

2024 Annual Report

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(MARK ONE)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2024

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number: 001-42199

ADAGIO MEDICAL HOLDINGS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware **(State or other jurisdiction of incorporation or organization)**	**99-1151466** **(I.R.S. Employer Identification No.)**
26051 Merit Circle, Suite 102 **Laguna Hills, CA**	**92653**
(Address of principal executive offices)	**(Zip Code)**

(949) 348-1188
(Issuer's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	**ADGM**	**The Nasdaq Stock Market LLC**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, anon-accelerated filer, a smaller reporting company or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of June 30, 2024, the last business day of the Registrant's most recently completed second fiscal quarter, there was no established public market for the Registrant's common stock. Therefore, the aggregate market value of its common stock held by non-affiliates as of such date cannot be calculated. The Registrant's common stock began trading on the Nasdaq Capital Market on August 1, 2024.

As of March 21, 2025, there were 15,381,565 shares of common stock, $0.0001 par value, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement to be filed in connection with the registrant's 2025 annual general meeting of shareholders are incorporated by reference into Part III of this Form 10 K.

Auditor Firm Id: 100 **Auditor Name:** WithumSmith+Brown, PC **Auditor Location:** New York, New York

ADAGIO MEDICAL HOLDINGS, INC.
Annual Report on Form 10-K
For the Fiscal Year Ended December 31, 2024

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Unless the context indicates otherwise, references in this Annual Report to the "Company," "Adagio," "Successor," "we," "us," "our" and similar terms refer to Adagio Medical Holdings, Inc. (f/k/a Aja Holdco, Inc.) and its consolidated subsidiaries. References to "ListCo" refer to Aja Holdco, Inc. prior to the consummation of the Business Combination (as defined below).

On July 31, 2024, or the Closing Date (as defined below), ARYA Sciences Acquisition Corp IV, a Cayman Islands exempted company ("ARYA"), Aja Holdco, Inc. ("ListCo"), a Delaware corporation and wholly-owned subsidiary of ARYA, Aja Merger Sub 1, a Cayman Islands exempted company and wholly-owned subsidiary of ListCo ("ARYA Merger Sub"), Aja Merger Sub 2, Inc., a Delaware corporation and wholly-owned subsidiary of ListCo ("Company Merger Sub"), and Adagio Medical, Inc., a Delaware corporation ("Legacy Adagio" or the "Predecessor"), consummated the business combination (the "Business Combination") pursuant to the terms of the Business Combination Agreement, dated February 13, 2024, by and among the foregoing parties, as amended by the Consent and Amendment No. 1 to Business Combination Agreement, dated as of June 25, 2024, by and between ARYA and Legacy Adagio (the "Business Combination Agreement").

Pursuant to the Business Combination Agreement, on the Closing Date, (i) ARYA Merger Sub merged with and into ARYA (the "ARYA Merger") and Company Merger Sub merged with and into Legacy Adagio (the "Adagio Merger" and, together with the ARYA Merger, the "Mergers"), with ARYA and Legacy Adagio surviving the Mergers and, after giving effect to such Mergers, each of ARYA and Legacy Adagio becoming a wholly-owned subsidiary of ListCo (the time that the ARYA Merger becomes effective being referred to as the "ARYA Merger Effective Time," the time that the Adagio Merger becomes effective being referred to as the "Adagio Merger Effective Time," the time after which both Mergers become effective being referred to as the "Closing," and the date on which the Closing occurs being referred to as the "Closing Date"), (ii) ListCo filed with the Secretary of State of the State of Delaware an amended and restated certificate of incorporation of ListCo (the "Charter"), and the board of directors of ListCo approved and adopt amended and restated bylaws of ListCo (the "Bylaws"), and (iii) ListCo changed its name to Adagio Medical Holdings, Inc.

Statement Regarding Forward Looking Statements

Some of the statements contained in this Annual Report on Form 10-K ("Annual Report") may constitute "forward-looking statements" for purposes of the federal securities laws. Our forward-looking statements include, but are not limited to, statements regarding our or our management team's expectations, hopes, beliefs, intentions or strategies regarding the future. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking.

The forward-looking statements contained in this Annual Report are based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, the following risks, uncertainties (some of which are beyond our control) or other factors:

- Our failure to recognize the anticipated benefits of the Business Combination (refer to "*Description of the Merger"* for additional details), which may be affected by, among other things, competition and our ability to grow and manage growth profitably and retain our key employees;
- We have no operating history and no revenues, and you have no basis on which to evaluate our ability to achieve our business objective;
- We are a medical device company that has incurred net losses in every period to date and expect to continue to incur significant losses as we develop our business;
- Our growth prospects partially depend on our ability to accelerate the commercialization of our products and to capitalize on market opportunities;
- Even if we are able to launch our pipeline portfolio successfully, we may experience material delays in our commercialization program relative to our current expectations;
- The life sciences technology market is highly competitive. Competitors include new entrants and established companies, many of which have significantly greater resources than we do. If we fail to compete effectively, our business and results of operation will suffer;
- If we are unable to establish manufacturing capacity by ourselves or with third-party partners in a timely and cost-effective manner, commercialization of our products would be delayed, which would result in lost revenue and harm our business;
- We may not be successful in the commercialization of our products if we fail to establish relationships and successfully collaborate with leading life science companies and research institutions;
- If we are unable to establish an effective network for commercialization, including effective distribution channels and sales and marketing functions, it may adversely affect our business, financial condition, results of operations, and prospects;
- Our operating results may fluctuate significantly in the future, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide;
- There is no assurance that we will be able to execute on our business model, including achieving market acceptance of our products;
- Our products may not be successful if there are inadequate physician training, practice and patient selection;
- Even if our products are commercialized and achieve broad scientific and market acceptance, if we fail to improve them or introduce compelling new products, our revenue and our prospects could be harmed;
- The size of the markets for our products may be smaller than estimated, limiting our ability to successfully sell our products;
- The loss of any third-party suppliers and manufacturers, or any difficulties encountered by these suppliers and manufacturers in the production of our products;

- Our failure to protect against software or hardware vulnerabilities;
- Our failure to raise additional capital to develop the business development and commercialization plans;
- The risks related to the unfavorable U.S. or global economic conditions as a result of political instability, natural disasters, or otherwise;
- The loss of one or more of our executive officers and other key employees;
- Our failure to hire and retain qualified employees;
- Our failure to comply with federal state and local laws and regulations; and
- Our inability to maintain the listing of our common stock on the Nasdaq Capital Market ("Nasdaq").

These forward-looking statements are based on information available as of the date of this Annual Report, reflect our management's current expectations, forecasts and assumptions, and involve a number of judgments regarding known and unknown risks, uncertainties, and other factors, many of which are outside of our control, and the control of our directors, officers and affiliates. Accordingly, forward-looking statements should not be relied upon as representing our views as of any subsequent date. We do not undertake any obligation to update, add or to otherwise correct any forward-looking statements contained herein to reflect events or circumstances after the date they were made, whether as a result of new information, future events, inaccuracies that become apparent after the date hereof or otherwise, except as may be required under applicable securities laws.

As a result of a number of known and unknown risks and uncertainties, our results or performance may be materially different from those expressed or implied by these forward-looking statements. Some factors that could cause actual results to differ are set forth under the heading "Risk Factor Summary" below and those described under Part I, Item 1A "*Risk Factors*" of this Annual Report.

Risk Factor Summary

Below is a summary of material factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found under the heading "*Risk Factors*" in Item 1A of Part I of this Annual Report and should be carefully considered, together with other information in this Annual Report and our other filings with the U.S. Securities and Exchange Commission ("SEC") before making investment decisions regarding our common stock.

Risks Related to Our Business

- We have incurred net losses and our financial conditions raise substantial doubt about our ability to continue as a going concern.
- We may not be able to successfully execute our new business strategy and strategic restructuring.
- Changes in our business strategy or restructuring of our businesses may affect the profitability of our business.
- Our growth and revenue prospects depend on our ability to accelerate the commercialization of our products.
- Our operating results may fluctuate significantly, which makes our future operating results difficult to predict.
- There is no assurance that we will be able to execute on our business model.
- We may need to raise additional capital to fund our development and commercialization plans.
- Our product market size may be smaller than estimated, limiting our ability to successfully sell products.
- Significant disruption in our information technology systems or security incidents could adversely affect us.
- We may be unable to manage our anticipated growth effectively.
- Acquisitions or strategic partnership increase our capital requirements and otherwise disrupt our operations.
- If we are unable to recruit and retain key executives and scientists, we may be unable to achieve our goals.
- Consolidation in the medical device industry could adversely effect on our revenue and results of operations.
- Unfavorable U.S. or global economic conditions could adversely affect us.
- Failure to maintain an effective system of internal control over financial reporting could harm our business.
- Incorrect estimates or judgments relating to our critical accounting policies could cause a decline in our stock.
- We are not in compliance with Nasdaq's requirements, which affect the liquidity of our common stock.
- Unavailable or inoperable facilities could adversely affect our business plans.
- Any claims relating to improper handling, storage or disposal of hazardous materials could be costly.

Risks Related to Our Products

- If our clinical trials are unsuccessful, significantly delayed or incomplete, our business may be harmed.
- Planned trials may not establish an adequate safety or efficacy profile for our products, which would affect market acceptance of our products.
- Failure to establish relationships with partners may affect the commercialization of our products.
- Failure to establish an effective network for commercialization may adversely affect our business.
- Failure to appropriately train physicians and select patients may negatively affect our products.
- If we fail to improve our products or introduce new products, our prospects could be harmed.
- Failure to establish manufacturing capacity would delay commercialization of our products.
- Difficulties with third-party suppliers and manufacturers could harm our business.
- Our products could have unknown defects or errors, which may give rise to claims against us.

Risks Related to Our Intellectual Property

- Failure to obtain and maintain sufficient intellectual property ("IP") protection could adversely affect us.
- Changes in U.S. law relating to intellectual property may adversely impact our business.
- We may not be able to protect our IP rights throughout the world, which could harm our business prospects.
- Expensive, time consuming IP lawsuits may prevent or delay our efforts.
- Issued patents covering our products could be found invalid or unenforceable if challenged and could materially impact our business.
- Failure to protect our trade secrets, the value of our technology could be materially adversely affected.
- We may be subject to claims challenging the inventorship or ownership of our patents and other IP.
- We may not be able to protect and enforce our trademarks and trade names or build name recognition.
- Patent terms may be inadequate to protect our competitive position of our products.
- Our patent protection could be reduced or eliminated for non-compliance with these requirements.
- We may be subject to claims that confidentiality or misappropriation claims.
- Failure to license rights to use technologies may affect commercialization of new products in the future.
- Failure to comply with the terms of the underlying open source software licenses could limit us.
- IP rights do not necessarily address all potential threats.

Risks Related to Regulatory and Legal Compliance Matters

- There are no assurances that we will obtain the necessary approvals from the U.S. Food and Drug Administration ("FDA") in the United States.
- We may be subject to enforcement action if we engage in improper or off-label marketing or promotion.
- Our business could be negatively impacted by changes in the United States political environment.
- Adverse findings in post-marketing vigilance or regulatory audits could materially and adversely us.
- We may be subject to enforcement action if we engage in improper marketing of our products.
- Our actual or perceived failure to comply with regulations could harm our business.
- Failure to comply with anti-corruption, anti-bribery and anti-money laundering and similar laws could adversely affect our reputation, business, financial condition and results of operations.
- Expansion will subject us to an increased risk of inadvertent violation the Foreign Corrupt Practices Act.
- Noncompliance with regulatory standards and requirements could harm our business.

Risks Related to Litigation and Regulation

- Failure to comply with laws and regulations could result in litigation and substantially harm our business.
- We are subject to risks relating to disputes and other legal proceedings, product liability lawsuits, that may be time consuming and costly.
- Failure to comply with applicable international trade and sanctions regulations may harm our business.

Risks Related to Financing Transactions

- There are no guarantees that we can obtain future investments at a reasonable cost or at all.
- There are risks associated with our convertible notes that could adversely affect our financial condition.
- We are subject to risks relating to increased interest rates and adverse developments in the credit markets.

Risks Related to Tax

- Our ability to use NOL carryforwards and other tax attributes may be limited.
- The 1% U.S. federal excise tax could be imposed on us in connection with redemptions by us of our stock.
- Any changes in tax law, or in the application thereof, may adversely impact our results of operations.

Risks Related to Ownership of Our Securities

- The Perceptive PIPE Investor (defined herein) may have control over key decision making as a result of its voting power.
- We may use our financial resources in ways with which you do not agree or yield a favorable return.
- Status as "emerging growth company" and "smaller reporting company" could make our stock not attractive.
- Our stock price may be volatile and may decline regardless of its operating performance.
- We may be unable to maintain the listing of our securities on Nasdaq in the future.
- An active trading market for our common stock may not be sustained.
- Future sales of shares by existing stockholders could cause our stock price to decline.
- Issuance of additional shares of common stock or other equity securities would dilute your ownership.
- Inaccurate or unfavorable research publication about could decline our common stock.
- Delaware law and provisions in our Charter and Bylaws could make a merger, tender offer, or proxy contest difficult, thereby depressing the trading price of its common stock.
- Court of Chancery of the State of Delaware as the exclusive forum for disputes could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.
- We do not intend to pay dividends for the foreseeable future.
- We will incur increased costs and obligations as a result of being a public company.
- The requirements of being a public company may strain our resources and negatively impact our business.
- Failure to have effective internal control over financial reporting could cause our common stock to decline.
- Failure to remediate these material weaknesses may adversely affect our business and stock price.
- Securities or class action litigation would be expensive and could divert management's attention.
- The lack of published research or reports about us or published negative reports may impact our stock price.
- Changes in laws or regulations or how such laws or regulations are interpreted or applied, or a failure to comply with any laws or regulations, may adversely affect our business and results of operations.

PART I

Item 1. Business

Overview

We are a medical device company focused on developing and commercializing products for the treatment of cardiac arrhythmias with our novel, proprietary, catheter-based Ultra-Low Temperature Cryoablation ("UTLC") technology. Our initial focus is on the treatment of ventricular tachycardia ("VT"). VT is a rapid, abnormal heart rhythm, or arrhythmia, that originates in the heart's lower chambers, or ventricles, leading to blood flow issues and significant symptoms. If sustained, VT can become fatal. VT is strongly associated with coronary artery disease, with an estimated 15% of patients with coronary artery disease found to have VT, and sudden cardiac deaths ("SCD") caused by VT account for approximately half of the deaths related to cardiac causes. Radiofrequency energy-based ("RF") ablation catheters currently used to treat VT were initially designed and approved for the treatment of atrial arrhythmias) and are therefore not optimized to treat the specifics of the ventricular anatomy and disease. As a result, VT procedures performed with current devices can be overly complex, often with sub-optimal outcomes potentially inhibiting growth in the market for VT ablations.

Our clinically tested VT Cryoablation System is purpose-built to treat patients with VT. Our highly differentiated vCLAS™ catheters are designed for large, durable, deep lesions within the ventricle through an endocardial – or from inside the heart - approach. Our ULTC approach is built on the hypothesis that large and durable lesions extending through the depth of both diseased and healthy muscular tissue of the ventricle of the heart (ventricular myocardium) is a foundation for improving the effectiveness of VT ablations and patient outcomes.

We believe that our purpose-built solution has the potential to drive additional market growth in ablative treatment of the large, underserved VT patient population.

We have established a robust cadence of clinical data designed to evaluate our VT Cryoablation System and to support regulatory approvals of our product portfolio. Preliminary data suggest that our approach to treating VT offers a favorable combination of safety, acute and chronic effectiveness, compared to the current standard of care, including ablations performed using RF energy. Our first-in-human CRYOCURE-VT trial included 64 patients in nine centers in the E.U. and Canada. The outcomes of this trial, which were used to support the EC certificate of conformity ("CE Mark") approval of our VT Cryoablation System, include a 0% rate of major adverse events, 94% acute procedural success, 60% freedom from sustained VT and 81% freedom from implantable cardioverter defibrillator shock at six months. In the U.S., our 206-patient FULCRUM-VT pivotal investigational device exemption ("Pivotal IDE") clinical trial is currently enrolling patients across 20 centers in the U.S. and Canada. Upon completion, which we anticipate in the second half of 2025, we expect to submit the results of this trial to support FDA approval of our VT Cryoablation System.

We have also developed a technology that utilizes ULTC in combination with Pulsed Field Ablation, which we call Pulsed Field Cryoablation ("PFCA"). Early demonstration of PFCA technology has been performed in the European PARALELL trial in patients with persistent atrial fibrillation and in preclinical studies targeting VT ablations.

Market Opportunity

The Electrophysiology ("EP") Market consists of tools for the diagnosis and treatment of abnormal heart rhythms, or arrhythmias. Within the EP market, we estimate the current global market for EP ablation catheters to be valued at approximately $4.5 billion. Advanced catheters, which include radiofrequency ("RF") ablation catheters, cryoballoon catheters, RF balloon catheters, laser balloon catheters, and pulsed field ablation ("PFA") catheters, are used in complex ablations, principally for AF and VT, and account for approximately 82% of the ablation catheter market segment, or an estimated market value of $3.7 billion. The advanced ablation catheter EP segment has grown approximately 54% over the last 2 years, driven primarily by the market availability of a new technology called PFA for AF ablations, which offers substantial improvement in speed of the procedure as compared to the RF ablation technologies conventionally used to treat AF.

Ventricular Tachyarrhythmias

VT is a potentially fatal disruption of normal electrical activation of the heart originating in the lower chambers of the heart (ventricles), with a heart rate exceeding 100 beats per minute. The symptoms of VT range from lightheadedness to - a temporary loss of consciousness caused by a sudden decrease in blood flow to the brain, known as syncope, to progression into ventricular fibrillation and possibly sudden cardiac death ("SCD"). VT-associated SCD accounts for approximately 300,000 deaths each year in the U.S. alone. Ventricular tachycardia is prevalent in patients with structural heart disease of both ischemic (related to coronary artery disease) and non-ischemic causes due to the electrically disruptive scarring within the muscle of the heart which blocks or delays normal propagation of the electric signal in the heart. The other relevant group of patients are those with "idiopathic" VT, which is not associated with underlying structural heart disease, including patients with premature ventricular complexes ("PVC"), which are extra heartbeats that begin in one of the heart's two ventricles. While occasional PVCs in people without underlying heart disease usually are not a concern, frequent PVCs can become highly symptomatic and lead to the development of cardiomyopathy, or disease affecting the heart muscle that makes it difficult for the heart to pump blood effectively, even without underlying ischemic or non-ischemic disease.

The first line treatment of VT is anti-arrhythmic drugs, which are unfortunately often toxic and poorly tolerated. Another first line treatment is to implant the patient with an implantable cardioverter-defibrillator ("ICD"), which senses and restores normal heart rhythm through the administration of electrical shocks. While the ICD implants do address the risk of SCD, the patients remain vulnerable to recurrent symptomatic episodes of ventricular arrhythmias. These symptomatic VT episodes could prompt harmful ICD shocks, resulting in reduced quality of life, hospitalizations and/or cardiac decompensations.

Catheter ablation procedures treat VT by addressing the underlying cause of the disease. In these procedures, electrodes at the tip of the catheter use energy to create what is known as myocardial lesions to destroy – or ablate – the electrical pathway in the muscular tissue of the heart that is causing the VT. It is estimated that there are approximately 100,000 VT ablations worldwide each year and that the global market for advanced catheters for the treatment of VT is approximately $0.3 billion, or approximately 9% of the total advanced EP ablation catheter market. VT ablation procedures have been growing by approximately 7% annually, driven in part by the advances in electroanatomic mapping technologies and operator training as well as by the aging population and the increased incidence of underlying cardiac disease.

Ablation therapy to address VT in patients with structural heart disease has been clinically shown to reduce the frequency of symptomatic ventricular arrhythmias, including repeat, uncontrollable arrhythmias known as VT storms and to reduce ICD shocks. Additionally, the recent VANISH-2 trial demonstrated that VT ablation may be a viable alternative to escalation of the anti-arrhythmic medications, however current clinical guidelines recommend VT ablation therapy for patients with structural heart disease as second-line therapy. We estimate that the world-wide incidence of VT episodes in patients with structural heart disease eligible for ablations is approximately 700,000 per year.

Symptomatic idiopathic VT comprises approximately 60% of current VT ablations. While the indications for ablative treatment of this patient groups vary significantly based on arrhythmia sub-type and site of origin, the estimated annual incidence of the condition is upwards of 250,000 in the United States, and we estimate that the world-wide incidence of these high-risk patients is approximately 800,000 per year.

Current Challenges

Several factors have limited the growth of ablation procedures for VT. Today, VT ablations are performed using RF catheters, which are almost exclusively designed and initially approved to atrial arrhythmias. The majority of atrial ablations are performed using a standardized set of lesions in tissue with thickness of 2 to 5 millimeters. In comparison, VT ablations are performed using a patient-specific and often very extensive set of lesions, which vary - depending on the location of the abnormal electrical circuit and preferred ablation strategy - in the forcefully contracting ventricular myocardium where tissue thickness routinely exceeds 10 millimeters.

The principal issue of RF technology for VT is the limited lesion depth of 5 to 6 millimeters in healthy tissue which is further attenuated – or reduced - by approximately 50% in the presence of the myocardial scar. Furthermore, performing RF ablation requires an operator to maintain consistent mechanical contact between the catheter and the tissue which can be technically challenging when ablating VT due to ventricular contractions. In addition, in order to cool the ablating electrode and minimize the chance of a life-threatening complication known as “steam-pop”, advanced RF catheters utilize irrigating fluid, which can lead to the development of acute cardiac decompensation, particularly in patients with structural heart disease. Additionally, the insufficient lesion depth with RF can impact the effectiveness of the preferred endocardial (internal surface of the heart) ablation in some patients. RF catheter stabilization and management of irrigating fluid overload add to the technical challenges of VT ablations.

VT ablations using current technology remain lengthy and technically complex and are associated with a nearly 11.5% rate of serious complications, including death, particularly -but not exclusively- in patients with structural heart disease. This complexity and procedural risk combined with current guidelines for VT ablations as a second-line therapy have limited the growth of the procedural volumes despite significant improvement in the adjunctive technologies such as electroanatomic mapping and emerging evidence on benefits of earlier and prophylactic VT ablations.

Our Solution

Our proprietary Ultra Low Temperature Cryoablation technology was created to consistently create large and durable lesions extending through the depth of both diseased and healthy ventricular myocardium, which we believe is a foundation for improving the effectiveness and outcomes of VT ablations. Our unique technology portfolio consists of ULTC alone and in combination with Pulsed Field Ablation (also known as Pulsed Field Cryoablation).

Our ULTC technology uses nitrogen (N2) gas, which is pressurized beyond its critical point and cooled to its boiling temperature of -196°C. This is in contrast to currently available cryoballoon and focal point cryocatheter technologies, which are based on the rapid evaporation (Joule-Thompson effect) of the compressed nitrous oxide (N2O) with a boiling temperature of -88.5°C. In ULTC, the “near- critical” nitrogen combines the flow properties of gas with density and thermal capacity of liquid, making it an ideal refrigerant for use in the endovascular environment. The high pressure suppresses evaporation and ensures continuous, vapor lock-free flow through small lumen catheters. Under such conditions, the refrigerant can be brought into close proximity and applied to the tissue targeted for ablation through a proprietary cryoablation catheter at temperatures close to -196°C. In pre-clinical experiments, the cryogenic power supplied by such technology was sufficient to achieve the temperatures at or below -30°C deep into the tissue, resulting in formation of intracellular ice and instantaneous and permanent death of cardiac tissue. The size and contiguity of such durable lesions could be assured by length, shape, and mechanical properties of the ablation element, while depth can be titrated by the duration of the freeze.

Key benefits of ULTC for VT ablations include:

- **Titratable lesion depth up to and exceeding 10 millimeters** provides physicians a new ability to use simple endocardial-only approach to ablate VT circuits in patients with both ischemic and non-ischemic cardiomyopathy, as well as PVCs.

- **The large lateral size** of the lesions enabled by the length and design of the ULTC ablation element could offer physicians the ability to utilize only a small number of ablations, performing otherwise complex procedures faster, safely, and effectively.

- **ULTC preserves intracellular matrix** thus avoiding potentially life-threatening complications known as steam-pop.

- **Cryoadhesion,** or the catheter adhesion to the endocardial surface upon freezing, eliminates the need for the physician to manually maintain contact between the catheter and the tissue during energy delivery, which is of critical importance when ablating in certain anatomic locations, and can also minimize physician's stress and fatigue.

