitors at our expense, our competitive position would be harmed. Additionally, any change in the regulatory compliance status of any of our vendors may impede our ability to receive and maintain approval for our product candidates. **We may be unable to successfully expand our manufacturing processes to fulfill demand for our products or** increase our production capabilities through the addition of new equipment, including if we do not obtain requisite approval from the FDA. We currently anticipate expanding the manufacturing capacity and product output capability of our Boca Facility. Following the expansion of any of our manufacturing processes or the addition of new equipment, such as our fill- finish machine, we will need to validate the expanded facility and equipment, make the necessary submissions to FDA, obtain any FDA- required approvals and have it inspected by the FDA. Given the significant delays that may result during the validation process, we may experience a supply shortage of our products or our production capabilities may be limited until completion of and validation of our facility expansion and new manufacturing equipment. Our products, and any additional products for which we may obtain marketing approval in the future, could be subject to post- marketing restrictions or withdrawal from the market and we could be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products following approval. Our products, and any additional products for which we may obtain marketing approval in the future, could be subject to post- marketing restrictions, new FDA guidance, or other regulatory actions, such as withdrawal from the market. Such products, as well as the manufacturing processes, post- marketing studies and measures, labeling and advertising and promotional activities for such products, among other things, are subject to ongoing regulatory compliance requirements, and oversight, review, and inspection by the FDA and other regulatory authorities. These requirements include submissions of safety and other post- marketing information and reports, registration and listing requirements, adherence with labeling and promotional requirements and restrictions, requirements related to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding safeguarding the drug supply chain as well as the distribution of samples to physicians and recordkeeping. For example, the FDA' s approval of our application supplement to allow for the commercial relaunch of BIVIGAM, as well as the FDA' s approval of our BLA for ASCENIV, ~~require~~ **required** us to conduct specified post- marketing studies, including pediatric and safety studies. If, during the post- marketing period (after marketing approval) previously unknown adverse events emerge, there is the discovery that the product is less effective than previously thought, or other potential concerns regarding our products or their manufacturing processes emerge, or we are observed in any way to fail to comply with the numerous regulatory requirements to which we are subject, those circumstances may yield various results, including: • restrictions on such products or manufacturing processes; • restrictions on the labeling or marketing of a product; • restrictions on product distribution or use; • clinical holds or termination of clinical trials; • requirements to conduct further post- marketing studies or clinical trials, implement risk mitigation strategies, or to issue corrective information; • warning letters or untitled letters; • withdrawal of the products from the market; • refusal to approve pending applications or supplements to approved applications that we submit; • recall of products; • restrictions on coverage by third- party payers; • fines, restitution or disgorgement of profits or revenues; • suspension or withdrawal of marketing approvals; • refusal to permit the import or export of products; • FDA debarment, suspension and debarment from government programs, refusal of orders under existing government contracts, exclusion from participation in federal healthcare programs, consent decrees, deferred or non- prosecution agreements or corporate integrity agreements; • product seizure or detention; or • injunctions or the imposition of civil penalties or criminal fines. Historically, a few customers have accounted for a significant amount of our total revenue and accounts receivable and the loss of any of these customers could have a material adverse effect on our business, results of operations and financial condition. For the ~~year~~ **years** ended December 31, **2024 and** 2023, two customers, BioCARE, Inc. (" BioCare ") and

Priority Healthcare Distribution, Inc. d / b / a CuraScript SD Specialty Distribution (" Curascript "), represented an aggregate of **approximately** 72 % of our consolidated revenues. **As of** ~~For the year ended~~ December 31, ~~2022~~ **2024** , **three** ~~BioCare and Curascript represented an aggregate of 74 % of our consolidated revenues. As of December 31, 2023, five~~ customers, BioCare, Healix Infusion Therapy, LLC (" Healix ") **and Cencora** , ~~Curascript,~~ **Inc. (f / k / a** AmerisourceBergen Corporation **), represented an aggregate of approximately 91 % of our consolidated accounts receivable. As of December 31, 2023, five customers, BioCare, Healix, Curascript, Cencora, Inc.** and Reliance Life Sciences Pvt. ~~Ltd.~~ **Limited (" Reliance ")** , represented an aggregate of approximately 98 ~~% of our consolidated accounts receivable. As of December 31, 2022, BioCare and Healix represented an aggregate of 92~~ % of our consolidated accounts receivable. The loss of any key customers or a material change in the revenue generated by any of these customers **, other than Reliance,** could have a material adverse effect on our business, results of operations and financial condition. Moreover, we anticipate deriving increased revenue from some of these customers over the next few years. Factors that could influence our relationships with our customers include, among other things: • our ability to sell our products at competitive prices; • our ability to maintain features and quality standards for our products sufficient to meet the expectations of our customers; • our ability to produce and deliver a sufficient quantity of our products in a timely manner to meet our customers' requirements; • the impact of a pandemic, or the resurgence of a pandemic, and government responses thereto on our customers and their businesses, operations and financial condition **; • the impact of a cyberattack or data breach on our customers or related entities** ; and • widespread economic conditions or geopolitical conditions, including the exacerbated conflicts in Europe, the Middle East and the surrounding areas. Additionally, an adverse change in the financial condition of any of our key customers could negatively affect revenue derived from such customer, which in turn could have a material adverse effect on our business and results of operations. **Issues with product quality and compliance could have a material adverse effect upon our business, subject us to regulatory actions and cause a loss of customer confidence in us or our products.** Our success depends upon the quality of our products. Quality management plays an essential role in meeting customer requirements, preventing defects, improving our products and services and assuring the safety and efficacy of our products. Our future success depends on our ability to maintain and continuously improve our quality management program. A quality or safety issue may result in failure to obtain product approval, adverse inspection reports, warning letters, product recalls or seizures, monetary sanctions, injunctions to halt manufacture and distribution of products, civil or criminal sanctions, costly litigation, patient injury, refusal of a government to grant approvals and licenses, restrictions on operations or withdrawal of existing approvals and licenses. An inability to address a quality or safety issue by us or by a third- party vendor in an effective and timely manner may also cause negative publicity or a loss of customer confidence in us or our current or future products, which may result in the loss of sales and difficulty in successfully commercializing our current products and launching new products. In addition, as a manufacturer of biological products, we are subject to the risks inherent in biological production, which could include normal course losses and failures inherent in the manufacturing process. As our biologics production levels increase, there may be normal course inventory losses or write- downs as we ensure product quality and compliance with cGMP, FDA ~~,~~ **and** state and local regulations, or due to testing results not meeting specifications. As a result, our operating results are subject to potentially significant variability from one reporting period to the next should such ~~normal course~~ losses **or write- downs** occur in any given period. ~~However~~ **Additionally** , because our products and product candidates are plasma- based products, not only are we subject to the FDA' s drug and biologic cGMP requirements, but we are also subject to special requirements for the collection, testing, handling, storage, and use of blood products. This adds an extra level of compliance and complexity to our operations, which we may not be able to successfully meet. Failure to meet any regulatory quality standards could have an adverse impact on our business. **If physicians, payers and patients do not accept and use our current products or our future product candidates, our ability to generate revenue from these products will be materially impaired.** Even if the FDA approves a product made by us, physicians, payers and patients may not accept and use it. Acceptance and use of our products depends on a number of factors including, but not limited to: • perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of our products; • cost-effectiveness of our products relative to competing products; • availability of reimbursement for our products from government or other healthcare payers; and • the effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any. The failure of our current or future products to find market acceptance would harm our business and could require us to seek additional financing or make such financing difficult to obtain on favorable terms, if at all **. Our accruals for U. S. Medicaid rebates and other liabilities related to the sale of our immunoglobulin products are estimates based on historical experience and other assumptions. These estimates are subject to change based on actual results and other factors. Any such change could have a material effect on our business, financial position, and operating results. Our gross product revenues are subject to a variety of deductions which are estimated and recorded in the same period that the revenues are recognized. These deductions primarily consist of rebates, distribution fees, chargebacks and sales allowances. These deductions represent estimates of the related obligations, some of which are contractual in nature and do not require extensive judgment to be exercised by management, while other estimates require complex or subjective matters of knowledge and judgment when estimating the impact of these revenue deductions on net revenues for a reporting period. Significant estimates include, among other things, accruals for U. S. Medicaid rebates related to the sale of our immunoglobulin products. We accrue these rebates at the time of sale based on our estimates of the sales mix of our products and the portion of the products we sell that will be prescribed to Medicaid beneficiaries. These estimates are based on historical experience and certain other assumptions, and while we believe that such estimates are reasonable, they are subject to change based on future experience, Medicaid utilization trends and other factors. If any of our ratios, factors, assessments, experiences or judgments are not indicative or accurate estimates of our future experience, our results could be materially affected. Estimates that are most at risk for material adjustment include those associated with U. S. Medicaid rebates because of the extensive time delay between the recording of the accrual and**

