

April 26, 2024

FORM C-AR

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ASPIRE BIOPHARMA INC.

*A Puerto Rico Corporation*



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This Form C-AR (including the cover page and all exhibits attached hereto, the “Form C-AR”) is being furnished by Aspire Biopharma Inc., a Puerto Rico Corporation (the “Company,” as well as references to “Aspire,” “we,” “us,” or “our”) for the sole purpose of providing certain information about the Company as required by the Securities and Exchange Commission (“SEC”).

No federal or state securities commission or regulatory authority has passed upon the accuracy or adequacy of this document. The SEC does not pass upon the accuracy or completeness of any disclosure document or literature. The Company is filing this Form C-AR pursuant to Regulation CF (§ 227.100 et seq.) which requires that it must file a report with the Commission and annually post the report on its website at <https://aspirebiolabs.com> no later than 120 days after the end of each fiscal year covered by the report. The Company may terminate its reporting obligations in the future in accordance with Rule 202(b) of Regulation CF (§ 227.202(b)) by (1) being required to file reports under Section 13(a) or Section 15(d) of the Exchange Act of 1934, as amended, (2) filing at least one annual report pursuant to Regulation CF and having fewer than 300 holders of record, (3) filing annual reports for three years pursuant to Regulation CF and having assets equal to or less than \$10,000,000, (4) the repurchase of all the Securities sold pursuant to Regulation CF by the Company or another party or (5) the liquidation or dissolution of the Company.

The date of this Form C-AR is April 26, 2024.

***THIS FORM C-AR DOES NOT CONSTITUTE AN OFFER TO PURCHASE OR SELL SECURITIES.***

**ABOUT THIS FORM C-AR**

You should rely only on the information contained in this Form C-AR. We have not authorized anyone to provide any information different from that contained in this Form C-AR. If anyone provides you with different or inconsistent information, you should not rely on it. Statements contained herein as to the content of any agreements or other documents are summaries and, therefore, are necessarily selective and incomplete and are qualified in their entirety by the actual agreements or other documents.

You should assume that the information contained in this Form C-AR is accurate only as of the date of this Form C-AR, regardless of the time of delivery of this Form C-AR. Our business, financial condition, results of operations, and prospects may have changed since that date.

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## **FORWARD-LOOKING STATEMENTS**

This Form C-AR and any documents incorporated by reference herein contain forward-looking statements and are subject to risks and uncertainties. All statements other than statements of historical fact or relating to present facts or current conditions included in this Form C-AR are forward-looking statements. Forward-looking statements give our current reasonable expectations and projections regarding our financial condition, results of operations, plans, objectives, future performance and business. You can identify forward-looking statements by the fact that they do not relate strictly to historical or current facts. These statements may include words such as “anticipate,” “estimate,” “expect,” “project,” “plan,” “intend,” “believe,” “may,” “should,” “can have,” “likely” and other words and terms of similar meaning in connection with any discussion of the timing or nature of future operating or financial performance or other events.

The forward-looking statements contained in this Form C-AR and any documents incorporated by reference herein are based on reasonable assumptions we have made in light of our industry experience, perceptions of historical trends, current conditions, expected future developments and other factors we believe are appropriate under the circumstances. As you read and consider this Form C-AR, you should understand that these statements are not guarantees of performance or results. Although we believe that these forward-looking statements are based on reasonable assumptions, you should be aware that many factors could affect our actual operating and financial performance and cause our performance to differ materially from the performance anticipated in the forward-looking statements. Should one or more of these risks or uncertainties materialize, or should any of these assumptions prove incorrect or change, our actual operating and financial performance may vary in material respects from the performance projected in these forward-looking statements.

Investors are cautioned not to place undue reliance on these forward-looking statements. Any forward-looking statements made in this Form C-AR or any documents incorporated by reference herein are accurate only as of the date of those respective documents. Except as required by law, we undertake no obligation to publicly update any forward-looking statements for any reason after the date of this Form C-AR or to conform these statements to actual results or to changes in our expectations.

## **OTHER INFORMATION**

The Company has not failed to comply with the ongoing reporting requirements of Regulation CF §227.202 in the past.

### **Bad Actor Disclosure**

The Company is not subject to any Bad Actor Disqualifications under any relevant U.S. securities laws.

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## SIGNATURE

Pursuant to the requirements of Sections 4(a)(6) and 4A of the Securities Act of 1933 and Regulation Crowdfunding (§ 227.100 et seq.), the issuer certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form C-AR and has duly caused this Form C-AR to be signed on its behalf by the duly authorized undersigned.

The issuer also certifies that the attached financial statements are true and complete in all material respects.

Aspire Biopharma Inc.  
(Company)

By: /s/ Kraig T. Higginson  
(Signature)

Kraig T. Higginson  
(Name)

Chief Executive Officer & Chairman of the Board  
(Title)

Pursuant to the requirements of Sections 4(a)(6) and 4A of the Securities Act of 1933 and Regulation Crowdfunding (§ 227.100 et seq.), this Form C-AR has been signed by the following persons in the capacities and on the dates indicated.

/s/ Kraig T. Higginson  
(Signature)

Kraig T. Higginson  
(Name)

Chief Executive Officer & Chairman of the Board  
(Title)

April 26, 2024  
(Date)

/s/ Ernest J. Scheidemann, Jr.  
(Signature)

Ernest J. Scheidemann, Jr.  
(Name)

Chief Financial Officer  
(Title)

April 26, 2024  
(Date)

/s/ Stephen Quesenberry  
(Signature)

Stephen Quesenberry  
(Name)

General Counsel and Corporate Secretary  
(Title)

April 26, 2024  
(Date)

## Instructions.

1. The form shall be signed by the issuer, its principal executive officer or officers, its principal financial officer, its controller or principal accounting officer and at least a majority of the board of directors or persons performing similar functions.
  2. The name of each person signing the form shall be typed or printed beneath the signature. Intentional misstatements or omissions of facts constitute federal criminal violations. See 18 U.S.C. 1001.
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## EXHIBIT A

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### ANNUAL REPORT (EXHIBIT A TO FORM C-AR) April 26, 2024

**Aspire Biopharma Inc.**



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#### SUMMARY

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*The following summary is qualified in its entirety by more detailed information that may appear elsewhere in the Form C-AR and the Exhibits hereto. This summary may not contain all of the information that may be important to you. You should read the entire Form C-AR carefully, including this Exhibit A and Exhibit B therein.*

#### **Description of the Business**

Aspire Biopharma Inc. ("Company") is a privately held, early-stage biopharmaceutical company. As a Puerto Rico corporation formed in September 2021, the Company is engaged in the business of developing and marketing the disruptive technology for novel delivery mechanisms, initially for "do no harm" drugs.

The Company is located at 194 Candelaro Drive, #223, Humacao, Puerto Rico 00791.

The Company's website is <https://aspirebiolabs.com>.

The Company, having sold securities pursuant to Regulation Crowdfunding under the Securities Act of 1933, is filing this annual report pursuant to Rule 202 of Regulation Crowdfunding for the fiscal year ended December 31, 2023. We have filed this report as of the filing date above, and the report may be found on the Company's website.

The information on the Company available on or through our website is not a part of this Form C-AR.

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## RISK FACTORS

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*The United States Securities and Exchange Commission requires the Company to identify risks that are specific to its business and financial condition. The Company is still subject to all the same risks that all companies in its business, and all companies in the economy, are exposed to. These include risks relating to economic downturns, political and economic events and technological developments (such as hacking and the ability to prevent hacking). Additionally, early-stage companies are inherently riskier than more developed companies. You should consider general risks as well as specific risks, including, but not limited to, those noted herein.*

### **Risks Relating to Our Business and Industry**

***We have a limited operating history upon which you can evaluate our performance, and accordingly, our prospects must be considered in light of the risks that any new company encounters.***

The Company is still in an early phase and we are just beginning to implement our business plan. There can be no assurance that we will ever operate profitably. The likelihood of our success should be considered in light of the problems, expenses, difficulties, complications and delays usually encountered by early-stage companies. The Company may not be successful in attaining the objectives necessary for it to overcome these risks and uncertainties.

***Global crises and geopolitical events, including without limitation, events such as COVID-19 can have a significant effect on our business operations and revenue projections.***

A significant outbreak of contagious diseases, such as COVID-19, in the human population could result in a widespread health crisis. Additionally, geopolitical events, such as wars or conflicts, could result in global disruptions to supplies, political uncertainty and displacement. Each of these crises could adversely affect the economies and financial markets of many countries, including the United States where we principally operate, resulting in an economic downturn that could reduce the demand for our product candidates and impair our business prospects, including as a result of being unable to raise additional capital on acceptable terms, if at all.

***The amount of capital available with the Company may not be enough to sustain the Company's current business plan.***

In order to achieve the Company's near and long-term goals, the Company may need to procure additional funds. There is no guarantee the Company will be able to raise such funds on acceptable terms or at all. If we are not able to raise sufficient capital in the future, we may not be able to execute our business plan, our continued operations will be in jeopardy and we may be forced to cease operations and sell or otherwise transfer all or substantially all of our remaining assets, which could cause an Investor to lose all or a portion of their investment.

***We may face potential difficulties in obtaining capital.***

We may have difficulty raising needed capital in the future as a result of, among other factors, our lack of revenues from sales, as well as the inherent risks associated with our business and present and future market conditions. Our business currently does not generate any sales and future sources of revenue may not be sufficient to meet our future capital requirements. We will require additional funds to execute our business strategy and conduct our operations. If adequate funds are unavailable, we may be required to delay, reduce the scope of or eliminate one or more of our research, development or commercialization programs, product launches or marketing efforts, any of which may materially harm our business, financial condition and results of operations.

***We may implement new lines of business or offer new products and services within existing lines of business.***

As an early-stage company, we may implement new lines of business at any time. There are substantial risks and uncertainties associated with these efforts, particularly in instances where the markets are not fully developed. In developing and marketing new lines of business and/or new products and services, we may invest significant time and resources. Initial timetables for the introduction and development of new lines of business and/or new products or services may not be achieved, and price and profitability targets may not prove feasible. We may not be successful in introducing new products and services in response to industry trends or developments in technology, or those new products may not achieve market acceptance. As a result, we could lose business, be forced to price products and services on less advantageous terms to retain or attract clients or be subject to cost increases. As a result, our business, financial condition or results of operations may be adversely affected.

***We rely on other companies to provide components and services for our product candidates.***

We depend on suppliers and contractors to meet our contractual obligations to our customers and conduct our operations. Our ability to meet our obligations to our customers may be adversely affected if suppliers or contractors do not provide the agreed-upon supplies or perform the agreed-upon services in compliance with customer requirements and in a timely and cost-effective manner. Likewise, the quality of our products may be adversely impacted if companies to whom we delegate manufacture of major components or subsystems for our products, or from whom we acquire such items, do not provide components which meet required specifications and perform to our and our customers' expectations. Our suppliers may be unable to quickly recover from natural disasters and other events beyond their control and may be subject to additional risks such as financial problems that limit their ability to conduct their operations. The risk of these adverse effects may be greater in circumstances where we rely on only one or two contractors or suppliers for a particular component. Our products may utilize custom components available from only one source. Continued availability of those components at acceptable prices, or at all, may be affected for any number of reasons, including if those suppliers decide to concentrate on the production of common components instead of components customized to meet our requirements. The supply of components for a new or existing product could be delayed or constrained, or a key manufacturing vendor could delay shipments of completed products to us adversely affecting our business and results of operations.

***We rely on various intellectual property rights, including trademarks, in order to operate our business.***

The Company relies on certain intellectual property rights to operate its business. The Company's intellectual property rights may not be sufficiently broad or otherwise may not provide us a significant competitive advantage. In addition, the steps that we have taken to maintain and protect our intellectual property may not prevent it from being challenged, invalidated, circumvented or designed-around, particularly in countries where intellectual property rights are not highly developed or protected. In some circumstances, enforcement may not be available to us because an infringer has a dominant intellectual property position or for other business reasons, or countries may require compulsory licensing of our intellectual property. Our failure to obtain or maintain intellectual property rights that convey competitive advantage, adequately protect our intellectual property or detect or prevent circumvention or unauthorized use of such property, could adversely impact our competitive position and results of operations. We also rely on nondisclosure and noncompetition agreements with our contract staff, consultants and other parties to protect, in part, trade secrets and other proprietary rights. There can be no assurance that these agreements will adequately protect our trade secrets and other proprietary rights and 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 other proprietary rights. As we expand our business, protecting our intellectual property will become increasingly important. The protective steps we have taken may be inadequate to deter our competitors from using our proprietary information. In order to protect or enforce our patent rights, we may be required to initiate litigation against third parties, such as infringement lawsuits. Also, these third parties may assert claims against us with or without provocation. These lawsuits could be expensive, take significant time and could divert management's attention from other business concerns. The law relating to the scope and validity of claims in the technology field in which we operate is still evolving and, consequently, intellectual property positions in our industry are generally uncertain. We cannot assure you that we will prevail in any of these potential suits or that the damages or other remedies awarded, if any, would be commercially valuable.

***The Company's success depends on the experience and skill of the board of directors, its executive officers and other key persons.***

We are dependent on our board of directors, executive officers and other key contract staff. These persons may not devote their full time and attention to the matters of the Company. The loss of our board of directors, executive officers and key contract staff could harm the Company's business, financial condition, cash flow and results of operations.

***Although dependent on certain key personnel, the Company does not have any key person life insurance policies on any such people.***

We are dependent on certain key personnel in order to conduct our operations and execute our business plan, however, the Company has not purchased any insurance policies with respect to those individuals in the event of their death or disability. Therefore, if any of these personnel die or become disabled, the Company will not receive any compensation to assist with such person's absence. The loss of such person could negatively affect the Company and our operations. We have no way to guarantee key personnel will stay with the Company, as many states do not enforce non-competition agreements, and therefore acquiring key man insurance will not ameliorate all of the risk of relying on key personnel.