- **No Irrigation.** ULTC technology does not require catheter irrigation, eliminating the possibility of fluid overload for VT patients, and thereby eliminating the associated increased risk of acute cardiac decompensation and renal failure in structural heart disease patients already susceptible to cardio-renal syndrome, and potentially shortening post-procedural recovery time.

Clinical Results

The performance of our vCLAS catheter for ablation of monomorphic, VTs in patients with structural heart disease was evaluated in the 64-patient CRYOCURE-VT study at nine sites in Europe and Canada. Monomorphic VTs arise from a single aberrant electrical circuit in the ventricle and are the most prevalent type of VT. The trial completed its primary chronic effectiveness endpoint, which supported CE-mark approval of Adagio's VT Cryoablation System and vCLAS catheter in the first quarter of 2024. The study demonstrated 94% acute procedural success, 60% freedom from sustained VT and 81% freedom from implantable cardioverter defibrillator shock at six months. In addition, the study demonstrated significant reduction in burden of the ventricular arrhythmias and over 50% reduction in use of antiarrhythmic medication. Further analysis demonstrated that these benefits were sustained through twelve months of follow-up and that the freedom from VT-related and Heart Failure-related hospitalizations remained high through the duration of the follow-up.

On November 4, 2022, we received FDA approval to conduct Early Feasibility IDE (EFS) FULCRUM-VT study of VT Cryoablation System in 20 patients with both ischemic and non-ischemic cardiomyopathy at up to 5 sites. Based on the results of this study, in April 2024 we received FDA approval to convert the EFS study to a single-cohort Pivotal IDE study of our VT Cryoablation System, expanding the number of sites to 20 and the number of patients to 206 for pooled analysis of patients with ischemic and non-ischemic heart disease, including patients with arrhythmogenic right ventricular cardiomyopathy. Subsequently, on September 30, 2024, we received a letter from U.S. Center for Medicare and Medicare Services ("CMS") granting FULCRUM-VT Class B designation with full reimbursement of both the ablation procedure and vCLAS catheter.

Pulsed Field Cryoablation

Our PFCA technology is intended to combine the proprietary benefits of ULTC and PFA while minimizing their respective limitations. PFCA consists of the short duration ULTC freeze followed by PFA delivered through the same catheter. Our work has shown that ULTC results in significant increase in the impedance and electric field generated by PFA within the frozen tissue while decreasing electric field and parasitic electric current elsewhere. This latter capability helps eliminate muscle and phrenic nerve capture while minimizing the microbubbles and possibility of vasospasm, thus potentially addressing a key limitation of stand-alone PFA. In effect, ULTC pre-treatment could have the effect to "focus" PFA, further increasing the selectivity of ablation and, since the area of the increased impedance extends deeper in the tissue than the -30°C isotherm, PFCA lesions of a desired depth could potentially be achieved in a fraction of time required for equivalent ULTC alone.

The principle of PFCA was demonstrated in PARALLEL study of atrial ablations in patients with persistent atrial fibrillation. In a cohort of the patients with cryogenic energy delivery above the threshold, PFCA was 100% effective in isolation of pulmonary veins and the posterior wall of the left atrium, with fewer than 1% of energy applications accompanied by observations of microbubbles or faint muscle contractions. The pre-clinical investigation of ventricular PFCA in the animal model demonstrated lesion depth is equivalent to the ULTC at half the total freeze duration with minimal attenuation by the scar tissue.

Our Current and Future Product Portfolio

First Generation Ablation System

Our VT Cryoablation System is comprised of the vCLAS™ catheter and ULTC cryoablation console. The vCLAS ventricular catheter has been purposefully designed for the treatment of the ventricular arrhythmia. The 9 French bi-directionally deflectable catheter features a 15 millimeter long non-flexible ablation element with eight electrodes for intracardiac sensing/pacing.

Second Generation Ablation System

In the second half of 2024 we initiated a product design optimization initiative intended to further improve the performance of our vCLAS catheter based on initial clinical feedback and to further improve catheter cost-structure to support future commercialization activities.

Competition

The major players in cardiac EP and advanced ablation catheter markets are Biosense Webster, Inc. (a division of Johnson & Johnson), Abbott, Medtronic, and Boston Scientific. Today, VT ablations are predominantly performed using point-by-point RF ablation catheter technology. In the U.S. the RF catheters by Biosense Webster (Navistar™ Thermocool® Deflectable Diagnostic/Ablation Catheter) and Abbott Electrophysiology (FlexAbility™ Ablation Catheter, Sensor Enabled™), both originally designed for treatment of AF, have expanded indications for the ablation of sustained, drug-refractory monomorphic ventricular tachycardia.

Saline-enhanced RF needle catheter has been suggested to overcome lesion-depth limitations of the standard RF ablations. The needle can be inserted deeper into myocardial tissue and the injected saline creates a virtual electrode for RF application, resulting in large and deep (9.9 ± 2.7 millimeter) myocardial lesions in the preclinical models. Several small clinical studies on catheters of two principal designs have been conducted in patients with both structural heart disease VTs and PVCs, all demonstrating moderate effectiveness with 13-20% rates of serious complications. Thermedical, Inc. is conducting an upcoming 130-patient multicenter U.S. FDA Trial, which is expected to conclude in 2027, but as of this print, the trial was not yet recruiting patients.

The rapid adoption of PFA technology for ablation of atrial arrhythmias combined with the mode of action not affected by lesion depth attenuation in the scar tissue spurred the interest to apply PFA to ventricular ablations. We believe the use of PFA in VT may require significant adjustment to achieve lesion depth required for ventricular ablations, including, potentially, substantial increase in pulse voltage. To date, the clinical evidence for ventricular PFA is limited to a small number of cases and a small case series of the off-label use of the atrial catheters. Three early human feasibility studies to study PFA for VT are currently ongoing: a 20-patient study using a combined RF-PFA spherical multi-electrode catheter by Medtronic in patients with ischemic cardiomyopathy, a 30-patient study using Biosense Webster RF-PFA dual energy endocardial ablation system with SmartTouch SF catheter in patients referred for VT ablations, and another 60-patient feasibility study sponsored by Field Medical, which uses their dedicated ventricular PFA system in patients with PVC and VT.

Intellectual Property

Our policy is to seek to protect our proprietary position by, among other methods, pursuing and obtaining patent protection in the United States and in jurisdictions outside of the United States related to our technology, inventions, improvements and products that are important to the development and implementation of our business. Our patent portfolio consists of 75 issued patents and 40 patent applications in the United States, Japan, China, Australia, Republic of Korea, Brazil, Israel, United Kingdom, and countries of European Union, covering 20-21 patent families ranging from the disclosures of foundational ULTC technology to the details and components of catheter and accessory designs. Our early patents were issued in 2004 and the latest disclosures related to Tissue Contact Verification, VT- and multi-modality PFCA catheters were filed in 2023. We believe that in combination with the trade secrets and other proprietary information related to the manufacturing processes of catheters and consoles, this patent portfolio creates significant entry barrier for competitive ULTC and PFCA entries near term, allowing the company to remain a single-source provider of these differentiating technologies in Cardiac EP. However, trade secrets and proprietary information can be difficult to protect. We seek to protect our trade secrets and proprietary information, in part, by confidentiality agreements and proprietary invention assignment agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in the measures we take to protect and preserve our trade secrets and proprietary information, there may be instances in which they may not provide meaningful protection. Such measures can be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors or misused by any collaborator to whom we disclose such information. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain or use information that we regard as proprietary. As a result, we may be unable to meaningfully protect our trade secrets and proprietary information.

Our trademark portfolio covers all of the main product families: iCLAS™ for ULTC AF ablation catheter and system, vCLAS™ for ULTC VT catheter, and Cryopulse™ for PFCA catheters. The trademarks have been registered or pending in Canada, United Kingdom, United States and European Union. We maintain our priority filings for trademarks in the United States through periodic extensions to ensure their availability at the time of products' commercial availability in the United States.

Government Regulation.

U.S. Food & Drug Administration

Our products and operations are subject to extensive and ongoing regulation by the FDA under the Federal Food, Drug, and Cosmetic Act ("FDCA"), and its implementing regulations, as well as other federal and state regulatory bodies in the United States. The laws and regulations govern, among other things, product design and development, laboratory testing, preclinical and clinical testing, manufacturing and release, packaging, labeling, storage, record keeping and reporting, premarket clearance or approval, establishment registration and device listing, marketing, distribution, promotion, import and export, product complaints, recalls and field safety corrective actions, and post-marketing surveillance.

Unless an exemption applies, each new or significantly modified medical device we seek to commercially distribute in the United States will require either a premarket notification to the FDA requesting permission for commercial distribution under Section 510(k) of the FDCA, also referred to as a 510(k) clearance, a de novo classification request, or approval from the FDA of a premarket approval ("PMA") application. Generally, if a new device is considered low- or moderate-risk and has a predicate that is already on the market under a 510(k) clearance, the FDA will allow that new device to be marketed under a 510(k) clearance; otherwise, a de novo or PMA is required. The 510(k) clearance, de novo classification request and PMA processes can be resource intensive, expensive, and lengthy, and require payment of significant user fees, unless an exemption is available.

Device Classification

Under the FDCA, medical devices are classified into one of three classes-Class I, Class II, or Class III-depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness.

Class I includes devices deemed to be the lowest risk to the patient and are those for which safety and effectiveness can be reasonably assured by adherence to general controls that include compliance with the applicable portions of the FDA's Quality System Regulation ("QSR"), facility registration and product listing, reporting of adverse events and malfunctions, and appropriate, truthful and non-misleading labeling, advertising and promotional materials. Some Class I devices, called Class I reserved devices, require premarket clearance by the FDA through the 510(k) premarket notification process described below. Most Class I products, however, are exempt from the premarket notification requirements and therefore may be commercially distributed without obtaining 510(k) clearance from the FDA.

Class II devices are those that are subject to the general controls, and special controls as deemed necessary by the FDA to provide reasonable assurance of the safety and effectiveness of the device. These special controls can include performance standards, patient registries, FDA guidance documents and post-market surveillance. Most Class II devices are subject to premarket review and clearance by the FDA. As a result, most Class II devices require the manufacturer to submit to the FDA a Premarket Notification 510(k) requesting permission to commercially distribute the devices meeting the threshold for substantial equivalence.

Class III devices include devices deemed by the FDA to pose the greatest risk such as life-supporting or life-sustaining devices, or implantable devices, in addition to those deemed novel and not substantially equivalent following the 510(k) process. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the general controls and special controls described above. Therefore, these devices are subject to the PMA application process, which is generally more costly and time consuming than the 510(k) process.

The Investigational Device Process

In the United States, absent certain limited exceptions, human clinical trials intended to support medical device clearance, de novo classification, or approval require compliance with FDA investigational device exemption ("**IDE**") regulations in 21 CFR Part 812. Trials that present "non-significant risk" do not require FDA review or approval of an IDE application. These non-significant risk trials are deemed to have an approved IDE once certain requirements are addressed, and institutional review board (IRB) approval is obtained. If a device presents a "significant risk" to human health, as defined by the FDA, the sponsor must submit an IDE application to the FDA and obtain IDE approval prior to commencing the human clinical trials. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that the risks to subjects are outweighed by the anticipated benefits and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of subjects at specified study sites. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the trial protocol and informed consent are approved by appropriate IRBs. An IRB is an appropriately constituted group that has been formally designated to review and monitor medical research involving subjects and which has the authority to approve, require modifications in, or disapprove research to protect the rights, safety and welfare of human research subjects. There can be no assurance that submission of an IDE application will result in the ability to commence clinical trials, and although the FDA's approval of an IDE application allows clinical testing to go forward for a specified number of subjects, it does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and effectiveness, even if the trial meets its intended success criteria. All clinical trials must be conducted in accordance with the FDA's IDE regulations that govern investigational device labeling, prohibit promotion and specify an array of recordkeeping, reporting and monitoring responsibilities of trial sponsors and trial investigators. Clinical trials must further comply with the FDA's good clinical practice regulations for IRB approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA. The FDA or the IRB may withdraw approval of a clinical trial, or place a trial on clinical hold at any time for various reasons, including a belief that the risks to study subjects outweigh the benefits or a failure to comply with FDA or IBM requirements. Even if a trial is complete, the results of clinical testing may be unfavorable, or, even if the intended safety and effectiveness success criteria are achieved, may not be considered sufficient for the FDA to grant marketing approval or clearance of a product.

The 510(k) Clearance Process

Under the 510(k) clearance process, the manufacturer must submit to the FDA a premarket notification with adequate information demonstrating that the device is "substantially equivalent," as defined in the FDCA, to a legally marketed predicate device.

A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was previously found substantially equivalent through the 510(k) process. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence.

After a 510(k) premarket notification is submitted, the FDA determines whether to accept it for substantive review. If it lacks necessary information for substantive review, the FDA will refuse to accept the 510(k) notification. If it is accepted for filing, the FDA begins a substantive review. By statute, the FDA is required to complete its review of a 510(k) notification within 90 days of receiving the 510(k) notification. As a practical matter, clearance often takes longer, and clearance is never assured. Although many 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including clinical data, to make a determination regarding substantial equivalence, which may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent, it will grant clearance for the new device, permitting the applicant to commercially market the device. The FDA may also require post-market surveillance for certain devices cleared under a 510(k) notification, such as implants or life-supporting or life-sustaining devices used outside a device user facility.

If the FDA determines that the device is not "substantially equivalent" to a predicate device, or if there is no adequate predicate to which a manufacturer can compare the device such that the device is automatically classified into Class III, the device sponsor must then fulfill the much more rigorous premarketing requirements of the PMA approval process, or seek reclassification of the device through the de novo process. A manufacturer can also submit a petition for direct de novo review if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents a moderate or low risk.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, could require a PMA application or de novo classification. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. Many minor modifications are accomplished by a letter-to-file in which the manufacture documents the change in an internal letter-to-file. The letter-to-file is in lieu of submitting a new 510(k) notification to obtain clearance for such change. The FDA can always review these letters to file in an inspection. If the FDA disagrees with a manufacturer's determination regarding whether a new premarket submission is required for the modification of an existing device, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a PMA application is obtained.

The PMA Approval Process

Through the PMA application process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA's satisfaction. Accordingly, a PMA application typically includes, but is not limited to, extensive technical information regarding device design and development, data from preclinical studies and one or more clinical trials, a full description of the methods, facilities and controls used for manufacturing, proposed labeling and financial disclosure information for the clinical investigators in device trials. The PMA application must provide valid scientific evidence that demonstrates to the FDA's satisfaction a reasonable assurance of the safety and effectiveness of the device for its intended use.

Following receipt of a PMA application, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If it is, the FDA will accept the application for filing and begin the review. The FDA, by statute and by regulation, has 180 days to review a filed PMA application, although the review of an application more often occurs over a significantly longer period. During this review period, the FDA may request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant's response to deficiencies communicated by the FDA. The FDA considers a PMA or PMA supplement to have been voluntarily withdrawn if an applicant fails to respond to an FDA request for information (e.g., major deficiency letter) within a total of 360 days. Before approving or denying a PMA, an FDA advisory committee may review the PMA at a public meeting and provide the FDA with the committee's recommendation on whether the FDA should approve the submission, approve it with specific conditions, or not approve it. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Prior to approval of a PMA, the FDA may conduct inspections of the clinical trial data and clinical trial sites, as well as inspections of the manufacturing facility and processes. Overall, the FDA review of a PMA application generally takes between one and three years but may take significantly longer. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- the device may not be shown safe or effective to the FDA's satisfaction;
- the data from preclinical studies and/or clinical trials may be found unreliable or insufficient to support approval;
- the manufacturing process or facilities may not meet applicable requirements;
- the application contains a false statement of material fact;
- preclinical or clinical studies were not conducted in accordance with applicable regulations;
- the proposed device labeling is false or misleading; and
- changes in FDA approval policies or adoption of new regulations may require additional data.

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval letter, or an approvable letter, the latter of which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facilities is not favorable, the FDA may deny approval of the PMA or issue a not approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data is submitted in an amendment to the PMA, or the PMA is withdrawn and resubmitted when the data are available. The PMA process can be expensive, uncertain and lengthy and a number of devices for which the FDA approval has been sought by other companies have never been approved by the FDA for marketing.

New PMA applications or PMA supplements are required for modification to the manufacturing process, equipment or facility, quality control procedures, sterilization, packaging, expiration date, labeling, device specifications, ingredients, materials or design of a device that has been approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA application and may or may not require as extensive technical or clinical data or the convening of an advisory committee panel, depending on the nature of the proposed change.

In approving a PMA application, as a condition of approval, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up clinical study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional or longer term safety and effectiveness data for the device. The FDA may also approve a PMA application with other post-approval conditions intended to ensure the safety and effectiveness of the device, such as, among other things, restrictions on labeling, promotion, sale, distribution and use.

Pervasive and Continuing Regulation

After a device is placed on the market in the U.S., numerous regulatory requirements continue to apply. These include:

- submitting and updating establishment registration and device listings with the FDA;
- the FDA's QSR, which requires manufacturers, including their suppliers, to follow stringent design, testing, control, documentation, record maintenance, including maintenance of complaint and related investigation files, and other quality assurance procedures during all aspects of the manufacturing process;
- routine or unannounced for-cause device facility inspections by the FDA, which may include the manufacturing facilities of subcontractors;
- labeling regulations, which prohibit the promotion of products for uncleared, unapproved or off-label uses and impose other restrictions relating to promotional activities;
- medical device reporting, or MDR, regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;
- medical device recalls, which require that manufacturers report to the FDA field corrections or removals of a medical device, provided the recall was initiated to either reduce a risk to health posed by the device, or to remedy a violation of the FDCA caused by the device that may present a risk to health; and
- post-market surveillance regulations, which apply to certain Class II or III devices when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

We have obtained a manufacturing license from the California Department of Public Health ("CDPH"). The FDA and CDPH have broad post-market and regulatory enforcement powers. We are (or upon FDA clearance or approval, will be) subject to announced and unannounced inspections by the FDA and the Food and Drug Branch of CDPH to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our suppliers. Additionally, our Notified Body, TÜV SÜD, regularly inspects our manufacturing, design and operational facilities to ensure ongoing ISO 13485:2016 compliance in order to maintain our CE Mark.

Failure to comply with applicable regulatory requirements can result in enforcement actions, which may include any of the following sanctions:

- warning letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products;
- withdrawing 510(k) clearance or premarket approvals that may have already been granted; and
- criminal prosecution.

Export of Our Products

Export of products subject to the 510(k) notification requirements, but not yet cleared to market in the United States, is permitted with FDA authorization provided certain requirements are met. Similarly, unapproved or uncleared products subject to the PMA requirements may be exported certain statutory criteria are met and the Company submits a "Simple Notification" to FDA when it begins to export. Importantly, however, export of such products may be limited to certain countries designated by statutory provisions, and petitions may need to be submitted to FDA to enable export to countries other than those designated in the statutory provisions. The petitioning process can be difficult, and FDA may not authorize unapproved or uncleared products to be exported to countries to which a manufacturer wishes to export. Devices that are adulterated, devices whose label and labeling does not comply with requirements of the country receiving the product, and devices that are not promoted in accordance with the law of the receiving country, among others, cannot be exported.

Foreign Government Regulation

The regulatory review process for medical devices varies from country to country, and many countries also impose product standards, packaging requirements, environmental requirements, labeling requirements and import restrictions on devices. Each country has its own tariff regulations, duties, and tax requirements. Failure to comply with applicable foreign regulatory requirements may subject a company to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, criminal prosecution or other consequences.

U.S. Federal, State and Foreign Fraud and Abuse Laws

The federal and state governments have enacted, and actively enforce, a number of laws to address fraud and abuse in federal healthcare programs. Our business is subject to compliance with these laws. Violations of such laws could result in significant civil, criminal and administrative sanctions, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations.

Anti-Kickback Statutes

The federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the furnishing, recommending, purchasing, leasing, ordering or arranging for a good or service, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation.

The definition of "remuneration" has been broadly interpreted to include anything of value, including, for example, gifts, certain discounts, the furnishing of free supplies, equipment or services, credit arrangements, payment of cash, waivers of payments and providing anything of value at less than fair market value. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered businesses, the statute has been violated. In addition, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act, codified case law 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. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection.

The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. The legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. However, conduct and business arrangements that do not fully satisfy an applicable statutory exception or regulatory safe harbor may result in increased scrutiny by government enforcement authorities such as the Office of Inspector General, or OIG, of U.S. Department of Health and Human Services.

Many states have adopted laws similar to the Anti-Kickback Statute. Some of these state prohibitions apply to referral of recipients for healthcare products or services reimbursed by any source, not only government healthcare programs, and may apply to payments made directly by the patient.

Government officials have continued their enforcement efforts related to the marketing of healthcare services and products, among other activities, and continue to bring cases against companies, and certain individual sales, marketing and executive personnel, for allegedly offering unlawful inducements to potential or existing customers in an attempt to procure their business.

Federal False Claims Act

The federal False Claims Act ("FCA"), imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The *qui tam* provisions of the FCA allow a private individual to bring actions on behalf of the federal government alleging that the defendant has violated the FCA and to share in any monetary recovery. In addition, various states have enacted false claims laws analogous to the FCA, and many of these state laws apply where a claim is submitted to any third-party payor and not only a federal healthcare program or other state program.

When an entity is determined to have violated the FCA, it may be required to pay up to three times the actual damages sustained by the government, plus significant civil fines and penalties. As part of any settlement, the government may require the entity to enter into a corporate integrity agreement, which imposes certain compliance, certification and reporting obligations. There are many potential bases for liability under the FCA. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. For example, the federal government has used the FCA to assert liability on the basis of kickbacks, or in instances in which manufacturers have provided billing or coding advice to providers that the government considered to be inaccurate. In these cases, the manufacturer faces liability for "causing" a false claim. In addition, the federal government has prosecuted companies under the FCA in connection with off-label promotion of products. Our future activities relating to information affecting federal, state and third-party reimbursement of our products and the sale and marketing of our products may be subject to scrutiny under these laws.

While we are unaware of any current matters, we are unable to predict whether it will be subject to actions under the FCA or a similar state law, or the impact of such actions. However, the costs of defending such claims, as well as any sanctions imposed, could significantly affect our financial performance.

Civil Monetary Penalties

The federal Civil Monetary Penalty laws imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent, or offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier.

Open Payments

The Physician Payments Sunshine Act, known as "Open Payments" and enacted as part of the Affordable Care Act, requires certain pharmaceutical and medical device manufacturers of products covered by Medicare, Medicaid or the Children's Health Insurance Program to report annually to the CMS: direct and indirect payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and applicable manufacturers and group purchasing organizations. Applicable manufacturers must also report annually ownership and investment interests held by physicians and their immediate family members. Applicable manufacturers are required to submit annual reports to the CMS. Failure to submit required information in a timely, complete and accurate manner may result in significant civil monetary penalties. We are subject to Open Payments and the information it discloses may lead to greater scrutiny, which may result in modifications to established practices and additional costs. Additionally, similar reporting requirements have also been enacted on the state level domestically, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring transparency of interactions with healthcare professionals.

Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act ("FCPA"), prohibits any U.S. individual; U.S. companies and officers, directors, and employees; foreign subsidiaries of U.S. entities; and agents or intermediaries operating on behalf of a U.S. company from paying, offering, promising to pay, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign government official, government staff member, political party or candidate for the purpose of improperly influencing any act or decision of a foreign government entity to obtain, retain, or direct business. The FCPA also obligates companies whose securities are listed on a national securities exchange in the United States to comply with accounting provisions which require the maintenance of books, records, and accounts that accurately and fairly reflect all transactions and dispositions of assets of the corporation, including international subsidiaries, if any, and to devise and maintain an adequate system of internal accounting controls.

International Laws

In Europe, various countries have adopted anti-bribery laws providing for severe consequences in the form of criminal penalties and significant fines for individuals or companies committing a bribery offense.

Violations of these anti-bribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation.

For instance, in the United Kingdom, the U.K. Bribery Act 2010 covers both public and private sector bribery, and prohibits the offer, provision, or promise to give a financial or other advantage to induce or reward another individual to improperly perform their relevant functions or activities, including any function of a public nature. Bribery of foreign public officials also falls within the scope of the U.K. Bribery Act 2010. An individual found in violation of the U.K. Bribery Act 2010 faces imprisonment of up to ten years. In addition, individuals can be subject to an unlimited fine, as can commercial organizations for failure to prevent bribery.