its ultimate settlement, an interval that can generally take up to several years or more. These estimates may change from time to time based on changes in utilization, payer and channel mixes or the ultimate settlement or resolution of payor claims. For example, during 2024 we engaged a third- party specialist to assist in the evaluation of our accrual for U. S. Medicaid rebates related to the sale of our immunoglobulin products. As a result of this evaluation, we recognized a reduction in this accrual and a corresponding increase to net revenues of $ 12. 6 million for the year ended December 31, 2024. We considered several qualitative factors when evaluating our rebate accrual, such as the absence of a statutory limitation on the rebate amounts drug manufacturers pay to state Medicaid programs and general uncertainty that pharmaceutical manufacturers have historically seen with government payors often submitting lagged claims many periods after the initial dispensing of a product to an end patient. There was additional new information that arose during June 2024 that suggested our liabilities for certain payor claims were successfully resolved, which resulted in the $ 12. 6 million adjustment to the accrual for U. S. Medicaid rebates in June 2024. In addition, the Patient Protection and Affordable Care Act (" ACA ") included a significant expansion of state Medicaid programs. As more individuals become eligible for coverage under these programs, Medicaid utilization of our products could increase, resulting in a corresponding increase in our rebate payments. Such rebate payments may exceed what we have accrued for during the applicable period. Increases in Medicaid rebate payments could decrease our net revenues from product sales, which in turn could adversely affect our business, financial position, and operating results . Our long- term success may depend on our ability to supplement our existing product portfolio through new product development or the in- license or acquisition of other new products, product candidates and label expansion of existing products, and if our business development efforts are not successful, our ability to ~~achieve~~ **maintain** profitability may be adversely impacted. Our current product development portfolio consists primarily of label expansion activities for ASCENIV, as well as expanding our IP estate with patents issued for S. ~~Pneumoniae~~ **pneumoniae** hyperimmune IG. We have initiated small- scale preclinical activities to potentially expand our current portfolio through new product development efforts. If we are not successful in developing or acquiring additional products and product candidates, we will have to depend on our ability to continue to generate revenues from ASCENIV, BIVIGAM, Nabi- HB, contract manufacturing ~~, intermediate fractions~~ and plasma attributable to the operations of ADMA BioCenters to support our operations. Our ADMA BioCenters operations collect information from donors in the **United States** ~~U. S.~~ that subjects us to consumer and health privacy laws, which could create enforcement and litigation exposure if we fail to meet their requirements. Consumer privacy is highly protected by federal and state law. The Health Insurance Portability and Accountability Act of 1996 (" HIPAA "), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (" HITECH "), and their respective implementing regulations, impose requirements with respect to safeguarding the privacy, security and transmission of protected health information (" PHI ") held by covered entities and business associates. ~~HIPPAA~~ **HIPAA** " covered entities " include health plans / insurers, healthcare providers engaging in ~~HIPPA~~ **HIPAA** standard electronic transactions and healthcare clearinghouses. A " business associate " provides services to covered entities (directly or as subcontractors to other business associates) involving arranging, creating, receiving, maintaining, or transmitting PHI on a covered entity' s behalf. In order to legally provide access to PHI to service providers, covered entities and business associates must enter into a " business associate agreement " ~~(" BAA ")~~ with the service provider that receives PHI on behalf of the entity. While we are not a covered entity or business associate subject to HIPAA, personal information that we obtain pursuant to a clinical trial may be subject to U. S. Federal Trade Commission (the " FTC ") privacy regulation. Failing to take appropriate steps to keep consumers' personal information secure may constitute an unfair act or practice violating Section 5 (a) of the Federal Trade Commission Act, 15 U. S. C § 45 (a). The FTC expects a company' s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. The FTC' s guidance for appropriately securing consumers' personal information is similar to, but less prescriptive than, what is required by the HIPAA Security Rule. In addition, states impose a variety of laws protecting consumer information, with certain sensitive information such as HIV / Sexually Transmitted Disease status subject to heightened standards. In addition, federal and state privacy, data security, and breach notification laws, rules and regulations, and other laws apply to the collection, use and security of personal information, including social security ~~number~~ **numbers** , driver' s license numbers, government identifiers, credit card and financial account numbers. For example, the CCPA was amended by the CPRA, effective January 1, 2023. The CCPA, among other things, imposes data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. We could be subject to enforcement action and litigation exposure if we fail to adhere to these data privacy and security laws. Virginia, Colorado, Connecticut and Utah have also enacted privacy laws that became effective in 2023 and are similar in many respects to the CCPA. Several other states have also enacted privacy laws similar to the CCPA that will become effective in the coming years, adding to potential privacy compliance obligations. The Ares Credit Facility is subject to acceleration in specified circumstances, which may result in Ares taking possession and disposing of any collateral. On December 18, 2023 (the " Ares Closing Date "), we entered into a ~~new senior secured~~ credit ~~facility~~ **agreement** with Ares (the " Ares Credit Agreement ") (see " Liquidity and Capital Resources "). The Ares Credit Agreement ~~provides~~ **provided** for a total of $ 135 million in senior secured credit facilities (the " Ares Credit Facility ") consisting of (i) a term loan in the aggregate principal amount of $ 62. 5 million and (ii) a revolving credit facility in the aggregate principal amount of $ 72. 5 million (collectively, the " Ares Loans "), both of which were fully drawn on the Ares Closing Date. The Ares Credit Facility has a maturity date of December 20, 2027 (the " Ares Maturity Date ") **. On August 14, 2024, we repaid $ 30. 0 million against the revolving credit facility and on December 19, 2024 we repaid $ 30. 0 million against the term loan. As of December 31, 2024, we had $ 42. 5 million and $ 32. 5 million of borrowings outstanding**

under the revolving credit facility and the term loan, respectively . The Ares Loans are secured by substantially all of our assets, including our intellectual property. Events of default include, among others, non- payment of principal, interest or fees, violation of covenants, inaccuracy of representations and warranties, bankruptcy and insolvency events, material judgments, cross- defaults to material contracts and events constituting a change of control. If there is an event of default, we would incur an increase in the rate of interest on the Ares Loans of 2 % per annum. The occurrence of an event of default could result in, among other things, the termination of commitments under the Ares Credit Facility, the declaration that all outstanding loans are immediately due and payable in whole or in part, and Ares taking immediate possession of, and selling, any collateral securing the Ares Loans. Developments by competitors may render our products or technologies obsolete or non- competitive. The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Our current products and any future product we may develop will have to compete with other marketed therapies. In addition, other companies may pursue the development of pharmaceuticals that target the same diseases and conditions that we are targeting. We face competition from pharmaceutical and biotechnology companies in the **United States** ~~U. S.~~ and abroad. In addition, companies pursuing different but related fields represent substantial competition. Many of these organizations competing with us have substantially greater financial resources, larger research and development staffs and facilities, longer product development history in obtaining regulatory approvals and greater manufacturing and marketing capabilities than we do. These organizations also compete with us to attract qualified personnel and parties for acquisitions, joint ventures or other collaborations. If we are unable to protect our patents, trade secrets or other proprietary rights, if our patents are challenged or if our provisional patent applications do not get approved, our competitiveness and business prospects may be materially damaged. As we move forward in clinical development, we continue to discover novel technologies related to our products and we may draft patent applications directed to these technologies. We rely on a combination of patent rights, trade secrets **, intellectual property assignment agreements** and nondisclosure and non- competition agreements to protect our proprietary intellectual property, and we will continue to do so. There can be no assurance that our patents, trade secret policies and practices or other agreements will adequately protect our intellectual property. Our issued patents may be challenged, found to be over- broad or otherwise invalidated in subsequent proceedings before courts, the U. S. Patent and Trademark Office or foreign patent offices. Even if enforceable, we cannot provide any assurances that they will provide significant protection from competition. The processes, systems, and / or security measures we use to preserve the integrity and confidentiality of our data and trade secrets may be breached, and we may not have adequate remedies as a result of any such breaches. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. There can be no assurance that the confidentiality **, invention assignment** , nondisclosure and non- competition agreements with employees, consultants and other parties with access to our proprietary information to protect our trade secrets, proprietary technology, processes and other proprietary rights, or any other security measures relating to such trade secrets, proprietary technology, processes and proprietary rights, will be adequate, will not be breached, that we will have adequate remedies for any breach, that others will not independently develop substantially equivalent proprietary information or that third parties will not otherwise gain access to our trade secrets or proprietary knowledge. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know- how and inventions. We could lose market exclusivity of a product earlier than expected. In the pharmaceutical and biotechnology industries, the majority of an innovative product' s commercial value is realized during its market exclusivity period. In the **United States** ~~U. S.~~ and in some other countries, when market exclusivity expires and generic or biosimilar versions are approved and marketed or when biosimilars are introduced (even if only for a competing product), there are usually very substantial and rapid declines in a product' s revenues. Market exclusivity for our products is based upon patent rights and certain regulatory forms of exclusivity. The scope of our patent rights may vary from country to country and may also be dependent on the availability of meaningful legal remedies in a country. The failure to obtain patent and other intellectual property rights, limitations on the use or loss of such rights ~~,~~ could be material to us. In some countries, basic patent protections for our products may not exist because certain countries did not historically offer the right to obtain specific types of patents and / or we (or our licensors) did not file in those markets. In addition, the patent environment can be unpredictable and the validity and enforceability of patents cannot be predicted with certainty. Absent relevant patent protection for a product, once the data exclusivity period expires, generic versions can be approved and marketed. Patent rights covering our products may become subject to patent litigation. In some cases, manufacturers may seek regulatory approval by submitting their own clinical trial data to obtain marketing approval or choose to launch a generic product " at risk " before the expiration of our patent rights / or before the final resolution of related patent litigation. Enforcement of claims in patent litigation can be very costly, time- consuming and no assurance can be given that we will prevail. In addition, any such litigation may divert our management' s attention from our core business and reduce the resources available for our clinical development, manufacturing and marketing activities, and consequently have a material and adverse effect on our business and prospects, regardless of the outcome. There is no assurance that ASCENIV, or any other of our products for which we are issued a patent, will enjoy market exclusivity for the full time period of the respective patent. Third parties could obtain patents that may require us to negotiate licenses to conduct our business, and there can be no assurance that the required licenses would be available on reasonable terms or at all. We may not be able to operate our business without infringing third- party patents. Numerous U. S. and foreign patents and pending patent applications owned by third parties exist in fields that relate to the development and commercialization of IG. In addition, many companies have employed intellectual property litigation as a way to gain a competitive advantage. It is possible that infringement claims may occur as the number of products and competitors in our market increases. In addition, to the extent that we gain greater visibility and market exposure as a public company, we face a greater risk of being the subject of intellectual property infringement claims. We cannot be certain that the conduct of our business does not and will not infringe intellectual property or other proprietary rights of others in the **United States** ~~U. S.~~ and in foreign jurisdictions. If our products, methods, processes and other technologies are