***Damage to our reputation could negatively impact our business, financial condition and results of operations.***

Our reputation and the quality of our brand are critical to our business and success in existing markets, and will be critical to our success as we enter new markets. Any incident that erodes consumer loyalty for our brand could significantly reduce its value and damage our business. We may be adversely affected by any negative publicity, regardless of its accuracy. Also, there has been a marked increase in the use of social media platforms and similar devices, including blogs, social media websites and other forms of internet-based communications that provide individuals with access to a broad audience of consumers and other interested persons. The availability of information on social media platforms is virtually immediate as is its impact. Information posted may be adverse to our interests or may be inaccurate, each of which may harm our performance, prospects or business. The harm may be immediate and may disseminate rapidly and broadly, without affording us an opportunity for redress or correction.

***Our business could be negatively impacted by cyber security threats, attacks and other disruptions.***

We continue to face advanced and persistent attacks on our information infrastructure where we manage and store various proprietary information and sensitive/confidential data relating to our operations. These attacks may include sophisticated malware (viruses, worms, and other malicious software programs) and phishing emails that attack our products or otherwise exploit any security vulnerabilities. These intrusions sometimes may be zero-day malware that are difficult to identify because they are not included in the signature set of commercially available antivirus scanning programs. Experienced computer programmers and hackers may be able to penetrate our network security and misappropriate or compromise our confidential information or that of our customers or other third-parties, create system disruptions, or cause shutdowns. Additionally, sophisticated software and applications that we produce or procure from third-parties may contain defects in design or manufacture, including "bugs" and other problems that could unexpectedly interfere with the operation of the information infrastructure. A disruption, infiltration or failure of our information infrastructure systems or any of our data centers as a result of software or hardware malfunctions, computer viruses, cyber-attacks, theft by contract staff professionals or misuse, power disruptions, natural disasters or accidents could cause breaches of data security, loss of critical data and performance delays, which in turn could adversely affect our business.

***Security breaches of confidential customer information, in connection with our electronic processing of credit and debit card transactions, or confidential information about contract staff professionals may adversely affect our business.***

Our business requires the collection, transmission and retention of personally identifiable information, in various information technology systems that we maintain and in those maintained by third parties with whom we contract to provide services. The integrity and protection of that data is critical to us. The information, security and privacy requirements imposed by governmental regulation are increasingly demanding. Our systems may not be able to satisfy these changing requirements and customer and expectations of contract staff professionals, or may require significant additional investments or time in order to do so. A breach in the security of our information technology systems or those of our service providers could lead to an interruption in the operation of our systems, resulting in operational inefficiencies and a loss of profits. Additionally, a significant theft, loss or misappropriation of, or access to, customers' or other proprietary data or other breach of our information technology systems could result in fines, legal claims or proceedings.



***The use of individually identifiable data by our business, our business associates and third parties is regulated at the state, federal and international levels.***

The regulation of individual data is changing rapidly, and in unpredictable ways. A change in regulation could adversely affect our business, including causing our business model to no longer be viable. Costs associated with information security – such as investment in technology, the costs of compliance with consumer protection laws and costs resulting from consumer fraud – could cause our business and results of operations to suffer materially. Additionally, the success of our online operations depends upon the secure transmission of confidential information over public networks, including the use of cashless payments. The intentional or negligent actions of our contract staff professionals, business associates or third parties may undermine our security measures. As a result, unauthorized parties may obtain access to our data systems and misappropriate confidential data. There can be no assurance that advances in computer capabilities, new discoveries in the field of cryptography or other developments will prevent the compromise of our customer transaction processing capabilities and personal data. If any such compromise of our security or the security of information residing with our business associates or third parties were to occur, it could have a material adverse effect on our reputation, operating results and financial condition. Any compromise of our data security may materially increase the costs we incur to protect against such breaches and could subject us to additional legal risk.

***The Company is not subject to Sarbanes-Oxley regulations and may lack the financial controls and procedures of public companies.***

The Company may not have the internal control infrastructure that would meet the standards of a public company, including the requirements of the Sarbanes Oxley Act of 2002. As a privately-held (non-public) company, the Company is currently not subject to the Sarbanes Oxley Act of 2002, and its financial and disclosure controls and procedures reflect its status as a development stage, non-public company. There can be no guarantee that there are no significant deficiencies or material weaknesses in the quality of the Company's financial and disclosure controls and procedures. If it were necessary to implement such financial and disclosure controls and procedures, the cost to the Company of such compliance could be substantial and could have a material adverse effect on the Company's results of operations.

***We operate in a highly regulated environment, and if we are found to be in violation of any of the federal, state, or local laws or regulations applicable to us, our business could suffer.***

We may also be subject to a wide range of federal, state, and local laws and regulations, such as local licensing requirements, and retail financing, debt collection, consumer protection, environmental, health and safety, creditor, wage-hour, anti-discrimination, whistleblower and other employment practices laws and regulations and we expect these costs to increase going forward. The violation of these or future requirements or laws and regulations could result in administrative, civil, or criminal sanctions against us, which may include fines, a cease and desist order against the subject operations or even revocation or suspension of our license to operate the subject business. As a result, we have incurred and will continue to incur capital and operating expenditures and other costs to comply with these requirements and laws and regulations.

***Our limited operating history may make it difficult for us to accurately forecast our operating results.***

Our planned expense levels are, and will continue to be, based in part on our expectations, which are difficult to forecast accurately based on our stage of development and factors outside of our control. We may be unable to adjust spending in a timely manner to compensate for any unexpected developments. Further, business development expenses may increase significantly as we expand operations. To the extent that any unexpected expenses precede, or are not rapidly followed by, a corresponding increase in revenue, our business, operating results, and financial condition may be materially and adversely affected.

***We have incurred net losses in every year since our inception and anticipate that we will continue to incur substantial and increasing net losses in the foreseeable future.***

We are a clinical-stage biopharmaceutical company with a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have financed our operations primarily through the sale of equity securities. Since our inception, most of our resources have been dedicated to the preclinical development of our product candidates. The size of our future net losses will depend, in part, on our future expenses and our ability to generate revenue, if any. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses since our inception. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates.

Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

***We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.***

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the clinical development of our product candidates. If we are able to receive regulatory approval for any of our product candidates, we will require significant additional amounts of cash in order to launch and commercialize any such product candidates. In addition, other unanticipated costs may arise. Because the design and outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates if clinical trials are successful;
- the cost of commercialization activities for our product candidates, if any of our product candidates is approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing our product candidates for clinical trials in preparation for regulatory approval and in preparation for commercialization;
- our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the timing, receipt and amount of sales of, or royalties on, our future products, if any; and
- the emergence of competing therapies and other adverse market developments.

We do not have any committed external source of funds or other support for our development efforts. Until we can generate sufficient product and royalty revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. Additional financing may not be available to us when we need it or it may not be available on favorable terms.

If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our clinical trials or research and development programs or our commercialization efforts.

***Our technology platforms and product candidates are based on novel technologies, and the development and regulatory approval pathway for such product candidates is unproven and may never lead to marketable products.***

We are developing novel targeted therapies to treat heart attacks and strokes. Any products we develop may not effectively inhibit or treat heart attacks and strokes. The scientific evidence to support the feasibility of developing product candidates including Instaprin is preliminary and limited. Advancing these novel therapies creates significant challenges for us, including, among others:

- obtaining approval from regulatory authorities to conduct clinical trials with our product candidates;
- successful enrollment and completion of preclinical studies and clinical trials with favorable results;
- obtaining approvals from regulatory authorities to manufacture and market our product candidates;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers for, or establishing, commercial manufacturing capabilities;
- manufacturing our product candidates at an acceptable cost;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with other partners;
- acceptance of our product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other heart attack and stroke therapies;
- obtaining and maintaining coverage and adequate reimbursement by third-party payors, including government payors, for our product candidates;
- protecting rights in our intellectual property portfolio;
- maintaining a continued acceptable safety profile of our product candidates, if approved, following approval; and
- maintaining and growing an organization of scientists and business people who can develop and commercialize our products and technology.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully develop and commercialize our product candidates, which could materially harm our business, financial condition and results of operations.

***Our business is highly dependent on the success of our lead product candidate, Instaprin which will require significant additional clinical testing before we can seek regulatory approval and potentially launch commercial sales.***

We do not have any products that have gained regulatory approval. Our business and future success depends on our ability to obtain regulatory approval of and then successfully commercialize our lead product candidate, Instaprin, which is in the early stages of Preclinical development. We are currently conducting our preclinical tests to compile and file an IND (investigational new drug application). Our ability to develop, obtain regulatory acceptance for Instaprin to enter clinical trials will depend on several factors, including the following:

- successfully demonstrating that the therapy is reasonably safe for human clinical studies;
- effectively demonstrating that the chemical composition and manufacturing methods and controls are consistent; and
- providing protocol detail proposed for clinical trials that ensure subjects will not be exposed to unnecessary risk and that the professionals overseeing the administration of the study are qualified.

Our product candidates, including Instaprin, will require additional clinical and non-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. If we are unable to develop or receive marketing approval for Instaprin or other products we develop in a timely manner or at all, we could experience significant delays or an inability to commercialize Instaprin or other products, which would materially and adversely affect our business, financial condition and results of operations.

***Clinical development involves a lengthy and expensive process with uncertain outcomes, and results of earlier studies and trials may not be predictive of future clinical trial results. Our clinical trials may fail to demonstrate adequately the safety and efficacy of one or more of our product candidates, which would prevent or delay regulatory approval and commercialization.***

Before obtaining regulatory approvals for the commercial sale of our product candidates, including Instaprin, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. We cannot be certain that we will not face similar setbacks. Most product candidates that commence clinical trials are never approved as commercial products.

We may experience delays in our ongoing clinical trials and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining institutional review board, or IRB, approval at each site;
- recruiting suitable patients to participate in a trial;

- having patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of product candidate for use in clinical trials.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash compensation in connection with such services. If certain of these relationships exceed specific financial thresholds, they must be reported to the FDA. If these relationships and any related compensation paid results in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay in approval, or rejection, of our marketing applications by the FDA. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

In addition, even if the trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and we may need to conduct additional trials before we submit applications seeking regulatory approval of our product candidates.

To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

***Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential, if approved, or result in significant negative consequences.***

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics.

If unacceptable side effects arise in the development of our product candidates, we could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

***If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.***

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. Moreover, because our product candidates represent a departure from more commonly used methods for heart attack and stroke treatments, potential patients and their doctors may be inclined to use conventional therapies, rather than enroll patients in any future clinical trials.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

***Clinical trials are expensive, time-consuming and difficult to design and implement.***

Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Because our product candidates are based on new technologies and engineered on a patient-by-patient basis, we expect that they will require extensive research and development and have substantial manufacturing and processing costs. In addition, costs to treat patients with heart attacks/ strokes and to treat potential side effects that may result from our product candidates may be significant. Accordingly, our clinical trial costs are likely to be significantly higher than for more conventional therapeutic technologies or drug products.

***If we fail to develop additional product candidates, our commercial opportunity will be limited.***

We expect to initially develop our lead product candidate, Instaprin, a fast-acting form of powdered aspirin that could instantly stop heart attacks and strokes. However, one of our strategies is to pursue clinical development of additional product candidates. Developing, obtaining regulatory approval for and commercializing additional product candidates will require substantial additional funding beyond the net proceeds of this offering and are prone to the risks of failure inherent in medical product development. We cannot assure you that we will be able to successfully advance any of these additional product candidates through the development process.

Even if we obtain FDA approval to market additional product candidates for the treatment of heart attacks and strokes, we cannot assure you that any such product candidates will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize additional product candidates, our commercial opportunity will be limited. Moreover, a failure in obtaining regulatory approval of additional product candidates may have a negative effect on the approval process of any other, or result in losing approval of any approved, product candidate.

***We are subject to a multitude of manufacturing and supply chain risks, any of which could substantially increase our costs and limit the supply of our product candidates.***

The process of manufacturing our product candidates is complex, highly regulated and subject to several risks, including:

- The manufacturing of drug products is susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment or vendor or operator error. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If foreign microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our products are made, these manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination;
- The manufacturing facilities in which our product candidates are made could be adversely affected by equipment failures, labor shortages, natural disasters, power failures and numerous other factors;
- We and our contract manufacturers must comply with the FDA's cGMP (current good manufacturing practices) regulations and guidelines. Any failure to follow cGMP or other regulatory requirements or any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our products as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our products, including leading to significant delays in the availability of products for our clinical studies or the termination or hold on a clinical study, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant noncompliance could also result in the imposition of sanctions, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation. If we are not able to maintain regulatory compliance, we may not be permitted to market our products and/or may be subject to product recalls, seizures, injunctions, or criminal prosecution.

Any adverse developments affecting manufacturing operations for our product candidates and/or damage that occurs during shipping may result in delays, inventory shortages, lot failures, withdrawals or recalls or other interruptions in the supply of our drug substance and drug product. We may also have to write off inventory, incur other charges and expenses for supply of drug product that fails to meet specifications, undertake costly remediation efforts, or seek more costly manufacturing alternatives. Inability to meet the demand for any of our product candidates, if approved, could damage our reputation and the reputation of our products among physicians, healthcare payors, patients or the medical community, which could adversely affect our ability to operate our business and our results of operations.

***We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.***

We currently have no sales, marketing or distribution capabilities and have no experience in marketing products. If we decide to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time, we will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our products; however, we cannot assure you that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

We cannot assure you that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or elsewhere.