International Trade Laws

Our company is subject to other laws and regulations governing its international operations, including regulations administered by the U.S. Department of Commerce's Bureau of Industry and Security, the U.S. Department of Treasury's Office of Foreign Assets Control ("OFAC"), and various non-U.S. government entities, including applicable export control regulations, economic sanctions on countries and persons, customs requirements, currency exchange regulations, and transfer pricing regulations.

Commerce regulates certain "dual use" items, as well as associated foreign assistance. OFAC administers and enforces economic sanctions programs primarily against countries and groups of individuals. Sanctions can be either comprehensive or selective, using the blocking of assets and trade restrictions to accomplish foreign policy and national security goals. U.S. persons must comply with OFAC regulations, including all U.S. citizens and permanent resident aliens regardless of where they are located, all persons and entities within the United States, all U.S. incorporated entities, and their foreign branches. In the cases of certain programs, foreign subsidiaries owned or controlled by U.S. companies also must comply.

Governmental authorizations may be required before we can export technology, equipment or materials, our services, or to collaborate with foreign entities.

Failure to comply with export control laws and regulations could expose us to civil or criminal penalties, fines, investigations, more onerous compliance requirements, loss of export privileges, debarment from government contracts or limitations on our ability to enter into contracts with the U.S. government.

U.S. Health Reform

Changes in healthcare policy could increase our costs and subject it to additional regulatory requirements that may interrupt commercialization of our current and future solutions. Changes in healthcare policy could increase our costs, decrease our revenue and impact sales of and reimbursement for our current and future products. For example, the Affordable Care Act substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the life sciences industry. The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our products. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our products.

The implementation of the Affordable Care Act in the United States, for example, has changed healthcare financing and delivery by both governmental and private insurers substantially, and affected medical device manufacturers significantly. Any changes to, or repeal of, the Affordable Care Act may have a material adverse effect on our results of operations.

We believe that there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the rates we will be able to charge for our current and future products or the amounts of reimbursement available for our current and future products from governmental agencies or third-party payors. Current and future healthcare reform legislation and policies could have a material adverse effect on our business and financial condition.

Coverage and Reimbursement

In both U.S. and non-U.S. markets, our ability to successfully commercialize and achieve market acceptance of our products depends, in significant part, on the availability of adequate financial coverage and reimbursement from third-party payors, including governmental payors (such as the Medicare and Medicaid programs in the United States), managed care organizations and private health insurers. Reimbursement systems in international markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis. In many international markets, a product must be approved for reimbursement before it can be approved for sale in that country. Further, many international markets have government-managed healthcare systems that control reimbursement for new devices and procedures. In most markets there are private insurance systems as well as government-managed systems. Should our products under development be cleared or approved for commercialization by the FDA, reimbursement may not be available in the United States or other countries, or the amount of reimbursement may not be sufficient to allow sales of our products on a profitable basis.

Third-party payors are increasingly examining the cost effectiveness of products, in addition to their safety and efficacy, when making coverage and payment decisions. Third-party payors have also instituted initiatives to limit the growth of healthcare costs using, for example, price regulation or controls and competitive pricing programs. Some third-party payors also require demonstrated superiority, on the basis of randomized clinical trials, or pre-approval of coverage, for new or innovative devices or procedures before they will reimburse healthcare providers who use such devices or procedures. Additionally, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations.

Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for procedures that utilize one or more products for which we might receive regulatory clearance and approval, less favorable coverage policies and reimbursement rates may be implemented in the future. It is uncertain whether our current products or any planned or future products will be viewed as sufficiently cost effective to warrant coverage and adequate reimbursement levels for procedures using such products.

Intellectual Property

Our policy is to seek to protect our proprietary position by, among other methods, pursuing and obtaining patent protection in the United States and in jurisdictions outside of the United States related to our technology, inventions, improvements and products that are important to the development and implementation of our business. Our patent portfolio consists of 75 issued patents and 40 patent applications in the United States, Japan, China, Australia, Republic of Korea, Brazil, Israel, United Kingdom, and countries of European Union, covering 20 to 21 patent families ranging from the disclosures of foundational ULTC technology to the details and components of catheter and accessory designs. Our early patents were issued in 2004 and the latest disclosures related to Tissue Contact Verification, VT- and multi-modality PFCA catheters were filed in 2023. We believe that in combination with the trade secrets and other proprietary information related to the manufacturing processes of catheters and consoles, this patent portfolio creates significant entry barrier for competitive ULTC and PFCA entries near term, allowing the Company to remain a single-source provider of these differentiating technologies in Cardiac EP. However, trade secrets and proprietary information can be difficult to protect. We seek to protect our trade secrets and proprietary information, in part, by confidentiality agreements and proprietary invention assignment agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in the measures we take to protect and preserve our trade secrets and proprietary information, there may be instances in which they may not provide meaningful protection. Such measures can be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors or misused by any collaborator to whom we disclose such information. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain or use information that we regard as proprietary. As a result, we may be unable to meaningfully protect our trade secrets and proprietary information.

Our trademark portfolio covers all of the main product families: iCLAS™ for ULTC AF ablation catheter and system, vCLAS™ for ULTC VT catheter, and Cryopulse™ for PFCA catheters. The trademarks have been registered or pending in Canada, United Kingdom, United States and European Union. We maintain our priority filings for trademarks in the United States through periodic extensions to ensure their availability at the time of products' commercial availability in the United States.

Facilities, Manufacturing and Supply

Our corporate headquarters and manufacturing, storage and distribution centers for our catheters and consoles are located at Laguna Hills, California. The facility is approximately 14,600 square feet, which includes clean room space. Our wholly-owned subsidiary, Adagio Germany, operates out of a leased facility of approximately 227 square meters in Holzkirchen, Germany, which is used for general administrative purposes and as a distribution center for our European operation. We do not own any real property and believe that our current facilities are sufficient to support our operations and growth plans and that, additional space, if needed, will be available on commercially reasonably terms.

Our manufacturing and distribution operations are subject to regulatory requirements of the European Medical Devices Directive 93/42/EEC and amendments ("MDD"), and certain aspects of the European Medical Devices Regulation 2017/745 and amendments, or MDR, for medical devices marketed in the European Union. When we begin marketing and distributing our products in the United States, we will be subject to the FDA's Quality System Regulation, or QSR, set forth in 21 CFR part 820. Our Laguna Hills facility is certified to have established and is maintaining a quality management system pursuant to the requirements of the ISO 13485:2016 standard. In February 2026, the FDA's QSR will be harmonized with ISO 13485 and will be titled the Quality Management System Regulation, with which we believe we are prepared to comply given our existing ISO 13485 certification. In addition, the Laguna Hills facility is licensed by the California Department of Public Health, or CDPH. We are also subject to applicable local regulations relating to the environment, waste management and health and safety matters, including measures relating to the release, use, storage, treatment, transportation, discharge, disposal, sale, labeling, collection, recycling, treatment and remediation of hazardous substances.

TÜV SÜD Product Service GmbH (München, Germany) (TÜV SÜD) monitors our compliance with the MDD requirements through annual scheduled audits and unannounced audits of the Laguna Hills facilities.

Our failure, or the failure of our suppliers or third-party manufacturers, to maintain acceptable quality requirements could result in the shutdown of our manufacturing operations or the recall of our products, which would harm our business. In the event that one of our suppliers or third-party manufacturers fails to maintain acceptable quality requirements, we may have to qualify a new supplier and could experience a material adverse effect to manufacturing and manufacturing delays as a result.

We procure a broad range of the components and raw materials required for manufacturing of our catheters and consoles, including plastic and precious metals components and raw materials, complex electromechanical assemblies, electronic components and electronic assemblies. In addition, the Esophageal Warming Balloon marketed as a part of iCLAS™ Cryoablation System is supplied to us by third party manufacturer. The identification and qualification of the suppliers is governed by the relevant provisions of our QMS. As such, we can be materially adversely affected by disruptions in global supply chain, as well as inability of our suppliers to maintain required quality of the components and raw materials supplied to us, resulting in temporary hold or shutdown of our manufacturing and distribution operations.

We will pursue the opportunities for facility expansion as well as the transfer of the part or whole of the manufacturing operation to qualified third-party suppliers as warranted by business conditions.

Adagio Team

As of December 31, 2024, we had 71 full-time employees, located in the U.S., and 9 full-time employees of Adagio Germany with five located in Germany, two in the Netherlands three in England, and one in Belgium. None of our employees are represented by a labor union or are a party to a collective bargaining agreement. We believe that the success of our business will depend, in part, on our ability to attract and retain qualified personnel. We have not experienced and do not expect any significant strikes or work stoppages and believe our relations with employees are in good standing.

Availability of SEC Filings

We file annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to reports filed or furnished pursuant to Sections 13(a), 14, and 15(d) of the Securities and Exchange Act of 1934, as amended, or the Exchange Act. The SEC maintains a website at http://www.sec.gov that contains reports, and other information regarding us and other companies that file materials with the SEC electronically. Copies of our reports on Forms 10-K, Forms 10-Q, and Forms 8-K, may be obtained, free of charge, electronically through our corporate website at https://us.adagiomedical.com as soon as reasonably practicable after we file such material electronically with, or furnish to, the SEC.

Item 1A. Risk Factors.

Our business, prospects, financial condition, or operating results could be harmed by any of these risks, as well as other risks not currently known to us or that we currently consider immaterial. If any of such risks and uncertainties actually occurs, our business, prospects, financial condition, cash flows, or operating results could differ materially from the plans, projections, and other forward-looking statements included in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Annual Report on Form 10-K and in our other public filings. For more information, see the section titled "Special Note Regarding Forward-Looking Statements" included elsewhere in this Annual Report on Form 10-K.

Risks Related to Our Business

We are a medical device company that has incurred net losses in every period to date and expect to continue to incur significant losses as we develop our business, and our financial conditions raise substantial doubt about our ability to continue as a going concern.

We are a medical device company that has incurred net losses in each quarterly and annual period since inception and that has not yet generated any meaningful revenue. We expect to incur increasing costs as we continue to devote substantially all of our resources towards the development and anticipated further commercialization of our main product, vCLAS. We cannot be certain if we will ever generate meaningful revenue or if or when we will produce sufficient revenue from operations to support our costs. Even if profitability is achieved, we may not be able to sustain profitability. Adagio Medical incurred net losses of $75.0 million and $36.6 million in 2024 and 2023, respectively. As of December 31, 2024 and December 31, 2023, Adagio Medical had an accumulated deficit of $70.6 and $133.6 million. We expect to incur substantial losses and negative cash flows for the foreseeable future. In addition, as a public company, we incur significant legal, accounting, and other expenses that we did not incur as a private company. These increased expenses make it harder for us to achieve and sustain future profitability. We may incur significant losses in the future for a number of reasons, many of which are beyond our control, including the other risks described in this report and in our other filings with the SEC. These conditions raise substantial doubt about our ability to continue as a going concern.

Our independent auditors have included an explanatory paragraph in their audit report regarding the Company's ability to continue as a going concern. This going concern risk may materially limit our ability to raise additional funds through the issuance of new debt or equity or may adversely affect the terms upon which such capital may be available. The inability to obtain sufficient financing on acceptable terms could have a material adverse effect on the Company's financial condition, results of operations, and business prospects

We are actively pursuing strategies to mitigate these risks, including a recent restructuring of its business. However, there can be no assurance that these efforts will prove successful or that we will achieve its intended financial stability. The failure to successfully address these going concern risks may materially and adversely affect our business, financial condition, and results of operations. Investors should consider the substantial risks and uncertainties inherent in our business before investing in our securities.

We may not be able to successfully execute our new business strategy and strategic restructuring.

In February 2025, we announced a corporate restructuring and realignment of resources to prioritize its FULCRUM-VT US Pivotal IDE clinical trial activities and its new product design optimization program. The streamlining of the Company operations includes a pause in the limited European launch of the vCLAS catheter, while the product design optimization program is instituted. The limited launch provided valuable insights from European electrophysiology professionals, including gaining a more in-depth understanding of the broad applicability and unique clinical benefits of Adagio's proprietary ultra-low temperature cryoablation technology. There can be no assurances that our new strategic direction will result in the commercialization and sale of our products, and we cannot provide any assurances that our focus on the FULCRUM-VT US Pivotal IDE will be successful.

We have forecasted cost savings from our plan to restructure our business strategy based on a number of assumptions and expectations which, if achieved, would improve our cash flows from operating activities. However, there can be no assurance that the expected results will be achieved. The estimated costs and benefits associated with the plan are preliminary and may vary based on various factors including: the timing of execution of the plan, outcome of negotiations with third parties, and changes in management's assumptions and projections. As a result, delays and unexpected costs may occur, which could result in our not realizing all, or any, of the anticipated benefits associated with the plan.

In connection with this new business strategy, the Company has been evaluating the prospects of its FULCRUM-VT US Pivotal IDE clinical trial. The Company is attempting to negotiate terminations of certain non-wearable injector customer and supplier contracts. There can be no assurance that the Company will be able to successfully negotiate the termination of these contracts and the Company may incur material expenses in exiting customer and/or supplier contracts. Certain of these customer contracts contain material cancellation penalties which the Company is in the process of negotiating. While the Company believes it may be able to eliminate or significantly reduce these penalties, there can be no assurance that the Company will be successful in doing so.

Further, our new business strategy can potentially present risks that may otherwise harm our business, including failure to meet customer or regulatory requirements due to the loss of employees or inadequate transfer of knowledge and negative impact on employee morale and increasing attrition among our workforce.

Changes in our business strategy or restructuring of our businesses may increase our costs or otherwise affect the profitability of our businesses or the value of our assets.

As changes in our business environment occur we have adjusted, and may further, adjust our business strategies to meet these changes and we may otherwise decide to further restructure our operations or particular businesses or assets. Our new organization and strategies may not produce the anticipated benefits, such as supporting our growth strategies and enhancing shareholder value. Our new organization and strategies could be less successful than our previous organizational structure and strategies. In addition, external events including changes in technology, changes in acceptance of our products and changes in macroeconomic conditions may impair the value of our assets. When these changes or events occur, we may incur costs to change our business strategy and may need to write-down the value of assets. For example, current economic conditions, including relatively high interest rates, inflation and potential economic slowdowns, as well as our business decisions, may reduce the value of some of our assets. We also make investments in existing or new businesses, including re-investing in the expansion of our sales and build-out of our efforts in Europe. In any of these events, our costs may increase or returns on new investments may be lower than prior to the change in strategy or restructuring.

Our growth and revenue prospects partially depend on our ability to accelerate the commercialization of our products and to capitalize on market opportunities.

Our future success is largely dependent on our ability to successfully develop and commercialize our pipeline products, which are based on innovative yet complex technologies and at any time, can be in various stages of development. We are investing substantially all of our management efforts and financial resources in the development and commercialization of such products. For planning purposes, we estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development and commercialization goals, which we sometimes refer to as milestones. These milestones include the commencement or completion of scientific studies and clinical studies and the submission of regulatory applications. We base these milestones on a variety of assumptions, which are subject to numerous risks and uncertainties. There is a risk we will not achieve these milestones on a timely basis or at all. Even if we achieve these milestones, the actual timing of the achievement of these milestones can vary dramatically compared to our estimates, often for reasons beyond our control. Our ability to achieve milestones and generate future revenue from our current and/or future products depends on a number of additional factors, including:

- the rate of progress and costs and results of our clinical studies and research and development activities;
- our ability to successfully complete clinical development of our products, including necessary clinical studies;
- our ability to achieve acceptance of our clinical trial data by the FDA or foreign regulatory authorities;
- our ability to successfully develop, optimize and scale up the manufacturing processes for our products;
- our ability to establish and maintain supply and manufacturing relationships with third parties that ensure adequate and legally-compliant production of our products;
- our ability and/or the ability of third parties to manufacture our products, including our ability to source critical components or materials for the manufacture of our products;
- our ability to complete and submit necessary applications for regulatory clearances, approvals or certifications for our products in the United States and elsewhere;
- our ability to comply with requirements enforced by the FDA, and other comparable regulatory authorities with respect to our marketing of products;
- our ability to meet the standards of FDA or foreign regulatory agencies and obtain necessary FDA or foreign regulatory clearances, approvals, or certifications, for our products or for future product modifications or proposed expansions in indication for any of our products that receive regulatory approval or certification;
- other actions by regulators, including actions related to a class of products;
- our ability to establish effective sales and marketing capabilities;
- our ability to compete against more established or better funded competitors;
- our ability to achieve patient, physician, and market acceptance for our products;
- our ability to establish, maintain and protect our intellectual property rights; and
- our ability to attract, hire and retain qualified personnel.

In addition, because of the numerous risks and uncertainties associated with completing clinical studies and obtaining necessary clearances, approvals or certifications, we are unable to predict the timing or amount of our expenses, or if or when we will achieve or maintain revenues or profitability. In addition, our expenses could increase beyond expectations if we decide to or are required by the FDA or foreign regulatory authorities to perform studies or trials for our products in addition to those that we currently anticipate. If we complete the development and regulatory processes of our products, we anticipate incurring significant costs associated with launching and commercializing our products. Even if we generate revenues from the sale of our products, we may not be profitable and may need to obtain additional funding to continue operations. If we fail to achieve profitability or do not sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

Our operating results may fluctuate significantly in the future, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.

Our quarterly and annual results of operations, including our revenue, profitability and cash flow, may vary significantly in the future, and period-to-period comparisons of our operating results may not be meaningful. Accordingly, the results of any one quarter or other period should not be relied upon as an indication of future performance. Our quarterly and annual financial results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business.

Factors that may cause fluctuations in our quarterly and annual results include, without limitation:

- the level of demand for our products, which may vary significantly from period to period;
- expenditures that we may incur to acquire, develop or commercialize additional products and technologies;
- the timing and cost of clinical trials, including obtaining regulatory approvals or clearances for planned or future products;
- the rate at which we grow our sales force and the speed at which newly hired salespeople become effective, and the cost and level of investment therein;
- the degree of competition in our industry and any change in the competitive landscape of our industry, including consolidation among our competitors or future partners;
- coverage and reimbursement policies with respect to the procedures using our products and potential future products that compete with our products;
- the timing and success or failure of clinical trials for our current or planned products or any future products we develop or competing products;
- the timing and cost of, and level of investment in, research, development, regulatory approval and commercialization activities relating to our products, which may change from time to time;
- the cost of manufacturing our products, which may vary depending on the quantity of production and the terms of our agreements with third-party suppliers and manufacturers;
  natural disasters, outbreaks of disease or public health crises;
- the timing and nature of any future acquisitions or strategic partnerships; and
- future accounting pronouncements or changes in our accounting policies.

Because our quarterly and annual results may fluctuate, period-to-period comparisons may not be the best indication of the underlying results of our business and should only be relied upon as one factor in determining how our business is performing.

In addition, this variability and unpredictability could result in us 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, it may result in a decrease in the share price of the common stock.

There is no assurance that we will be able to execute on our business model, including achieving market acceptance of our products.

Our ability to execute our business model is dependent on a number of factors, including:

- the ability of our senior management team to execute our business model;
- the ability to begin or maintain our pace of product development, manufacturing and commercialization;
- the ability to meet the changing needs of the catheter market;
- the ability to achieve market acceptance of our product; and
- the ability of our employees to perform at a high level.

If we are unable to execute our business model, or if our business model does not drive the growth that we anticipate, or if our market opportunity is not as large as we have estimated, it could adversely affect our business and our prospects.

Our success will depend, in part, on the acceptance of our products as safe, effective and, with respect to providers, cost-effective. We cannot predict how quickly, if at all, hospitals, physicians, patients or payors will accept our products or, if accepted, how frequently they will be used. Our products and planned or future products we may develop or market may never gain broad market acceptance for some or all of our targeted indications. Hospitals, physicians, patients and payors must believe that our products offer benefits over alternative treatment methods. Our future growth and profitability largely depend on our ability to increase physician awareness of our system and our products and on the willingness of hospitals, physicians, patients or payors to adopt them. These parties may not adopt our products unless they are able to determine, based on experience, clinical data, medical society recommendations and other analyses, that our products are safe, effective and, with respect to providers, cost-effective, on a stand-alone basis and relative to competitors' products. Healthcare providers must believe that our products offer benefits over alternative treatment methods. Even if we are able to raise awareness, physicians tend to be slow in changing their medical treatment practices and may be hesitant to select our products for recommendation to their hospitals or patients for a variety of reasons, including:

- long-standing relationships with competing companies and distributors that sell other products;
- competitive response and negative selling efforts from providers of alternative products;
- lack of experience with our products and concerns that we are relatively new to the market;
- lack or perceived lack of sufficient clinical evidence, including long-term data, supporting safety or clinical benefits; and
- time commitment and skill development that may be required to gain familiarity and proficiency with our products.

Physicians play a significant role in determining the course of a patient's treatment, and, as a result, the type of treatment that will be utilized and provided to a patient. We focus our sales, marketing and education efforts primarily on cardiac electrophysiologists, and aim to educate referring physicians regarding the patient population that would benefit from our products. However, we cannot assure you that we will achieve broad market acceptance among these practitioners.

For example, if electrophysiologists are not made aware of our products, they may not recommend ablation for their patients or the use of our product in their hospitals. In addition, some physicians may choose to utilize our products on only a subset of their total patient population or may not adopt our products at all. If we are not able to effectively demonstrate that the use of our products is beneficial in a broad range of patients, adoption of our products will be limited and may not occur as rapidly as we anticipate or at all, which would have a material adverse effect on our business, financial condition and results of operations. We cannot assure you that our products will achieve broad market acceptance among hospitals and physicians. Additionally, even if our products achieve market acceptance, they may not maintain that market acceptance over time if competing products, procedures or technologies are considered safer or more cost-effective or otherwise superior. Any failure of our products to generate sufficient demand or to achieve meaningful market acceptance and penetration will harm our future prospects and have a material adverse effect on our business, financial condition and results of operations.

Our reputation among our current or potential customers, as well as among electrophysiologists, could also be negatively affected by safety or customer satisfaction issues involving us or our products, including product recalls. Future product recalls or other safety or customer satisfaction issues relating to our reputation could negatively affect our ability to establish or maintain broad adoption of our products, which could harm our future prospects and have a material adverse effect on our business, financial condition and results of operations.

In the United States, before a hospital can purchase our product for the first time, our system must be approved for use by a hospital's new product or value analysis committee, or the staff of a hospital or health system. Such approvals could deter or delay the use of our products by physicians. We cannot provide assurance that our efforts to obtain such approvals or generate adoption will be successful or increase the use of our products, and if we are not successful, it could have a material adverse effect on our business, financial condition and results of operations.

We may need to raise additional capital to fund our development and commercialization plans.

If our available cash resources are insufficient to satisfy our liquidity requirements including because the realization of other risks described in this Annual Report, we may be required to raise additional capital prior to such time through issuances of equity or convertible debt securities, enter into a credit facility or another form of third-party funding or seek other debt financing.

We may consider raising additional capital in the future to expand our business, to pursue strategic investments, to take advantage of financing or acquisition opportunities or for other reasons, including:

- funding development and marketing efforts of our ablation technology or any other future products;
- increasing our sales and marketing and other commercialization efforts to drive market adoption of our ablation technology;
- expanding our technologies into additional markets;
- preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- acquiring, licensing or defending against third party intellectual property rights;
- acquiring or investing in complementary technologies, businesses or assets; and
- financing capital expenditures and general and administrative expenses.

Our present and future funding requirements will depend on many factors, including:

- delays in execution of our development plans;
- the scope and timing of our investment in our sales, marketing, and distribution capabilities;
- changes we may make to our business that affect ongoing operating expenses;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- changes we may make in our business or commercialization strategy;
- changes we may make in our research and development spending plans;
- our need to implement additional infrastructure and internal systems; and
- other items affecting our forecasted level of expenditures and use of cash resources including potential acquisitions.

The various ways we could raise additional capital carry potential risks. If we raise funds by issuing equity securities, dilution to our stockholders could result. If we raise funds by issuing debt securities, those debt securities could have rights, preferences and privileges senior to those of holders of common stock. The terms of debt securities issued or borrowings pursuant to a credit agreement could impose significant restrictions on our operations. If we raise funds through collaborations or licensing arrangements, we might be required to relinquish significant rights to our technologies or products or grant licenses on terms that are not favorable to us.

If we are unable to obtain adequate financing or financing on terms satisfactory to us, if we require it, our ability to continue to pursue our business objectives and to respond to business opportunities, challenges, or unforeseen circumstances could be significantly limited, and could have a material adverse effect on our business, financial condition, results of operations and prospects.

The size of the markets for our products may be smaller than estimated, limiting our ability to successfully sell our products.