found to infringe third- party patent rights, we could be prohibited from manufacturing and commercializing the infringing technology, process or product unless we obtain a license under the applicable third- party patent and pay royalties or are able to design around such patent. We may be unable to obtain a license on terms acceptable to us, or at all, and we may not be able to redesign our products or processes to avoid infringement. Even if we are able to redesign our products or processes to avoid an infringement claim, our efforts to design around the patent could require significant time, effort and expense and ultimately may lead to an inferior or more costly product and / or process. Any claim of infringement by a third party, even those without merit, could cause us to incur substantial costs defending against the claim and could distract our management from our business. Furthermore, if any such claim is successful, a court could order us to pay substantial damages, including compensatory damages for any infringement, plus prejudgment interest and could, in certain circumstances, treble the compensatory damages and award attorney fees. These damages could be substantial and could harm our reputation, business, financial condition and operating results. A court also could enter orders that temporarily, preliminarily or permanently prohibit us, our licensees, if any, or our customers from making, using, selling, offering to sell or importing one or more of our products or practicing our proprietary technologies or processes, or could enter an order mandating that we undertake certain remedial activities. Any of these events could seriously harm our business, operating results and financial condition. If we are unable to successfully manage our growth, our business may be harmed. Our success will depend on the expansion of our commercial and manufacturing activities, supply of raw material plasma and overall operations and the effective management of our growth, which will place a significant strain on our management and on our administrative, operational and financial resources. To manage this growth, we must expand our operational, financial and management systems and hire and train additional qualified personnel. If we are unable to manage our growth effectively, our business could be harmed. The loss of one or more key members of our management team could adversely affect our business. Our performance is substantially dependent on the continued service and performance of our management team, who have extensive experience and specialized expertise in our business. In particular, the loss of Adam S. Grossman, our President and Chief Executive Officer, could adversely affect our business and operating results. We do not have " key person " life insurance policies for any members of our management team. We have employment agreements with each of our executive officers; however, the existence of an employment agreement does not guarantee retention of members of our management team and we may not be able to retain those individuals for the duration of or beyond the end of their respective terms. The loss of services of key personnel, or the inability to attract and retain additional qualified personnel, could result in delays in development or approval of our product candidates and diversion of management resources. **Cyberattacks and other security breaches could compromise our proprietary and confidential information or otherwise penetrate our network, which could harm our business and reputation.** In the ordinary course of our business, we generate, collect and store proprietary information, including intellectual property and business information. The secure storage, maintenance, and transmission of and access to this information is important to our operations and reputation. Computer hackers may attempt to penetrate our computer systems and, if successful, misappropriate our proprietary and confidential information including e- mails and other electronic communications. **Cybersecurity vulnerabilities can also arise from human error, fraud or malice on the part of our employees, other insiders or third parties, or from technology or product enhancements or the migration of information and data to new technology platforms, systems or applications. Hackers may impersonate our vendors, suppliers or other third parties with whom we do business, which may result in financial harm to our business.** Further, while many of our employees and certain suppliers with whom we do business operate in a remote working environment, the risk of cybersecurity attacks and data breaches, particularly through phishing attempts, may be increased as we and third parties with whom we interact leverage our IT infrastructure in unanticipated ways. In addition, an employee, contractor, or other third party with whom we do business may attempt to obtain such information and may purposefully or inadvertently cause a breach involving such information. While we have certain safeguards in place to reduce the risk of and detect cyberattacks, including a Company- wide cybersecurity policy, our information technology networks and infrastructure may be vulnerable to unpermitted access by hackers or other breaches, such as the IT disruption described elsewhere in this report, or employee error or malfeasance. Any such compromise of our data security and access to, or public disclosure or loss of, confidential business or proprietary information could disrupt our operations, damage our reputation, provide our competitors with valuable information and subject us to additional costs which could adversely affect our business. If we are unable to hire and retain a substantial number of qualified personnel, our ability to sustain and grow our business may be harmed. Our success depends in part on our ability to attract, motivate, and retain a sufficient number of qualified employees across various areas of our operations, such as research and development, manufacturing operations ,~~–~~and sales, who understand and appreciate our strategy and culture and are able to contribute to our mission. We will need to hire additional qualified personnel with expertise in commercialization, sales, marketing, medical affairs, reimbursement, government regulation, formulation, quality control, manufacturing, finance, general and operational management and plasma collections. In particular, over the next 12- 24 months, we expect to hire several new employees devoted to our plasma collection centers, commercialization, sales, marketing, medical and scientific affairs, regulatory affairs, quality control, information technology, finance and general and operational management. Qualified individuals of the requisite caliber and number needed to fill these positions may be in short supply in some areas. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals is intense, and we cannot assure you that our search for such personnel will be successful. If we are unable to hire and retain personnel capable of consistently performing at a high level, our business and operations could be materially adversely affected. Additionally, any material increases in existing employee turnover rates or increases in labor costs could have a material adverse effect on our business, financial condition or operating results. We currently collect human blood plasma at our ADMA BioCenters facilities, and if we cannot maintain FDA licensure for these facilities or obtain FDA licensure for additional facilities that we may construct or acquire rights to, we may be adversely affected and may not be able to sell or use this human

blood plasma for future commercial purposes. We intend to maintain FDA licensure of our current and future ADMA BioCenters collection facilities for the collection of human blood plasma and we may seek other governmental and regulatory approvals for these facilities. Collection facilities are subject to FDA and potentially other governmental and regulatory inspections and extensive regulation, including compliance with current cGMP and blood standards and FDA licensure and other governmental approvals, as applicable. Failure to comply with applicable governmental regulations or to receive applicable approvals for our current or future facilities may result in enforcement actions, such as adverse inspection reports, warning or untitled letters, product recalls or seizures, monetary sanctions, injunctions to halt manufacture and distribution of products, civil or criminal sanctions, costly litigation, refusal of regulatory authority approvals and licenses, restrictions on operations or withdrawal of existing approvals and licenses, any of which may significantly delay or suspend our operations for these locations, potentially having a material adverse effect on our ability to manufacture our products or offer for sale plasma collected at the affected sites. Failure to comply with applicable governmental regulations may also impact the ultimate quality and compliance of our finished biologic products, which may have a material adverse effect on our business. We manufacture our current marketed products, pipeline products, and products for third parties in our manufacturing and testing facilities, and if we or our vendors cannot maintain appropriate FDA status for these facilities, we may be adversely affected, and may not be able to sell, manufacture or commercialize these products. There are no assurances we will be able to maintain compliance with all FDA or other regulations. There is also no guarantee that we will be able to fulfill our contractual requirements to our customers. Moreover, to the extent that we use third- party vendors to fulfill our regulatory or contractual requirements, these third- party vendors may perform activities for themselves or other clients and we may not be privy to all regulatory findings or issues discovered by the FDA or other regulatory agencies. Such findings, which are out of our control, may adversely affect our ability to continue to work with these vendors, or our ability to release commercial drug product or perform necessary testing or other actions for us or our clients, which may be required in order to remain FDA compliant or to commercialize our products. If we are not able to maintain manufacturing compliance at our facilities or our vendors' facilities for our products and product candidates, we may not be able to successfully develop and commercialize our products and product candidates and we may face potential contractual or regulatory actions, which would have an adverse impact on our business. We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits. The testing and marketing of medical products entail an inherent risk of product liability. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Product liability claims may also result in recalls and / or regulatory enforcement actions. Even successful defense, however, could impair our results of operations. Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop, either alone or with collaborators. Many of our business practices are subject to scrutiny by federal and state regulatory authorities, as well as to lawsuits brought by private citizens under federal and state laws. Failure to comply with applicable law or an adverse decision in lawsuits may result in adverse consequences to us. The laws governing our conduct in the **United States** ~~U. S.