***A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.***

We might plan to seek regulatory approval of our product candidates outside of the United States and, if so, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees/ contract staff professionals living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;



- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

***We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.***

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds, drugs or delivery systems that are able to achieve similar or better results. Many major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions continue to invest time and resources in developing novel approaches to preventing heart attacks and strokes. Many of our competitors have substantially greater financial, technical and other resources than we do, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety, tolerability, reliability, convenience of use, price and reimbursement.

Even if we obtain regulatory approval of our product candidates, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances.

***We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.***

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel. The loss of the services of any of our executive officers, other key contract staff professionals, and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

***Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches.***

Despite the implementation of security measures, our internal computer systems and those of our future CROs and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. While we have not to our knowledge experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

***Our contract staff professionals, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.***

We are exposed to the risk that our contract staff professionals, independent contractors, consultants, commercial partners and vendors may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (1) the laws of the FDA and other similar foreign regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulators; (2) manufacturing standards; (3) healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or (4) laws that require the true, complete and accurate reporting of financial information or data. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations.

***Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals and others in the medical community.***

The use of the Instaprin product candidates as potential heart and stroke treatments, even if approved, may not become broadly accepted by physicians, patients, hospitals and others in the medical community. Additional factors will influence whether our product candidates are accepted in the market, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, medical treatment centers and patients considering our product candidates as a safe and effective treatment;

- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors and government authorities; and
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and the effectiveness of our sales and marketing efforts.

Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

***If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.***

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with corporate collaborators.

We intend to obtain customary product liability insurance, which we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks, but which may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise, if at all. Our insurance policy contains various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

***We rely and will rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.***

We depend and plan to continue to depend upon independent investigators, other third parties and collaborators, such as universities, medical institutions, CROs and strategic partners, to conduct our preclinical and clinical trials under agreements with us. We expect to have to negotiate budgets and contracts with CROs and study sites, which may result in delays to our development timelines and increased costs. We rely and plan to continue relying heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with good clinical practices, or GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with biologic product produced under current good manufacturing practices (cGMPs) regulations and guidelines and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials are not our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical, clinical and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with third parties conducting our clinical trials, we cannot assure you that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

***We rely and expect to continue to rely on third parties to manufacture our clinical product supplies, and we intend to rely on third parties to produce and process our product candidates, if approved, and our commercialization of any of our product candidates could be stopped, delayed or made less profitable if those third parties fail to obtain approval of government regulators, fail to provide us with sufficient quantities of drug product or fail to do so at acceptable quality levels or prices.***

We do not currently have nor do we plan to acquire the infrastructure or capability internally to manufacture our clinical supplies for use in the conduct of our clinical trials, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. We currently rely on outside vendors to manufacture our clinical supplies of our product candidates and plan to continue relying on third parties to manufacture our product candidates on a commercial scale, if approved.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our marketing applications to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as cGMPs, for manufacture of our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing of our product candidates, and the actual cost to manufacture our product candidates could materially and adversely affect the commercial viability of our product candidates. As a result, we may never be able to develop a commercially viable product.

In addition, our reliance on third-party manufacturers exposes us to the following additional risks:

- We may be unable to identify manufacturers on acceptable terms or at all;
- Our third-party manufacturers might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- Contract manufacturers may not be able to execute our manufacturing procedures appropriately;
- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products;
- Manufacturers 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 corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards;
- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our products; and
- Our third-party manufacturers could breach or terminate their agreements with us.

Each of these risks could delay our clinical trials, the approval, if any of our product candidates by the FDA or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenue. In addition, we rely on third parties to perform release testing on our product candidates prior to delivery to patients. If these tests are not appropriately conducted and test data are not reliable, patients could be put at risk of serious harm and could result in product liability suits.

The manufacture of medical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of biologic products often encounter difficulties in production, particularly in scaling up and validating initial production and absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of our product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability or other issues relating to the manufacture of our product candidates will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our product candidates to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

***If our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.***

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

#### **Risks Related to Government Regulation**

***The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.***

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not previously submitted a biologics license application (BLA) or new drug application (NDA) to the FDA, or similar marketing applications filings to comparable foreign authorities. A BLA or NDA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety, purity and potency, or safety and effectiveness for each desired indication. The BLA or NDA must also include significant information regarding the chemistry, manufacturing and controls for the product. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; or
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

***Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.***

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our product candidates would also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

***Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.***

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or the conditions of approval, or contain requirements for potentially costly post-market testing and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a risk evaluation and mitigation strategy, or REMS, as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

***Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates profitably.***

Successful sales of our product candidates, if approved, depend, in part, on the availability of adequate coverage and reimbursement from third-party payors. In addition, because our product candidates represent new approaches to the treatment of heart attacks/ strokes, we cannot accurately estimate the potential revenue from our product candidates.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.



Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Further, we plan to develop our product candidates for use in combination with other products, which may make them cost prohibitive or less likely to be covered by third-party payors. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific, clinical and cost-effectiveness data and support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the EU, the pricing of biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate.

***Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.***

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, the Affordable Care Act, was enacted. The Affordable Care Act and its implementing regulations, among other things, subjected biologic products to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, provided incentives to programs that increase the federal government's comparative effectiveness research and established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013, and will remain in effect through 2024 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, further reduced Medicare payments to several providers, including hospitals and medical treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Under the new administration, there likely will continue to be legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

***Our future relationships with customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.***

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which we sell, market and distribute any drugs for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by the U.S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other third-party payors that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating these statutes without actual knowledge of the statutes or specific intent to violate them;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;
- the federal Physician Payment Sunshine Act, created under the Affordable Care Act, and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members and payments or other "transfers of value" made to such physician owners;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time- and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in federal and state healthcare programs and the curtailment or restricting of our operations, any of which could harm our ability to operate our business and our financial results. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

***We are subject to the environmental laws and potential exposure to environmental liabilities.***

We are subject to various federal, state and local environmental laws and regulations that govern our current and proposed operations, including the handling and disposal of non-hazardous and hazardous wastes, including medical and biological wastes, and emissions and discharges into the environment, including air, soils and water sources. Failure to comply with such laws and regulations could result in costs for corrective action, penalties or the imposition of other liabilities. We also are subject to laws and regulations that impose liability and clean-up responsibility for releases of hazardous substances into the environment. Under certain of these laws and regulations, a current or previous owner or operator of property may be liable for the costs of remediating its property or locations to which wastes were sent from its facilities, without regard to whether the owner or operator knew of, or necessarily caused, the contamination. Such obligations and liabilities, which to date have not been material, could have a material impact on our business and financial condition.

**Risks Related to Our Intellectual Property**

***Our business is substantially dependent on intellectual property which we purchased from Instaprin Pharmaceuticals Inc. If our intellectual property rights are threatened, diminished, or eliminated, for any number of reasons, our operating results would be adversely affected.***

We have entered into an asset purchase agreement with Instaprin Pharmaceuticals Inc. (“Instaprin Pharmaceuticals”), pursuant to which Aspire acquired all of the intellectual property of Instaprin Pharmaceuticals including patents (including Patent No. 62/794141) filed with the United States Patent and Trademark Office (“USPTO”) on January 18, 2019), copyrights, trademarks (including the “Instaprin” Trademark Serial No. 86274378 (Registration No. 4823125) filed with the USPTO on May 7, 2014) trade secrets and proprietary information, all applications for any of the foregoing, and any license or agreements granting rights related to the foregoing. See “Company Overview - Description of Business – Asset Purchase Agreement with Instaprin Pharmaceuticals Inc.” Currently, to our knowledge, which is based solely on the actual knowledge (i.e. direct and clear awareness) of Aspire’s directors, no third party is asserting that we are infringing upon their patent rights or other intellectual property, nor are we aware or believe that we are infringing or will infringe upon any third party’s patent rights or other intellectual property. However, if our rights are challenged by a third party under a claim of infringement and/or invalidity, such rights could be limited or eliminated entirely and in such event, our future operating results would be significantly and adversely affected.

Furthermore, Instaprin Pharmaceuticals and its former CEO were the subject of a Securities and Exchange Commission (“SEC”) complaint, filed on May 29, 2019 in federal court in the District of New Jersey (Case 2:19-cv-13024-ES-MAH). The complaint alleged that the former CEO falsely told investors that their money would be used to pay for the operating expenses of Instaprin Pharmaceuticals, which was developing a revolutionary fast acting aspirin to instantly stop heart attacks and strokes. Instead, the former CEO allegedly used investors’ money to largely pay for personal expenses, such as a vacation, clothing, spa treatments, divorce expenses, and on Island Raceway & Hobby, Inc., his now-defunct remote-controlled toy racecar business, which had previously operated in Lindenhurst, New York. On June 5, 2019, the U.S. District Court issued a judgment against the former CEO of Instaprin Pharmaceuticals and one other defendant in the amount of \$4,182,627.

***From time to time we may need to license patents, intellectual property and proprietary technologies from third parties, which may be difficult or expensive to obtain.***

We may need to obtain licenses to patents and other proprietary rights held by third parties to successfully develop, manufacture and market our future products. If we are unable to timely identify and obtain such licenses on reasonable terms, our ability to commercially exploit our future products may be inhibited or prevented.

***Intellectual property litigation is increasingly common and increasingly expensive and may result in restrictions on our business and substantial costs, even if we prevail.***

Patent and other intellectual property litigation is becoming more common in the biopharmaceutical and pharmaceutical industries. Litigation may be necessary to defend against or assert claims of infringement, to enforce our patent rights, including those we may license from others, to protect trade secrets or to determine the scope and validity of proprietary rights of third parties. Currently, to our knowledge, which is based solely on the actual knowledge (i.e. direct and clear awareness) of Aspire's directors, no third party is asserting that we are infringing upon their patent rights or other intellectual property, nor are we aware or believe that we are infringing or will infringe upon any third party's patent rights or other intellectual property. We may, however, be infringing or will infringe upon a third party's patent rights or other intellectual property, and litigation asserting such claims might be initiated in which we would not prevail, or we would not be able to obtain the necessary licenses on reasonable terms, if at all. All such litigation, whether meritorious or not, as well as litigation initiated by us against third parties, is time-consuming and very expensive to defend or prosecute and to resolve. In addition, if we infringe the intellectual property rights of others, we could lose our right to develop, manufacture, or sell our products or could be required to pay monetary damages or royalties to license proprietary rights from third parties. An adverse determination in a judicial or administrative proceeding or a failure to obtain necessary licenses could prevent us from manufacturing or selling our products, which could harm our business, financial condition, and prospects. If our competitors prepare and file patent applications in the United States that claim technology we also claim, we may have to participate in interference or derivation proceedings required by the U.S. Patent and Trademark Office to determine priority of invention or inventorship, which could result in substantial costs, even if we ultimately prevail. Results of interference and derivation proceedings are highly unpredictable and may result in us having to try to obtain licenses in order to continue to develop or market our future product candidates.

***Changes in patent law, including recent patent reform legislation, could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.***

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve technological and legal complexity, and obtaining and enforcing pharmaceutical patents is costly, time-consuming, and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts, and the U.S. Patent and Trademark Office, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents to enforce existing patents and patents we may obtain in the future. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

In September 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first to file" system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the U.S. Patent and Trademark Office and may become involved in opposition, derivation, reexamination, inter-parties review or interference proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, which could adversely affect our competitive position.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the U.S. Patent and Trademark Office and foreign patent agencies in several stages over the lifetime of the patent. The U.S. Patent and Trademark Office and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our product candidates, our competitive position would be adversely affected.

***Intellectual property rights do not necessarily address all potential threats to our competitive advantage.***

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make compounds or biologics that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- We or any strategic partners might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed;
- We might not have been the first to file patent applications covering certain of our inventions;
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- It is possible that our pending patent applications will not lead to issued patents;
- Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages or may be held invalid or unenforceable as a result of legal challenges;
- Our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- We may not develop additional proprietary technologies that are patentable; and
- The patents of others may have an adverse effect on our business.

***If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate for our technology and product candidates, our competitive position could be harmed.***

Our commercial success will depend in part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our proprietary technology and products. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with contract staff professionals and third parties, all of which offer only limited protection. We seek to protect our proprietary position by filing and prosecuting patent applications in the United States and abroad related to our novel technologies and products that are important to our business.

The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patents, including those patent rights licensed to us by third parties, are highly uncertain. The steps we or have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside of the United States. Further, the examination process may require us to narrow the claims for our pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The rights already granted under any of our currently issued patents or those licensed to us and those that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we or are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our technology and products may be adversely affected. It is also possible that we or will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them.

With respect to patent rights, we do not know whether any of the pending patent applications for any of our compounds or biologic products will result in the issuance of patents that effectively protect our technology or products, or if any of our issued patents will effectively prevent others from commercializing competitive technologies and products. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all, until they are issued as a patent. Therefore, we cannot be certain that we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or were the first to file for patent protection of such inventions.

Our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we own or have licensed from third parties may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products or limit the duration of the patent protection for our technology and products. Protecting against the unauthorized use of our patented technology, trademarks and other intellectual property rights is expensive, difficult and may in some cases not be possible. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult.

***Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could harm our business.***

Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidates, and to use our related proprietary technologies without infringing the intellectual property rights of third parties. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates, including interference or derivation proceedings before the U.S. Patent and Trademark Office, or USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue commercializing our product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Under certain circumstances, we could be forced, including by court order, to cease commercializing our product candidates. In addition, in any such proceeding or litigation, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business.

While our product candidates are in preclinical studies and clinical trials, we believe that their use in these preclinical studies and clinical trials falls within the scope of the exemptions provided by 35 U.S.C. Section 271(e) in the United States, which exempts from patent infringement liability activities reasonably related to the development and submission of information to the FDA. As our product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. We attempt to ensure that our product candidates and the methods we employ to manufacture them, as well as the methods for their use we intend to promote, do not infringe other parties' patents and other proprietary rights. We cannot assure you they do not, however, and competitors or other parties may assert that we infringe their proprietary rights in any event.