Our estimates of the total addressable markets for our current products and products under development are based on a number of internal and third-party estimates, including, without limitation, the number of patients with cardiac arrhythmias and the assumed prices at which we can sell our products in markets that have not been established or that we have not yet entered. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these estimates. As a result, our estimates of the total addressable market for our current or future products may prove to be incorrect. If the actual number of patients who would benefit from our products, the price at which we can sell products, or the total addressable market for our products is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business.

If we experience a significant disruption in our information technology systems or security incidents, our business could be adversely affected, including our ability to operate, the loss of confidential and proprietary information, increased remediation costs, and reputational damage.

We rely, or will rely, on information technology systems to keep financial records, facilitate our research and development initiatives, manage our manufacturing operations, maintain quality control, fulfill customer orders, maintain corporate records, communicate with staff and external parties and operate other critical functions. Our information technology systems and those of our vendors and partners are potentially vulnerable to disruption due to breakdown, malicious intrusion and computer viruses or other disruptive events, including, but not limited to, natural disasters and catastrophes. Cyberattacks and other malicious internet-based activity continue to increase, and cloud-based platform providers of services have been and are expected to continue to be targeted. Methods of attacks on information technology systems and data security breaches change frequently, are increasingly complex and sophisticated, including social engineering and phishing scams, and can originate from a wide variety of sources. In addition to traditional computer "hackers," malicious code, such as viruses and worms, employee theft or misuse, denial-of-service attacks and sophisticated nation-state and nation-state supported actors now engage in attacks, including advanced persistent threat intrusions. Despite our efforts to create security barriers to such threats, it is virtually impossible for us to entirely mitigate these risks. In addition, we have not finalized our information technology and data security procedures and therefore, our information technology systems may be more susceptible to cybersecurity attacks than if such security procedures were finalized. Despite any of our current or future efforts to protect against cybersecurity attacks and data security breaches, there is no guarantee that our efforts are adequate to safeguard against all such attacks and breaches. Moreover, it is possible that we may not be able to anticipate, detect, appropriately react and respond to, or implement effective preventative measures against, all cybersecurity incidents.

If our security measures, or those of our vendors and partners, are compromised due to any cybersecurity attacks or data security breaches, including as a result of third-party action, employee or customer error, malfeasance, stolen or fraudulently obtained log-in credentials or otherwise, our business and reputation may be harmed, we could become subject to litigation and we could incur significant liability. If we were to experience a prolonged system disruption in our information technology systems or those of certain of our vendors and partners, it could negatively impact our ability to serve our customers, which could adversely impact our business, financial condition, results of operations and prospects. If operations at our facilities were disrupted, it may cause a material disruption in our business if we are not capable of restoring functionality on an acceptable timeframe. In addition, our information technology systems, and those of our vendors and partners, are potentially vulnerable to data security breaches, whether by internal bad actors, such as employees or other third parties with legitimate access to our or our third-party providers' systems, or external bad actors, which could lead to the exposure of personal data, sensitive data and confidential information to unauthorized persons. Any such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the exposure of personal information, including sensitive personal information, of our employees, customers and others, any of which could have a material adverse effect on our business, reputation, financial condition and results of operations.

In addition, any such access, disclosure or other loss or unauthorized use of information or data could result in legal claims or proceedings, regulatory investigations or actions, and other types of liability under laws that protect the privacy and security of personal information, including federal, state and foreign data protection and privacy regulations, violations of which could result in significant penalties and fines. In addition, U.S. and international laws and regulations that have been applied to protect user privacy (including laws regarding unfair and deceptive practices in the U.S. and the General Data Protection Regulation in the European Union) may be subject to evolving interpretations or applications. Furthermore, defending a suit, regardless of its merit, could be costly, divert management's attention and harm our reputation. In addition, although we seek to detect and investigate data security incidents, security breaches and other incidents of unauthorized access to our information technology systems and data can be difficult to detect and any delay in identifying such breaches or incidents may lead to increased harm and legal exposure. Moreover, there could be public announcements regarding any cybersecurity incidents and any steps we take to respond to or remediate such incidents, and if securities analysts or investors perceive these announcements to be negative, it could, among other things, have a material adverse effect on the price of common stock.

The cost of protecting against, investigating, mitigating and responding to potential breaches of our information technology systems and data security breaches and complying with applicable breach notification obligations to individuals, regulators, partners and others can be significant. As cybersecurity incidents continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any information security vulnerabilities. The inability to implement, maintain and upgrade adequate safeguards could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be unable to manage our anticipated growth effectively.

Our anticipated growth will place significant strains on our management, operational and manufacturing systems and processes, sales and marketing team, financial systems and internal controls and other aspects of our business. We must upgrade our internal business processes and capabilities to create the scalability that a growing business demands. As of December 31, 2024, we had 80 employees. To execute our anticipated growth successfully, we must continue to attract and retain qualified personnel and manage and train them effectively. Developing and commercializing the ablation technology will require us to hire and retain scientific, sales and marketing, software, manufacturing, customer service, distribution and quality assurance personnel. In addition, we expect that we will need to hire additional accounting, finance and other personnel as a public company. As a public company, our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements and effectively manage these growth activities. We may face challenges integrating, developing and motivating our rapidly growing employee base.

Further, our anticipated growth will place additional strain on our suppliers and manufacturing facilities, resulting in an increased need for us to carefully monitor quality assurance. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals.

Our ability to successfully transition from a largely development stage company to a full scale commercial operation is uncertain given the fact that we have been in operation since 2011. As we continue to grow, we will be required to implement more complex organizational management structures and may find it increasingly difficult to maintain the benefits of our corporate culture, including our ability to quickly develop and launch new and innovative products. If we do not successfully manage our anticipated growth, our business, financial condition, results of operations, and prospects could be harmed.

We may acquire other companies or technologies, or form strategic partnerships with other companies, which could divert our management's attention, increase our capital requirements, and otherwise disrupt our operations, subject us to other risks and harm our operating results.

We may in the future seek to acquire or invest in businesses, applications or technologies that we believe could complement or expand our ablation technology product or future products, enhance our technical capabilities or otherwise offer growth opportunities. The pursuit of potential acquisitions may divert the attention of our management and cause us to incur various costs and expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. We may not be able to identify desirable acquisition targets or be successful in entering into an agreement with any particular target or obtain the expected benefits of any acquisition or investment.

To date, the growth of our operations has been organic, and we have limited experience in acquiring other businesses or technologies. We may not be able to successfully integrate acquired personnel, operations and technologies, or effectively manage the combined business following an acquisition. Acquisitions could also result in dilutive issuances of equity securities, the use of our available cash, or the incurrence of debt, which could harm our operating results. In addition, if an acquired business fails to meet our expectations, our operating results, business and financial condition may suffer.

If we are unable to recruit and retain key executives and scientists, we may be unable to achieve our goals.

Our success depends largely on the continued services of key members of our executive management team and others in key management positions. We do not currently maintain key person life insurance policies on any of our employees. If we lose one or more key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategy.

In addition, our research and development programs, clinical operations and sales and marketing efforts depend on our ability to attract and retain highly skilled scientists, engineers and sales professionals. Competition for skilled personnel in our market is intense, and we have from time to time experienced, and expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications on acceptable terms, or at all. Many of the companies with which we compete for experienced personnel have greater resources than we do, and any of our employees may terminate their employment with us at any time. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources and, potentially, damages. In addition, job candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, it may harm our ability to recruit and retain highly skilled employees. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects could be harmed.

Consolidation in the medical device industry could have an adverse effect on our revenue and results of operations.

Many medical device companies are consolidating to create new companies with greater market power. As the medical device industry consolidates, competition to provide goods and services to industry participants will become more intense. These industry participants may try to use their market power to negotiate price concessions or reductions for their products. If we reduce our prices because of consolidation in the medical device industry, our revenue would decrease, which could have a material adverse effect on our business, financial condition and results of operations.

Unfavorable U.S. or global economic conditions as a result of a pandemic, political instability, natural disasters, or otherwise, could adversely affect our ability to raise capital and our business, financial condition and results of operations.

Any future health related crisis or pandemic may result in extreme volatility and disruptions in the capital and credit markets, reducing our ability to raise additional capital through equity, equity-linked or debt financings, which could negatively impact our short-term and long-term liquidity and our ability to operate in accordance with our operating plan, or at all. In addition, our results of operations could be adversely affected by general conditions in the global economy and financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for our products and our ability to raise additional capital when needed on favorable terms, if at all. A weak or declining economy could strain our customers' budgets or cause delays in their payments to us. Further, health related crises and pandemics could in the future continue to cause, and other factors could contribute to causing delays or disruptions in our supply chain and labor shortages and shutdowns. Any of the foregoing could harm our business, and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our ability to raise capital and our business, financial condition and results of operations.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results in a timely manner or prevent fraud, which could harm our business.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations in a timely manner, or at all. In addition, any testing by us conducted in connection with Section 404(a) of the Sarbanes-Oxley Act of 2002 (the "**Sarbanes-Oxley Act**") or any subsequent testing by our independent registered public accounting firm in connection with Section 404(b) of the Sarbanes-Oxley Act, may reveal deficiencies in our internal controls over financial reporting that are deemed to be significant deficiencies or material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Ineffective internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of common stock.

We will be required to disclose material changes made in our internal controls over financing reporting and procedures on a quarterly basis and our management will be required to assess the effectiveness of these controls annually. We will be required to make a formal assessment of the effectiveness of our internal control over financial reporting, and once we cease to be an "emerging growth company" within the meaning of the Securities Act as modified by the Jumpstart Our Business Startups Act of 2012, as amended (the "**JOBS Act**"), we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, for as long as we are an emerging growth company, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act.

To achieve compliance with Section 404(a) of the Sarbanes-Oxley Act within the prescribed period, we will be engaging in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a plan to assess and document the adequacy of our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively and implement a continuous reporting and improvement process for internal control over financial reporting.

We could be an emerging growth company for up to five years from the date of the ARYA initial public offering. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not identify. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our results of operation could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of common stock.

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. We base our estimates on historical experience and estimates and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, and expenses that are not readily apparent from other sources. For example, in connection with the implementation of the new revenue accounting standard if and when we have product sales, management makes judgments and assumptions based on our interpretation of the new standard. The new revenue standard is principle-based and interpretation of those principles may vary from company to company based on their unique circumstances. It is possible that interpretation, industry practice and guidance may evolve as we apply the new standard. If our assumptions underlying our estimates and judgements relating to our critical accounting policies change or if actual circumstances differ from our assumptions, estimates or judgements, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of common stock.

We are not in compliance with Nasdaq's audit committee requirements, and as a result our common stock may be delisted, which could have a material adverse effect on the liquidity of our common stock.

On December 19, 2024, Shahram Moaddeb notified our Board Directors (the "Board") of his resignation as a director of the Company, effective January 1, 2025. Mr. Moaddeb was an independent director, serving on the audit committee and compensation committee and as a result of his resignation, we are no longer in compliance with Nasdaq's audit committee requirements as set forth in Listing Rule 5605. Under Nasdaq Listing Rule 5605(c)(4), Nasdaq provided the Company a cure period in order to regain compliance as follows: (i) until the earlier of the Company's next annual shareholders' meeting or January 2, 2026 or (ii) if the next annual shareholders' meeting is held before June 30, 2025, then the Company must evidence compliance no later than June 30, 2025. The Company is in the process of reviewing and evaluating potential options to regain compliance with these continued listing requirements noted above in a manner consistent with the cure period. There can be no assurance that the Company will successfully regain compliance with these continued listing requirements within the applicable cure period.

If our facilities become unavailable or inoperable, our research and development program and commercialization launch plan could be adversely affected, which could materially and adversely impact our business, financial condition and results of operations.

We currently maintain our research, development, manufacturing and administrative operations in a building located in Laguna Hills, California, and we do not have redundant facilities. Should our building be significantly damaged or destroyed by natural or man-made disasters, such as earthquakes, fires (both of which are prevalent in California) or other events, it could take months to relocate or rebuild, during which time our employees may seek other positions, our research, development and manufacturing would cease or be delayed and our products may be unavailable. Because of the time required to authorize manufacturing in a new facility under federal, state and non-U.S. regulatory requirements, we may not be able to resume production on a timely basis even if we were able to replace production capacity. While we maintain property and business interruption insurance, such insurance has limits and would not cover all damages, including losses caused by earthquakes or losses we may suffer due to our products being replaced by competitors' products. If our facilities become inoperable, the inability to perform our research, development and manufacturing activities, combined with our limited inventory of materials and components and manufactured products, may cause physicians to discontinue using our products or harm our reputation, and we may be unable to re-establish relationships with such physicians in the future. Consequently, a catastrophic event at our current facility or any future facilities could have a material adverse effect on our business, financial condition and results of operations.

We use hazardous chemicals and biological materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our research and development processes and manufacturing involve the controlled use of hazardous materials, including select chemicals that may be flammables, toxic or corrosives. We do not currently have research processes involving biohazard materials. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. In addition, the products involve the use of a high-powered laser system, which could result in injury. We may be sued for any injury or contamination that results from our use or the use by third parties of these materials. We do not currently maintain separate environmental liability coverage and any such contamination or discharge could result in significant cost to us in penalties, damages and suspension of our operations.

Risks Related to our Products

If our clinical trials are unsuccessful or significantly delayed, or if we do not complete our clinical trials, our business may be harmed.

Clinical development is a long, expensive and uncertain process and is subject to delays and the risk that products may ultimately prove unsafe or ineffective in treating the indications for which they are designed. Completion of clinical trials may take several years or more. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a trial, in reaching an agreement on acceptable clinical trial terms with prospective sites, in obtaining institutional review board ("**IRB**") approval at each site, in recruiting patients to participate in a trial or in obtaining sufficient supplies of clinical trial materials.

In September 2023, we announced the first Ventricular Tachycardia (VT) ULTC procedure performed using the Adagio VT Cryoablation System in the United States as part of the FULCRUM-VT early feasibility (EFS IDE) clinical trial. Delays in the completion of these and other clinical testing could significantly affect our product development costs. The completion of clinical trials can be delayed for a number of reasons, including delays related to: inability to enroll sufficient numbers of study subjects in a timely manner; unexpected or serious adverse effects related to our medical device candidate experienced by patients in a clinical trial; and retaining patients who have initiated a clinical trial, but may withdraw due to treatment protocol, adverse effects from the therapy, lack of effectiveness from the treatment or personal issues or who may not return for a sufficient number of post-operative visits. Clinical trials may also be delayed, suspended or terminated as a result of ambiguous or negative interim results, or results that are inconsistent with earlier results. In addition, a clinical trial may be suspended or terminated by us, the FDA, other regulatory authorities, or other numerous unforeseen factors or events during or because of the clinical trial process, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- enrollment in our clinical trials may be slower than we anticipate, or we may experience high screen failure rates in our clinical trials, resulting in significant delays;
- our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or preclinical testing which may be expensive and time-consuming;
- trial results may not meet the level of statistical significance required by the FDA or other regulatory authorities;
- the FDA or similar foreign regulatory authorities may find the product is not sufficiently safe for investigational use in humans;
- the FDA or similar foreign regulatory authorities may interpret data from preclinical testing and clinical trials in different ways than we do;
- there may be delays or failure in obtaining approval of our clinical trial protocols from the FDA or other regulatory authorities;
- there may be delays in obtaining IRB approvals or governmental approvals to conduct clinical trials at prospective sites;
- the FDA or similar foreign regulatory authorities may find our or our suppliers' manufacturing processes or facilities unsatisfactory;
- the FDA or similar foreign regulatory authorities may change their review policies or adopt new regulations that may negatively affect or delay our ability to bring a product to market or receive approvals or clearances to treat new indications;
- we may have trouble in managing multiple clinical sites;
- we may experience delays in agreeing on acceptable terms with third-party research organizations and trial sites that may help us conduct the clinical trials; and

- we, or regulators, may suspend or terminate our clinical trials because the participating patients are being exposed to unacceptable health or safety risks, such as the death of a patient in our iCLAS IDE trial in October 2021, which caused our to voluntarily pause the study for six months (between November 2021 and April 2022) in order to investigate and take corrective actions and obtain FDA approval to resume the study.

Delays in clinical development or delays in our ability to achieve regulatory clearance or approval, if at all, may impact the costs, timing or successful completion of a clinical trial. Moreover, failures or perceived failures in our clinical trials will delay and may prevent our product development and regulatory clearance or approval process, damage our business prospects and negatively affect our reputation and competitive position.

We have limited data and experience regarding the safety and efficacy of our products. Results of earlier trials may not be predictive of future clinical trial results, and planned trials may not establish an adequate safety or efficacy profile for such products and other planned or future products, which would affect market acceptance of these products.

We have performed clinical trials with only limited patient populations. The long-term effects of using our products in a large number of patients has not been studied and the results of short-term clinical use of such products do not necessarily predict long-term clinical benefits or reveal long-term adverse effects. The results of clinical trials of our products conducted to date and ongoing or future trials and trials of our current, planned or future products may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Our interpretation of data and results from our clinical trials do not ensure that we will achieve similar results in future clinical trials in other patient populations. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in preclinical studies and earlier clinical trials have nonetheless failed to replicate such results in later clinical trials and subsequently failed to obtain marketing approval. Products in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier clinical trials.

We may not be successful in the commercialization of our products if we fail to establish relationships and successfully collaborate with leading life science companies and research institutions.

To remain competitive, we must launch new products and technologies. To accomplish this, we will need to work with leading life science companies, research institutions and other third-party collaborators and service providers in the design, development and commercialization of our products and product candidates. Establishing collaborations is difficult, time consuming and may require our significant financial investment, including substantial upfront payments in such collaborations, which may negatively impact our reported earnings. In addition, potential collaborators may elect not to work with us based on their assessment of our financial, regulatory, or intellectual property position. Further, once news of discussions regarding possible collaborations are known in the general public, regardless of whether the news is accurate, failure to announce a collaboration agreement, or the entity's announcement of a collaboration with an entity other than us, could result in adverse speculation about us, our products or our technology, resulting in harm to our reputation and our business. In addition, even if we establish new collaborations, they may not result in the successful development or commercialization of our products or technology. Relatedly, collaborating with such parties for multiple aspects of our drug development and commercialization activities might lead to less control over many aspects of those activities. Third parties may not complete activities on schedule or in accordance with our expectations. Failure by one or more of these third parties to meet their contractual, regulatory or other obligations to us, or any disruption in the relationships between us and these third parties, could delay or prevent the development, approval or commercialization of our products and product candidates, and could also result in non-compliance or reputational harm, all with potential negative implications for our product pipeline and business.

If we are unable to establish an effective network for commercialization, including effective distribution channels and sales and marketing functions, it may adversely affect our business, financial condition, results of operations, and prospects.

Our limited commercialization experience and no approved or cleared products in the United States make it difficult to evaluate our current business and assess our prospects. We also currently have limited sales and marketing experience. If we are unable to establish effective sales and marketing capabilities or if we are unable to commercialize any of our products, we may not be able to effectively generate product revenue, sustain revenue growth and compete effectively. In order to generate future growth, we plan to continue to expand and leverage our sales and marketing infrastructure to increase our customer base and grow our business. Identifying and recruiting qualified sales and marketing personnel and training them on our products, applicable federal and state laws and regulations, and on our internal policies and procedures requires significant time, expense and attention. It often takes several months or more before a sales representative is fully trained and productive. Our business may be harmed if our efforts to expand and train our sales force do not generate a corresponding increase in revenue, and our higher fixed costs may slow our ability to reduce costs in the face of a sudden decline in demand for our products. Any failure to hire, develop and retain talented sales and marketing personnel, to achieve desired productivity levels in a reasonable timeframe or timely leverage our fixed costs could have a material adverse effect on our business, financial condition and results of operations. Moreover, the members of our direct sales force are at-will employees. The loss of these personnel to competitors or otherwise could materially harm our business. If we are unable to retain our direct sales force personnel or replace them with individuals of equivalent technical expertise and qualifications, or if we are unable to successfully instill technical expertise in replacement personnel, our revenue and results of operations could be materially harmed.

Our ability to increase our customer base and achieve broader market acceptance of our products will also depend to a significant extent on our ability to expand our marketing efforts as we plan to dedicate significant resources to our marketing programs. Our business may be harmed if our marketing efforts and expenditures do not generate a corresponding increase in revenue. In addition, we believe that developing and maintaining broad awareness of our brand in a cost-effective manner is critical to achieving broad acceptance of our products and penetrating new customer accounts. Brand promotion activities may not generate patient or physician awareness or increased revenue, and even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain and protect our brand, or if we incur substantial expenses in an unsuccessful attempt to promote and maintain our brand, we may fail to attract or retain the physician acceptance necessary to realize a sufficient return on our brand building efforts, or to achieve the level of brand awareness that is critical for broad adoption of our products, which would have an adverse effect on our business, financial condition and results of operations.

These factors also make it difficult for us to forecast our financial performance and growth, and such forecasts are subject to a number of uncertainties, including our ability to successfully develop additional products that add functionality, reduce the cost of products sold, broaden our commercial portfolio offerings and obtain FDA 510(k) clearance or PMA approval for, and successfully commercialize, market and sell, our planned or future products in the United States or in international markets. If our assumptions regarding the risks and uncertainties we face, which we use to plan our business, are incorrect or change due to circumstances in our business or our markets, or if we do not address these risks successfully, our operating and financial results could differ materially from our expectations and our business could suffer.

Our products may not be successful if there are inadequate physician training, practice and patient selection.

The success of our products depends in part on the skill of the physician performing the catheter-based procedures and on their adherence to our stated patient selection criteria and proper techniques that we provide in training sessions. For example, we train physicians to ensure correct use of our products; however, physicians rely on their previous medical training and experience when performing catheter-based procedures, and we cannot guarantee that all such physicians will have the necessary skills or experience to safely and effectively perform these procedures. We do not control which physicians perform these procedures or how much training they receive, and physicians who have not completed our training sessions may nonetheless attempt to perform catheter-based procedures with our products. In addition, a perception by physicians that our products are difficult to use may negatively impact adoption. If physicians perform these procedures in a manner that is inconsistent with our labeled indications, with components that are not our products, with patients who are not indicated for treatment with our products or without adhering to or completing our training sessions, the patient outcomes may be negative or inconsistent with the outcomes achieved in clinical trials. This could negatively impact the perception of patient benefits and safety associated with our products and limit adoption of our products and catheter-based thrombectomy procedures generally, which could have a material adverse effect on our business, financial condition and results of operations.

The life sciences industry is highly competitive. Even if our products are commercialized and achieve broad scientific and market acceptance, if we fail to improve them or introduce compelling new products, our revenue and our prospects could be harmed.

The life sciences industry is characterized by rapid and significant technological changes, frequent new product introductions and enhancements and evolving industry standards. We compete primarily on the basis that our products are designed to enable more physicians to treat more patients more efficiently and effectively. Our continued success depends on our ability to:

- continue to develop innovative, proprietary products that address significant clinical needs in a manner that is safe and effective for patients and easy-to-use for physicians;
- obtain and maintain regulatory clearances or approvals;
- demonstrate safety and effectiveness in our sponsored and third-party clinical trials;
- expand our sales force across key markets to increase physician awareness;
- obtain and maintain coverage and adequate reimbursement for procedures using our products;
- attract and retain skilled research, development, sales and clinical personnel;
- cost-effectively manufacture, market and sell our products; and
- obtain, maintain, enforce and defend our intellectual property rights and operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of others.

Even if we are able to achieve broad scientific and market acceptance of our ablation technologies, any one of our competitors could reduce or eliminate our commercial opportunities if they develop or market products that:

- are more effective;
- have fewer or less severe adverse side effects;
- are easier to use; or
- are less expensive than our products.

In addition, our ability to attract new customers and increase revenue from existing customers will depend in large part on our ability to enhance and improve our technologies and to introduce compelling new products. The success of any enhancement to our ablation technologies or introduction of new products depends on several factors, including:

- timely completion and delivery;
- competitive pricing;
- adequate quality testing;
- integration with existing technologies;
- freedom from intellectual property encumbrance;
- appropriately timed and staged introduction; and
- overall market acceptance.

Any new product or enhancement to the ablation technologies that we develop may not be introduced in a timely or cost-effective manner, may contain defects, errors, vulnerabilities or bugs, or may not achieve the market acceptance necessary to generate significant revenue. The typical development cycle of new life sciences products can be lengthy and complicated, and may require new scientific discoveries or advancements, considerable resources and complex technology and engineering. Such developments may involve external suppliers and service providers, making the management of development projects complex and subject to risks and uncertainties regarding timing, timely delivery of required components or services and satisfactory technical performance of such components or assembled products. If we do not achieve the required technical specifications or successfully manage new product development processes, or if development work is not performed according to schedule, then such new technologies or products may be adversely impacted.