~~ are enforceable on the federal, state and local levels by criminal, civil and administrative sanctions. Violations of laws such as the **FDCA** ~~Federal Food, Drug, and Cosmetic Act~~ , the Social Security Act (including the Anti-Kickback Statute), the Public Health Service Act, the civil and criminal federal False Claims Act, the civil monetary penalty statute, requirements regarding the reporting and repayment of overpayments, other fraud and abuse laws and any regulations promulgated under the authority of the preceding, may result in significant criminal and / or civil sanctions, including jail sentences, fines or exclusion from participation in or debarment from federal and state healthcare or government procurement programs, pursuant to enforcement actions by DOJ, Medicare, Medicaid, OIG and other regulatory authorities. Similarly, the violation of applicable laws, rules and regulations of states, including the State of Florida, with respect to the manufacture and marketing of our products and product candidates may result in significant criminal and / or civil sanctions, including jail sentences, fines or exclusion from participation in applicable state healthcare programs. There can be no assurance that our activities will not come under the scrutiny of federal and / or state regulators and other government authorities or that our practices will not be found to violate applicable laws, rules and regulations or prompt lawsuits by private citizen " relators " under federal or state false claims laws. For example, under the Anti- Kickback Statute and similar state laws and regulations, the offer or payment of anything of value to induce or reward patient referrals, or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease, or ordering of any item or service reimbursable in whole or in part by a federal healthcare program is prohibited. This places constraints on the marketing and promotion of products and on common business arrangements, such as discounted terms and volume incentives for customers in a position to recommend or choose products for patients, such as physicians and hospitals, and these practices can result in substantial legal penalties, including, among others, exclusion from participation in the Medicare and Medicaid programs. Arrangements with referral sources such as purchasers, group purchasing organizations, healthcare organizations, physicians and pharmacists must be structured with care to comply with applicable requirements. Legislators and regulators may seek to further restrict the scope of financial relationships that are considered appropriate. For example, HHS recently promulgated a regulation that is effective in two phases. First, the regulation excludes from the definition of " remuneration " limited categories of (a) PBM rebates or other reductions in price to a plan sponsor under Medicare Part D or a Medicaid Managed Care Organization plan reflected in point-of- sale reductions in price and (b) PBM service fees paid by a manufacturer to a PBM. Second, effective January 1, 2023, the regulation expressly provides that rebates to plan sponsors under Medicare Part D either directly to the plan sponsor under Medicare Part D, or indirectly through a pharmacy benefit manager, will not be protected under the Anti- Kickback Statute discounts safe harbor. Recent legislation and a final rule promulgated on December 29, 2023 delayed implementation of this portion of the rule until January 1, 2032. Also, certain business practices, such as payments of consulting fees to healthcare professionals, sponsorship of educational or research grants, charitable donations, interactions with healthcare professionals who

prescribe products for uses not approved by the FDA and financial support for continuing medical education programs, must be conducted within narrowly prescribed and controlled limits to avoid any possibility of wrongfully influencing healthcare professionals to prescribe or purchase particular products or as a reward for past prescribing. Under the Healthcare Reform Law, payments and transfers of value by pharmaceutical manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program (with certain exceptions) to or at the request of covered recipients, such as, but limited to, U. S.- licensed physicians, physician assistants, nurse practitioners, clinical nurse specialists and certified registered nurse anesthetists and U. S. teaching hospitals, must be tracked and reported to CMS, and are publicly disclosed. Such " applicable manufacturers " are also required to report certain ownership interests held by physicians and their immediate family members. A number of states have similar laws in place. Additional and stricter prohibitions could be implemented by federal and state authorities. Where such practices have been found to be improper incentives to use such products, government investigations and sanctions against manufacturers have resulted in substantial fines, penalties and damages. Many manufacturers have been required to enter into consent decrees or orders that prescribe allowable corporate conduct and / or Corporate Integrity Agreements that impose ongoing compliance requirements on a manufacturer. Failure to satisfy requirements under the **FDCA** ~~Federal Food, Drug, and Cosmetic Act~~ can also result in penalties, as well as requirements to enter into consent decrees or orders that prescribe allowable corporate conduct. In addition, while regulatory authorities generally do not regulate physicians' discretion in their choice of treatments for their patients, they do restrict communications by manufacturers on unapproved uses of approved products or on the potential safety and efficacy of unapproved products in development. Companies in the **United States** ~~U. S.~~, Canada and the European Union cannot promote approved products for other indications that are not specifically approved by the competent regulatory authorities such as the FDA in the **United States** ~~U. S.~~, nor can companies promote unapproved products. In limited circumstances, companies may disseminate to physicians information regarding unapproved uses of approved products or results of studies involving investigational products. If such activities fail to comply with applicable regulations and guidelines of the various regulatory authorities, we may be subject to warnings from, or enforcement action by, these authorities. Furthermore, if such activities are prohibited, it may harm demand for our products. Promotion of unapproved drugs or devices or unapproved indications for a drug or device is a violation of the **FDCA** ~~Federal Food, Drug, and Cosmetic Act~~ and subjects us to civil and criminal sanctions. Furthermore, sanctions under the federal False Claims Act have been brought against companies accused of promoting off- label uses of drugs, because such promotion induces unapproved ~~the~~ use and subsequent claims for reimbursement under Medicare and other federal programs. Similar actions for off- label promotion have been initiated by several states for Medicaid fraud. The Healthcare Reform Law significantly strengthened provisions of the federal False Claims Act, the federal Anti- Kickback Statute that applies to government healthcare programs, and other healthcare fraud provisions, leading to the possibility of greatly increased lawsuits by whistleblowers for perceived violations. Violations or allegations of violations of the foregoing restrictions could materially and adversely affect our business. We are required to report detailed pricing information, net of included discounts, rebates and other concessions, to CMS for the purpose of calculating national reimbursement levels, certain federal prices and certain federal and state rebate obligations. Inaccurate or incomplete reporting of pricing information could result in criminal and / or civil liability under the federal False Claims Act, the federal Anti- Kickback Statute and various other laws, rules and regulations. We have established systems for collecting and reporting this data accurately to CMS and have instituted a compliance program to assure that the information collected is complete in all respects. If we report pricing information that is not accurate to the federal government, we could be subject to fines and other sanctions that could adversely affect our business. If we choose to pursue clinical development and commercialization in the European Union or otherwise market and sell our products outside of the **United States** ~~U. S.~~, we must obtain and maintain regulatory approvals and comply with regulatory requirements in such jurisdictions. The approval procedures vary among countries in complexity and timing. We may not obtain approvals from regulatory authorities outside the **United States** ~~U. S.~~ on a timely basis, if at all, which would preclude us from commercializing products in those markets. In addition, some countries, particularly the countries of the European Union, regulate the pricing of prescription pharmaceuticals. In these countries, pricing discussions with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost- effectiveness of our product candidate to other available therapies. Such trials may be time- consuming and expensive and may not show an advantage in efficacy for our products. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, in either the U. S. or the European Union, we could be adversely affected. Also, under the U. S. Foreign Corrupt Practices Act, the **United States** ~~U. S.~~ has increasingly focused on regulating the conduct by U. S. businesses occurring outside of the **United States** ~~U. S.~~, generally prohibiting remuneration to foreign officials for the purpose of obtaining or retaining business. To enhance compliance with applicable healthcare laws, and mitigate potential liability in the event of noncompliance, regulatory authorities such as the HHS Office of Inspector General (the " OIG ") have recommended the adoption and implementation of a comprehensive healthcare compliance program that generally contains the elements of an effective compliance and ethics program described in Section 8B2. 1 of the U. S. Sentencing Commission Guidelines Manual. Most U. S.- based pharmaceutical companies have such programs. We will need to adopt healthcare compliance and ethics programs that would incorporate the OIG' s recommendations and voluntary industry guidelines and train our employees. Such a program may be expensive and may not provide assurance that we will avoid compliance issues. We are also required to comply with the applicable laws, rules, regulations and permit requirements of the various states and localities in which our business operates, including the State of Florida where our manufacturing facility is located. These regulations and permit requirements are not always in concert with applicable federal laws, rules and regulations regulating our business. Although compliant with applicable federal requirements, we may be required to comply with additional state and local laws, rules, regulations and permits. Failure to appropriately comply with such state and local requirements could result in temporary or