In addition, we are testing our product candidates administered with other product candidates or products that are covered by patents held by other companies or institutions. In the event that a labeling instruction is required in product packaging recommending that combination, we could be accused of, or held liable for, infringement of the third-party patents covering the product candidate or product recommended for administration with our product candidates. In such a case, we could be required to obtain a license from the other company or institution to use the required or desired package labeling, which may not be available on commercially reasonable terms, or at all.

Generally, conducting clinical trials and other development activities in the United States is not considered an act of infringement. If and when products are approved by the FDA, that certain third party may then seek to enforce its patents by filing a patent infringement lawsuit against us or our licensee(s). In such lawsuit, we may incur substantial expenses defending our rights or our licensee(s) rights to commercialize such product candidates, and in connection with such lawsuit and under certain circumstances, it is possible that we or our licensee(s) could be required to cease or delay the commercialization of a product candidate and/or be required to pay monetary damages or other amounts, including royalties on the sales of such products. Moreover, such lawsuit may also consume substantial time and resources of our management team and board of directors. The threat or consequences of such a lawsuit may also result in royalty and other monetary obligations, which may adversely affect our results of operations and financial condition.

***We may not be able to protect our intellectual property rights throughout the world.***

Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws and practices of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally in those countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful.

The laws of certain foreign countries may not protect our rights to the same extent as the laws of the United States, and these foreign laws may also be subject to change. For example, methods of treatment and manufacturing processes may not be patentable in certain jurisdictions, and the requirements for patentability may differ in certain countries, particularly developing countries. Furthermore, generic and/or biosimilar product manufacturers or other competitors may challenge the scope, validity or enforceability of our or' patents, requiring us or to engage in complex, lengthy and costly litigation or other proceedings.

Generic or biosimilar product manufacturers may develop, seek approval for, and launch biosimilar versions or generic versions, respectively, of our products. The FDA has published four draft guidance documents on biosimilar product development. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biosimilar and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation, which are still being worked out by the FDA. To date, no biosimilar or interchangeable biologic has been licensed under the Biologics Price Competition and Innovation Act of 2009, or BPCIA, framework, although such approvals have occurred in Europe, and it is anticipated that the FDA will approve a biosimilar in the relatively near future. If any of our product candidates are approved by the FDA, the approval of a biologic product biosimilar to one of our products could have a material impact on our business. In particular, a biosimilar could be significantly less costly to bring to market and priced significantly lower than our products, if approved by the FDA.



*Some jurisdictions may require us to grant licenses to third parties. Such compulsory licenses could be extended to include some of our product candidates, which may limit our potential revenue opportunities.*

Many countries, including European Union countries, have compulsory licensing laws under which a patent owner may be compelled under certain circumstances to grant licenses to third parties. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

*Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time, and our product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.*

Given the amount of time required for the development, testing and regulatory review of new product candidates, such as our product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

The BPCIA established legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as “interchangeable” based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

We anticipate being awarded market exclusivity for each of our biological product candidates that is subject to its own BLA for 12 years in the United States, 10 years in Europe and significant durations in other markets. However, the term of the patents that cover such product candidates may not extend beyond the applicable market exclusivity awarded by a particular country. For example, in the United States, if all of the patents that cover a particular biologic product expire before the 12-year market exclusivity expires, a third party could submit a marketing application for a biosimilar product four years after approval of the biologic product, and the FDA could immediately review the application and approve the biosimilar product for marketing 12 years after approval of the biologic. Alternatively, a third party could submit a BLA for a similar or identical product any time after approval of our biologic product, and the FDA could immediately review and approve the similar or identical product for marketing and the third party could begin marketing the similar or identical product upon expiry of all of the patents that cover our particular biologic product.

Additionally, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. The extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

***We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful and have a material adverse effect on the success of our business.***

Competitors may infringe our patents or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Also, third parties may initiate legal proceedings against us to challenge the validity or scope of intellectual property rights we own or control. These proceedings can be expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments in any such proceedings. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of the Securities.

***We may be subject to claims by third parties asserting that, employees/ contract staff professionals or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.***

Our contract staff professionals, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these personnel, including each member of our senior management, executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. Although we try to ensure that our contract personnel do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these contract personnel have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

***Intellectual property rights do not necessarily address all potential threats to our competitive advantage.***

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make compounds or biologics that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- We or any strategic partners might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed;
- We might not have been the first to file patent applications covering certain of our inventions;
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;

- It is possible that our pending patent applications will not lead to issued patents;
- Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- Our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- We may not develop additional proprietary technologies that are patentable; and
- The patents of others may have an adverse effect on our business.

***If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.***

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, know-how and confidential and proprietary information. To maintain the confidentiality of trade secrets and proprietary information, we will enter into confidentiality agreements with our contract staff professionals, employees, consultants and collaborators upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with contract staff professionals also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our contract staff professionals, consultants or other contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations.

#### **Risks Related to Our Financial Results**

***Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations our guidance.***

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into license or collaboration agreements with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. Accordingly, our revenue may depend on development funding and the achievement of development and clinical milestones under current and any potential future license and collaboration agreements and sales of our products, if approved. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

In addition, we measure compensation cost for stock-based awards made to contract staff professionals at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the person's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including, after the closing of this offering, our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to our current and any future product candidates, which will change from time to time;
- our ability to enroll patients in clinical trials and the timing of enrollment;
- the cost of manufacturing our current and any future product candidates, which may vary depending on FDA; guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies;
- the timing and outcomes of clinical studies for our product candidates or competing product candidates;
- competition from existing and potential future drugs that compete with our product candidates, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval of Instaprin or any of our other product candidates;
- the level of demand for our product candidates, if approved, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our products candidates, if approved, and existing and potential future drugs that compete with our product candidates;
- our ability to commercialize our product candidates, if approved, inside and outside of the United States, either independently or working with third parties;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

The cumulative effect of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of the Securities could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue and/or earnings guidance we may provide.

**IN ADDITION TO THE RISKS LISTED ABOVE, RISKS AND UNCERTAINTIES NOT PRESENTLY KNOWN, OR WHICH WE CONSIDER IMMATERIAL AS OF THE DATE OF THIS REPORT, MAY ALSO HAVE AN ADVERSE EFFECT ON OUR BUSINESS.**

**The foregoing list of risk factors does not purport to be a complete enumeration or explanation of the risks involved in an investment in the Company. Prospective Investors should consult with their own legal, tax and financial advisers before deciding to invest in the Company. In addition, as the Company's business plan develops and changes over time, the Company may be subject to additional and different risk factors.**

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## COMPANY OVERVIEW

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*This Company overview should be read in conjunction with the more detailed information and financial data appearing elsewhere in this report and other exhibits hereto. Some of the information contained herein is based upon or derived from information provided by third-party consultants, advisors, and other industry sources. We cannot guarantee the accuracy of such information and have not independently verified the assumptions on which projections of future trends and performance are based.*

### **Business Overview**

Aspire Biopharma Inc. (“Company” or “Aspire”) is a privately held, early-stage biopharmaceutical company. As a Puerto Rico corporation formed in September 2021, the Company engaged in the business of developing and marketing the disruptive technology for novel delivery mechanisms initially for “do no harm” drugs.

### **Business Plan**

We expect to generate revenue through developing and marketing the technology for the novel delivery mechanisms for “do no harm drugs”. Further, from time to time, we may enter into license or collaboration agreements with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. Accordingly, our revenue may depend on development funding and the achievement of development and clinical milestones under current and any potential future license and collaboration agreements and sales of our products, if approved.

### **Manufacturing**

We currently contract with third parties for the manufacture of our product candidates for preclinical studies and clinical trials and intend to do so in the future. We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. To meet our projected needs for commercial manufacturing, third parties with whom we currently work will need to increase their scale of production or we will need to secure alternate suppliers. Although we rely on contract manufacturers, we have personnel with manufacturing experience to oversee our relationships with contract manufacturers.

We expect to enter into a development and manufacturing agreement with a contract manufacturer in the second quarter of 2024 to produce sufficient quantities of our Instaprin drug product for our completed Phase 1 clinical trial and our Phase 2a Challenge Study. While we believe that Glatt Air Techniques, Inc. (“Glatt”) is capable of producing drug substance to support our Instaprin development plan, including our planned Phase 2 and Phase 3 clinical trials, we believe there are a number of alternative third-party manufacturers that have similar capabilities and would be capable of providing sufficient quantities of drug substance for our Instaprin development plan. Glatt currently has the capabilities to manufacture Instaprin drug substance for potential commercial use, however, their current capacity may be insufficient to meet our planned needs and may require us to engage additional or alternative third-party manufacturers in the future. In addition, we have entered into a fill and finish agreement with a contract manufacturer to convert Instaprin drug substance manufactured by Glatt into drug product that can be utilized in clinical trials. The fill and finish contract manufacturer has converted the Instaprin drug substance that has been produced by Glatt into drug product to be used in our planned Phase 2a and Phase 2b clinical trials. We believe that both Glatt and the fill and finish contract manufacturer are compliant under current good manufacturing practice, or cGMP, requirements and have experience with cGMP inspections of their respective facilities.

### **Commercialization**

We have not yet established a sales, marketing or product distribution infrastructure because our lead product candidates are still in early-stage clinical development. We generally plan to retain commercial rights in the United States for our product candidates for which we hope to receive marketing approvals. We believe that it will be possible for us to access the heart attack and stroke prevention market through a targeted hospital and/or specialty care sales force.

Subject to receiving marketing approvals, we expect to commence commercialization activities by building a focused sales and marketing organization in the United States to sell our products, as well as the creation of a dedicated Medical Affairs team to support commercialization efforts. We believe that such an organization will be able to address the physicians who are the key specialists in treating the patient populations for which our product candidates are being developed. Outside the United States, we expect to enter into distribution and other marketing arrangements with third parties for any of our product candidates that obtain marketing approval.

We also plan to build a marketing and sales management organization to create and implement marketing strategies for any products that we market through our own sales organization and to oversee and support our sales force. The responsibilities of the marketing organization would include developing educational initiatives with respect to approved products and establishing relationships with thought leaders in relevant fields of medicine.

## **Our Products**

The Company has developed and acquired disruptive technologies that are a Novel Soluble Formulation which address emergencies and drug efficacy, dosage management, and response time.

In March 2023, the Company filed application number 63/456,290 with the United States Patent and Trademark Office (“USPTO”) with the goal of securing patent protection for its new technology and aspirin formulation. The Company’s new patent pending formulation is a significant improvement on the previously patented formulation which was acquired by the Company through the Instaprin Pharmaceuticals, Inc. acquisition (described below). This technology will facilitate development of any number of products in a soluble, PH neutral, fast acting powder form which has been developed by using our patented formulation, and “trade secret” process. Aspire’s drug delivery comes from a new mechanism of action (absorption pathway) which allows for instant absorption in the mouth. The benefits of “instant absorption” are to provide nearly instant treatment impact and also allows high dose absorption. The Company’s patented and patent pending delivery system includes components specifically formulated to allow rapid sublingual absorption of drugs into the blood stream, thus by-passing the gastrointestinal tract.

In the initial launch of its “Instaprin” product, Aspire has focused on the delivery of aspirin, which may be the most studied and accepted analgesic and anti-inflammatory. Aspirin is over a century old and is traditionally available in several forms, effervescence, powder and tablet. Over 100 years of documented safety and efficacy data is readily available. Aspirin is the only drug in history to receive a certified recommendation by the FDA for heart attack, stroke and colon cancer. However, current aspirin applications are limited due to side effects from acidity. Instaprin has no acidic side effects, nor is it metabolized through the liver. We expect that Instaprin will be well positioned to target the current Opioid Crisis globally due to its ability to have large doses rapidly be absorbed in the bloodstream with no harmful effects to the gastric system and its mucous membrane, as well as, at full strength with no dilution due to metabolic impact providing true anti-inflammatory therapeutic effects to users providing true pain management relief to them Instaprin Regulatory Status. The Company plans to file Instaprin to be OTC FDA monograph compliant and expects the FDA ruling in this regard sometime in early 2025. Additionally, Aspire plans to seek FDA 505(b)(2) Fast Track designation for the prescription strength given the history of safety in Q2 of 2023.

### ***Asset Purchase Agreement (APA) with Instaprin Pharmaceuticals Inc.***

On March 28, 2022, Aspire closed an Asset Purchase Agreement (“Asset Purchase Agreement” or “APA”) with Instaprin Pharmaceuticals Inc. (“Instaprin Pharmaceuticals”), pursuant to which Aspire acquired all of the intellectual property of Instaprin Pharmaceuticals including patents (including Patent No. 62/794141) filed with the United States Patent and Trademark Office (“USPTO”) on January 18, 2019), copyrights, trademarks (including the “Instaprin” Trademark Serial No. 86274378 (Registration No. 4823125) filed with the USPTO on May 7, 2014) trade secrets and proprietary information, all applications for any of the foregoing, and any license or agreements granting rights related to the foregoing, as part of an overall settlement sanctioned by a U.S. federal court, as described in the following paragraph (the “Settlement”).

Instaprin Pharmaceuticals was a Nevada corporation and its former CEO was the subject of a Securities and Exchange Commission (“SEC”) complaint, filed on May 29, 2019 in federal court in the District of New Jersey (Case 2:19-cv-13024-ES-MAH). The complaint alleged that the former CEO falsely told investors that their money would be used to pay for the operating expenses of Instaprin Pharmaceuticals, which was developing a revolutionary fast acting aspirin to instantly stop heart attacks and strokes. Instead, the former CEO allegedly used investors’ money to largely pay for personal expenses, such as a vacation, clothing, spa treatments, divorce expenses, and on Island Raceway & Hobby, Inc., his now-defunct remote-controlled toy racecar business, which had previously operated in Lindenhurst, New York. On June 5, 2019, the U.S. District Court issued a judgment against the former CEO of Instaprin Pharmaceuticals, Inc. and one other defendant in the amount of \$4,182,627.