We cannot provide assurance that we will be successful in developing new products or commercializing them in ways that achieve market acceptance. If we develop new products, sales of those products may reduce revenue generated from our existing products or may not compete effectively with competitor products. Moreover, any significant delays in our product launches may significantly impede our ability to enter or compete in a given market and may reduce the sales that we are able to generate from these products. We may experience delays in any phase of product development, including during research and development, clinical trials, regulatory review, manufacturing and marketing. Delays in product introductions could have a material adverse effect on our business, financial condition and results of operations.

If we are unable to successfully develop new products, enhance our ablation technologies to meet customer requirements, compete with alternative products, or otherwise gain and maintain market acceptance, our business, financial condition and results of operations could be harmed.

If we are unable to establish manufacturing capacity by ourselves or with third-party partners in a timely and cost-effective manner, commercialization of our products would be delayed, which would result in lost revenue and harm our business.

We may encounter production delays or shortfalls because of our limited experience in manufacturing our products in commercial quantities. Such production delays or shortfalls may be caused by many factors, including the following:

- our intent to expand our manufacturing capacity, as a result of which our production processes may have to change;
- key components of our products are provided by a single supplier or limited number of suppliers, and we do not maintain large inventory levels of these components; if we experience a shortage or quality issues in any of these components, we would need to identify and qualify new supply sources, which could increase our expenses and result in manufacturing delays;
- a delay in completing validation and verification testing for new controlled environment rooms at our manufacturing facility;
- state and federal regulations, including the FDA's Quality System Regulation ("QSR"), for the manufacture of our products, noncompliance with which could cause an interruption in our manufacturing; and
- attraction and retention of qualified employees for our operations in order to significantly increase our manufacturing output.

If we are unable to keep up with demand for our products, our growth could be impaired, and market acceptance for our products could be harmed and physicians may instead elect to use our competitors' products. Our inability to successfully manufacture our products in sufficient quantities could materially harm our business.

In addition, our manufacturing facility and processes and those of our third-party suppliers are subject to announced or unannounced FDA and state regulatory inspections or audits for compliance with the QSR, state equivalent requirements, and international manufacturing standards. Developing and maintaining a compliant quality system is time consuming and expensive. Failure to maintain compliance with, or not fully complying with the requirements of the FDA, state, or foreign regulators, could result in enforcement actions against us or our third-party suppliers, which could include the issuance of warning letters, seizures, prohibitions on product sales, recalls and civil and criminal penalties, any one of which could significantly impact our manufacturing supply and impair our financial results.

We are dependent on limited third-party suppliers and manufacturers for some of the components and materials used in our products, and so long as we remain dependent on them, the loss of any of these suppliers and manufacturers, or any difficulties encountered by these suppliers and manufacturers in the production of our products, could harm our business.

We rely on third-party suppliers to provide us with certain components of our products, some of which are single-source suppliers. In some cases, we do not have long-term supply agreements with, or guaranteed commitments from, our suppliers, including single-source suppliers. We depend on our suppliers to provide us and our customers with components and materials in a timely manner that meet our and their quality, quantity and cost requirements. These suppliers may encounter problems during manufacturing for a variety of reasons, any of which could delay or impede their ability to meet our demand. Our suppliers may also fail to comply with applicable federal, state or foreign laws or regulations, cease producing the components and materials required for our products or otherwise decide to cease doing business with us. If the suppliers, including the single-source suppliers, that we use are unable or unwilling to manufacture the components or materials in our required volumes, or at specified times, we may have to identify and qualify acceptable additional or alternative suppliers. This qualification process could take up to a few months and we may not find sufficient capacity in a timely manner or at an acceptable cost to satisfy our production requirements. Any supply interruption from our suppliers or failure to obtain alternative suppliers for any of the components used in our products would limit our ability to manufacture our products and could have a material adverse effect on our business, financial condition and results of operations.

FDA review and approval of a new supplier may be required if these components or materials become unavailable from our current suppliers. Although there may be other suppliers that have equivalent components or materials that would be available to us, FDA approval of any alternate suppliers, if required, could take several months or more to obtain, if it is able to be obtained at all. Any delay, interruption or cessation of production by our third-party suppliers of important components or materials, or any delay in qualifying new components or materials, if necessary, would prevent or delay our ability to manufacture our products.

Our products could have unknown defects or errors, which may give rise to claims against us and adversely affect market adoption of our products.

Our business is subject to significant risks associated with the design, manufacturing, distribution and use of medical devices that are placed inside the human body, including the risk that patients may be severely injured by or even die from the misuse or malfunction of our products caused by design flaws or manufacturing defects. In addition, component failures, design defects, off-label uses, or inadequate disclosure of product-related information discovered after commercial shipment or during commercial use could result in an unsafe condition or the injury or death of a patient. These problems could lead to a voluntary recall or market withdrawal of, or issuance of a safety alert relating to, our products and could result in significant costs, negative publicity and adverse competitive pressure. Furthermore, the reporting of product defects or voluntary recalls to the FDA or analogous regulatory bodies outside the United States could result in manufacturing audits, inspections and broader recalls or other disruptions to our manufacturing processes. The circumstances giving rise to recalls are unpredictable, and any recalls of existing or future products could have a material adverse effect on our business, financial condition and results of operations.

We provide a limited warranty that our products are free of material defects and conform to specifications, and offers to repair, replace or refund the purchase price of defective products. As a result, we bear the risk of potential warranty claims on our products. In the event that we attempt to recover some or all of the expenses associated with a warranty claim against us from our suppliers or vendors, we may not be successful in claiming recovery and any recovery from such vendor or supplier may not be adequate.

The medical device industry has historically been subject to extensive litigation over product liability claims. We may be subject to product liability claims if our products cause, or merely appear to have caused, an injury or death, even if due to physician error. In addition, an injury or death that is caused by the activities of our suppliers, such as those that provide us with components and raw materials, or by an aspect of a treatment used in combination with our products, such as a complementary drug or anesthesia, may be the basis for a claim against us by patients, hospitals, physicians or others purchasing or using our products, even if our products were not the actual cause of such injury or death. We may choose to settle any such claims even if we believe that such injuries were not due to failure of our products. An adverse outcome of any such claim involving one of our products could result in reduced market acceptance and demand for any or all of our products and could harm our reputation or brand and our ability to market our products in the future. In some circumstances, adverse events arising from or associated with the design, manufacture or marketing of our products could result in the suspension or delay of regulatory reviews of our premarket notifications or applications for marketing. Any of the foregoing problems could disrupt our business and have a material adverse effect on our business, financial condition and results of operations.

Although we carry product liability insurance, including for clinical trials and product marketing, we can give no assurance that such coverage will be available or adequate to satisfy any claims. Product liability insurance is expensive, subject to significant deductibles and exclusions, and may not continue to be available on acceptable terms, if at all. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our reputation, significantly increase our expenses, and reduce product sales. If we are unable to obtain or maintain insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we could be exposed to significant liabilities. Product liability claims could cause us to incur significant legal fees and deductibles and claims in excess of our insurance coverage would be paid out of cash reserves, harming our financial condition and operating results. Defending a suit, regardless of our merit or eventual outcome, could be costly, could divert management's attention from our business and might result in adverse publicity, which could result in reduced acceptance of our products in the market, product recalls or market withdrawals.

We are required to file adverse event reports under Medical Device Reporting ("MDR") regulations with the FDA, which reports are publicly available on the FDA's website. We are required to file MDRs if our products may have caused or contributed to a serious injury or death or malfunctioned in a way that would be likely to cause or contribute to a serious injury or death if it were to recur. Any such MDR that reports a significant adverse event could result in negative publicity, which could harm our reputation and future sales. If we fail to report these events to the FDA within the required timeframes, or at all, the FDA could take enforcement action against us. Any such adverse event involving our products could also result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending against potential lawsuits, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results. Analogous reporting obligations exist in the European Union and other jurisdictions outside the United States. See "- *Risks Related to Regulatory and Legal Compliance Matters*" for further detail.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our products and technology, or if the scope of the intellectual property protection obtained is not sufficiently broad, competitors could develop and commercialize products similar or identical to our products, and our ability to successfully commercialize our products may be impaired.

We rely on patent protection as well as trademark, copyright, trade secret and other intellectual property rights protection and contractual restrictions to protect our proprietary products and technologies, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we fail to obtain, maintain, protect and enforce our intellectual property, third parties may be able to compete more effectively against us. In addition, we may incur substantial litigation costs in our attempts to maintain, recover, enforce or otherwise restrict the use of our intellectual property.

To the extent our intellectual property offers inadequate protection, or is found to be invalid or unenforceable, we would be exposed to a greater risk of direct competition. If our intellectual property does not provide adequate coverage of our products, our competitive position could be adversely affected, as could our business, financial condition, results of operations and prospects. Both the patent application process and the process of managing patent and other intellectual property disputes can be time-consuming and expensive.

Our success depends in large part on our and our licensors' ability to obtain and maintain protection of the intellectual property we may own solely and jointly with, or license from, third parties, particularly patents, in the United States and other countries with respect to our products and technologies. We apply for patents covering our products and technologies and uses thereof, as we deem appropriate. However, obtaining, maintaining, and enforcing patents is costly, time-consuming and complex, and we may fail to apply for patents on important products and technologies in a timely fashion or at all, or we may fail to apply for patents in potentially relevant jurisdictions. We may not be able to file and prosecute all necessary or desirable patent applications, or maintain, enforce and protect any patents that may issue from such patent applications, at a reasonable cost or in a timely manner or in all jurisdictions. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, assignment, recordation, document formalities, fees, claim scope or requests for patent term adjustments. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. If we delay filing a patent application, and a competitor files a patent application on the same or similar invention before we do, or the subject matter otherwise is made public by us or a competitor, our ability to secure patent rights may be limited or we may not be able to patent the invention at all. Even if we can patent the invention, we may be able to patent only a limited scope of the invention, and the limited scope may be inadequate to protect our products and technologies, or to block a competitor's products and technologies that are similar or adjacent. Our earliest patent filings have been published. A competitor may review our published patents and arrive at the same or similar technology advances for our products as it develops. If the competitor files a patent application on such an advance before we do, then we may no longer be able to protect that aspect of our products and technologies and we may require a license from the competitor, which may not be available on commercially viable terms. Moreover, we may not develop additional proprietary products, methods and technologies that are patentable. It may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents licensed from or to third parties. Therefore, these patents and applications may not be prosecuted and enforced by such third parties in a manner consistent with the best interests of our business.

The U.S. law relating to the patentability of certain inventions in the life sciences technology industry is uncertain and rapidly changing, which may adversely impact our existing patents or our ability to obtain patents in the future.

Changes in either the patent laws or interpretation of the patent laws in the United States or in other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In the last decade, the U.S. Congress made sweeping changes to patent law in passing the America Invents Act (the "AIA"). These changes include, among others, allowing third-party submission of prior art to the United States Patent and Trademark Office (the "USPTO") during patent prosecution and additional procedures to challenge the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. The changes brought about by the AIA have not been extensively tested, and therefore increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Various courts, including the U.S. Supreme Court, have recently rendered decisions that impact the scope of patentability of certain inventions or discoveries relating to our technology and commercial goals. Specifically, these decisions have substantially increased the probability that patent claims will be ruled patent ineligible for reciting a natural phenomenon, law of nature or abstract idea. Furthermore, in view of these decisions, since December 2014, the USPTO has published and continues to publish revised guidelines for patent examiners to apply when examining claims for patent eligibility. Patent claims relating to software algorithms, biologically-derived reagents, methods for analyzing biological systems and other subject matters that underlies our technology and commercial goals are impacted by these changes.

Actions taken by the U.S. Congress, federal courts and USPTO have from time to time narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. Similar changes have been made by authorities in other jurisdictions. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, such changes create uncertainty with respect to the value of patents, once obtained. Depending on decisions by authorities in various jurisdictions, the laws and regulations governing patents could change in unpredictable ways that may have a material adverse effect on our ability to obtain new patents and to defend and enforce our existing patents and patents that we might obtain in the future. We cannot assure you that our patent portfolio will not be negatively impacted by the current uncertain state of the law, new court rulings or changes in guidance or procedures issued by governments or patent offices around the world. From time to time, the U.S. Supreme Court, other federal courts, the U.S. Congress or the USPTO may change the standards of patentability, scope and validity of patents within the life sciences technology and any such changes, or any similar adverse changes in the patent laws of other jurisdictions, could have a negative impact on our business, financial condition, prospects and results of operations.

We may not be able to protect our intellectual property rights throughout the world, which could harm our business prospects.

Filing, prosecuting, maintaining, and defending patents on our products in all countries 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.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and we and any future licensor may encounter difficulties in protecting and defending such rights in foreign jurisdictions. Consequently, we and any future licensor may not be able to prevent third parties from practicing our inventions in some or all countries outside the United States, or from selling or importing products made using our or any future licensor's inventions in and into the United States or other jurisdictions. Competitors and other third parties may be able to use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and technologies and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products. Our and any future licensor's patents or other intellectual property rights may not be effective or sufficient to prevent competitors from marketing competing products. In addition, certain countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to other parties. Furthermore, many countries limit the enforceability of patents against other parties, including government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of any patents.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many other countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the misappropriation or other violations of our intellectual property rights including infringement of our patents in such countries. The legal systems in certain countries may also favor state-sponsored companies or companies headquartered in particular jurisdictions over our patents and other intellectual property protection. The absence of harmonized intellectual property protection laws and effective enforcement makes it difficult to ensure consistent respect for patent, trade secret, and other intellectual property rights on a worldwide basis. As a result, it is possible that we will not be able to enforce our rights against third parties that misappropriate our proprietary technology in those countries.

Proceedings to enforce our or any future licensor's patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business, could put us and any future licensor's patents at risk of being invalidated or interpreted narrowly and us and any future licensor's patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We and any future licensor may not prevail in any lawsuits that we and any future licensor initiates, or that are initiated against us or any future licensor, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our products, services and other technologies and the enforcement of intellectual property. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Any of the foregoing events could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may become involved in lawsuits to defend against third-party claims of infringement, misappropriation or other violations of intellectual property or to protect or enforce our intellectual property, any of which could be expensive, time consuming and unsuccessful, and may prevent or delay our development and commercialization efforts.

Litigation may be necessary for us to enforce our patent and proprietary rights and/or to determine the scope, coverage and validity of others' proprietary rights. Litigation on these matters has been prevalent in our industry, and we expect that this will continue. To determine the priority of inventions, we may have to initiate and participate in interference proceedings declared by the U.S. Patent and Trademark Office that could result in substantial legal fees and could substantially affect the scope of our patent protection. Also, our intellectual property may be subject to significant administrative and litigation proceedings such as invalidity, unenforceability, re-examination and opposition proceedings against our patents. The outcome of any litigation or other proceeding is inherently uncertain and might not be favorable to us, and we might not be able to obtain licenses to technology that we require, or a competitor may have already obtained an exclusive license to such technology in some or all fields. Even if such licenses are obtainable, they may not be available at a reasonable cost. We could therefore incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins. In some cases, the outcome of litigation may be to enjoin us from commercializing a patent protected technology. We could encounter delays in product introductions, or interruptions in product sales, as we develop alternative methods or products.

In addition, if we resort to legal proceedings to enforce our intellectual property rights or to determine the validity, scope and coverage of the intellectual property or other proprietary rights of others, the proceedings could be burdensome and expensive, even if we were to prevail.

Our commercial success may depend in part on our non-infringement of the patents or proprietary rights of third parties. Numerous significant intellectual property issues have been litigated, and will likely continue to be litigated, between existing and new participants in the life sciences market and competitors may assert that our products infringe their intellectual property rights as part of a business strategy to impede our successful entry into those markets. Third parties may assert that we are employing their proprietary technology without authorization.

In addition, our competitors and others may have patents or may in the future obtain patents and may claim that use of our products infringes these patents. As we move into new markets and applications for our products, incumbent participants in such markets may assert their patents and other proprietary rights against us as a means of slowing or preventing our entry into such markets, or as a means to extract substantial license and royalty payments from us.

Issued patents covering our products could be found invalid or unenforceable if challenged, and could materially impact our business.

Our owned patents and any future licensed patents and patent applications may be subject to validity, enforceability, inventorship, and priority disputes. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability. Some of our patents or patent applications may be challenged at a future point in time in litigation, opposition, derivation, reexamination, *inter partes* review, post-grant review or interference or other similar proceedings. Any successful third-party challenge to our patents in this or any other proceeding could result in the unenforceability or invalidity of such patents, which may lead to increased competition to our business, and which could have a materially adverse effect on our business, financial condition, results of operations and prospects. In addition, if we or any future licensor initiates legal proceedings against a third party to enforce a patent covering our products, the defendant could counterclaim that such patent covering our products, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. There are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements for validity/patentability, including, but not limited to, patentable subject matter, lack of novelty, obviousness, non-enablement or sufficiency of the written description of the invention. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld materially relevant information from the relevant patent office, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include ex parte re-examination, *inter partes* review, post-grant review, derivation and equivalent proceedings in non-U.S. jurisdictions, such as opposition proceedings. Such proceedings could result in revocation of or amendment to our patents in such a way that they no longer cover and protect our products or exclude competing products. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which us, any future licensor, our patent counsel and the patent examiner were unaware during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. If a defendant or other third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection for our products and technologies, which could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license intellectual property or develop or commercialize current or future products.

We may not be aware of all third-party intellectual property rights potentially relating to our 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 approximately 18 months after filing or, in some cases, not until such patent applications issue as patents. We might not have been the first to make the inventions covered by each of our pending patent applications and we might not have been the first to file patent applications for these inventions. To determine the priority of these inventions, we may have to participate in interference proceedings, derivation proceedings or other post-grant proceedings declared by the USPTO, or other similar proceedings in non-U.S. jurisdictions, that could result in substantial cost to us and the loss of valuable patent protection. The outcome of such proceedings is uncertain. No assurance can be given that other patent applications will not have priority over our patent applications. In addition, changes to the patent laws of the United States in the last decade allow for various post-grant opposition proceedings that have not been extensively tested, and their outcome is therefore uncertain. Furthermore, if third parties bring these proceedings against our patents, regardless of the merit of such proceedings and regardless of whether we are successful, we could experience significant costs and our management may be distracted. Any of the foregoing events could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected, and our business could be harmed.

We rely heavily on trade secrets and confidentiality agreements to protect our unpatented know-how, technology and other proprietary information, including parts of the ULTC and PFCA products, and to maintain our competitive position. However, trade secrets and know-how can be difficult to protect. In particular, we anticipate that with respect to our technologies, these trade secrets and know how will over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology, and the movement of personnel between academic and industry scientific positions.

In addition to pursuing patents on our technology, we take steps to protect our intellectual property and proprietary technology by entering into agreements, including confidentiality agreements, non-disclosure agreements and intellectual property assignment agreements, with our employees, consultants, academic institutions, corporate partners and, when needed, our advisers. However, we cannot be certain that such agreements have been entered into with all relevant parties, and we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors or other third parties will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized disclosure, which could adversely impact our ability to establish or maintain a competitive advantage in the market, business, financial condition, results of operations and prospects.

Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third party had wrongfully obtained and was using our trade secrets, it would be expensive and time-consuming, it could distract our personnel, and the outcome would be unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets.

We also seek to preserve the integrity and confidentiality of our confidential proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a competitor or other third party, absent patent protection, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Competitors or third parties could purchase our products and attempt to reverse-engineer or replicate some or all of the competitive advantages we derive from our development efforts, design around our protected technology, develop their own competitive technologies that fall outside the scope of our intellectual property rights or independently develop our technologies without reference to our trade secrets. If any of our trade secrets were to be disclosed to or independently discovered by a competitor or other third party, it could materially and adversely affect our business, financial condition, results of operations and prospects.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property, which could have a material adverse effect on our business.

We or any future licensor may be subject to claims that former employees, collaborators or other third parties have an interest in our patents, trade secrets or other intellectual property. For example, we or any future licensor may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our products. In addition, counterparties to our consulting, software development, and other agreements may assert that they have an ownership interest in intellectual property developed under such arrangements. Litigation may be necessary to defend against claims challenging ownership or inventorship of our or any future licensor's ownership of our patents, trade secrets or other intellectual property. If we or any future licensor fails in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our products. In such an event, we may be required to obtain licenses from third parties and such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture or commercialization of our products and technologies. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees, and certain customers or partners may defer engaging with us until the particular dispute is resolved. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may not be able to protect and enforce our trademarks and trade names or build name recognition in our markets of interest thereby harming our competitive position, which could have a material adverse effect on our business.

The registered or unregistered trademarks or trade names that we own may be challenged, infringed, circumvented, declared generic, lapsed or determined to be infringing on or dilutive of other marks owned by third parties. We may not be able to protect our rights in these trademarks and trade names, which we need in order to build name recognition. In addition, third parties may have filed, and may in the future file, for registration of trademarks similar or identical to our trademarks, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Further, we may in the future enter into agreements with owners of such third party trade names or trademarks to avoid potential trademark litigation which may limit our ability to use our trade names or trademarks in certain fields of business. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business, financial condition, results of operations and prospects may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources. Any of the foregoing events could have a material adverse effect on our business, financial condition and results of operations.

Patent terms may be inadequate to protect our competitive position of our products for an adequate amount of time and may adversely affect our business.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest effective U.S. non-provisional filing date. While extensions may be available, the life of a patent, and the protection it affords, is limited. In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date. Even if patents covering our products are obtained, once the patent life has expired, we may be open to competition from competitive products. If one of our products requires extended development, testing and/or regulatory review, patents protecting such products might expire before or shortly after such products are commercialized. As a result, our portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours, which could have a material adverse effect on our business, financial condition and results of operations.

Obtaining and maintaining our patent protection depends on compliance with various required procedures, document submissions, fee payments and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements, which could have a material adverse effect on our business.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States at several stages over the lifetime of the patents and/or applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payments and other similar provisions during the patent application process, and during the lifetime of the patent. In certain circumstances, we may rely on any future licensor, or third-party annuity payment service, to pay these fees due to the U.S. and non-U.S. patent agencies and to take the necessary action to comply with these requirements with respect to any future licensed intellectual property. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors may be able to enter the market without infringing our patents and this circumstance would have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims that our employees, consultants, independent contractors or any third parties that have access to our confidential information or trade secrets have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed trade secrets of their former employers, which could have a material adverse effect on our business.

We have employed and expect to employ individuals who were previously employed at universities or other companies, including, for example, our competitors or potential competitors. Although we try to ensure that our employees, consultants, advisors and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that our employees, advisors, consultants or independent contractors have inadvertently or otherwise misappropriated, used or disclosed intellectual property, including trade secrets or other proprietary information of their former employers or other third parties, or to claims that we have improperly used or obtained such trade secrets. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights and face increased competition to our business. Any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with advisors, contractors and consultants. A loss of key research personnel work product could hamper or prevent our ability to commercialize potential products, which could harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. Some of our competitors may be able to sustain the costs of this type of litigation or proceedings more effectively than we can because of their substantially greater financial resources.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Furthermore, individuals executing agreements with us may have pre-existing or competing obligations to a third party, such as an academic institution, and thus an agreement with we may be ineffective in perfecting ownership of inventions developed by that individual, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Furthermore, we or any future licensor may in the future be subject to claims by former or current employees, consultants or other third parties asserting an ownership right or inventorship in our owned, or any future licensed, patents or patent applications. An adverse determination in any such proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar technology, without payment to us, or could limit the duration of the patent protection covering our technology and products. Such challenges may also result in our inability to develop, manufacture or commercialize our products without infringing third-party patent rights. Any of the foregoing could harm our business, financial condition, results of operations and prospects.

If we cannot license rights to use technologies on reasonable terms, we may not be able to commercialize new products in the futured and thus materially harm our business.

We may identify third-party technology that we may need to license or acquire in order to develop or commercialize our products or technologies, including the ULTC and PFCA products. However, we may be unable to secure such licenses or acquisitions. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources, or greater development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us.

We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. In return for the use of a third party's technology, we may agree to pay the licensor royalties based on sales of our products or services. Royalties are a component of cost of products or technologies and would affect the margins on our products. We may also need to negotiate licenses to patents or patent applications before or after introducing a commercial product. We may not be able to obtain necessary licenses to patents or patent applications, and our business may suffer if we are unable to enter into the necessary licenses on acceptable terms or at all, if any necessary licenses are subsequently terminated, if the licensor fails to abide by the terms of the license or fails to prevent infringement by third parties, or if the licensed intellectual property rights are found to be invalid or unenforceable.