long- term cessation of our manufacturing operations, as well as fines and other sanctions. Any such penalties may have a material adverse effect on our business and results of operations. We are subject to extensive and rigorous governmental regulation, including the requirement of FDA and other federal, state and local business ~~regulatoryapprovals~~ **regulatory approvals** before our products and product candidates may be lawfully marketed, and our ability to obtain regulatory approval of our products and product candidates from the FDA in a timely manner, access the public markets and obtain necessary capital in order to properly capitalize and continue our operations may be hindered by inadequate funding for the FDA, the SEC and other state and local government agencies. Both before and after the approval of our products, our products, operations, facilities, suppliers and CROs are subject to extensive regulation by ~~Federal~~ **federal** , state and local governmental authorities in the **United States** ~~U. S.~~ and other countries, with regulations differing from country to country. In the **United States** ~~U. S.~~ , the FDA regulates, among other things, the pre- clinical and nonclinical testing, clinical trials, manufacturing, safety, efficacy, potency, labeling, storage, record keeping, quality systems, advertising, promotion, sale and distribution of therapeutic products. Failure to comply with applicable requirements could result in, among other things, one or more of the following actions: notices of violation, untitled letters, warning letters, CRLs, fines and other monetary penalties, unanticipated expenditures, delays in approval or refusal to approve a product or product candidate, product recall or seizure, interruption of manufacturing or clinical trials, operating restrictions, injunctions and criminal prosecution. Our products and product candidates cannot be lawfully marketed in the **United States** ~~U. S.~~ without FDA and other ~~Federal~~ **federal** , state and local business regulatory approvals. Any failure to receive the marketing approvals necessary to commercialize our products or product candidates could harm our business. Additionally, the ability of the FDA and other federal, state and local business regulatory agencies to review and approve products and product candidates can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and to accept the payment of user fees, as well as statutory, regulatory, and policy changes. Average review times at the FDA and other federal, state and local business regulatory agencies have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for products and product candidate submissions to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last few years, including in December 2018 and January 2019, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. **Separately, in response to the COVID- 19 pandemic, the FDA postponed most inspections at domestic and foreign manufacturing facilities from March 2020 until July 2021.** If a prolonged government shutdown **or regulatory agency disruption** reoccurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions and other reporting requirements which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain **capital that may be** necessary ~~capital~~ in order to properly capitalize and continue our operations. The manufacturing processes for plasma- based biologics are complex and involve biological intermediates that are susceptible to contamination and impurities. Plasma is a raw material that is susceptible to damage and contamination and may contain human pathogens, any of which would render the plasma unsuitable as raw material for further manufacturing. For instance, improper storage of plasma, by us or third- party suppliers, may require us to destroy some of our raw material. If unsuitable plasma is not identified and discarded prior to the release of the plasma to the manufacturing process, it may be necessary to discard intermediate or finished product made from that plasma or to recall any finished product released to the market, resulting in a charge to cost of product revenue. The manufacture of our plasma products is an extremely complex process of fractionation, purification, testing, filling and finishing. Our products can become non- releasable or otherwise fail to meet our stringent specifications or regulatory agencies' specifications through a failure in one or more of these process steps. We may detect instances in which an unreleased product was produced without adherence to our manufacturing procedures or plasma used in our production process was not collected or stored in a compliant manner consistent with ~~our~~ cGMP or other regulations. Such an event of noncompliance would likely result in our determination that the implicated products should not be released or maybe replaced or withdrawn from the market and therefore should be destroyed. Once manufactured, our plasma- derived products must be handled carefully and kept at appropriate temperatures. Our failure, or the failure of third parties that supply, test, ship or distribute our products or product components to properly care for our products, may require that those products be destroyed. Even if handled properly, biologics may form or contain particulates or have other issues or problems after storage which may require products to be destroyed or recalled. While we expect to write off certain amounts of raw materials and work- in- process inventory in the ordinary course of business due to the complex nature of plasma, our processes and our products, unanticipated events may lead to write- offs and other costs materially in excess of our expectations and the reserves we have established for these purposes. Such write- offs or losses and other costs could cause material fluctuations in our results of operations. Product or component quality issues may also result in regulatory enforcement actions, liability, corrective actions and recalls, among other actions, as described elsewhere in this ~~annual~~ **Annual** ~~report~~ **Report on Form 10- K** . Furthermore, contamination of our products could cause investors, consumers, or other third parties with whom we conduct business to lose confidence in the reliability of our manufacturing procedures, which could adversely affect our revenues. In addition, faulty or contaminated products that are unknowingly distributed could result in patient harm, threaten the reputation of our products and expose us to product liability damages and claims from companies for whom we do contract manufacturing. Our ability to continue to produce safe and effective products depends on the safety of our plasma supply, testing by third parties and the timing of receiving the testing results, and manufacturing processes ~~against~~ **we have in place to counter** transmittable diseases. Despite overlapping safeguards, including the screening of donors and other steps to remove or inactivate viruses and other infectious disease- causing agents, the risk of transmissible disease through blood plasma products cannot be entirely eliminated. For example, since plasma- derived therapeutics involves

the use and purification of human plasma, there has been concern raised about the risk of transmitting HIV, prions, West Nile virus, H1N1 virus or " swine flu " and other blood- borne pathogens through plasma- derived products. There are also concerns about the future transmission of H5N1 virus, or " bird flu. " In the 1980s, thousands of hemophiliacs worldwide were infected with HIV through the use of contaminated Factor VIII. Other producers of Factor VIII, though not us, were defendants in numerous lawsuits resulting from these infections. New infectious diseases emerge in the human population from time to time. If a new infectious disease has a period during which time the causative agent is present in the bloodstream but symptoms are not present, it is possible that plasma donations could be contaminated by that infectious agent. Typically, early in an outbreak of a new disease, tests for the causative agent do not exist. During this early phase, we must rely on screening of donors for behavioral risk factors or physical symptoms to reduce the risk of plasma contamination. Screening methods are generally less sensitive and specific than a direct test as a means of identifying potentially contaminated plasma units. During the early phase of an outbreak of a new infectious disease, our ability to manufacture safe products would depend on the manufacturing process' capacity to inactivate or remove the infectious agent. To the extent our manufacturing processes are inadequate to inactivate or remove an infectious agent, our ability to manufacture and distribute our products would be impaired. If a new infectious disease were to emerge in the human population or if there were a reemergence of an infectious disease, the regulatory and public health authorities could impose precautions to limit the transmission of the disease that would impair our ability to procure plasma, manufacture our products or both. Such precautionary measures could be taken before there is conclusive medical or scientific evidence that a disease poses a risk for plasma- derived products. In recent years, new testing and viral inactivation methods have been developed that more effectively detect and inactivate infectious viruses in collected plasma. There can be no assurance, however, that such new testing and inactivation methods will adequately screen for, and inactivate, infectious agents in the plasma used in the production of our products. We could become supply- constrained and our financial performance would suffer if we cannot obtain adequate quantities of FDA- approved source and high- titer plasma with proper specifications or other necessary raw materials. In order for plasma to be used in the manufacturing of our products, the individual centers at which the plasma is collected must generally be licensed by the FDA and approved by the regulatory authorities of any country in which we may wish to commercialize our products. When we open a new plasma center, and on an ongoing basis after licensure, it must be inspected by the FDA for compliance with cGMP and other regulatory requirements. Therefore, even if we are able to construct new plasma collection centers to complement our current plasma collection facilities, an unsatisfactory inspection could prevent a new center from being licensed or risk the suspension or revocation of an existing license, among other enforcement actions. Additionally, although we achieved **normal source** plasma supply self- sufficiency with the approval of our tenth plasma collection center in November 2023, we remain reliant on the purchase of **RSV** plasma from third parties and the collection of **RSV and normal source** plasma from our FDA- licensed plasma collection centers to manufacture our products. We can give no assurances that appropriate plasma will be available to us through our own plasma collection facilities or on commercially reasonable terms, or at all, to manufacture our products **, or that third parties will be able to supply plasma to us in accordance with plasma purchase agreements** . Further, the COVID- 19 pandemic resulted in significant constraints in raw material supply across various different industries, including the supply of plasma. It is possible that in the future, pandemics and government responses thereto will have an adverse effect on our ability to source plasma from donors in quantity and quality sufficient for our manufacturing processes. In order to maintain a plasma center' s license, its operations must continue to conform to cGMP and other regulatory requirements. In the event that we determine that plasma was not collected in compliance with cGMP and other applicable regulatory requirements, we may be unable to use and may ultimately destroy plasma collected from that center, which would be recorded as a charge to cost of product revenue. Additionally, if non- compliance in the plasma collection process is identified after the impacted plasma has been pooled with compliant plasma from other sources, entire plasma pools, in- process intermediate materials and final products could be impacted. Consequently, we could experience significant inventory impairment provisions and write- offs which could adversely affect our business and financial results. We plan to increase our supplies of plasma for use in the manufacturing processes through increased purchases of plasma from third- party suppliers as well as collections from our existing ADMA BioCenters plasma collection facilities. This strategy is dependent upon our ability to maintain a cGMP compliant environment at our plasma collection facilities and to expand production and attract donors to our facilities. There is no assurance that the FDA will inspect and license any of our current or future unlicensed plasma collection facilities in a timely manner consistent with our production plans. If we misjudge the readiness of a center for an FDA inspection, we may lose credibility with the FDA and cause the FDA to more closely examine all of our operations. Such additional scrutiny could materially hamper our operations and our ability to increase plasma collections. Our ability to expand production and increase our plasma collection facilities to more efficient production levels may be affected by changes in the economic environment and population in selected regions where ADMA BioCenters operates its current or future plasma facilities, by the entry of competitive plasma centers into regions where ADMA BioCenters operates such centers, by misjudging the demographic potential of individual regions where ADMA BioCenters expects to expand production and attract new donors, by unexpected facility related challenges, or by unexpected management challenges at selected plasma facilities held by us from time to time. ~~Additionally, our supply contract with Grifols for the purchase of normal source plasma (" NSP ") expired on December 31, 2022 and was not renewed. Although we have executed additional agreements with other third- party suppliers of NSP, we anticipate that the NSP used in IG production in 2024 and beyond will be sourced from our ADMA BioCenters plasma collection facilities. There can be no assurances that we will be able to obtain an adequate supply of NSP from other third- party suppliers or be able to collect NSP in the same quantities, or at all, through our ADMA BioCenters plasma collection facilities at a cost that is not higher than the price we paid to Grifols for NSP. If our costs to obtain NSP through collections at our ADMA BioCenters plasma collection facilities or from other third- party suppliers are higher than what we paid to Grifols under our supply contract, our liquidity and results of operations could be adversely impacted.~~ Our ability to commercialize our products, alone or with collaborators, will depend in part upon the extent to which