The purchase price for the Acquired Assets (as defined in the APA) was \$3,628,325 plus interest thereon, to be paid to the SEC in satisfaction of the SEC's judgment against the former CEO, from sales of the product, as follows: 20% from the first \$5,000,000 of sales and 10% from sales thereafter until the entire contingent purchase price obligation is satisfied. Additionally, ten percent (10%) of Buyer's equity was to be delivered at Closing, in proportion to their equity holdings in the Company, to be issued to a Trustee for the former Instaprin Shareholders, along with an additional ten percent (10%) of Buyer's equity to be issued to the Company's service providers, pursuant to a stock incentive plan to be adopted. The foregoing description of the Asset Purchase Agreement is qualified in its entirety by reference to the full text of the Asset Purchase Agreement.

There is no assurance that the acquisition of Instaprin will be successful or profitable for investors. As an asset of Aspire Biopharma Inc., Instaprin could pose risks to Aspire Biopharma Inc. and its shareholders, including but not limited to those described under "Risk Factors" in this report above.

### ***Competition***

The biopharmaceutical industry is characterized by rapidly advancing technologies, intense competition and strong emphasis on proprietary products. While we believe that our Instaprin technology, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and government agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of treatments and commercializing those treatments. These same competitors may invent technology that competes with our product candidates.

Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and subject registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We expect any products that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price, the level of generic or biosimilar competition and the availability of adequate reimbursement from government and other third-party payors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, we expect that our products, if approved, will be priced at a premium over competitive generic products and our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products.

We expect that Instaprin will compete with currently approved products, such as Bayer aspirin, Advil and Tylenol, and, if approved, other product candidates currently under development.

## Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary or intellectual property protection for our drug candidates, including Instaprin, and other know-how; to operate without infringing on the proprietary rights of others; and to prevent others from infringing our proprietary or intellectual property rights. Our practice is to seek to protect our proprietary and intellectual property position by, among other methods, filing U.S. and international patent applications related to our proprietary drug candidates, inventions and improvements that are important to the development and implementation of our business. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position.

The following table sets forth details of our intellectual property registrations and applications:

<b>Application or Registration or Serial #</b>	<b>Title</b>	<b>Description</b>	<b>File Date</b>	<b>Grant Date (if granted)</b>	<b>Country/ Authority</b>
62/794141 <sup>(1)</sup>	Micronized Aspirin Formulation	Rapid pain relief formulations of Aspirin	January 18, 2019	N/A	United States
86274378 <sup>(2)</sup>	Instaprin	Trademark	May 7, 2014	September 29, 2015	United States
WO 2020/150460 A1 <sup>(3)</sup>	Micronized Aspirin Formulation	Rapid pain relief formulations of Aspirin	January 16, 2020	July 23, 2020	WIPO International Publication
63456290	Oral Mucosal Formulations of Aspirin	Rapid pain relief formulations of Aspirin	March 31, 2023	N/A	United States

<sup>(1)</sup> The patent is currently in the process of being transferred in the name of Instaprin Pharmaceuticals and will subsequently be transferred in the name of the Company in accordance with the terms agreed to in the APA.

<sup>(2)</sup> Trademark Registration No. 4823125. The trademark has been transferred in the name of Instaprin Pharmaceuticals and is in the process of being transferred in the name of the Company in accordance with the terms agreed to in the APA.

<sup>(3)</sup> The patent is currently in the process of being transferred in the name of Instaprin Pharmaceuticals and will subsequently be transferred in the name of the Company in accordance with the terms agreed to in the APA.

The Company also holds numerous domains, including, but not limited to, aspire-biopharma.com and aspirebiolabs.com. Additionally, the Company plans to enter into customer and license agreements to protect its intellectual property.

All other intellectual property is in the form of trade secrets, business methods and know-how and is protected through intellectual assignment and confidentiality agreements with the Company's contract staff professionals, advisors and consultants.

## Government/ Regulatory Approval and Compliance

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, pricing, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining marketing approvals in the United States and in foreign countries and jurisdictions, along with compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.



## *Licensure and Regulation of Biologics in the United States*

In the United States, our candidate mAb products are licensed as biological products, or biologics, under the Public Health Service Act, or PHSA, and regulated under the Federal Food, Drug and Cosmetic Act, or FDCA, and applicable implementing regulations and guidance. The failure of an applicant to comply with the applicable regulatory requirements at any time during the product development process, including non-clinical testing, clinical testing, the approval process or post-approval process, may result in delays to the conduct of a study, regulatory review and approval, and/or administrative or judicial sanctions. These sanctions may include, but are not limited to, the FDA's refusal to allow an applicant to proceed with clinical trials, refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, warning letters, adverse publicity, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, and civil or criminal investigations and penalties brought by the FDA or Department of Justice, or DOJ, or other government entities, including state agencies.

An applicant seeking approval to market and distribute a new biologic in the United States generally must satisfactorily complete each of the following steps before the product candidate will be licensed by the FDA:

- preclinical testing including laboratory tests, animal studies and formulation studies, some of which must be performed in accordance with the FDA's good laboratory practice, or GLP, regulations and standards;
- submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety, potency and purity of the product candidate for each proposed indication, in accordance with current good clinical practices, or GCP;
- preparation and submission to the FDA of a BLA for a biologic product which includes not only the results of the clinical trials, but also, detailed information on the chemistry, manufacture and quality controls for the product candidate and proposed labelling for one or more proposed indication(s);
- review of the product candidate by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities, including those of third parties, at which the product candidate or components thereof are manufactured to assess compliance with current good manufacturing practices, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of any FDA audits of the non-clinical and clinical trial sites to assure compliance with GCP and the integrity of clinical data in support of the BLA;
- payment of user fees and securing FDA approval of the BLA and licensure of the new biologic product; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and the potential requirement to conduct any post-approval studies required by the FDA.

### ***Preclinical Studies and Investigational New Drug Application***

Before an applicant begins testing a compound with potential therapeutic value in humans, the product candidate or compound enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as other studies to evaluate, among other things, the toxicity of the product candidate. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements, including GLP regulations and standards. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, and long-term toxicity studies, may continue after the IND is submitted.

### **Valuation Pricing Report on our Lead Product, Instaprin**

We had requested that Evans & Evans, Inc. (“Evans”), a Canadian valuation advisory firm, prepare a Calculation Pricing Report (the “Valuation Report”) with regards to the potential price of Aspire, as at September 30, 2022 (the “Pricing Date”). Evans had calculated, given the scope of work conducted as part of the Valuation Report, a potential price or market value of Aspire as at the Pricing Date (i.e., September 30, 2022) in the range of \$270,000,000 to \$310,000,000.

### **Litigation**

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

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## DIRECTORS, OFFICERS, MANAGERS, AND KEY PERSONS

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The directors, officers, managers, and key persons of the Company are listed below along with all positions and offices held at the Company and their principal occupation and employment responsibilities for the past three (3) years.

Name	Positions and Offices Held at the Company	Principal Occupation and Employment Responsibilities for the Last Three (3) Years	Education
Kraig T. Higginson	Chief Executive Officer & Chairman of the Board	<p><u>Employer:</u> Aspire Biopharma Inc.  <u>Employer's Principal Business:</u> Developing and marketing the technology for the novel delivery mechanisms for "do no harm drugs".  <u>Title:</u> Chief Executive Officer &amp; Chairman of the Board  <u>Dates of Service:</u> September 2021 - Present  <u>Responsibilities:</u> Responsible for all aspects of the company, including strategy and development of business plan, investor relations, product development, strategic partnerships and day-to-day operations.</p> <p><u>Employer:</u> Kitts Group, LLC  <u>Employer's Principal Business:</u> Investment, Capital Markets, and Real Estate development  <u>Title:</u> President  <u>Dates of Service:</u> 2015 - Present  <u>Responsibilities:</u> Responsible for all aspects of the company, including strategy and development of business plans, investor relations, product development, strategic partnerships and day-to-day operations.</p>	Brigham Young University (Chemistry and Biology); University of Utah (Chemistry and Biology, minor in Business Management)
Ernest J. Scheidemann, Jr.	Chief Financial Officer	<p><u>Employer:</u> Aspire Biopharma Inc.  <u>Employer's Principal Business:</u> Developing and marketing the technology for the novel delivery mechanisms for "do no harm drugs"  <u>Title:</u> Chief Financial Officer  <u>Dates of Service:</u> July 2022 - Present  <u>Responsibilities:</u> Responsible for all financial aspects of the company, including financial strategy and development of business plans, investor relations, accounting, financial planning, and day-to-day operations</p> <p><u>Employer:</u> FinTrust Consulting, LLC  <u>Title:</u> Principal  <u>Dates of Service:</u> 2019 - Present  <u>Responsibilities:</u> Fractional Chief Financial Officer, Consultant</p>	William Paterson University (BA in Accounting); Seton Hall University (MBA in Finance and International Business); Duke University's Fuqua School of Business (Advanced Management Program); American Institute of CPAs (Certified Global Management Accountant and Certified Financial Forensics designation)

<b>Name</b>	<b>Positions and Offices Held at the Company</b>	<b>Principal Occupation and Employment Responsibilities for the Last Three (3) Years</b>	<b>Education</b>
<b>Stephen Quesenberry</b>	<b>General Counsel and Corporate Secretary</b>	<p><u>Employer:</u> Aspire Biopharma Inc.</p> <p><u>Employer's Principal Business:</u> Developing and marketing the technology for the novel delivery mechanisms for "do no harm drugs"</p> <p><u>Title:</u> General Counsel and Corporate Secretary</p> <p><u>Dates of Service:</u> September 2021 - Present</p> <p><u>Responsibilities:</u> Responsible for all corporate legal matters</p> <p><u>Employer:</u> Kitts Group, LLC</p> <p><u>Title:</u> General Counsel and Corporate Secretary</p> <p><u>Dates of Service:</u> 2015 - Present</p> <p><u>Responsibilities:</u> Responsible for all corporate legal matters</p>	Brigham Young University (BA in English); University of Kansas School of Law (JD)
<b>Lance Friedman</b>	<b>Director of Investor Relations</b>	<p><u>Employer:</u> Aspire Biopharma Inc.</p> <p><u>Employer's Principal Business:</u> Developing and marketing the technology for the novel delivery mechanisms for "do no harm drugs"</p> <p><u>Title:</u> Director of Investor Relations</p> <p><u>Dates of Service:</u> June 2022 - Present</p> <p><u>Responsibilities:</u> Responsible for investor relations and capital markets transactions</p> <p><u>Employer:</u> First Choice Healthcare Solutions, Inc.</p> <p><u>Title:</u> Chief Executive Officer</p> <p><u>Dates of Service:</u> 2020 - Present</p> <p><u>Responsibilities:</u> Responsible for all aspects of the company, including strategy and development of business plans, investor relations, product development, strategic partnerships and day-to-day operations.</p> <p><u>Education:</u> American University (BA in Political Science); Benjamin N. Cardozo School of Law (JD)</p>	American University (BA in Political Science); Benjamin N. Cardozo School of Law (JD)

<b>Name</b>	<b>Positions and Offices Held at the Company</b>	<b>Principal Occupation and Employment Responsibilities for the Last Three (3) Years</b>	<b>Education</b>
<b>Roderic Prat</b>	<b>Director</b>	<u>Employer:</u> Aspire Biopharma Inc. <u>Employer's Principal Business:</u> Developing and marketing the technology for the novel delivery mechanisms for "do no harm drugs" <u>Title:</u> Director <u>Dates of Service:</u> May 2023 - Present <u>Responsibilities:</u> Independent director  <u>Employer:</u> British Columbian Investment Management Corporation <u>Title:</u> Managing Director, Public Markets, Head of Absolute Return Co-Investments <u>Dates of Service:</u> October 2019 - Present <u>Responsibilities:</u> Capital markets, risk management and structuring	Queen's University (BA in Economics); University of Chicago (MBA in Finance)
<b>Edward J. Kimball, MD,</b>	<b>Director</b>	<u>Employer:</u> Aspire Biopharma Inc. <u>Employer's Principal Business:</u> Developing and marketing the technology for the novel delivery mechanisms for "do no harm drugs" <u>Title:</u> Director <u>Dates of Service:</u> September 2021 - Present <u>Responsibilities:</u> Independent director  <u>Employer:</u> University of Utah Health Sciences Center; Salt Lake VA Medical Center <u>Title:</u> Professor of Surgery (University of Utah Health Sciences Center) and Medical Director of Surgical Critical Care (Salt Lake VA Medical Center) <u>Dates of Service:</u> May 1999 - Present <u>Responsibilities:</u> Professor of surgery and medical director of surgical critical care	University of Utah (M.D.); University of Utah (M.Sc. - Genetics); University of Utah (B.S.)

### Biographical Information

Below are brief biographies of directors, officers, managers, and key persons, including members of our scientific board:

#### (1) Kraig T. Higginson, Chief Executive Officer & Chairman of the Board

Mr. Higginson was appointed Chief Executive Officer (CEO) and Chairman of the Board of Directors of Aspire Biopharma Inc. in September 2021. Mr. Higginson served as Chief Executive Officer of VIA Motors, Inc. ("Via Motors"), a hybrid electric vehicle company (PHEV), from November 2010 to January 2014, where he was responsible for overseeing the management and business of Via Motors and its employees. From October 2003 until November 2010, he served as Chairman of the Board of Directors of Raser Technologies, Inc. ("Raser Technologies"), which was an NYSE listed company at that time. Mr. Higginson also founded American Telemedia Network, Inc. ("American Telemedia"), a publicly-traded NASDAQ company that developed a nationwide satellite network broadcasting data, video programming and advertising to shopping centers and malls, and he served as President and Chief Executive Officer of American Telemedia from 1984 through 1988. Mr. Higginson's years of experience in the management of public companies is a great asset to the Company.