Our use of open source software and failure to comply with the terms of the underlying open source software licenses could impose limitations on our ability to commercialize our products and provide third parties access to our proprietary software, which could have a material adverse effect on our business.

Our products utilize open source software that contains modules licensed for use from third-party authors under open source licenses. In particular, some software may be provided under license arrangements that allow use of the software for research or other noncommercial purposes. Use and distribution of open source software may entail greater risks than use of third-party commercial software, as open source software licensors generally do not provide warranties or other contractual protections regarding infringement claims or the quality of the code. Some open source software licenses contain requirements that the licensee make its source code publicly available if the licensee creates modifications or derivative works using the open source software, depending on the type of open source software the licensee uses and how the licensee uses it. If we combine our proprietary software with open source software in a certain manner, we could, under certain open source software licenses, be required to release the source code of our proprietary software to the public for free. This would allow our competitors and other third parties to create similar products with less development effort and time and ultimately could result in a loss of our product sales and revenue, which could have a materially adverse effect on our business, financial condition, results of operations and prospects. In addition, some companies that use third-party open source software have faced claims challenging their use of such open source software and their compliance with the terms of the applicable open source license. We may be subject to suits by third parties claiming ownership of what we believe to be open source software, or claiming non-compliance with the applicable open source licensing terms. Use of open source software may also present additional security risks because the public availability of such software may make it easier for hackers and other third parties to compromise or attempt to compromise our technology platform and systems.

Although we review and monitor our use of open source software to avoid subjecting our proprietary software to conditions we do not intend, the terms of many open source software licenses have not been interpreted by United States courts, and there is a risk that these licenses could be construed in a way that could impose unanticipated conditions or restrictions on our ability to commercialize our products and proprietary software. Moreover, we cannot assure investors that our processes for monitoring and controlling our use of open source software in our products will be effective. If we are held to have breached the terms of an open source software license, we could be subject to damages, required to seek licenses from third parties to continue offering our products on terms that are not economically feasible, to re-engineer our products, to discontinue the sale of our products if re-engineering could not be accomplished on a timely basis, or to make generally available, in source code form, our proprietary code, any of which could adversely affect our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats, and such risk could have a material adverse effect on our business.

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.

For example:

- others may be able to make products that are similar to products and technologies we may develop or may be able to utilize similar technologies that are not covered by the claims of the patents that we own or license now or in the future;
- we, or any future licensor(s), might not have been the first to make the inventions covered by the issued patent or pending patent application that we own, license or may own in the future;
- we, or any future licensor(s), might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our owned or future licensed intellectual property rights;
- it is possible that our pending patent applications or those that we may license or own in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities 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;
- the patents of others may harm our business; and
- we may choose not to file a patent for certain trade secrets or know-how, and a third party may independently derive, use, commercialize, publish or patent such intellectual property.

Should any of these events occur, they could materially adversely affect our business, financial condition, results of operations and prospects.

Risks Related to Regulatory and Legal Compliance Matters

We expect to incur substantial expenses in our pursuit of regulatory clearances and approvals for our products in the United States and can provide no assurances that we will obtain the necessary approvals from the FDA to market our products in the United States.

The United States is a key market for commercialization of our products. Before we can market our products in the United States, we must conduct and successfully complete extensive clinical trials and then receive 510(k) clearance or Premarket Approval ("PMA") from the FDA. The time required to obtain approval by the FDA and comparable non-U.S. regulatory authorities may be unpredictable and depends upon numerous factors, including the substantial discretion of such regulatory authorities. In addition, policies, regulations or the type and amount of preclinical and clinical data necessary to gain clearance or approval may change during the course of a product's lifecycle. We are required to undertake and complete certain studies to generate data required to support submissions to the FDA and certain other regulatory authorities, which studies may require additional capital and time. The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our products are safe and effective for their intended uses;
- the disagreement of the FDA or the applicable foreign regulatory body with the design or implementation of our clinical trials or the interpretation of data from preclinical studies or clinical trials;
- serious and unexpected adverse device effects experienced by participants in our clinical trials;
- the data from our preclinical studies and clinical trials may be insufficient to support clearance or approval, where required;
- our inability to demonstrate that the clinical and other benefits of the product outweigh the risks;
- the manufacturing process, facilities, or third-party manufacturers or suppliers we use may not meet applicable requirements;
- inadequate compliance with preclinical, clinical or other regulations by us, our clinical investigators, or clinical trial service provides (e.g., contract research organizations); and
- the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval.

It is possible that none of our products or any products we may seek to develop in the future will ever be cleared or approved by the FDA. Any delays in, or failure to receive or maintain, clearance or approval for our products could prevent us from generating revenue from these products or achieve profitability. Furthermore, even if we were to obtain 501(k) clearance or PMA approval for our products, neither clearance nor approval by the FDA nor our existing CE Marks ensures approval by regulatory authorities in other countries or jurisdictions that we may target for commercialization of the vCLAS system, and approval by one regulatory authority does not ensure approval by regulatory authorities in other countries or clearance or approval by the FDA. If we do not receive or maintain regulatory clearances or approvals for our products in the United States and other jurisdictions that we target for commercialization of our products, we will not be able to successfully commercialize our products, which could substantially impair our ability to generate revenues and materially harm our business, financial condition and results of operations.

We may be subject to enforcement action if we engage in improper or off-label marketing or promotion of our products, including significant legal liability, fines, penalties, and injunctions, which could materially and adversely affect our business, financial condition, and results of operations.

We are not permitted to promote or market our products in the United States until FDA clearance or approval is obtained. After clearance or approval, our promotional materials and user training methods must comply with the requirements of the FDA and other applicable laws and regulations, including the prohibition of the promotion of unapproved, or "off-label," uses. Practitioners may use our products off-label, as the FDA does not restrict or regulate a practitioner's choice of treatment within the practice of medicine. However, if the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine, or criminal prosecution. Other federal, state, or foreign enforcement authorities, including the U.S. Department of Justice, might also take action if they consider our promotional or training materials to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged, which may lead to reduced or non-acceptance of our proposed product candidates by the market. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert the attention of our management, result in substantial damage awards against us, and harm our reputation.

Our business could be negatively impacted by changes in the United States political environment.

Any policy changes as a result of the new presidential administration and Congress could significantly affect our business. Specific legislative and regulatory proposals discussed during election campaigns and more recently that might materially impact our business include, but are not limited to, promoting access to healthcare via market competition and pricing transparency, enhancing flexibility and choice in healthcare at the state and individual level, prioritizing domestic production and increasing tariffs on imports (which may complicate and increase costs associated with our supply chain), and rolling back regulatory initiatives adopted under the previous administration. We cannot predict whether industry initiatives to seek tariff carve-outs for devices or other life sciences goods and products will be successful. Additionally, the new administration is expected to evaluate potential budgetary cuts and reallocation of regulatory priorities by key federal agencies that oversee our products, services, and associated reimbursement, including FDA and the U.S. Department of Health and Human Services more broadly. The new administration also has issued, and is expected to continue relying upon, Executive Orders to address a wide range of policy areas, some of which may impact our business. Such political developments may require us to allocate significant time, resources, and expense to modifying our policies and procedures, processes, systems, and practices to ensure compliance or adapt to the new regulatory climate, particularly to the extent such actions are subject to protracted and uncertain legal challenges. To the extent changes in the political environment have a negative impact on us or on our markets, our business, results of operation, and financial condition could be materially and adversely affected in the future.

Adverse findings in post-marketing vigilance or regulatory audits could subject us to suspension or withdrawal of our certificates of conformity, mandatory product recalls and significant legal liability, which could materially and adversely affect our business, financial condition, and results of operations.

In May 2020, Adagio Medical received a CE Mark from its notified body (a private organization designated by the competent authorities of the European Economic Area ("EEA"), to conduct conformity assessments and verify the conformity of manufacturers and their medical devices with the Essential Requirements of the EU Medical Devices Directive and the EU Medical Devices Regulations) for its Cryoablation Console, iCLAS Cryoablation Catheter, Shaped Stylets, and Esophageal Warming Balloon Catheter allowing the CE Mark to be affixed to such products permitting such products to be placed on the market within any state in the EEA and, through mutual recognition agreements, Switzerland (subject to certain localized registration and language requirements). In March 2024, Adagio Medical received an EC certificate of conformity for the VT Cryoablation System (vCLAS™ Catheter and updated Cryoablation Console) under the EU Medical Devices Regulation (i.e., European Union Regulation 2017/745). The updated Console is compatible with both iCLAS and vCLAS catheters. Manufacturers of medical devices in the EEA are required to implement post-marketing vigilance procedures with respect to their CE Marked medical devices in accordance with the rules governing the Medical Device Vigilance System provided for in European Commission's MDR Chapter VII. Such post-marketing vigilance procedures include surveillance of patient and user complaints and alleged incidents associated with the use of CE Marked medical devices. MDR Article 2(64) and (65) define incidents as any malfunction or deterioration in the characteristics and/or performance of a device made available on the market, including user error due to ergonomic features, as well as any inadequacy in information supplied by the manufacturer and any undesirable side-effects and serious incidents as any incident which, directly or indirectly, led, might lead to or might have led to (a) the death of a patient, or user or of other persons, (b) to the temporary or permanent serious deterioration in their state of health, or (c) serious public health threat. When a medical device is suspected to have a causal relationship with an incident that led or might have led to death of or the serious deterioration of the health of a patient, or user or of other person, its manufacturer or authorized representative in the EU must report it to the competent authority in whose territory the incident occurred. Serious incidents must be reported no later than 15 calendar days, and in some cases no later than 2 calendar days, after the manufacturer becomes aware of the incident. In addition to reporting the serious incidents, the manufacturer must investigate and take any corrective action required, including Field Safety Corrective Actions ("**FSCAs**"). For a reportable serious incident, the manufacturer's investigation is monitored by the competent authority, which may intervene, or initiate an independent investigation if considered appropriate. The required corrective action depends on the seriousness of the incident and varies from the issuance of advisory notices to the implementation of FSCAs or product recalls. FSCAs must be reported by the manufacturer or its authorized representative to the competent authorities of the countries affected by the FSCA. Customers and/or the end users of the medical device must also be notified. Incidents not requiring reporting to the competent authorities must be documented, reviewed, investigated and analyzed on a regular basis by the manufacturer to determine whether trending conclusions can be made concerning the safety or performance of the medical device and whether actions must be taken in relation to the continued marketing of medical devices currently on the market.

In May 2022, for example, Adagio Medical submitted a FSCA to the competent authorities relating to a serious adverse event that occurred in October 2021 during the U.S. pivotal IDE clinical study of the CE marked iCLAS™ Cryoablation System. The U.S. IDE clinical study was put on a voluntary hold during the investigation of the incident, even though the iCLAS™ Cryoablation Catheter remained commercially available in the EU during such investigation. The procedure was performed with a guiding sheath that Adagio Medical had not authorized for use with the Adagio iCLAS™ Cryoablation Catheter in the study. After the catheter successfully completed 20 freeze cycles, it was removed from the patient for post-mapping and was subsequently re-inserted into the patient without completing the functional test freeze. After re-insertion, the freeze application was initiated followed by the receipt of a console alert of a system error. The patient's heart rate declined rapidly and the presence of nitrogen in the left atrium was confirmed with intracardiac echocardiography. The patient subsequently died. After investigation, it was determined that the guiding sheath was damaged and therefore, severely compromised the Adagio iCLAS™ Cryoablation Catheter. During catheter removal, the force applied to retract the Adagio iCLAS™ Cryoablation Catheter caused its electrode band to cut into its freezing element and sever the two layers of high-pressure tubes containing the cryogen. This resulted in an external gas leak into the patient leading to air/gas embolism and death. The FSCA reported to the competent authorities described the corrective actions implemented by us including software and labeling update and retraining requirements, and the competent authorities accepted the corrective actions. The patient's death was also reported to the FDA.

We expect to incur ongoing costs to comply with these post-market vigilance obligations in EEA markets for so long as we continue to market and sell products in those markets. Moreover, any patient or user complaints and/or adverse events discovered during such post-market vigilance could subject us to suspension or withdrawal of our EC certificates of conformity or CE Mark, mandatory product recalls and significant legal liability, which would materially and adversely affect our business, financial condition and results of operation. In addition, a notified body or competent authority in an EEA country may perform post-marketing audits on our products and premises from time to time. Failure to comply with such requests in a timely manner, and any adverse findings in any such audit, could subject us to suspension or withdrawal of our EC certificates of conformity or CE Mark, mandatory product recalls and significant legal liability, which could materially and adversely affect our business, financial condition and results of operations.

We may be subject to enforcement action if we engage in marketing of our products pursuant to improper regulatory classifications in the EU, including suspension or withdrawal of our certificates of conformity, mandatory product recalls and significant legal liability, fines, penalties, and injunctions, which could materially and adversely affect our business, financial condition and results of operations.

To place a medical device on the market in the EU, a manufacturer must have a valid CE mark for the device, issued after the completion of a conformity assessment. For class I, II, or III medical devices, a third-party notified body must be involved in the conformity assessment procedure and issue an EC Certificate. For Class I devices, the manufacturer conducts its own conformity assessment and self-certifies the devices; the notified body is not involved. The components of the iCLAS and VT Cryoablation systems as placed on the market in the EU are individually classified and fall into different classifications. If an EU competent authority determines that an Adagio medical device is marketed under improper classification and/or improper or invalid EC Certificate, the authority may initiate enforcement action, such as ordering us to recall and withdraw the respective medical device from the market and/or pursue criminal penalties under national member state law.

We are currently subject to, and may in the future become subject to additional, U.S. federal and state laws and regulations imposing obligations on how we collect, store and process personal information. Our actual or perceived failure to comply with such obligations could harm our business. Ensuring compliance with such laws could also impair our efforts to maintain and expand our future customer base and thereby decrease our revenue.

In the ordinary course of our business, we currently, and, in the future, will collect, store, transfer, use or process sensitive data, including personally identifiable information of employees, and intellectual property and proprietary business information owned or controlled by us and other parties. The secure processing, storage, maintenance, and transmission of this critical information are vital to our operations and business strategy. We are, and may increasingly become, subject to various laws and regulations, as well as contractual obligations, relating to data privacy and security in the jurisdictions in which we operate. The regulatory environment related to data privacy and security is increasingly rigorous, with new and constantly changing requirements applicable to our business, and enforcement practices are likely to remain uncertain for the foreseeable future. These laws and regulations may be interpreted and applied differently over time and from jurisdiction to jurisdiction, and it is possible that they will be interpreted and applied in ways that may have a material adverse effect on our business, financial condition, results of operations and prospects.

In the United States, various federal and state regulators, including governmental agencies like the Federal Trade Commission, have adopted, or are considering adopting, laws and regulations concerning personal information and data security. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to personal information than federal, international or other state laws, and such laws may differ from each other, all of which may complicate compliance efforts. For example, the California Consumer Privacy Act (the "CCPA"), which increases privacy rights for California residents and imposes obligations on companies that process their personal information, came into effect on January 1, 2020. Among other things, the CCPA requires covered companies to provide new disclosures to California consumers and provide such consumers new data protection and privacy rights, including the ability to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal information. This private right of action may increase the likelihood of, and risks associated with, data breach litigation. It is possible that these consumer, health-related and data protection laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, laws in all 50 U.S. states require businesses to provide notice to consumers whose personal information has been disclosed as a result of a data breach. State laws are changing rapidly and there is discussion in the U.S. Congress of a new comprehensive federal data privacy law to which we would become subject if it is enacted.

Furthermore, regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), establish privacy and security standards that limit the use and disclosure of individually identifiable health information (known as "protected health information") and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can require complex factual and statistical analyses and may be subject to changing interpretation. Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breaches due to employee error, malfeasance or other malicious or inadvertent disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, manipulated, publicly disclosed, lost or stolen. Any such access, breach or other loss of information could result in legal claims or proceedings, and liability under federal or state laws that protect the privacy of personal information, such as the HIPAA, the Health Information Technology for Economic and Clinical Health Act (HITECH), and regulatory penalties. Notice of breaches must be made to affected individuals, the Secretary of the Department of Health and Human Services, and for extensive breaches, notice may need to be made to the media or State Attorneys General. Such a notice could harm our reputation and our ability to compete.

We are in the process of evaluating compliance needs but do not currently have in place formal policies and procedures related to the storage, collection and processing of information, and has not conducted any internal or external data privacy audits, to ensure our compliance with all applicable data protection laws and regulations. Additionally, we do not currently have policies and procedures in place for assessing our third-party vendors' compliance with applicable data protection laws and regulations. All of these evolving compliance and operational requirements impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants, which are likely to increase over time. In addition, such requirements may require us to modify our data processing practices and policies, distract management or divert resources from other initiatives and projects, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Any failure or perceived failure by us or our third-party vendors, collaborators, contractors and consultants to comply with any applicable federal, state or similar foreign laws and regulations relating to data privacy and security, or could result in damage to our reputation, as well as proceedings or litigation by governmental agencies or other third parties, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, sanctions, awards, penalties or judgments, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We are or will be subject to anti-corruption and anti-bribery and anti-money laundering and similar laws, and non-compliance with such laws can subject us to administrative, civil and criminal fines and penalties, collateral consequences, remedial measures and legal expenses, all of which could adversely affect our reputation, business, financial condition and results of operations.

We are or will be subject to anti-corruption and anti-bribery and anti-money laundering and similar laws, which prohibit corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity.

This includes the FCPA, which prohibits corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. We are also subject to the UK Anti-Bribery Act, which prohibits both domestic and international bribery, as well as bribery across both public and private sectors.

As we expand our commercial operations outside of the United States, we will need to comply with non-U.S. regulatory requirements, will need to expand business relationships with various third parties, and will interact more frequently with foreign officials, including regulatory authorities. Expanded programs to maintain compliance with such laws will be costly and may not be effective. Any interactions with any such parties or individuals where compensation is provided that are found to be in violation of such laws could result in substantial fines and penalties and could materially harm our business. Furthermore, any finding of a violation under one country's laws may increase the likelihood that we will be prosecuted and be found to have violated another country's laws. If our business practices outside the United States are found to be in violation of the FCPA, UK Anti-Bribery Act or other similar laws, we may be subject to significant civil and criminal penalties which could have a material adverse effect on our financial condition and results of operations.

If we expand our developments and commercialization activities outside of the United States, we will be subject to an increased risk of inadvertently conducting activities in a manner that violates the FCPA and similar laws. If that occurs, we may be subject to civil or criminal penalties, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

If we choose to establish and expand our commercial operations outside of the United States, we will need to comply with non-U.S. regulatory requirements, will need to establish and expand business relationships with various third parties, and we will interact more frequently with foreign officials, including regulatory authorities. Expanded programs to maintain compliance with such laws will be costly and may not be effective. Any interactions with any such parties or individuals where compensation is provided that are found to be in violation of such laws could result in substantial fines and penalties and could materially harm our business. Furthermore, any finding of a violation under one country's laws may increase the likelihood that we will be prosecuted and be found to have violated another country's laws. If our business practices outside the United States are found to be in violation of the FCPA or other similar laws, we may be subject to significant civil and criminal penalties, which could have a material adverse effect on our financial condition and results of operations.

Our employees, independent contractors, consultants, commercial partners, distributors 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 employees, independent contractors, consultants, commercial partners, distributors, and vendors may engage in misconduct or other improper activities. Misconduct by these parties could include failures to comply with applicable FDA regulations, provide accurate information to the FDA, comply with federal and state health care fraud and abuse laws and regulations, accurately report financial information or data or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by these parties, and the precautions we take to detect and prevent such misconduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. If any of the physicians or other health care providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded health care programs.

Risks Related to Litigation and Regulation

We are subject to extensive laws and regulations of the United States and foreign regulatory agencies that could impose substantial costs, legal prohibitions and restrictions, or unfavorable changes upon our operations, and any failure to comply with these laws and regulations, including as they evolve, could delay or entirely prevent the commercialization of our products or result in litigation and substantially harm our business and results of operations.

We are and will be subject to environmental, manufacturing, and health and safety laws and regulations at numerous jurisdictional levels, including laws relating to the use, handling, storage, recycling, disposal and human exposure to hazardous materials and with respect to constructing, expanding and maintaining our facilities. Any violations of these laws may result in substantial fines and penalties, remediation costs, third party damages, or a suspension or cessation of our operations. The costs of compliance, including remediating contamination, if any, is found on our properties, or any related changes to our operations, may be significant. We may also face unexpected delays in obtaining permits and approvals required by such laws in connection with our manufacturing facilities, which would hinder our ability to commence or continue our commercial manufacturing operations. Such costs and delays may adversely impact our business prospects and results of operations.

In addition, the medical device industry is regulated extensively by governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies and authorities, such as the EU legislative bodies and the EEA Member State Competent Authorities. The FDA and foreign regulatory agencies regulate, among other things, with respect to medical devices: design, development, manufacturing and release; laboratory, preclinical and clinical testing; labeling, packaging, content and language of instructions for use and storage; product safety and effectiveness; establishment registration and device listing; marketing, sales and distribution; regulatory authorization, including but not limited to pre-market clearance and approval; service operations; product traceability and record keeping procedures; advertising and promotion; recalls and field safety corrective actions; post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; post-market studies; and product import and export. Any failures to comply with applicable laws, regulations and standards could result in significant expenses, delays, fines, or other sanctions. The laws and regulations to which we are subject are complex and change from time to time. Legal or regulatory changes, and FDA's interpretation of regulations and guidance, could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. The FDA and foreign regulatory agencies enforce these regulatory requirements through, among other means, periodic announced and unannounced inspections. We do not know whether we will be found compliant in connection with any future FDA inspections. Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as: warning letters; fines; injunctions; civil penalties; termination of distribution; recalls or seizures of products; delays in the introduction of products into the market; total or partial suspension of production; refusal to grant future clearances or approvals; withdrawals or suspensions of current approvals, resulting in prohibitions on sales of our products; and in the most serious cases, criminal penalties. Regulatory enforcement or inquiries, or other increased scrutiny of us, could dissuade physicians from using our products and adversely affect our reputation and the perceived safety and effectiveness of our products.

We also expect to become subject to laws and regulations applicable to the supply, manufacture, import, sale, and service of our products, including in those countries and markets we intend to enter in the future. Compliance with such regulations will require additional time, effort and expense to ensure regulatory compliance in those countries. There can be no assurance that we will be able to achieve foreign regulatory compliance in a timely manner and at our expected cost, or at all, and the costs of achieving international regulatory compliance or the failure to achieve international regulatory compliance could harm our business, prospects, results of operations and financial condition.

We are subject to risks relating to disputes and other legal proceedings, product liability lawsuits, that may be time consuming and costly.

Our business exposes us to the risk of product liability claims that are inherent in the design, development, testing, manufacture and marketing of medical devices. This risk exists even if a device or product is cleared or approved for commercial sale or testing by FDA or other foreign regulators and manufactured in facilities registered with and regulated by FDA or an applicable foreign regulatory authority. Any manufacturing or design defects, misuse (including, but not limited to, inadequate sterilization or product cooling) by trained medical professionals or others, or abuse associated with our products could result in patient injury or death. The medical device industry has historically been subject to extensive litigation over product liability claims, and we cannot offer any assurance that we will not face product liability suits.

In addition, an injury that is caused by the activities of our suppliers, such as those who provide us with components and raw materials, or hired medical professional field specialists, such as third-party hospitals and medical professionals carrying out field tests, may be the basis for a claim against us. Product liability or wrongful death claims may be brought against us by patients, health care providers or others coming into contact with, or providing services using, our products. If we cannot successfully defend ourselves against these or similar claims, or if we or our suppliers have inadequate product liability insurance, we may incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our brand and/or business reputation;
- costly litigation;
- distraction of management's attention from our primary business;
- loss of revenue;
- the inability to commercialize our products;
- decreased demand for our products;
- product recall or withdrawal from the market;
- withdrawal of clinical trial participants; and
- substantial monetary awards to patients or other claimants.

While we may attempt to manage our product liability exposure and other related legal liabilities by proactively recalling or withdrawing from the market any defective products, any recall or market withdrawal of our products may delay the supply of those products to our customers and may impact our reputation. We can provide no assurance that we will be successful in initiating appropriate recall or market withdrawal efforts, or adequate medical training regarding the use of our devices, that may be required in the future or that these efforts will have the intended effect of preventing product malfunctions or wrongful use and the accompanying product liability that may result. Any such recalls and market withdrawals may also be used by our competitors to harm our reputation for safety or be perceived by patients as a safety risk when considering the use of our products, either of which could have an adverse effect on our business, financial condition and results of operations.