reimbursement will be available from governmental agencies, health administration authorities, private health maintenance organizations and health insurers and other healthcare payers, and also depends upon the approval, timing and representations by the FDA or other governmental authorities for our product candidates. Our ability to generate product revenues will be diminished if our products sell for inadequate prices or patients are unable to obtain adequate levels of insurance coverage. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products, as well as to the timing, language, specifications and other details pertaining to the approval of such products. Healthcare payers, including Medicare, are challenging the prices charged for medical products and services. Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for products. Even if one of our product candidates is approved by the FDA, insurance coverage may not be available, and reimbursement levels may be inadequate, to cover such product. If government and other healthcare payers do not provide adequate coverage and reimbursement levels for one of our products, once approved, market acceptance of such product could be reduced. Prices in many countries, including many in Europe, are subject to local regulation and certain pharmaceutical products, such as plasma-derived products, are subject to price controls in several of the world' s principal markets, including many countries within the European Union. In the **United States** ~~U. S.~~, where pricing levels for our products are substantially established by third- party payers, including Medicare, if payers reduce the amount of reimbursement for a product, it may cause groups or individuals dispensing the product to discontinue administration of the product, to administer lower doses, to substitute lower cost products or to seek additional price- related concessions. These actions could have a negative effect on our financial results, particularly in cases where our products command a premium price in the marketplace, or where changes in reimbursement induce a shift in the site of treatment. The existence of direct and indirect price controls and pressures over our products could materially adversely affect our financial prospects and performance. The biosimilar pathway established as part of healthcare reform may make it easier for competitors to market biosimilar products. The **ACA and the companion Healthcare and Education Reconciliation Act (which together are referred to as the "** Healthcare Reform Law **")** introduced an abbreviated licensure pathway for biological products that are demonstrated to be biosimilar to an FDA- licensed biological product. A biological product may be demonstrated to be " biosimilar " if data shows that, among other things, the product is " highly similar " to an already- approved biological product, known as a reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product. The law provides that a biosimilar application may be submitted as soon as four years after the reference product is first licensed, and that the FDA may not make approval of an application effective until 12 years after the reference product was first licensed. Since the enactment of the law, the FDA has issued several guidance documents to assist sponsors of biosimilar products in preparing their approval applications. Moreover, in an effort to increase competition in the biologic product marketplace, Congress, the executive branch, and the FDA have taken certain legislative and regulatory steps. For example, in 2020 the FDA finalized a guidance to facilitate biologic product importation. The 2020 Further Consolidated Appropriations Act included provisions requiring that sponsors of approved biologic products provide samples of the approved products to persons developing biosimilar products within specified timeframes, in sufficient quantities, and on commercially reasonable market- based terms. The FDA approved the first biosimilar product in 2015 and has since approved a number of biosimilars. As a result of the biosimilar pathway in the **United States** ~~U. S.~~, we expect in the future to face greater competition from biosimilar products, including a possible increase in patent challenges. The implementation of the Healthcare Reform Law in the **United States** ~~U. S.~~may adversely affect our business. Through the March 2010 adoption of the Healthcare Reform Law in the **United States** ~~U. S.~~, substantial changes are being made to the current system for paying for healthcare in the **United States** ~~U. S.~~, including programs to extend medical benefits to millions of individuals who currently lack insurance coverage. This reform establishes significant cost- saving measures with respect to several government healthcare programs, including Medicaid and Medicare Parts B and D, that may cover the cost of our future products, and these efforts could have a material adverse impact on our future financial prospects and performance. For example, in order for a manufacturer' s products to be reimbursed by federal funding under Medicaid, the manufacturer must enter into a Medicaid rebate agreement with the Secretary of HHS and pay certain rebates to the states based on utilization data provided by each state to the manufacturer and to CMS and pricing data provided by the manufacturer to the federal government. The states share these savings with the federal government, and sometimes implement their own additional supplemental rebate programs. Under the Medicaid drug rebate program, the rebate amount for most branded drug products was previously equal to a minimum of 15. 1 % of the Average Manufacturer Price (" AMP ") or the AMP less Best Price, whichever is greater, plus the inflation penalty if applicable. Effective January 1, 2010, the Healthcare Reform Law generally increased the size of the Medicaid rebates paid by manufacturers for single source and innovator multiple source (brand name) drug products from a minimum of 15. 1 % to a minimum of 23. 1 % of AMP, subject to certain exceptions, plus the inflation penalty if applicable. For non- innovator multiple source (generic) products, the rebate percentage was increased from a minimum of 11. 0 % to a minimum of 13. 0 % of AMP, and the Bipartisan Budget Act of 2015 established a new inflation penalty for these drugs. In 2010, the Healthcare Reform Law also newly extended the Medicaid drug rebate obligation to prescription drugs covered by Medicaid managed care organizations. These increases in required rebates may adversely affect our future financial prospects and performance. In order for a pharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U. S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. As the 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase, and recent regulations have established a civil monetary penalty for failure to refund these overcharges. Effective in 2011, the Healthcare Reform Law imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government

healthcare programs. These fees may adversely affect our future financial prospects and performance. The Healthcare Reform Law also created new rebate obligations for our products under Medicare Part D, a partial, voluntary prescription drug benefit created by the U. S. federal government primarily for persons 65 years old and over. The Part D drug program is administered through private insurers that contract with CMS. Beginning in 2011, the Healthcare Reform Law generally requires that in order for a drug manufacturer' s products to be reimbursed under Medicare Part D, the manufacturer must enter into a Medicare Coverage Gap Discount Program agreement with the Secretary of HHS, and reimburse each Medicare Part D plan sponsor an amount now equal to 70 % savings for the manufacturer' s brand name drugs and biologics which the Part D plan sponsor has provided to its Medicare Part D beneficiaries who are in the " donut hole " (or a gap in Medicare Part D coverage for beneficiaries who have expended certain amounts for drugs). The Part D plan sponsor is responsible for calculating and providing the discount directly to its beneficiaries and for reporting these amounts paid to CMS' s contractor, which notifies drug manufacturers of the rebate amounts it must pay to each Part D plan sponsor. The rebate requirement could adversely affect our future financial performance, particularly if contracts with Part D plans cannot be favorably renegotiated or the Part D plan sponsors fail to accurately calculate payments due in a manner that overstates our rebate obligation. Regarding access to our products, the Healthcare Reform Law established and provided significant funding for a Patient- Centered Outcomes Research Institute to coordinate and fund Comparative Effectiveness Research (" CER "). While the stated intent of CER is to develop information to guide providers to the most efficacious therapies, outcomes of CER could influence the reimbursement or coverage for therapies that are determined to be less cost- effective than others. Should any of our products be determined to be less cost effective than alternative therapies, the levels of reimbursement for these products, or the willingness to reimburse at all, could be impacted, which could materially impact our future financial prospects and results. There have been repeated legal challenges and attempts by Congress to repeal or change the Healthcare Reform Law and the possibility of future challenges or legislative changes contribute to the uncertainty of the ongoing implementation and impact of the law and also underscores the potential for additional reform going forward. We cannot assure that the law, as currently enacted or as amended in the future, will not adversely affect our business and financial results and we cannot predict how future ~~Federal~~ **federal** or state legislative or administrative changes relating to healthcare reform will affect our business. Certain provisions of enacted or proposed legislative changes may negatively impact coverage and reimbursement of, or rebates paid by manufacturers for, healthcare items and services. We will continue to evaluate the effect that the Healthcare Reform Law and any potential changes may have on our business. Corporate responsibility, specifically related to Environmental, Social and Governance (" ESG ") matters, may impose additional costs and expose us to new risks. Public ESG and sustainability reporting is becoming more broadly expected by investors, stockholders and other third parties. Certain organizations that provide corporate governance and other corporate risk information to investors and stockholders have developed, and others may in the future develop, scores and ratings to evaluate companies and investment funds based upon ESG or " sustainability " metrics. Many investment funds focus on positive ESG business practices and sustainability scores when making investments and may consider a company' s ESG or sustainability scores as a reputational or other factor in making an investment decision. In addition, investors, particularly institutional investors, use these scores to benchmark companies against their peers and if a company is perceived as lagging, these investors may engage with such company to improve ESG disclosure or performance and may also make voting decisions, or take other actions, to hold these companies and their boards of directors accountable. Board diversity is an ESG topic that is, in particular, receiving heightened attention by investors, stockholders, lawmakers and listing exchanges. Certain states have passed laws requiring companies to meet certain gender and ethnic diversity requirements on their boards of directors. We may face reputational damage in the event our corporate responsibility initiatives or objectives, including with respect to board diversity, do not meet the standards set by our investors, stockholders, lawmakers, listing exchanges or other constituencies, or if we are unable to achieve an acceptable ESG or sustainability rating from third- party ~~ratingservices~~ **rating services** . A low ESG or sustainability rating by a third- party rating service could also result in the exclusion of our common stock from consideration by certain investors who may elect to invest with our competition instead. Ongoing focus on corporate responsibility matters by investors and other parties as described above may impose additional costs or expose us to new risks.