## **(2) Ernest J. Scheidemann, Jr., Chief Financial Officer**

Mr. Scheidemann was appointed Chief Financial Officer (CFO) of Aspire Biopharma Inc. in July 2022. Mr. Scheidemann has advised or was retained as an outsourced Chief Financial Officer (CFO), and/or financial advisor for many companies, including public and private companies, special situations, and start-ups, through his firm FinTrust Consulting, LLC. Mr. Scheidemann was the CFO of Benchmark Builders, Inc. from April 2017 through November 2018. From 2008 to 2015, Mr. Scheidemann was CFO of ASG Technologies, Inc., a private global software company later acquired by Rocket Software. Prior to that, Mr. Scheidemann was the Treasurer and CFO of WCI Communities, a \$2.0 billion publicly traded homebuilder from 2004 to 2008 and held various progressive finance and accounting leadership roles with AT&T Corp from 1984 through 1999. Mr. Scheidemann is a Certified Public Accountant (CPA).

## **(3) Stephen Quesenberry, General Counsel and Corporate Secretary**

Mr. Quesenberry was appointed General Counsel and Corporate Secretary of Aspire Biopharma Inc. in September 2021. Mr. Quesenberry has practiced law since 1989 in Washington and Utah, including complex business litigation and SEC matters. Mr. Quesenberry was one of the attorneys representing Exxon Shipping in the Exxon Valdez litigation in Alaska in the early 1990s. Mr. Quesenberry has also been a principal in various property development projects in Washington and elsewhere. Mr. Quesenberry graduated from Brigham Young University in 1986 with a degree in English and was a pitcher for the BYU Cougars varsity baseball team from 1983-1986. He attended law school at the University of Kansas from 1986-1989, where he was an editor of the Kansas Law Review and a member of the Order of the Coif. He also speaks fluent German. Mr. Quesenberry's legal expertise makes him a great resource for the board of directors.

## **(4) Lance Friedman, Director of Investor Relations**

Mr. Friedman was appointed Director of Investor Relations of Aspire Biopharma Inc. in June 2022. Mr. Friedman began his career in the legal field with a focus in corporate, securities and merger and acquisition transactions, before transitioning to merchant/Investment Banking and business operations in 1987. In the mid-90s, he was hired by healthcare and real estate magnates Abraham Gosman and Bernard Marden to become a part of senior management in various investment led healthcare focused companies, including WirelessMD and WebMD. Subsequently, Mr. Friedman was invited to join EGL Holdings as Managing Director/Partner, a well-known cross border venture capital and boutique investment banking firm in 2003 to manage the healthcare investment and advisory practice, including serving as an internal senior level capital markets and M&A member of VertiSoft resulting in its sale to Optio Software. He also served as COO and EVP of Finance of Fletcher-Flora Health Care Systems, Inc., resulting in the sale of the company to Merge Healthcare. Recent appointments include CEO of First Choice Healthcare Solutions, Inc., and formerly of Instaprin Pharmaceuticals, Inc to execute an exit due to an SEC matter consent judgment issued to the Company and its founder, and VIA Motors International leading its capital markets strategy for a period of 8 years culminating in a merger valued at \$630mm. Mr. Friedman has advised or was retained as an outsourced senior manager, work out specialist and/or business development advisor for many companies and at several large independent broker dealers, through his firm Blackstone Capital Advisors, Inc., which is an international boutique financial advisory and merchant banking organization participating in several billion dollars of transactions, including IPO's, M&A, reverse merger, PIPE, Private Placements, and many other alternative equity and debt transactions. Currently, Mr. Friedman sits on the Board of Directors and serves as the Chief Executive Officer of First Choice Healthcare Solutions, Inc.

## **(5) Roderic Prat, Director**

Roderic Prat is also a Director of Aspire and was appointed in May 2023. Mr. Prat has had an extensive career in the capital markets in both the private and public sector. He began his career at Goldman Sachs, Toronto in Derivative Sales and structuring. After spending 20 years in sales and trading Mr. Prat has developed extensive risk management and structuring skills. Mr. Prat has an MBA in Finance from the University in Chicago and a B.A. in Economics from Queen's University. He currently serves as the Founding and Managing Partner of Trident Merchant Partners and as CEO of Vulture Peak Gold, an Arizona based gold mining operation.

#### **(6) Edward J. Kimball, MD, Director**

Edward J. Kimball, MD is a Director of Aspire. Dr. Kimball is a Professor of Surgery at the University of Utah Health Sciences Center and Medical Director of Surgical Critical Care at the Salt Lake VA Medical Center. He is the Chief Medical Officer for Outreach Network Development and Telehealth and Medical Director of TeleICU services for U Health. Dr. Kimball's research in critical care medicine has been focused on shock resuscitation, inflammation and its effects on abdominal organ function. He and his colleagues designed the device used as an international standard for assessing intra-abdominal pressures in critically ill patients. He is the current president of the World Abdominal Compartment Society. Dr. Kimball served as a medical officer in the US Army and continues to provide training for US Special Forces.

#### **Scientific Board**

##### **Dr. James K. Dzandu, PhD**

Dr. Dzandu was appointed as a Medical Advisor of Aspire Biopharma Inc. in June 2022. Dr. Dzandu received his Doctor of Philosophy Degree in Biochemistry from Wayne State University, Detroit Michigan in 1980. He was appointed Assistant Professor of Pathology and Associate Director of the DNA/Identity laboratory at University of Texas Health Science center, Fort Worth Texas. Dr. Dzandu is well published in peer-reviewed journals and has received many awards and funding support for his work on sickle cell, proteomics and genomics. In the last few years, Dr. Dzandu has turned his attention to a successful collaborative research partnership with Dr. Mangram and the trauma dream team on trauma research with special emphasis on G60.

##### **Dr. Paul Montanarella, MD**

Dr. Monterella was appointed as a Medical Advisor of Aspire Biopharma Inc. in October 2022. Dr. Monterella earned his medical degree from the Universidad Nacional Autónoma de Honduras Facultad de Ciencias Médicas. Upon graduating, he relocated to the United States and completed his residency in internal medicine at the Highland Hospital of Rochester in 1988, and his residency in anesthesiology at Westchester Medical Center and SUNY Upstate Medical University in 1991. With an unwavering commitment to his specialty, the doctor is board-certified in anesthesiology by the American Board of Anesthesiology (ABA). As the certifying body for anesthesiologists since 1938, the ABA is committed to partnering with physicians to advance the lifelong learning and exceptional patient care. Its mission is to advance the highest standards of the practice of anesthesiology. Anesthesiology is the medical specialty concerned with the total perioperative care of patients before, during, and after surgery. It encompasses anesthesia, intensive care medicine, critical emergency medicine, and pain medicine. Anesthesiologists have the primary responsibility of monitoring the patient's vital signs during surgery. In addition to basic measurements such as pulse, blood pressure, and temperature, they measure the patient's respiration.

##### **Dr. Jeffrey Barletta, PharmD**

Dr. Barletta was appointed as a Medical Advisor of Aspire Biopharma Inc. in October 2022. Dr. Barletta, BS, PharmD, FCCM, is Professor and Vice Chair of Pharmacy Practice at Midwestern University, College of Pharmacy in Glendale, Arizona. Prior to joint MWU, Dr. Barletta was a clinical specialist in surgical critical care at Spectrum Health in Grand Rapids, MI and Detroit Receiving Hospital in Detroit, MI. He has more than 20 years of experience in critical care and has published numerous peer-reviewed manuscripts and textbook chapters related to clinical outcomes with drug therapy in the critically ill or injured patient. Dr. Barletta has been highly active within SCCM serving in various roles throughout his career including a current member of Council, Vice-Chair of Strategic Planning, past-Editor for Critical Connections and past-Section Chair for the Clinical Pharmacy and Pharmacology Section. Dr. Barletta is also a member of the American Board of Internal Medicine, Critical Care Specialty Board.

### **Edward Kimball, MD**

Dr. Kimball was appointed as a Medical Advisor of Aspire in October 2021. Dr. Edward Kimball is a Professor of Surgery at the University of Utah Health Sciences Center and Medical Director of Surgical Critical Care at the Salt Lake VA Medical Center. He is the Chief Medical Officer for Outreach Network Development and Telehealth and Medical Director of TeleICU services for U Health. Dr. Kimball's research in critical care medicine has been focused on shock resuscitation, inflammation and its effects on abdominal organ function. He and his colleagues designed the device used as an international standard for assessing intra-abdominal pressures in critically ill patients. He is the current president of the World Abdominal Compartment Society. Dr. Kimball served as a medical officer in the US Army and continues to provide training for US Special Forces.

### **Morah Ibrahim, MD, FHRS, FACC**

Dr. Ibrahim was appointed as Medical Advisor to Aspire in July 2023. As an Electrophysiologist and Cardiologist, Dr. Morhaf Ibrahim is passionate about all aspects of cardiology. He completed his fellowship in cardiac electrophysiology at the University of Florida Jacksonville and Mayo Clinic Jacksonville. He is excited to connect with his patients and make a significant impact in each of their lives. He brings with him a commitment and experience to treat not only cardiac arrhythmias but other aspects of heart diseases as well. Dr. Ibrahim graduated from the University of Damascus in Syria. He then completed his residency in Houston at the University of Texas, Texas Medical Center. He was fascinated about the field of cardiology and decided to complete his training in cardiology at the University of South Alabama where he served as a chief cardiology fellow. During his cardiology training, he became interested in cardiac electrophysiology and he came to Jacksonville where he was trained in cardiac electrophysiology.

### **Gary Bernard, MD**

Dr. Bernard was appointed as Medical Advisor to Aspire in August 2023. Dr. Bernard is President and CEO, Pointe Medical Services, Inc., President and CEO, Pointe Med Pharmacy, Inc., Owner Live, Well MD, LLC, Majority Owner and Managing Member, Live Well Drugstore, LLC, d/b/a TruLife Pharmacy. Dr. Bernard completed Residency in Internal Medicine at the University of Florida Health Science Center, Residency in Internal Medicine, Rotation in Cardiology at the Brown University School of Medicine, and Residency in Anesthesiology at the Dartmouth-Hitchcock Medical Center. He earned a B.S. Degree in Chemistry from Hobart and William Smith College, and medical degrees from the University of South Florida and Meharry Medical College.

### **John A. Mansour Jr, DO**

Dr. Mansour was appointed as medical advisor to Aspire in August 2023. Dr. Mansour is a board certified and fellowship trained orthopedic surgeon specializing in orthopedic traumatology and fracture care. he is Chief of Orthopedic surgery as well as Medical Director of Orthopedic trauma for the Hughston clinic at HCA Florida Orange Park hospital. He earned a Bachelor of science degree in biological sciences, graduating summa cum laude, from Delta State University. He then went on to earn his medical degree in osteopathic medicine from Nova Southeastern University. After finishing his internship at the Peninsula/NS-LIJ Hospital Consortium, he completed his orthopedic surgery residency at the Philadelphia College of Osteopathic Medicine and continued his training through an Orthopedic Taumatology Fellowship at Grant Medical Center.

### **Indemnification**

Indemnification is authorized by the Company to its directors and officers (or, at the discretion of the board of directors, an employee or agent of the Company, or a person serving at the request of the corporation as a director, officer, employee, or agent of another corporation, partnership, joint venture, trust, or other enterprise) by reason of any threatened, pending, or completed action, suit, or proceeding, whether civil, criminal, administrative or investigative for such persons acting in their respective capacities or on behalf of the corporation in such actions, pursuant to Puerto Rico law and the bylaws of the Company. Indemnification includes expenses such as attorney's fees and, in certain circumstances, judgments, fines and settlement amounts actually paid or incurred in connection with actual or threatened actions, suits or proceedings involving such person, except in certain circumstances where a person is adjudged to be guilty of willful misconduct or may not have acted in good faith, unless a court of competent jurisdiction determines that such indemnification is fair and reasonable under the circumstances.

### **Employees**

The Company currently has seven contract staff professionals and no full time employees. The Company also utilizes independent contractors and advisors.



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## CAPITALIZATION, DEBT, AND OWNERSHIP

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### Capitalization

The Company's authorized capital stock consists of seven hundred and fifty million (750,000,000) shares of common stock of which four hundred and forty million (440,000,000) are issued and outstanding, par value \$0.001 per share (the "**Common Stock**"), and twenty-five million (25,000,000) shares of Series A Preferred Stock of which 322,057 are issued and outstanding, par value \$ 0.0001 per share (the "**Series A Preferred Stock**").

### Outstanding Capital Stock

As of the date of this Form C-AR, the Company's outstanding capital stock consists of:

Type	Common Stock
Amount Outstanding	440,000,000
Par Value Per Share	\$0.001
Voting Rights	1 vote per share
Anti-Dilution Rights	None
How this security may limit, dilute or qualify the security issued pursuant to Regulation CF	The Company may issue additional shares of Common Stock at a later date. The issuance of such additional shares of Common Stock would be dilutive.

  

Type	Series A Preferred Stock
Amount Outstanding	322,057
Par Value Per Share	\$0.0001
Voting Rights	None
Anti-Dilution Rights	None
How this security may limit, dilute or qualify the security issued pursuant to Regulation CF	The Company may issue additional shares of the Series A Preferred Stock which may dilute the security.