Our lack of a trade compliance program leaves certain regulatory trade risk inherent in international business unmitigated. If we fail to comply with applicable international trade and sanctions regulations, we may become subject to regulatory investigations, penalties, and fines. A trade compliance program including a screening process for customers, independent contractors, and other third parties would help avoid violations, and if a violation occurred, having a trade compliance program is often a mitigating factor in determining penalties.

We have business activities and contracts with customers, independent contractors, vendors/suppliers, or other third parties in North America and internationally. However, we do not have any policies related to trade controls, including export and import controls, economic sanctions, anti-boycott requirements, and regulations, or anti-bribery and anti-corruption laws. We also do not have any dedicated international trade or sanctions compliance personnel or process for monitoring compliance with the international trade-related legal and regulatory obligations.

Risks Related to Financing Transactions

We are subject to financing risks. There are no guarantees that we can meet our financing needs for our operations and future investments at a reasonable cost or at all.

Our ability to generate cash is essential for the funding of our operations and the servicing of our debt. If existing cash balances together with the borrowing capacity under our credit facilities were not sufficient to make future investments, make acquisitions or provide needed working capital, we may require financing from other sources. Our ability to obtain such additional financing in the future will depend on a number of factors including prevailing capital market conditions, conditions in the industries in which we operate, our credit rating, our operating results and creditworthiness, and the purpose for such financing. These factors may affect our ability to arrange additional financing (including any additional financing) on terms that are acceptable to us. If additional funds are not available on acceptable terms, we may not be able to make future investments, take advantage of acquisitions or pursue other opportunities.

There are risks associated with our convertible notes that could adversely affect our business and financial condition.

We have an aggregate principal amount of $20,000,000 of outstanding indebtedness under the Convertible Securities Notes, (as defined below) which have a maturity of April 30, 2028. The Convertible Securities Notes accrue interest at a rate of 13% per annum, which is due quarterly and, at our election, either payable-in-kind (in which case, such interest will accrue and remain unpaid until maturity) or payable in cash. Further, the Convertible Securities Notes are, at the option of the holders of the Convertible Securities Notes (subject to certain conditions), convertible into shares of common stock at a rate of $10.00 per share, each subject to adjustment in accordance with the terms and conditions of the Convertible Securities Notes.

The Convertible Securities Notes provide for certain customary events of default, including, among others, payment defaults (subject to customary grace for interest and fees), voluntary or involuntary bankruptcy, material misrepresentations, covenants breaches (subject to grace in certain instances), material judgements and material cross-defaults to other indebtedness. The Convertible Securities Notes also include certain customary affirmative and negative covenants, including, among others, limitations on incurring additional indebtedness, the creation of additional liens on our assets, and entering into investments, in each case subject to customary exceptions, as well as a minimum liquidity requirement and an asset sale mandatory prepayment requirement, subject to customary reinvestment rights. In addition, a Change of Control, as defined in the Convertible Securities Notes, includes, among others, certain mergers, asset sales, tender offers, business combinations and reorganizations, which would give the holders of the Convertible Securities Notes the right to redeem the outstanding indebtedness in cash.

Our ability to remain in compliance with the covenants under the Convertible Securities Notes depends on, among other things, our operating performance, competitive developments and financial market conditions, all of which are significantly affected by financial, business, economic and other factors, many of which we are not able to control.

The Convertible Notes could have other important consequences, including the following:

- the limitations imposed by the Convertible Notes on our ability to incur additional debt and to take other actions might significantly impair our ability to obtain other financing. This could have serious consequences to our financial condition and results of operations and could cause us to become bankrupt or insolvent;
- we may need to use a substantial portion of our cash flow from operations to repay the principal and accrued and unpaid interest on the Convertible Notes if an event of default occurs prior to maturity, which would reduce funds available to us to fund our business plan and other general corporate purposes;
- we may be unable to refinance the Convertible Notes (at all or on terms that are satisfactory) or to otherwise repay the Convertible Notes at maturity, including any unpaid and accrued interest therein, and we may be unable to obtain additional financing for our business plan, working capital, capital expenditures, acquisitions or general corporate purposes. Any refinancing of the Convertible Note could be at significantly higher interest rates, incur significant transaction fees or include more restrictive covenants;
- we may be unable to comply with the covenants in the Convertible Notes due to business developments or financial market conditions, which could result in an event of default that, if not cured or waived, gives the holders of the Convertible Notes the right to accelerate the Convertible Notes or otherwise exercise any other remedies available to them under applicable law. Among those remedies, the holders would have the right to seize any of our assets pledged to the holders of the Convertible Notes and/or to convert the Convertible Notes into shares of common stock. An event of default could cause a significant decline in the value of the shares of common stock and may force us into bankruptcy or liquidation;
- The conversion of the Convertible Notes into shares of common stock could result in significant dilution to our existing stockholders and cause the market price of the common stock to decline; and
- we may be more vulnerable to an economic downturn or recession and adverse developments in our business given our lack of revenues as a development stage company.

There can be no assurance that we will be able to manage any of the risks described above successfully. Further, capital and credit markets, which have been disrupted by macroeconomic pressures, have experienced increased volatility. As a result, access to additional financing may be challenging and is largely dependent upon evolving market conditions and other factors, which could materially impact our business, results of operations, financial condition and prospects.

We are subject to risks relating to increased interest rates and any adverse developments in the credit markets.

Adverse developments in the credit markets, including reduced liquidity or rising interest rates, could reduce the availability of funding for our projects. Volatility in the credit and equity markets could reduce our ability to raise additional capital through equity, equity-linked or debt financings, which could negatively impact our short-term and long-term liquidity and our ability to operate in accordance with our operating plan, or at all, or our ability to fund our growth. Additionally, our results of operations could be adversely affected by general conditions in the global economy and financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for our products and technologies, and our ability to raise additional capital when needed on favorable terms, if at all. In addition, increased interest rates could strain our customers' budgets or cause delays in their payments to us. Any of the foregoing could harm our business, and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our ability to raise capital, business, results of operations and financial condition.

Risks Related to Tax

Our ability to use net operating loss ("NOL") carryforwards and other tax attributes may be limited as a result of the Business Combination or other ownership changes.

We have incurred NOLs during our history that have yet to be utilized. To the extent that we continue to generate NOLs, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire, if at all (depending on the tax year in which such losses were incurred). Under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended (the "Code") and similar provisions of state and local law, U.S. federal, state, and local NOL carryforwards and other tax attributes (e.g., tax credits) may become subject to an annual limitation in the event of certain cumulative changes in our ownership. An "ownership change" pursuant to Section 382 of the Code generally occurs if one or more stockholders or groups of stockholders who own at least 5% of the Company's stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state or local tax laws.

Our ability and/or the ability of the U.S. federal consolidated group of which we are a member to utilize NOL carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes, including potential changes arising as a result of the Business Combination or other transactions. Similar rules may apply under state tax laws. We have not yet determined the amount of the cumulative change in our ownership resulting from the Business Combination or other transactions, or any resulting limitations on our ability to utilize our NOL carryforwards and other tax attributes. In addition, under current U.S. federal income tax laws, NOLs arising in future tax years may be utilized to offset no more than 80% of the taxable income annually. If we (or the consolidated group of which we are a member) earn taxable income, such limitations could result in increased future income tax liability to us and our future cash flows could be adversely affected.

A new 1% U.S. federal excise tax could be imposed on us in connection with redemptions by us of our stock.

The Inflation Reduction Act provides for, among other things, a U.S. federal 1% excise tax on certain repurchases (including certain redemptions) of stock by publicly traded U.S. corporations and certain U.S. subsidiaries of publicly traded non-U.S. corporations (each, a "covered corporation") that occur after December 31, 2022.

The excise tax is imposed on the repurchasing corporation itself, not its stockholders from which shares are repurchased.

Because we are a Delaware corporation and our securities trade on Nasdaq, we are a "covered corporation." Accordingly, any redemptions by us may be subject to the excise tax. However, certain exceptions apply to the excise tax. Whether and to what extent we would be subject to the excise tax on a redemption of our stock would depend on a number of factors. As noted above, the excise tax would be payable by us, and not by the redeeming holder. Any redemptions by us may be subject to the excise tax. Whether and to what extent we would be subject to the excise tax on a redemption of our stock would depend on a number of factors. As noted above, the excise tax would be payable by us, and not by the redeeming holder.

Unanticipated tax laws or any changes in tax rates or in the application of the existing tax laws to us may adversely impact our results of operations.

We operate and are subject to income and other taxes in the United States and a growing number of other jurisdictions throughout the world. Existing domestic and foreign tax laws, statutes, rules, regulations, or ordinances could be interpreted, changed, modified, or applied adversely to us (possibly with retroactive effect), which could require us to pay additional tax amounts, fines or penalties, surcharges, and interest charges for past amounts due, the amounts and timing of which are difficult to discern. Existing tax laws, statutes, rules, regulations, or ordinances could also be interpreted, changed, modified, or applied adversely to our customers (possibly with retroactive effect) and, if our customers are required to pay additional surcharges, it could adversely affect demand for our products. Furthermore, changes to federal, state, local, or international tax laws on income, sales, use, import/export, indirect, or other tax laws, statutes, rules, regulations, or ordinances on multinational corporations continue to be considered by the United States and other countries where we currently operate or plans to operate. These contemplated tax initiatives, if finalized and adopted by countries or subnational jurisdictions, and the other tax issues described above may materially and adversely impact our operating activities, effective tax rate, deferred tax assets, operating income, and cash flows.

In particular, the U.S. government may enact significant changes to the taxation of business entities including, among others, an increase in the corporate income tax rate, the imposition of minimum taxes or surtaxes on certain types of income, significant changes to the taxation of income derived from international operations, and an addition of further limitations on the deductibility of business interest. Additionally, the Organization for Economic Cooperation and Development's ("OECD") Base Erosion and Profit Shifting ("BEPS") project has resulted in considerable new reporting obligations worldwide as OECD member countries have implemented its guidance and includes a global minimum tax of 15%. The OECD continues to publish guidance pursuant to the BEPS and other projects which, if adopted by member countries, may increase our tax obligations and affect our tax positions in many of the countries in which we do business. Furthermore, our effective tax rate may also vary significantly from period to period, including due to changes in the relative proportions of revenues and income before taxes in the various jurisdictions in which we operate that have differing statutory tax rates, changes in overall levels of pretax earnings, the future levels of tax benefits of stock-based compensation, and settlement of income tax audits.

Risks Related to Ownership of Our Securities

The Perceptive PIPE Investor has control over key decision making as a result of its control of a majority of the voting power of our outstanding common stock.

The Perceptive PIPE Investor is able to exercise voting rights with respect to over 66% of the voting power of our common stock. For so long as the Perceptive PIPE Investor continues to beneficially own at least approximately 66% of the issued and outstanding shares of common stock, the Perceptive PIPE Investor will continue to control the outcome of matters submitted to stockholders of the Company for approval. This concentrated control will limit or preclude your ability to influence corporate matters for the foreseeable future.

This concentrated control could delay, defer, or prevent a change of control, merger, consolidation, or sale of all or substantially all of our assets that our other stockholders support, or conversely this concentrated control could result in the consummation of such a transaction that our other stockholders do not support. This concentrated control could also discourage a potential investor from acquiring our common stock and might harm the trading price of our common stock. As a stockholder, even a controlling stockholder, the Perceptive PIPE Investor is entitled to vote its shares in its own interests, which may not always be in the interests of our stockholders generally.

We may use our financial resources in ways with which you do not agree and in ways that may not yield a favorable return.

Our management has broad discretion over the use of our financial resources, including the net proceeds from all of our equity financings. Stockholders may not deem such uses desirable. Our use of our financial resources may vary substantially from our currently planned uses. We cannot assure you that we will apply such proceeds effectively or that we will invest such proceeds in a manner that will yield a favorable return or any return at all.

We are an "emerging growth company" and "smaller reporting company" within the meaning of the Securities Act and if it takes advantage of certain exemptions from disclosure requirements available to emerging growth companies, it could make our securities less attractive to investors and may make it more difficult to compare our performance to the performance of other public companies.

We are an "emerging growth company" as defined in Section 2(a)(19) of the Securities Act, as modified by the JOBS Act. As such, we are eligible for and intends to take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies for as long as it continues to be an emerging growth company, including, but not limited to, (a) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (b) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (c) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, our stockholders may not have access to certain information they may deem important. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which the market value of shares of common stock that are held by non-affiliates exceeds $700 million as of June 30 of that fiscal year, (ii) the last day of the fiscal year in which it has total annual gross revenue of $1.235 billion or more during such fiscal year (as indexed for inflation), (iii) the date on which it has issued more than $1 billion in non-convertible debt in the prior three-year period or (iv) December 31, 2026, which is the last day of the fiscal year following the fifth anniversary of the date of the first sale of ordinary shares in the ARYA initial public offering. We cannot predict whether investors will find our securities less attractive because it will rely on these exemptions. If some investors find our securities less attractive as a result of its reliance on these exemptions, the trading prices of our securities may be lower than they otherwise would be, there may be a less active trading market for our securities and the trading prices of our securities may be more volatile.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. We have elected not to opt out of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of our financial statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

As an emerging growth company, we may also take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to obtain an assessment of the effectiveness of our internal controls over financial reporting from our independent registered public accounting firm pursuant to Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our shares of common stock less attractive because we will rely on these exemptions. If some investors find our shares of common stock less attractive as a result, there may be a less active market for our shares of common stock and our share price may be more volatile.

Additionally, we qualify as a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We expect that we will remain a smaller reporting company until the last day of any fiscal year for so long as either (a) the market value of the common stock held by non-affiliates does not equal or exceed $250 million as of the end of that year's second quarter, or (b) our annual revenues did not equal or exceed $100 million during such completed fiscal year and the market value of the common stock held by non-affiliates did not equal or exceed $700 million as of the end of that year's second quarter. To the extent we take advantage of such reduced disclosure obligations, it may also make comparison of our financial statements with other public companies difficult or impossible.

Our stock price may be volatile and may decline regardless of its operating performance.

The market price of our common stock may fluctuate significantly in response to numerous factors and may continue to fluctuate for these and other reasons, many of which are beyond our control, including, but not limited to:

- actual or anticipated fluctuations in our revenue and results of operations;
- any financial projections we may provide to the public in the future, any changes in these projections or its failure to meet these projections;
- failure of securities analysts to initiate and maintain our coverage, changes in financial estimates or ratings by any securities analysts who follow us or its failure to meet these estimates or the expectations of investors;
- announcements by us or our competitors of significant technical innovations, acquisitions, strategic partnerships, joint ventures, results of operations or capital commitments;
- changes in operating performance and stock market valuations of other life sciences companies generally, or those in the biotechnology industry in particular;
- price and volume fluctuations in the overall stock market, including as a result of trends in the economy as a whole;
- trading volume of our common stock;
- the inclusion, exclusion or removal of our common stock from any indices;
- changes in the Board or management;
- transactions in common stock by directors, officers, affiliates and other major investors;
- lawsuits threatened or filed against us;
- changes in laws or regulations applicable to our business;
- changes in our capital structure, such as future issuances of debt or equity securities;
- short sales, hedging and other derivative transactions involving our capital stock;
- general economic conditions in the United States and other markets in which we operate;
  pandemics or other public health crises, including, but not limited to;
- other events or factors, including those resulting from war, incidents of terrorism or responses to these events; and
- the other factors described in this "*Risk Factors*" section.

The stock market has recently experienced extreme price and volume fluctuations. The market prices of securities of companies have experienced fluctuations that often have been unrelated or disproportionate to their operating results. In the past, stockholders have sometimes instituted securities class action litigation against companies following periods of volatility in the market price of their securities. Any similar litigation against us could result in substantial costs, divert management's attention and resources and harm its business, financial condition and results of operations.

We may be unable to maintain the listing of our securities on Nasdaq in the future.

Our common stock is currently listed on the Nasdaq. However, we cannot guarantee that our securities will continue to be listed on Nasdaq. If we fail to meet the requirements of the applicable listing rules, such failure may result in a suspension of the trading of our shares or delisting in the future. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our securities to become listed again, stabilize the market price or improve the liquidity of our securities, prevent our securities from dropping below the minimum share price requirement or prevent future non-compliance with the listing requirements. This may further result in legal or regulatory proceedings, fines and other penalties, legal liability for us, the inability for our stockholders to trade their shares and negatively impact our share price, reputation, operations and financial position, as well as our ability to conduct future fundraising activities. If Nasdaq delists our securities and we are not able to list our securities on another national securities exchange, we expect that our securities could be quoted on an over-the-counter market. If this were to occur, we could face significant material adverse consequences, including but not limited to:

- a limited availability of market quotations for our securities;
- reduced liquidity for our securities;
- a limited amount of news and analyst coverage for the Company; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

An active trading market for our common stock may not be sustained.

Our common stock is listed on The Nasdaq Capital Market under the symbol "ADGM" and trades on that market. We cannot assure you that an active trading market for our common stock will be sustained. Accordingly, we cannot assure you of the liquidity of any trading market, your ability to sell your shares of our common stock when desired or the prices that you may obtain for your shares.

Future sales of shares by existing stockholders could cause our stock price to decline.

If our existing stockholders sell or indicate an intention to sell substantial amounts of common stock in the public market, the trading price of the common stock could decline. All the shares of common stock subject to stock options outstanding and reserved for issuance under its equity incentive plans are expected to be registered on Form S-8 under the Securities Act and such shares are eligible for sale in the public markets, subject to Rule 144 under the Securities Act limitations applicable to affiliates. If these additional shares are sold, or if it is perceived that they will be sold in the public market, the trading price of the common stock could decline.

Although the ARYA Sponsor (as defined herein) and certain selling stockholders will be subject to restrictions regarding the transfer of shares of common stock held by them, as described elsewhere in this Annual Report, these shares may be sold after the expiration of their respective lock-ups. As restrictions on resale end and the registration statements for the resale of our securities are available for use, the market price of common stock could decline if the holders of currently restricted shares sell them or are perceived by the market as intending to sell them.

We may issue additional shares of common stock or other equity securities without your approval, which would dilute your ownership interests and may depress the market price of the common stock.

We will have the ability to initially issue such shares of common stock pursuant to our equity incentive plans and employee stock purchase plan. We may also issue additional shares of common stock or other equity securities of equal or senior rank in the future in connection with, among other things, future acquisitions or repayment of outstanding indebtedness, without stockholder approval, in a number of circumstances.

Our issuance of additional shares of common stock or other equity securities of equal or senior rank could, without limitation, have the following effects:

- our existing stockholders' proportionate ownership interest in us will decrease;
- the amount of cash available per share, including for payment of dividends (if any) in the future, may decrease;
- the relative voting strength of each previously outstanding share of common stock may be diminished; and
- the market price of our shares of common stock may decline.

If securities or industry analysts either do not publish research about us or publish inaccurate or unfavorable research about us, our business, or its market, or if they change their recommendations regarding common stock adversely, the trading price or trading volume of the common stock could decline.

The trading market for common stock is influenced in part by the research and reports that securities or industry analysts may publish about us, our business, market, or competitors. If one or more of the analysts initiate research with an unfavorable rating or downgrade the common stock, provide a more favorable recommendation about our competitors, or publish inaccurate or unfavorable research about its business, the trading price of the common stock would likely decline. In addition, we currently expect that securities research analysts will establish and publish their own periodic projections for its business. These projections may vary widely and may not accurately predict the results we actually achieve. Our stock price may decline if the actual results do not match the projections of these securities research analysts. While we expect research analyst coverage, if no analysts commence coverage, the trading price and volume for the common stock could be adversely affected. If any analyst who may cover us were to cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the trading price or trading volume of common stock to decline.

Delaware law and provisions in our Charter and Bylaws could make a merger, tender offer, or proxy contest difficult, thereby depressing the trading price of its common stock.

Our Charter and Bylaws contain provisions that could depress the trading price of common stock by acting to discourage, delay, or prevent a change of control of us or changes in our management that our stockholders may deem advantageous.

These provisions include, without limitation, the following:

- a classified Board so that not all members of the Board are elected at one time;
- the right of the Board to establish the number of directors and fill any vacancies and newly created directorships;
- director removal by stockholders solely for cause and with the affirmative vote of at least two-thirds (2/3) of the voting power of our then-outstanding shares of capital stock entitled to vote generally in the election of directors;
- "blank check" preferred stock that the Board could use to implement a stockholder rights plan;
- the right of the Board to issue our authorized but unissued common stock and preferred stock without stockholder approval;
- no ability of our stockholders to call special meetings of stockholders;
- no right of our stockholders to act by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- limitations on the liability of and the provision of indemnification to, our director and officers;
- the right of the Board to make, alter, or repeal the Bylaws; and
- advance notice requirements for nominations for election to the Board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

Any provision of our Charter or Bylaws that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of common stock and could also affect the price that some investors are willing to pay for common stock.

Our Charter provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our Charter provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our Charter or Bylaws or any action asserting a claim against us that is governed by the internal affairs doctrine. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees and may discourage these types of lawsuits. This provision would not apply to claims brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Our Charter provides further that, to the fullest extent permitted by law, the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. However, Section 22 of the Securities Act provides that federal and state courts have concurrent jurisdiction over lawsuits brought under the Securities Act or the rules and regulations thereunder. To the extent the exclusive forum provision restricts the courts in which claims arising under the Securities Act may be brought, there is uncertainty as to whether a court would enforce such a provision. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find the exclusive-forum provision contained in our Charter to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm its business.

We do not intend to pay dividends for the foreseeable future.

We currently intend to retain any future earnings to finance the operation and expansion of its business and we do not expect to declare or pay any dividends in the foreseeable future. Moreover, the terms of any revolving credit facility into which we or any of our subsidiaries enter may restrict our ability to pay dividends and any additional debt we or any of our subsidiaries may incur in the future may include similar restrictions. As a result, stockholders must rely on sales of their common stock after price appreciation as the only way to realize any future gains on their investment.

We will incur increased costs and obligations as a result of being a public company.

As a publicly traded company, we will incur significant legal, accounting and other expenses that we were not required to incur in the recent past, particularly after we are no longer an "emerging growth company" as defined under the JOBS Act. In addition, new and changing laws, regulations and standards relating to corporate governance and public disclosure, including the Dodd Frank Wall Street Reform and Consumer Protection Act and the rules and regulations promulgated and to be promulgated thereunder, as well as under the Sarbanes-Oxley Act, the JOBS Act and the rules and regulations of the SEC and national securities exchanges have created uncertainty for public companies and increased the costs and the time that the Board and management must devote to complying with these rules and regulations. We expect these rules and regulations to increase our legal and financial compliance costs and lead to a diversion of management time and attention from revenue generating activities.

Furthermore, the need to establish the corporate infrastructure demanded of a public company may divert management's attention from implementing our growth strategy, which could prevent us from improving our business, results of operations and financial condition. We have made and will continue to make, changes to our internal controls and procedures for financial reporting and accounting systems to meet our reporting obligations as a publicly traded company. However, the measures we take may not be sufficient to satisfy our obligations as a publicly traded company.

The requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain qualified board members.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and any rules promulgated thereunder, as well as the rules of the national stock exchange under which the Company's shares are listed. The requirements of these rules and regulations increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and increase demand on our systems and resources. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal controls for financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight are required and, as a result, management's attention may be diverted from other business concerns. These rules and regulations can also make it more difficult for us to attract and retain qualified independent members of the Board. Additionally, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance. We may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. The increased costs of compliance with public company reporting requirements and our potential failure to satisfy these requirements could have a material adverse effect on our operations, business, financial condition or results of operations.

If we fail to establish and maintain proper and effective internal control over financial reporting, as a public company, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of the common stock may decline.

Pursuant to Section 404 of the Sarbanes-Oxley Act, the report by management on internal control over financial reporting will be on our financial reporting and internal controls (as accounting acquirer) and, when we are no longer an emerging growth company, an attestation of the independent registered public accounting firm may also be required. The rules governing the standards that must be met for management to assess internal control over financial reporting are complex and require significant documentation, testing and possible remediation. We have not historically had to comply with all of these rules and to comply with the Sarbanes-Oxley Act, the requirements of being a reporting company under the Exchange Act and any complex accounting rules in the future, we may need to upgrade our legacy information technology systems, implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff.

If we are unable to hire the additional accounting and finance staff necessary to comply with these requirements, we may need to retain additional outside consultants. If we or, if required, our independent registered public accounting firm, are unable to conclude that our internal controls over financial reporting are effective, investors may lose confidence in our financial reporting, which could negatively impact the price of our securities.