Risks Relating to our Finances, Capital Requirements and Other Financial ~~Matters~~ **MattersWe** ~~If we are unable to continue to generate positive cashflows and net income, we may require additional funding and may be unable to raise capital when needed, which would adversely affect our operations and could force us to delay, curtail or eliminate some of our commercialization efforts or one or more of our research and development programs. Although we generated positive cash flow from operations for the year ended December 31, 2023, our operations have consumed substantial amounts of cash since inception. While we generated positive cash flow of $ 8. 8 million for the year ended December 31, 2023, for the years ended December 31, 2022 and 2021, we had negative cash flows from operations of $ 59. 5 million and $ 112. 4 million, respectively. We expect to continue to spend substantial amounts for collecting plasma at our plasma collection centers, maintaining our plasma collection centers, procurement of raw material plasma and other raw materials necessary to scale up our manufacturing operations, commercial product launches and capacity expansion at the Boca Facility. In addition, our end- to- end production cycle from collecting and procuring raw material source plasma to commercial release of finished product can take between seven and 12 months or potentially longer, requiring substantial investments in raw material plasma and other manufacturing materials. We had a net loss of $ 28. 2 million for the year ended December 31, 2023 and although we achieved adjusted net income of $ 0. 7 million which, as further described under " Non- GAAP Financial Measures ", excludes charges related to the refinancing of our senior debt of $ 26. 2 million and an IT systems disruption of $ 2. 7 million (see Management' s Discussion and Analysis of Financial Condition and Results of Operations), at present we cannot be certain that we will be able to generate a sufficient amount of product revenue to achieve profitability on an ongoing basis. If we are unable to continue to generate positive cash flow throughout fiscal 2024, we may need to continue to finance our operations through additional equity or debt financings or corporate collaboration and licensing agreements. We currently anticipate, based upon our projected revenue and expenditures,**

~~that our current cash, cash equivalents and accounts receivable, along with our projected future operating cash flow, will be sufficient to fund our operations, as currently conducted, through the first quarter of fiscal 2025. Our current outlook with respect to cash flows and profitability may change based upon how effective we are in continuing to execute on our commercialization efforts and operational initiatives and whether or not the assumptions underlying our projected revenues and expenses are correct. If we are required to raise additional capital and if such capital is not available due to widespread liquidity constraints or significant market instability that could result from widespread economic or geopolitical conditions, we may have to delay, curtail or eliminate our commercialization efforts or our product development activities. We~~ may not have cash available to us in amounts sufficient to enable us to make interest or principal payments on our indebtedness when due. The Ares Credit Facility ~~provides~~ **provided** for total senior secured loans in an aggregate principal amount of ~~up to~~ $ 135. 0 million, ~~all~~ of which ~~has been drawn down and~~ **$ 75. 0 million** is currently outstanding. Borrowings under the Ares Credit Facility currently bear interest at a weighted- average rate of approximately ~~10~~ **9** . 4 % per annum, which reflects the three- month term SOFR rate; provided, however, that upon, and during the continuance of, an event of default, the interest rate will automatically increase by an additional 200 basis points. We are currently required to make quarterly payments of interest during the **remaining** term of the Ares Credit Facility of approximately $ ~~3~~ **1** . ~~7~~ **8** million, with all principal and unpaid interest due at maturity. In addition, our monthly interest rate obligation is subject to rising interest rates. The Ares Credit Facility has a maturity date of December 20, 2027, subject to acceleration pursuant to the Ares Credit Agreement, including upon an event of default. All of our obligations under the Ares Credit Facility are secured by a first- priority lien and security interest in substantially all of our and our subsidiaries' tangible and intangible assets, including intellectual property, and all of the equity interests in our subsidiaries. Our current and projected cash, cash equivalents and accounts receivable may not be sufficient to repay all of our current outstanding debt obligations as they mature. If we are unable to ~~achieve~~ **maintain** sufficient positive cash flow to repay our outstanding debt obligations as they mature, we ~~will~~ **would** need to obtain additional financing in the amounts necessary to repay our outstanding debt obligations when due. If we are unable to repay our outstanding debt obligations when they mature, our creditors would be able to accelerate all of the amounts due and, in the case of the Ares Credit Facility, seek to enforce their security interests, which could lead to our creditors taking immediate possession of and selling substantially all of our assets with no return provided to our stockholders. Raising additional funds by issuing securities or through licensing or lending arrangements may cause dilution to our existing stockholders, restrict our operations or require us to relinquish proprietary rights. To the extent that we raise additional capital by issuing equity securities, the share ownership of existing stockholders will be diluted. Any future debt financing may involve covenants that, among other restrictions, limit our ability to incur liens or additional debt, pay dividends, redeem or repurchase our common stock, make certain investments or engage in certain merger, consolidation or asset sale transactions. In addition, if we raise additional funds through licensing arrangements or the disposition of any of our assets, it may be necessary to relinquish potentially valuable rights to our product candidates or grant licenses on terms that are not favorable to us. Our cash and cash equivalents could be adversely affected if the financial institutions in which we hold our cash and cash equivalents fail. We regularly maintain cash balances at third- party financial institutions in excess of the Federal Deposit Insurance Corporation insurance limit. While we monitor the cash balances in our operating accounts on a daily basis and adjust the balances as appropriate, these balances could be impacted, and there could be a material adverse effect on our business, if one or more of the financial institutions with which we deposit cash fails or is subject to other adverse conditions in the financial or credit markets. To date, we have experienced no loss or lack of access to our invested cash or cash equivalents; however, we can provide no assurance that access to our invested cash and cash equivalents will not be impacted by adverse conditions in the financial and credit markets. If we fail to maintain proper and effective internal control over financial reporting in the future, our ability to produce accurate and timely financial statements could be impaired, which could result in investors losing confidence in the accuracy and completeness of our financial statements, harm our operating results and negatively affect the market price of our common stock. Pursuant to Section 404 of the Sarbanes- Oxley Act of 2002 and related rules (the " Sarbanes- Oxley Act "), we are required to maintain internal control over financial reporting and our management is required to report on the effectiveness of our internal control over financial reporting, including any material weaknesses in such internal controls. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we have been required to upgrade, and ~~may~~ **will** need to implement further upgrades, to our financial, information and operating systems, implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff. Because we became a large accelerated filer effective December 31, 2023, the Sarbanes- Oxley Act requires our independent registered public accounting firm to attest to the effectiveness of our internal control over financial reporting. Our transition to large accelerated filer status and becoming subject to additional requirements of the Sarbanes- Oxley Act **has been and** will **continue to** be time- consuming, and there is a risk of noncompliance. Further, the costs associated with the compliance with and implementation of procedures under these and future laws and related rules could have a material impact on our results of operations. Consequently, we have incurred increased costs related to our compliance with Section 404 of the Sarbanes- Oxley Act and will continue to do so. Our Audit Committee has retained the services of BDO, a Sarbanes- Oxley advisor, to assist with our internal control over financial reporting and information technology related to the Sarbanes- Oxley Act. Moreover, if we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. If we identify material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 of the Sarbanes- Oxley Act in a timely manner, if we are unable to assert that our internal ~~controls~~ **control** over financial reporting is effective or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, and the market price of our