**Outstanding Options, SAFEs, Convertible Notes, Warrants**

As of the date of this Form C-AR, the Company has the following outstanding warrants:

<b>Type</b>	Warrants
<b>Amount Outstanding</b>	47,500,000
<b>Voting Rights</b>	Voting rights accrue upon conversion of the warrants into Common Stock
<b>Anti-Dilution Rights</b>	N/A
<b>Material Terms</b>	N/A
<b>How this security may limit, dilute or qualify the security issued pursuant to Regulation CF</b>	If exercised prior to conversion of the Series A Preferred Stock, any additional issuances of the Common Stock further to conversion of the warrants will dilute the securities and could adversely affect the value of the securities issued pursuant to this Regulation CF.

**Outstanding Debt**

Details of the outstanding debt of the Company are as follows:

<b>Type</b>	Short term working capital advances
<b>Creditor</b>	Related parties
<b>Amount Outstanding</b>	\$360,636 (as at December 31, 2023)
<b>Interest Rate and Amortization Schedule</b>	None
<b>Description of Collateral</b>	No collateral
<b>Other Material Terms</b>	None
<b>Maturity Date</b>	None
<b>Date Entered Into</b>	Agreements for the advances entered into on multiple dates

**Ownership**

The table below lists the beneficial owners (including individuals and entities) of twenty percent (20%) or more of the Company's outstanding voting equity securities, calculated on the basis of voting power, along with the amount they own.

<b>Name of Beneficial Owner</b>	<b>Amount of Shares of Common Stock Beneficially Owned</b>	<b>Percentage of Shares of Common Stock Beneficially Owned</b>
Kraig T. Higginson	170,000,000	38.6%

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## TRANSACTIONS WITH RELATED PERSONS AND CONFLICTS OF INTEREST

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### Transactions with Related Persons

From time to time the Company may engage in transactions with related persons. Related persons are defined as any director or officer of the Company; any person who is the beneficial owner of twenty percent (20%) or more of the Company's outstanding voting equity securities, calculated on the basis of voting power; any promoter of the Company; any immediate family member of any of the foregoing persons or an entity controlled by any such person or persons.

The Company has conducted the following transactions with related persons as of December 31, 2023:

Name of the related party	Relationship to the Company	Nature of interest in the transaction	Amount/ value of the transaction
Kraig T. Higginson	CEO & Chairman	Short term working capital advance	\$181,061

### Conflicts of Interest

To the best of our knowledge, the Company has not engaged in any transactions or relationships, which may give rise to a conflict of interest with the Company, its operations or its security holders.

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## FINANCIAL INFORMATION

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*Please see the financial information listed on the cover page of this Form C-AR and in the financial statements attached hereto as **Exhibit B**, in addition to the following information.*

### **Cash and Cash Equivalents**

As of January 1, 2024, the Company had an aggregate of \$14,990 in cash and cash equivalents, together with commitments for short-term working capital advances from related parties, leaving the Company with approximately six to nine months of runway. Runway is calculated by dividing cash-on-hand by average monthly net loss (if any).

### **Liquidity and Capital Resources**

The Company recently completed the following offerings: (a) An offering of the Company's Series A Preferred Stock pursuant to Regulation CF, raising \$229,084; (b) An offering of the Company's Series A Preferred Stock pursuant to Regulation D, Rule 506(d), raising \$28,561.

### **Capital Expenditures and Other Obligations**

The Company does not intend to make any material capital expenditures in the near future.

### **Valuation**

The Company has ascribed no valuation to the Company; the securities of the Company are priced arbitrarily and the Company makes no representations as to the reasonableness of any specified valuation cap.

### **Material Changes and Other Information**

#### ***Trends and Uncertainties***

After reviewing the above discussion of the steps the Company intends to take, potential investors should consider whether achievement of each step within the estimated time frame will be realistic in their judgment. Potential investors should also assess the consequences to the Company of any delays in taking these steps and whether the Company will need additional financing to accomplish them.

The financial statements are an important part of this Form C-AR and should be reviewed in their entirety. Please see the financial statements attached as **Exhibit B** to this Form C-AR.

#### ***Restrictions on Transfer***

Any securities sold pursuant to Regulation CF being offered may not be transferred by any investor of such securities during the one-year holding period beginning when the securities were issued, unless such securities are transferred: (1) to the Company; (2) to an accredited investor, as defined by Rule 501(d) of Regulation D promulgated under the Securities Act; (3) as part of an IPO; or (4) to a member of the family of the Investor or the equivalent, to a trust controlled by the Investor, to a trust created for the benefit of a member of the family of the Investor or the equivalent, or in connection with the death or divorce of the Investor or other similar circumstances. "Member of the family" as used herein means a child, stepchild, grandchild, parent, stepparent, grandparent, spouse or spousal equivalent, sibling, mother/father/daughter/son/sister/brother-in-law, and includes adoptive relationships. Each investor should be aware that although such securities may legally be able to be transferred, there is no guarantee that another party will be willing to purchase them.

In addition to the foregoing restrictions, prior to making any transfer of the securities or any capital stock into which they are convertible, such transferring Company must either make such transfer pursuant to an effective registration statement filed with the SEC or provide the Company with an opinion of counsel reasonably satisfactory to the Company stating that a registration statement is not necessary to effect such transfer.

In addition, the Company may not transfer the securities or any capital stock into which they are convertible to any of the Company's competitors, as determined by the Company in good faith.

Furthermore, upon the event of an IPO, the capital stock into which the securities are converted will be subject to a lock-up period and may not be lent, offered, pledged, or sold for up to 180 days following such IPO.

#### Previous Offerings of Securities

We have made the following issuances of securities within the last three years:

Security Type	Principal Amount of Securities Sold	Amount of Securities Issued	Use of Proceeds	Issue Date	Exemption from Registration Used or Public Offering
Common Stock	\$0	182,800,000	N/A	Sept 28, 2021	Section 4(a)(2)
Common Stock	\$79,500	90,000,000	Legal and Professional Fees	September 28, 2021	Section 4(a)(2)
Common Stock	\$750,000	30,000,000	Product Development, Legal and Professional Fees, Working Capital	October 18, 2021	Section 4(a)(2)
Common Stock	\$0	40,000,000	Instaprin Pharmaceuticals Inc. Asset Acquisition	March 15, 2022	Section 4(a)(2)
Common Stock	\$150,000	3,000,000	Product Development, Legal and Professional Fees, Working Capital	August 16, 2022	Section 4(a)(2)
Series A Preferred Stock	\$229,084	286,355	GMP Batch Production and Clinical Trials, Professional Services Fees, Working Capital and Intermediary Commission	March 1, 2024	Regulation CF
Series A Preferred Stock	\$28,561	35,702	GMP Batch Production and Clinical Trials, Professional Services Fees, Working Capital and Intermediary Commission	April 16, 2024	Regulation D Rule 506(d)

See the section "*Capitalization, Debt and Ownership*" of this Form C-AR above for more information regarding the securities issued in our previous offerings of securities.

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**EXHIBIT B**

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**FINANCIAL STATEMENTS  
(EXHIBIT B TO FORM C-AR)  
April 26, 2024**

**Aspire Biopharma Inc.**



ASPIRE BIOPHARMA INC.  
FINANCIAL STATEMENTS  
DECEMBER 31, 2023 & DECEMBER 31, 2022

ASPIRE BIOPHARMA INC.  
FINANCIAL STATEMENTS  
DECEMBER 31, 2023 & DECEMBER 31, 2022  
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**ASPIRE BIOPHARMA INC.  
CONSOLIDATED BALANCE SHEETS**

	<u>December 31, 2023</u>	<u>December 31, 2022</u>
<b>ASSETS:</b>		
Current Assets:		
Cash	\$ 11,174	\$ 38
Prepaid expenses	35,000	22,500
Total Current Assets	<u>46,174</u>	<u>22,538</u>
Property and Equipment, net	4,971,007	4,895,106
<b>Total Assets</b>	<u>\$ 5,017,181</u>	<u>\$ 4,917,644</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY:</b>		
Current Liabilities:		
Accounts Payable	\$ 172,773	\$ 122,734
Short-term loans from shareholders	360,636	27,967
Other Current Liabilities	119,081	43,180
Total Current Liabilities	<u>652,490</u>	<u>193,881</u>
Long-Term Liabilities:		
Contingent Liability (SEC)	3,852,552	3,852,552
Total Long-Term Liabilities	<u>3,852,552</u>	<u>3,852,552</u>
<b>Total Liabilities</b>	<u>4,505,042</u>	<u>4,046,433</u>
Stockholders' Equity:		
Common stock - Par Value \$0.01	220,000	220,000
Additional paid-in-capital	1,759,500	1,759,500
Accumulated Deficit	(1,467,361)	(1,108,290)
Total Equity	<u>512,139</u>	<u>871,210</u>
<b>TOTAL LIABILITIES AND EQUITY</b>	<u>\$ 5,017,181</u>	<u>\$ 4,917,644</u>

The accompanying notes are an integral part of these consolidated financial statements.

**ASPIRE BIOPHARMA INC.**  
**CONSOLIDATED STATEMENT OF OPERATIONS**  
**FOR THE YEARS ENDING DECEMBER 31, 2023 AND 2022**

	<b>FOR THE YEAR ENDING</b>	
	<b>DECEMBER 31,</b>	
	<b>2023</b>	<b>2022</b>
<b>REVENUE</b>		
Gross Receipts	\$ 0	\$ 0
Net Revenue	0	0
<b>COST OF REVENUE</b>		
Cost of goods sold	0	0
Total cost of revenue	0	0
<b>GROSS PROFIT</b>	0	0
<b>OPERATING EXPENSES</b>		
Research and development	72,050	175,316
Marketing and sales	39,644	45,483
General and administrative	246,896	375,692
Total operating expenses	358,590	596,491
<b>OTHER INCOME (EXPENSE)</b>		
Interest expense, net of interest income	0	0
Total other income (expense)	0	0
<b>Net gain/(loss) before income tax provision</b>	(358,590)	(596,491)
Provision for Income Taxes	481	626
<b>NET GAIN (LOSS)</b>	<b>\$ (359,071)</b>	<b>\$ (597,117)</b>
<b>Loss per share - basic and diluted</b>	<b>\$ (0.001)</b>	<b>\$ (0.001)</b>
<b>Weighted average number of shares outstanding - basic and diluted</b>	<b>487,500,000</b>	<b>462,235,616</b>

The accompanying notes are an integral part of these consolidated financial statements.

**ASPIRE BIOPHARMA INC.**  
**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)**  
**FOR THE YEARS ENDING DECEMBER 31, 2023 AND 2022**

	<b>Common Stock</b>		<b>Additional Paid-In Capital</b>	<b>Accumulated Deficit</b>	<b>Total</b>
	<b>Shares</b>	<b>Amount</b>			
Balance – December 31, 2021	386,700,000	\$ 193,350	\$ 386,150	\$ (511,172)	\$ 68,327
Issuance of common stock for cash	10,000,000	5,000	245,000	-	250,000
Issuance of common stock for assets	40,000,000	20,000	980,000	-	1,000,000
Issuance of common stock for cash	3,000,000	1,500	148,500	-	150,000
Issuance of common stock for services	200,000	100	(100)	-	0
Issuance of common stock for services	100,000	50	(50)	-	0
Net (loss) gain for the period	-	-	-	(597,117)	(597,117)
Balance – December 31, 2022	<u>440,000,000</u>	<u>\$ 220,000</u>	<u>\$ 1,759,500</u>	<u>\$ (1,108,290)</u>	<u>\$ 871,210</u>
Issuance of common stock for cash	-	-	-	-	-
Issuance of common stock for assets	-	-	-	-	-
Issuance of common stock for cash	-	-	-	-	-
Issuance of common stock for services	-	-	-	-	-
Issuance of common stock for services	-	-	-	-	-
Net (loss) gain for the period	-	-	-	(359,071)	(359,071)
Balance – December 31, 2023	<u>440,000,000</u>	<u>\$ 220,000</u>	<u>\$ 1,759,500</u>	<u>(1,467,361)</u>	<u>\$ 512,139</u>

The accompanying notes are an integral part of these consolidated financial statements.

**ASPIRE BIOPHARMA INC.**  
**CONSOLIDATED STATEMENT OF CASH FLOWS**

	<b>FOR THE YEAR ENDING</b>	
	<b>DECEMBER 31,</b>	
	<b>2023</b>	<b>2022</b>
<b>OPERATING ACTIVITIES:</b>		
Net Income	\$ (359,071)	\$ (597,117)
Adj. to reconcile net income to net cash flow		
Depreciation and amortization	0	0
	0	0
Decrease (increase) in current assets		
Prepaid expenses	(12,500)	(22,500)
	(12,500)	(22,500)
Increase (decrease) in current liabilities		
Accounts payable	50,039	102,734
Short-term loans from shareholders	332,669	(68,576)
Accrued expense	75,901	42,554
	458,609	76,713
<b>Net cash flow provided by operating activities</b>	<b>(87,038)</b>	<b>(542,905)</b>
<b>INVESTING ACTIVITIES:</b>		
Fixed assets, acquired intangibles	75,902	(4,895,106)
	75,902	(4,895,106)
<b>FINANCING ACTIVITIES:</b>		
Contingent liabilities, SEC	-	3,852,552
Common stock, par value \$0.005	-	26,650
Additional paid in capital	-	1,373,350
	-	5,252,552
<b>Net increase (decrease) in cash</b>	<b>11,136</b>	<b>(185,459)</b>
<b>Cash at beginning of period</b>	<b>38</b>	<b>185,496</b>
<b>Cash at end of period</b>	<b>\$ 11,174</b>	<b>\$ 38</b>

The accompanying notes are an integral part of these consolidated financial statements.