common stock could be negatively affected. In addition, we could become subject to investigations by any stock exchange on which our securities are listed, the SEC or other regulatory authorities, which could require additional financial and management resources, which could have an adverse impact on our business. Our ability to use our net operating loss carryforwards (“ NOLs ”) may be limited. We have incurred substantial losses during our history. As of December 31, ~~2023~~ **2024**, we had federal and state NOLs of $ ~~315~~ **265**. 6 million and $ ~~216~~ **203**. 4 million, respectively. Federal and state NOLs of approximately $ ~~35~~ **33**. ~~6~~ **4** million and $ ~~95~~ **62**. ~~1~~ **0** million, respectively, will begin to expire at various dates beginning in 2028, if not limited by triggering events prior to such time. Under the provisions of the Internal Revenue Code of 1986, as amended (the “ Code ”), changes in our ownership, in certain circumstances, will limit the amount of federal NOLs that can be utilized annually in the future to offset taxable income. In particular, Section 382 of the Code (" Section 382") imposes limitations on a company’ s ability to use NOLs upon certain changes in such ownership. If we are limited in our ability to use our NOLs in future years in which we have taxable income, we will pay more taxes than if we were able to fully utilize our NOLs. The acquisition transaction that we completed on June 6, 2017 resulted in a change in ownership of ADMA under Section 382 and, as a result, we were required to write off $ 57. 6 million of ~~Federal~~ **federal** NOLs. On October 25, 2021, we completed a public offering of our common stock whereby we issued 57, 500, 000 shares of our common stock resulting in another change of ownership for ADMA under section 382 of the Code, resulting in an additional write- off of $ 3. 0 million of ~~Federal~~ **federal** NOLs, $ 28. 1 million of state NOLs and $ 1. 0 million of research and development credits. Although we did not experience any ownership changes for the years ended December 31, **2024 and** 2023 ~~and 2022~~, we may experience ownership changes in the future as a result of subsequent changes in our stock ownership that we cannot predict or control that could result in further limitations being placed on our ability to utilize our ~~Federal~~ **federal** NOLs **. Fluctuations in our tax obligations and effective tax rate and realization of our net deferred tax assets may result in volatility of our operating results and materially impact our financial condition or financial results. We are subject to taxes by the U. S. federal, state, and local tax authorities. We record income tax expense based on our estimates of future payments, which may include the recording of, or adjustments to, liabilities for uncertain tax positions, and changes in the valuation allowance related to our net deferred tax assets. In addition, at any one time multiple tax years may be subject to audit by various tax authorities. The results of these audits and negotiations with taxing authorities may affect the ultimate settlement of these issues and impact our results of operations. We expect that during fiscal year 2025 and beyond there could be ongoing variability in our effective tax rate as events occur and exposures are evaluated. The volatility of our future effective tax rate could be materially impacted by a number of factors, including: • changes in the valuation of our deferred tax assets and liabilities; • expected timing and amount of the release of any valuation allowance on our deferred tax assets; or • changes in U. S. federal, state and local tax rates, tax laws, regulations, or interpretations thereof. In addition, our effective tax rate in a given financial statement period may be materially impacted by a variety of factors including, but not limited to, changes in the mix and level of earnings, deductible expenses and availability of NOLs in the different states in which we operate, fluctuations in the valuation allowance on our deferred tax assets, or by changes to existing accounting rules or regulations. Further, tax legislation may be enacted or amended, as applicable, in the future which could materially impact our current or future tax structure and effective tax rates. We may be subject to audits of our income, sales, and other transaction taxes by U. S. federal, state, and local taxing authorities. Outcomes from these audits could have a material effect on our financial condition or financial results** . Risks Associated with our Common Stock Our stock price may experience substantial volatility as a result of a number of factors, including: • sales or potential sales of substantial amounts of our common stock; • delay or failure in initiating or completing preclinical or clinical trials or unsatisfactory results of these trials; • delay in a decision by ~~Federal~~ **federal**, state or local business regulatory authority; • the timing of acceptance, third- party reimbursement and sales of BIVIGAM and ASCENIV; • announcements about us or about our competitors, including clinical trial results, regulatory approvals or new product introductions; • developments concerning our licensors or third- party vendors; • litigation and other developments relating to our patents or other proprietary rights or those of our competitors; • conditions in the pharmaceutical or biotechnology industries; • governmental regulation and legislation; • overall market volatility; • global and economic uncertainty; • variations in our anticipated or actual operating results; and • change in securities analysts’ estimates of our performance, or our failure to meet analysts’ expectations. Many of these factors are beyond our control. The stock markets in general, and the market for pharmaceutical and biotechnology companies in particular, have historically experienced extreme price and volume fluctuations. These fluctuations often have been unrelated or disproportionate to the operating performance of these companies. These broad market and industry factors could reduce the market price of our common stock, regardless of our actual operating performance. Sales of a substantial number of shares of our common stock, or the perception that such sales may occur, may adversely affect the market price of our common stock. As of ~~February 23~~ **March 10**, ~~2024~~ **2025**, most of our ~~228~~ **237**, ~~220~~ **615**, ~~236~~ **100** outstanding shares of common stock, as well as a substantial number of shares of our common stock underlying outstanding warrants, were available for sale in the public market, subject to certain restrictions with respect to sales of our common stock by our affiliates, either pursuant to Rule 144 under the Securities Act, or under effective registration statements. Sales of a substantial number of shares of our common stock, or the perception that such sales may occur, could cause the market price of our common stock to decline or adversely affect demand for our common stock. Our affiliates control a substantial amount of our shares of common stock. Provisions in our Second Amended and Restated Certificate of Incorporation, as amended (the “ Certificate of Incorporation ”), our Amended and Restated Bylaws (the “ Bylaws ”) and Delaware law might discourage, delay or prevent a change in control of our Company or changes in our management and, therefore, depress the trading price of our common stock. As of December 31, ~~2023~~ **2024**, BlackRock Inc., **The** Vanguard Group **, Inc., State Street Corporation, Invesco Ltd.** and our directors and executive officers and their affiliates owned approximately ~~16~~ **37** % of the outstanding shares of our common stock. Provisions of our Certificate of Incorporation, our Bylaws and Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing

a change in control of our Company or changes in our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interests. These provisions include: • the inability of stockholders to call special meetings; • classification of our Board and limitation on filling of vacancies could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of our Company; and • authorization of the issuance of " blank check " preferred stock, with such designation rights and preferences as may be determined from time to time by the Board, without any need for action by stockholders. In addition, Section 203 of the Delaware General Corporation Law prohibits a publicly- held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years, has owned 15 % of our voting stock, 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. The existence of the foregoing provisions and anti- takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our Company, thereby reducing the likelihood that you could receive a premium for your common stock in an acquisition. In addition, as a result of the concentration of ownership of our shares of common stock, our stockholders may, from time to time, observe instances where there may be less liquidity in the public markets for our securities. We have never paid and do not intend to pay cash dividends in the foreseeable future. As a result, capital appreciation, if any, will be your sole source of gain. We have never paid cash dividends on any of our capital stock, and we currently intend to retain future earnings, if any, to fund the development and growth of our business. In addition, the terms of existing and future debt agreements may preclude us from paying dividends. For example, the Ares Credit Agreement prohibits us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. If we fail to adhere to the strict listing requirements of the Nasdaq Global Market (" Nasdaq "), we may be subject to delisting. As a result, our stock price may decline and our common stock may be delisted. If our stock were no longer listed on Nasdaq, the liquidity of our securities likely would be impaired. Our Common Stock currently trades on the Nasdaq Global Market under the symbol " ADMA. " If we fail to adhere to Nasdaq' s strict listing criteria, including with respect to stock price, market capitalization and stockholders' equity, our stock may be delisted. This could potentially impair the liquidity of our securities not only in the number of shares that could be bought and sold at a given price, which may be depressed by the relative illiquidity, but also through delays in the timing of transactions and the potential reduction in media coverage. As a result, an investor might find it more difficult to dispose of our common stock. We believe that current and prospective investors would view an investment in our common stock more favorably if it continues to be listed on Nasdaq. Any failure at any time to meet the Nasdaq continued listing requirements could have an adverse impact on the value and trading activity of our common stock. Although we currently satisfy the listing criteria for Nasdaq, if our stock price declines dramatically, we could be at risk of failing to meet the Nasdaq continued listing criteria. Our Board may, without stockholder approval, issue and fix the terms of shares of preferred stock and issue additional shares of common stock adversely affecting the rights of holders of our common stock. Our Certificate of Incorporation authorizes the issuance of up to 10, 000, 000 shares of " blank check " preferred stock, with such designation rights and preferences as may be determined from time to time by the Board. Currently, our Certificate of Incorporation authorizes the issuance of up to 300, 000, 000 shares of common stock. As of December 31, ~~2023~~ **2024**, there were ~~31~~ **36**, ~~033~~ **093**, ~~333~~ **118** shares remaining available for issuance, after giving effect to ~~23~~ **11**, ~~066~~ **854**, ~~387~~ **060** shares of our common stock that were subject to outstanding stock options, RSUs and warrants as of December 31, ~~2023~~ **2024** that may be issued by us without stockholder approval, as well as an additional ~~19~~ **15**, ~~837~~ **432**, ~~248~~ **277** shares reserved for the future issuance of awards under our equity compensation plans. Item 1B. Unresolved Staff Comments