**ASPIRE BIOPHARMA, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**December 31, 2023 and 2022**

**NOTE 1 – ORGANIZATION AND DESCRIPTION OF BUSINESS**

Aspire Biopharma Inc. (the “Company”) was incorporated in Puerto Rico on September 28, 2021. Aspire Biopharma Inc. is engaged in the business of developing and marketing the disruptive technology for novel delivery mechanisms, initially for “do no harm” drugs.

**NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

***Basis of Presentation***

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America.

***Use of Estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. Actual results could differ from those estimates.

***Cash***

Cash includes cash in banks, money market funds, and certificates of term deposits with maturities of less than three months from inception, which are readily convertible to known amounts of cash and which, in the opinion of management, are subject to an insignificant risk of loss in value.

***Accounts Receivables***

Accounts receivables are recorded at the invoice amount and do not bear interest.

***Property and Equipment***

The Company’s property and equipment are recorded at cost and depreciated using the straight-line method over the useful lives of the assets, generally from three to seven years. Upon sale or disposal of property and equipment, the related asset cost and accumulated depreciation or amortization are removed from the respective accounts and any gain or loss is reflected in current operations.

### ***Long-Lived Intangible Assets***

Long-lived intangible assets established in connection with business combinations consist of patents, trademarks, and trade names. The impairment test for identifiable indefinite-lived intangible assets consists of a comparison of the estimated fair value of the intangible asset with its carrying value. If the carrying value exceeds its fair value, an impairment loss is recognized in an amount equal to that excess. With the acquisition of Instaprin Pharmaceutical, Inc.'s assets on March 28, 2022 the Company added a value of \$4,844,982 in patents and trademarks to its balance sheet (see Note 7 below)

As of December 31, 2023, the Company believes that based upon qualitative factors, no impairment of indefinite-lived intangible assets is necessary.

### ***Revenue Recognition***

The Company applies Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) topic 606, Revenue from Contracts with Customers (ASC 606). ASC 606 establishes a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes all of the existing revenue recognition guidance. This standard requires an entity to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASC 606 requires us to identify distinct performance obligations. A performance obligation is a promise in a contract to transfer a distinct good or service to the customer. When distinct performance obligations exist, the Company allocates the contract transaction price to each distinct performance obligation. The standalone selling price is used to allocate the transaction price to the separate performance obligations. The Company recognizes revenue when, or as, the performance obligation is satisfied.

Generally, revenues are recognized at the time of shipment to the customer with the price being fixed and determinable and collectability assured, provided title and risk of loss is transferred to the customer. Most of our shipping and handling costs are built into the transaction price, but if the customer asks for express shipping, the costs charged to customers are classified as sales, and the shipping and handling costs incurred are included in cost of sales.

The Company evaluates the criteria outlined in ASC 606-10-55, Principal versus Agent Considerations, currently we are the principal and have not engaged any agents at this time. Currently, we have not recognized any revenues under the agent considerations.

Revenue is recognized when, or as, control of a promised merchandise or service is shipped to the customer, in an amount that reflects the consideration to which the Company expects to be entitled in exchange for transferring title of those products or services and are recorded net of and discounts or allowances. Shipping costs paid by the customer are included in revenue.

Revenue recognition is evaluated through the following five-step process:

1. identification of the contract with a customer;
2. identification of the performance obligations in the contract;
3. determination of the transaction price;
4. allocation of the transaction price to the performance obligations in the contract; and
5. recognition of revenue when or as a performance obligation is satisfied.

These steps are met when an order is received, a price agreed and the product shipped or delivered to that customer.

### ***Concentration***

As the Company is in a pre-revenue stage, there is no concentration of revenue for the twelve months ended December 31, 2023 and for the twelve months ended December 31, 2022.

### ***Income Taxes***

The Company accounts for income taxes using the asset and liability method in accordance with ASC 740, "Accounting for Income Taxes". The asset and liability method provides that deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the financial reporting and tax bases of assets and liabilities and for operating loss and tax credit carry forwards. Deferred tax assets and liabilities are measured using the currently enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company records a valuation allowance to reduce deferred tax assets to the amount that is believed more likely than not to be realized. For the periods ending December 31, 2023 and December 31, 2022, the Company did not have any amounts recorded pertaining to uncertain tax positions.

### ***Fair Value Measurements***

The Company adopted the provisions of ASC Topic 820, "Fair Value Measurements and Disclosures", which defines fair value as used in numerous accounting pronouncements, establishes a framework for measuring fair value and expands disclosure of fair value measurements.

The estimated fair value of certain financial instruments, including cash and cash equivalents are carried at historical cost basis, which approximates their fair values because of the short-term nature of these instruments.

ASC 820 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820 also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. ASC 820 describes three levels of inputs that may be used to measure fair value:

Level 1 — quoted prices in active markets for identical assets or liabilities

Level 2 — quoted prices for similar assets and liabilities in active markets or inputs that are observable

Level 3 — inputs that are unobservable (for example cash flow modeling inputs based on assumptions)

For the periods ended December 31, 2023 and December 31, 2022, the Company had no financial liabilities to measure at fair value on a recurring basis.

### ***Recent Accounting Pronouncements***

In May 2014, the Financial Accounting Standards Board (“FASB”) issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). ASU 2014-09 amends the guidance for revenue recognition to replace numerous, industry specific requirements and converges areas under this topic with those of the International Financial Reporting Standards. The ASU implements of five-step process for customer contract revenue recognition that focuses on transfer of control, as opposed to transfer of risk and rewards. The amendment also requires enhanced disclosures regarding the nature, amount, timing and uncertainty of revenues and cash flows from contracts with customers. Other major provisions include the capitalization and amortization of certain contract cost, ensuring the time value of money is considered in the transaction price, and allowing estimates of variable consideration to be recognized before contingencies are resolved in certain circumstances. The amendments in this ASU are effective for reporting period beginning after December 15, 2016, and early adoption is prohibited. Entities can transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption.

The Company’s revenues are recognized when control of the promised goods or services is transferred to our clients (upon shipment of goods) in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods and services. To achieve this core principle, we apply the following five steps: (1) Identify the contract with a client; (2) Identify the performance obligations in the contract; (3) Determine the transaction price; (4) Allocate the transaction price to performance obligations in the contract; and (5) Recognize revenues when or as the Company satisfies a performance obligation.

We adopted ASC 2014-09 on January 1, 2023. Although the new revenue standard is expected to have an immaterial impact, if any, on our ongoing net income, we did implement changes to our processes related to revenue recognition and the control activities with them.

### ***Convertible Instruments***

The Company evaluates and account for conversion options embedded in convertible instruments in accordance with ASC 815 “*Derivatives and Hedging Activities*”. Applicable GAAP requires companies to bifurcate conversion options from their host instruments and account for them as free-standing derivative financial instruments according to certain criteria. The criteria include circumstances in which (a) the economic characteristics and risks of the embedded derivative instrument are not clearly and closely related to the economic characteristics and risks of the host contract, (b) the hybrid instrument that embodies both the embedded derivative instrument and the host contract is not re-measured at fair value under other GAAP with changes in fair value reported in earnings as they occur and (c) a separate instrument with the same terms as the embedded derivative instrument would be considered a derivative instrument.

The Company accounts for convertible instruments (when it has been determined that the embedded conversion options should not be bifurcated from their host instruments) as follows: The Company records when necessary, discounts to convertible notes for the intrinsic value of conversion options embedded in debt instruments based upon the differences between the fair value of the underlying common stock at the commitment date of the note transaction and the effective conversion price embedded in the note. Debt discounts under these arrangements are amortized over the term of the related debt to their stated date of redemption.

The Company accounts for the conversion of convertible debt when a conversion option has been bifurcated using the general extinguishment standards. The debt and equity linked derivatives are removed at their carrying amounts and the shares issued are measured at their then-current fair value, with any difference recorded as a gain or loss on extinguishment of the two separate accounting liabilities. During the years ended December 31, 2023 and December 31, 2022, the Company did not issue any convertible debt.



### ***Common Stock Purchase Warrants***

The Company classifies as equity any contracts that require physical settlement or net-share settlement or provide a choice of net-cash settlement or settlement in the Company's own shares (physical settlement or net-share settlement) provided that such contracts are indexed to our own stock as defined in ASC 815-40 ("Contracts in Entity's Own Equity"). The Company classifies as assets or liabilities any contracts that require net-cash settlement (including a requirement to net cash settle the contract if an event occurs and if that event is outside our control) or give the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement). The Company assesses classification of common stock purchase warrants and other free-standing derivatives at each reporting date to determine whether a change in classification is required.

### **NOTE 3 – GOING CONCERN**

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has generated no revenues from operations. Since its inception, the Company has been engaged substantially in financing activities, developing its intellectual property, developing its business plan and incurring startup costs and expenses. As a result, the Company incurred accumulated net losses from Inception (September 28, 2021) through the period ended December 31, 2023 of \$1,467,361. Due to our negative cash flow, there may exist substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. In addition, the Company's development activities since inception have been financially sustained through equity financing. Management plans to begin generating revenue within the next twelve months and in the interim, continue to seek funding through debt and equity financing which are intended to mitigate the conditions that have raise substantial doubt about the entity's ability to continue as a going concern.

### **NOTE 4 – RELATED PARTY**

For the twelve months ended December 31, 2023 and 2022, the Company had expenses totaling \$90,000 and \$135,000 respectively, to officers and directors for compensation, which is included in general and administrative expenses on the accompanying statement of operations.

Prior to January 1, 2023 the company was leasing a corporate office facility on a month-to-month basis from an officer and director, which is included in general and administrative expenses on the accompanying statement of operations.

As of December 31, 2023 and 2022, there was a total of \$181,061 and \$27,967 of credit card advances and short-term non-interest bearing loans due to an officer and director.

As of December 31, 2023 and 2022, there was a total of \$179,575 and \$0 of short-term non-interest bearing working capital loans payable to shareholders and an officer and director.

As of December 31, 2023, there was a total of convertible debt of \$0 and accrued interest payable of \$0 due to an officer and director, employees, and shareholders.

### **NOTE 5 – LEASES**

The company does not lease facilities under any operating lease or month-to-month arrangement. Prior to January 1, 2022 the company was leasing a corporate office facility on a month-to-month basis from a related party.

Total rent expense for the months ended December 31, 2023 and 2022 was \$0 and \$0.

## **NOTE 6 – NOTES PAYABLE**

As of December 31, 2023, the Company had no outstanding notes payable.

## **NOTE 7 – INSTAPRIN ACQUISITION**

On March 28, 2022, the Company closed on an asset purchase of Instaprin Pharmaceuticals, Inc. (Instaprin), inclusive of U.S. Patent No. 62/794141, International Publication No. 2020/15460 A1 and WO 2020/150685 A1, and the Instaprin U.S. Trademark No. 86274378.

The Company assumed one liability in the transaction, which is a contingent liability to the Securities and Exchange Commission (SEC) in the amount of \$3,844,982, inclusive of accrued interest thereon to the date of the acquisition. This contingent liability is to be paid to the SEC in satisfaction of the SEC's judgment against the former Instaprin CEO, from sales of the product, as follows: 20% from the first \$5,000,000 of sales and 10% from sales thereafter until the entire contingent purchase price obligation is satisfied.

Also, the Company was required to deliver 10% of its equity at closing to the Trustee for the former Instaprin shareholders and service providers. As such, 2,000,000 shares of common stock at a value of \$0.50 per share were issued to the trust in connection with the acquisition.

Also, on the date of the Instaprin acquisition, the Company recorded long-lived intangible assets of \$4,844,982.

## **NOTE 8 – CONVERTIBLE DEBT**

As of December 31, 2023, the Company had no outstanding convertible debt.

## **NOTE 9 – STOCKHOLDERS' EQUITY**

### ***Authorized Stock***

#### **Preferred Stock**

During October 2023, the Company authorized 25,000,000 Series A Preferred Stock with a par value of \$0.0001. The series A convertible preferred shares have all rights as common stock, with the exception of voting rights, and can be converted into common shares on a one for one basis upon an IPO or liquidity event.

As of December 31, 2023, there were no series A preferred shares outstanding.

#### **Common Stock**

As of December 31, 2023, the Company had authorized 750,000,000 common shares with a par value of \$0.01 per share. Each common share entitles the holder to one vote on any matter on which action of the stockholders of the corporation is sought.

During May 2023, the Company effectuated a 20:1 stock split and increased the authorized number of shares to 750,000,000.

### ***Common Share Issuances***

During the twelve months ended December 31, 2023, the Company did not issued shares of common stock.

During the twelve months ended December 31, 2022, the Company issued 650,000 shares of common stock in a direct security purchase agreement, and 2,000,000 shares of common stock to a shareholder trust for the benefit of the former shareholders of Instaprin, as a condition to the Instaprin asset purchase agreement.

### ***Warrant Issuances***

During the year ending December 31, 2021, on a post-split basis, the Company issued 126,000,000 warrants to 7 parties at a per share price of \$0.025.

During the year ending December 31, 2022, on a post-split basis, the Company issued 6,000,000 warrants to 1 party at a per share price of \$0.025 and 8,000,000 warrants to 2 parties at a per share price of \$0.375. As of December 31, 2022, there were 40,000,000 warrants outstanding, all of which are fully vested.

### **NOTE 10 – SUBSEQUENT EVENTS**

The Company evaluated its December 31, 2023 financial statements for subsequent events and transactions through April 20, 2024, the date the financial statements were available to be issued for possible disclosure and recognition in the financial statements.

On March 1, 2024, the Company closed its Reg-CF round, issuing 386,355 Series A Convertible Preferred shares for \$229,084.

On April 16, 2024, the Company completed a partial closing of its Reg-D round, issuing 35,702 Series A Convertible Preferred shares for \$28,561.