We have identified material weaknesses in our internal controls over financial reporting. If we are unable to remediate these material weaknesses, if management identifies additional material weaknesses in the future or if we otherwise fail to maintain effective internal controls over financial reporting, we may not be able to accurately or timely report our financial position or results of operations, which may adversely affect our business and stock price or cause our access to the capital markets to be impaired.

We have identified material weaknesses in our internal controls over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal controls over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The Company's management identified a material weakness related to the inadequate design and operation of management's review controls over valuation reports prepared by third-party specialists in conjunction with the accounting for certain debt and equity instruments, resulting in the conclusion that the Company's internal control over financial reporting and the Company's disclosure controls and procedures were not effective as of December 31, 2023, and in a material misstatement to our financial statements. Accordingly, we determined that these control deficiencies constitute material weaknesses.

We are in the early stages of designing and implementing a plan to remediate the material weaknesses identified. Our plan for remediation includes: 1) additional review of third-party valuation reports utilized in the accounting for certain debt and equity instruments; 2) additional review of the manual journal entries based on externally generated reports and agreements with regard to accounting issues in certain debt and equity instruments; and 3) enhanced oversight controls on the work performed by third-party specialists. We cannot assure you that these measures will significantly improve or remediate the material weaknesses described above. The implementation of these remediation measures is in the early stages and will require validation and testing of the design and operating effectiveness of our internal controls over a sustained period of financial reporting cycles and, as a result, the timing of when we will be able to fully remediate the material weaknesses is uncertain. If the steps we take do not remediate the material weaknesses in a timely manner, there could be a reasonable possibility that these control deficiencies or others may result in another material misstatement of our annual or interim financial statements that would not be prevented or detected on a timely basis. This, in turn, could jeopardize our ability to comply with our reporting obligations, limit our ability to access the capital markets and adversely impact our stock price.

We and our independent registered public accounting firm were not required to perform an evaluation of our internal control over financial reporting as of December 31, 2024 and December 31, 2023, in accordance with the provisions of the Sarbanes-Oxley Act. Accordingly, we cannot assure you that we have identified all, or that we will not in the future have additional material weaknesses. Material weaknesses may still exist when we report on the effectiveness of our internal control over financial reporting as required by reporting requirements under Section 404.

Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our stock price and make it more difficult for us to effectively market and sell our products and services to new and existing customers.

However, if we identify future deficiencies in our internal control over financial reporting or if we are unable to comply with the demands that are placed upon us as a public company, including the requirements of Section 404 of the Sarbanes-Oxley Act, in a timely or effective manner, we may be unable to accurately report our financial results, or report them within the timeframes required by the SEC. We also could become subject to sanctions or investigations by the SEC or other regulatory authorities. In addition, if we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting when required, investors may lose confidence in the accuracy and completeness of our financial reports, we may face restricted access to the capital markets and our stock price may be adversely affected.

Our current controls and any new controls that we develop may also become inadequate because of poor design or changes in our business, including increased complexity resulting from any international expansion, and weaknesses in our disclosure controls and internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls or any difficulties encountered in their implementation or improvement could cause us to fail to meet our reporting obligations, result in a restatement of our financial statements for prior periods, undermine investor confidence in us and adversely affect the trading price of our common stock. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on Nasdaq.

We may become subject to securities or class action litigation, which is expensive and could divert management's attention.

Our share price may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities litigation, including class action litigation. We may be the target of this type of litigation in the future. Litigation of this type could result in substantial costs and diversion of management's attention and resources, which could have a material adverse effect on our business, financial condition, and results of operations. Any adverse determination in litigation or any amounts paid to settle any such actual or threatened litigation could require that we make significant payments and/or could also subject us to significant liabilities.

If securities or industry analysts do not publish research or reports about our business or publish negative reports, the market price of our common stock could decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us and our business. If regular publication of research reports ceases, we could lose visibility in the financial markets, which in turn could cause the market price or trading volume of our common stock to decline. Moreover, if one or more of the analysts who cover us downgrade our common stock or if reporting results do not meet their expectations, the market price of our common stock could decline.

Changes in laws or regulations or how such laws or regulations are interpreted or applied, or a failure to comply with any laws or regulations, may adversely affect our business and results of operations.

We are subject to laws and regulations enacted by national, regional and local governments. In particular, we are required to comply with certain SEC and other legal requirements. Compliance with and monitoring of, applicable laws and regulations may be difficult, time consuming and costly. A failure to comply with applicable laws or regulations, as interpreted and applied, could have a material adverse effect on our business and results of operations. In addition, those laws and regulations and their interpretation and application may change from time to time, including as a result of changes in economic, political, social and government policies and those changes could have a material adverse effect on our business and results of operations.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity

Risk Management and Strategy

Our Information and Technology service providers manages the Company's security program, which is focused on assessing, identifying, and managing cyber risk and information security threats. We evaluate cybersecurity on an ongoing basis, and it is a risk monitored through our overall enterprise risk management program, including by the executive leadership and Board, described below under *"Governance."*

To proactively manage cybersecurity risk in our organization, our management team has instituted a security policy that is available to all employees.

To proactively identify, mitigate, and prepare for potential cybersecurity incidents, we maintain both a business continuity plan and cyber incident response plan. We recognize that we are exposed to cybersecurity threats associated with our use of third-party service providers. To minimize the risk and vulnerabilities to our own systems stemming from such use, our Information Technology providers identifies and addresses known cybersecurity risks on a continuous basis. In addition, we strive to minimize cybersecurity risks when we first select or renew a vendor by including cybersecurity risk as part of our overall vendor evaluation and due diligence process.

To date, our business strategy, results of operations, and financial condition have not been materially affected by risks from cybersecurity threats, but we cannot provide assurance that they will not be materially affected in the future. For more information on our cybersecurity-related risks, see *"Risk Factors*" in Item 1A of Part I of this Annual Report.

Governance

Our Board of Directors and our Audit Committee oversee our enterprise-wide risk management, including with respect to cybersecurity. Our Chief Executive Officer or Chief Financial Officer presents information on our enterprise-wide risks to the Board of Directors at each of its regularly scheduled meetings. Our CEO and CFO have extensive experience managing risks at our company and at similar companies in the past, including risks arising from cybersecurity threats.

Item 2. Properties.

Our corporate headquarters and manufacturing, storage and distribution centers for our catheters and consoles are located at Laguna Hills, California. We lease approximately 14,600 square feet, which includes clean room space, under an operating lease that expires in January 2030.

We also maintain offices in Holzkirchen, Germany, which are used for general administrative purposes and as a distribution center for our European operation.

We do not own any real property and believe that our current facilities are sufficient to support our operations and growth plans and that, additional space, if needed, will be available on commercially reasonably terms.

Item 3. Legal Proceedings.

From time to time, we may become involved in various claims and legal proceedings. Regardless of outcome, litigation and other legal and administrative proceedings can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors. We are currently not a party to any legal proceedings, the outcome of which, if determined adversely to us, would individually or in the aggregate have a material adverse effect on our business, financial condition, and results of operations.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock trades on the Nasdaq under the symbol "ADGM".

Holders of Record

As of March 21, 2025, there were approximately 62 holders of record of our common stock.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any future earnings and do not expect to pay any dividends in the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our Board and will depend on our financial condition, operating results, capital requirements and general business conditions and other factors that our Board may deem relevant.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by this item will be included in our Definitive Proxy Statement for the 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2024, and is incorporated herein by reference.

Recent Sales of Unregistered Securities

None.

Use of Proceeds

None.

Issuer Purchases of Equity Securities

None.

Item 6. Reserved.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of financial condition and results of operations should be read together with the consolidated financial statements as of and for the years ended December 31, 2023 and 2024, together with the related notes and other financial information included elsewhere in this Annual Report. Certain information contained in the discussion and analysis set forth below includes forward-looking statements that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors. Please see "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors" in this report.

Overview

We are a medical device company focused on developing and commercializing products for the treatment of cardiac arrhythmias with our novel, proprietary, catheter-based UTLC technology. Our initial focus is on the treatment of VT. VT is a rapid, abnormal heart rhythm, or arrhythmia, that originates in the heart's lower chambers, or ventricles, potentially leading to blood flow issues and, if sustained, VT can be fatal. VT is strongly associated with coronary artery disease, with an estimated 15% of patients with coronary artery disease found to have VT, and SCD caused by VT account for approximately half of the deaths related to cardiac causes. RF ablation catheters currently used to treat VT were primarily designed and approved for the treatment of AF and are therefore not designed to optimally treat the specifics of the ventricular anatomy and disease. As a result, VT procedures performed with current devices can be overly complex, with sub-optimal outcomes, potentially leading to limited growth in the market for VT ablations.

Our clinically tested ULTC products are purpose-built to treat patients with VT. Our highly differentiated catheters are designed for large, durable, deep lesions within the ventricle through an endocardial approach. Our ULTC approach is built on the hypothesis that large and durable lesions extending through the depth of both diseased and healthy muscular tissue of the ventricle of the heart (ventricular myocardium) is a foundation for improving the effectiveness of VT ablations and patient outcomes.

We believe that our purpose-built solution has the potential to drive additional market growth in ablative treatment of the large, underserved VT patient population.

We have established a robust cadence of clinical data designed to evaluate our technology and gain regulatory approvals of our product portfolio. Preliminary data suggest that our approach to treating VT offers a favorable combination of safety, acute and chronic effectiveness, compared to the current standard of care, including ablations performed using RF energy. Our first-in-human CRYOCURE-VT trial included 64 patients in nine centers in the E.U. and Canada. The outcomes of this trial, which were used to support CE Mark approval, include a 0% rate of major adverse events, 94% acute procedural success, 60% freedom from sustained VT and 81% freedom from implantable cardioverter defibrillator shock at six months. Our VT Cryoablation System has obtained European CE Mark approval. In the U.S., our 206-patient FULCRUM-VT IDE pivotal clinical trial is currently enrolling patients across twenty (20) centers in the U.S. and Canada. Upon completion, which we anticipate in the second half of 2025, we expect to submit the results of this trial to support FDA approval of our VT Cryoablation System.

We have also developed a technology that utilizes ULTC in combination with Pulsed Field Ablation, which we call Pulsed Field Cryoablation. Early demonstration of PFCA technology has been performed in the European PARALELL trial in patients with persistent atrial fibrillation and in preclinical studies targeting VT ablations.

We have not launched commercially in the U.S. but are working towards obtaining the necessary regulatory approvals to do so. We have incurred net losses in each year since our inception in 2011. As of December 31, 2024 and December 31, 2023, we had an accumulated deficit of $70.6 million and $133.6 million, respectively. Our net loss was $(53.8) million for the period from July 31, 2024 to December 31, 2024 (Successor), $(21.3) million for the period from January 1, 2024 to July 30, 2024 (Predecessor), and $(36.6) million for the year ended December 31, 2023 (Predecessor), respectively. The net cash used in operating activities was $13.5 million, $16.0 million, and $25.7 million, respectively. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. As of December 31, 2024 and December 31, 2023, we had cash of $20.6 million and $1.4 million, respectively.

The accompanying consolidated financial statements have been prepared on a basis that assumes we will continue as a going concern, which contemplate the realization of assets and liabilities in the normal course of business. We have limited revenue and have experienced recurring operating losses and negative cash flows from operations since our inception and anticipate that we will continue to do so for at least the next several years. These factors raise substantial doubt about the ability to continue as a going concern for the twelve-month period from the date the consolidated financial statements were made available. Additionally, management believes our current cash and cash equivalents are not sufficient to fund operations for at least the next 12 months from the issuance date of the consolidated financial statements and therefore there is substantial doubt about our ability to continue as a going concern. See *Note 1-Organization and Description of Business* in our consolidated financial statements for additional information on the going concern assessment.

The need for additional capital will depend in part on the scope and costs of our development activities. To date, we have not generated any significant revenue from the sale of commercialized products. Our ability to generate product revenue will depend on the successful development and eventual commercialization of our products in the United States. Until such time, if ever, we expect to finance our operations through the sale of equity or debt, borrowings under credit facilities, or through potential collaborations, other strategic transactions or government and other grants. Adequate capital may not be available to us when needed or on acceptable terms. If we are unable to raise capital, we could be forced to delay, reduce, suspend or cease our research and development programs or any future commercialization efforts, which would have a negative impact on our business, prospects, operating results and financial condition. See the section titled "Risk Factors" for additional information.

Description of the Merger

On July 31, 2024, the Closing Date, we consummated the Business Combination pursuant to the terms of the Business Combination Agreement. Pursuant to the Business Combination Agreement, on the Closing Date, (i) ARYA Merger Sub merged with and into ARYA, and Company Merger Sub merged with and into Legacy Adagio, with ARYA and Legacy Adagio surviving the Mergers and, after giving effect to such Mergers, each of ARYA and Legacy Adagio becoming a wholly-owned subsidiary of ListCo, (ii) ListCo filed with the Secretary of State of the State of Delaware an amended and restated certificate of incorporation of ListCo, and the board of directors of ListCo approved and adopt amended and restated bylaws of ListCo, and (iii) ListCo changed its name to Adagio Medical Holdings, Inc.

Prior to the annual general meeting, holders of 2,707,555 shares of ARYA's redeemable Class A ordinary shares exercised their right to redeem such shares for cash at a redemption price of approximately $11.56 per share, for an aggregate redemption amount of approximately $31.3 million.

Upon the consummation of the Business Combination,

a) Each issued and outstanding Class A ordinary share of ARYA, par value $0.0001 per share, were automatically cancelled, extinguished and converted into one share of common stock, par value $0.0001 per share, of the Company ("Company's common stock").

b) Each issued and outstanding Class B ordinary share of ARYA, par value $0.0001 per share, are automatically cancelled, extinguished and converted into the right to receive one share of the Company's common stock, other than (i) 1,000,000 Class B ordinary shares that are forfeited by the ARYA Sponsor, and issued to the PIPE Investors (as defined below), including the Perceptive PIPE Investor (as defined below); (ii) 1,147,500 shares of the Company's common stock issuable to the ARYA Sponsor are subject to share trigger price vesting and will vest if, prior to the tenth anniversary of the Closing, the post-closing share price of the Company equals or exceeds $24.00 per share for any 20 trading days within any 30 trading day period (the "Share Trigger Price Vesting").

c) Each warrant of Legacy Adagio (other than the Series E Pre-funded Warrants) was terminated in accordance with the terms of the applicable warrant agreement.

d) All issued and outstanding convertible promissory notes of Legacy Adagio (excluding the Bridge Financing Notes and the February 2024 Convertible Notes), including any accrued and unpaid interest thereon, are automatically and fully converted into shares of Legacy Adagio common stock in accordance with the terms of such convertible promissory notes, and such convertible promissory notes are cancelled, satisfied, extinguished, discharged and retired in connection with such conversion.

e) Each share of Legacy Adagio preferred stock, par value $0.001 per share, that is issued and outstanding are automatically converted into shares of Legacy Adagio common stock on a one-to-one basis.

f) All issued and outstanding shares of Legacy Adagio common stock including Series E Pre-funded Warrants that had been issued and outstanding are automatically cancelled and extinguished and converted into shares of the Company's common stock based on the exchange ratio set forth in the Business Combination Agreement.

g) Each issued, outstanding and unexercised option to purchase Legacy Adagio common stock ("Legacy Adagio Option") that had been vested prior to the Closing with an aggregate value that exceeds the aggregate exercise price of such Legacy Adagio Option (each an "In-the-Money Adagio Options") are cancelled and extinguished in exchange for options to purchase shares of the Company's common stock, and each issued and outstanding Legacy Adagio equity award (other than an In-the-Money Adagio Options) are automatically cancelled and extinguished for no consideration, and each holder thereof will cease to have any rights with respect thereto.

h) $7.0 million of February 2024 Convertible Notes (as defined below) is converted into Convertible Securities Notes and Convert Warrants (as defined below).

In connection with the execution of the Business Combination Agreement, ListCo and ARYA entered into Subscription Agreements (the "Initial Subscription Agreements"), with Perceptive Life Sciences Master Fund, Ltd, a Cayman Islands exempted company (the "Perceptive PIPE Investor") and certain other investors (the "Initial Other PIPE Investors", and together with the Perceptive PIPE Investor, the "Initial PIPE Investors"). In June 2024, ListCo and ARYA entered into additional Subscription Agreements (the "June Subscription Agreements" and, together with the Initial Subscription Agreements, the "Subscription Agreements") with certain additional investors, (the "June PIPE Investors", and together with the Initial Other PIPE Investors, the "Other PIPE Investors", and the Other PIPE Investors, together with the Perceptive PIPE Investor, the "PIPE Investors").

Pursuant to the subscription agreements, the PIPE Investors have committed financing valued at $64.5 million (the "PIPE Financing").

The PIPE Financing included:

(i) Commitments by certain Other PIPE Investors to purchase $2.5 million in Class A shares of ARYA in the open market and not to redeem such shares before the Closing, resulting in the issuance of 355,457 shares of Company's common stock and 299,902 warrants exercisable for shares of the Company's common stock (the "Base Warrants").

(ii) Commitments by certain Other PIPE Investors that were shareholders of ARYA to not to redeem 247,700 Class A shares of ARYA, resulting in the issuance of 405,772 shares of Company's common stock and 343,756 Base Warrants.

(iii) Agreements to purchase 1,036,666 shares of Company's common stock, 1,440,000 Base Warrants, and 670,000 PIPE Pre-funded Warrants for a cash investment of $12 million in the Company.

(iv) Contribution of total $29.5 million in April 2023 Convertible Notes, November 2023 Convertible Notes, May 2024 Convertible Notes, June 2024 Convertible Notes, and July 2024 convertible Notes (collectively, "Bridge Financing Notes"), and accrued interest of $1.7 million by the Perceptive PIPE Investor.

(v) An additional cash investment of $15.9 million by the Perceptive PIPE Investor.

In return for the investment specified in (iv) and (v) above, the Perceptive PIPE Investor received 6,622,959 shares of Company's common stock and 5,445,069 Base Warrants.

Further, in connection with the execution of the Business Combination Agreement, certain investors ("Convert Investors") executed a securities purchase agreement, dated February 13, 2024, with ListCo (the "Convertible Security Subscription Agreement"), pursuant to which ListCo issued on the Closing Date to the Convert Investors $20.0 million of 13% senior secured convertible notes (the "Convertible Securities Notes"), which were converted into shares of the Company's common stock at a conversion price of $10.00 per share, subject to adjustment, and 1,500,000 warrants (the "Convert Warrants"), each Convert Warrant being exercisable on a cashless basis or for cash at a price of $24.00 per share, subject to adjustment. Such $20.0 million of financing in the form of Convertible Securities Notes includes the conversion of the February 2024 Convertible Notes (as defined below) into Convertible Securities Notes and Convert Warrants at Closing, as further described in Note 9- Debt in our consolidated financial statements.

Key Factors Affecting Our Performance

We compete primarily on the basis that our products are designed to enable more physicians to treat more patients more efficiently and effectively. Our continued success depends on our ability to:

- continue to develop innovative, proprietary products that address significant clinical needs in a manner that is safe and effective for patients and easy-to-use for physicians;
- obtain and maintain regulatory clearances or approvals;
- demonstrate safety and effectiveness in our sponsored and third-party clinical trials;
- expand our sales force across key markets to increase physician awareness;
- obtain and maintain coverage and adequate reimbursement for procedures using our products;
- attract and retain skilled research, development, sales and clinical personnel;
- cost-effectively manufacture, market and sell our products; and
- obtain, maintain, enforce and defend our intellectual property rights and operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of others.

Innovation

Our business strategy relies significantly on innovation to develop and introduce new products and to differentiate our products from our competitors. We expect our research and development expenditures to increase as we make additional investments to support our growth strategies. We plan to increase our research and development expenditures with internal initiatives, as well as potentially licensing or acquiring technology from third parties. We also expect expenditures associated with our manufacturing organization to grow over time as production volume increases and we bring new products to market. Our internal and external investments will be focused on initiatives that we believe will offer the greatest opportunity for growth and profitability. With a significant investment in research and development, a strong focus on innovation and a well-managed innovation process, we believe we can continue to innovate and grow.

Regulatory

Our commercial success will depend upon a number of factors, some of which are beyond our control, including the receipt of regulatory clearances, approvals, or authorizations for existing or new product offerings by us, or product enhancements. We must complete additional clinical testing before we can seek regulatory approval in the United States and begin commercialization of our products. After our products are cleared, approved, or authorized, numerous and pervasive regulatory requirements continue to apply. As such, our ability to navigate, obtain and maintain the required regulatory clearances, approvals, or authorizations, as well as comply with other regulatory requirements, for our products will in part drive our results of operations and impact our business.

Investments in Our Growth

In order to generate future growth, we plan to continue to expand and leverage our sales and marketing infrastructure to increase our customer base and grow our business. Identifying and recruiting qualified sales and marketing personnel and training them on our products, applicable federal and state laws and regulations, and on our internal policies and procedures requires significant time, expense and attention. It often takes several months or more before a sales representative is fully trained and productive. Our ability to increase our customer base and achieve broader market acceptance of our products will also depend to a significant extent on our ability to expand our marketing efforts as our plans to dedicate significant resources to our marketing programs.

Competition

Our industry is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. Our most significant competitors are large, well-capitalized companies. We must continue to successfully compete considering our competitors' existing and future products and related pricing and their resources to successfully market to the physicians who could use our products. Publications of clinical results by us, our competitors and other third parties can also have a significant influence on whether, and the degree to which, we are able to gain market share and increase utilization of our products.

Reimbursement and Insurance Coverage

In both U.S. and non-U.S. markets, our ability to successfully commercialize and achieve market acceptance of our products depends, in significant part, on the availability of adequate financial coverage and reimbursement from third-party payors, including governmental payors (such as the Medicare and Medicaid programs in the United States), managed care organizations and private health insurers. Third-party payors decide which treatments they will cover and establish reimbursement rates for those treatments. Our products are purchased by hospitals and other providers who will then seek reimbursement from third-party payors for the procedures performed using our products. Reimbursement systems in international markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis. In certain international markets, a product must be approved for reimbursement before it can be approved for sale in that country. Furthermore, many international markets have government-managed healthcare systems that control reimbursement for new devices and procedures. In most markets there are private insurance systems as well as government-managed systems.

Key Components of Results of Operations

Revenues

We generate product revenue primarily from the sale of the catheters used with our consoles. We sell our products directly to hospitals and medical centers. To a lesser extent, we also generate lease revenue from the implied rental of consoles loaned to customers at no charge. We recognize revenue in accordance with ASC Topic 606, Revenue from Contracts with Customers, when we transfer 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. Please refer to *Note 2- "Summary of Significant Accounting Policies"* in our consolidated financial statements for additional details on our revenue recognition policy.

Costs and Operating Expenses

Cost of Revenue

Cost of revenue includes raw materials, direct labor, manufacturing overhead, shipping and receiving costs and other less significant indirect costs related to the production of our products. Cost of revenue also includes the depreciation expense of Consoles loaned to the customers.

Research and Development Expenses

Research and development expenses are expensed when incurred and are related to the development of our product candidates which includes pre-clinical, clinical, quality assurance, and research and development operational activities. These costs consist of:

- salaries, benefits, and other employee-related costs, including stock-based compensation expense for personnel engaged in research and development functions;
- activities associated with clinical trials performed by third parties;
- professional fees;
- equipment, materials, and costs related to product manufacturing; and
- other operational costs including rent and facilities costs, and depreciation.

We do not track research and development expenses by project or product, as we are at an earlier stage in our pre-clinical and clinical development. Management believes that the breakdown of research and development expenses by project or product would be arbitrary and would not provide a meaningful assessment.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries, and employee-related costs (including stock-based compensation) for personnel in executive, finance and other administrative functions, allocated rent and facilities costs, legal fees relating to intellectual property and corporate matters, professional fees for accounting and consulting services, marketing costs and corporate insurance costs, and transaction costs in connection with the Business Combination. We expense all selling, general and administrative costs as incurred.

Convertible notes fair value adjustment

We recorded the October 2022 Convertible Notes, the Bridge Financing Notes, and Convertible Securities Notes at fair value at issuance and subsequently remeasure them to fair value at each reporting period. The change in fair value of the Convertible Securities Notes, excluding amounts related to interest, is recorded in "Convertible notes fair value adjustment," while amounts related to interest are recorded as interest expense in the consolidated statements of operations and comprehensive loss.

Warrant liabilities fair value adjustment

We accounted for certain common stock warrants outstanding as warrant liabilities at fair value, determined using the Black-Scholes-Merton option pricing model. The liability is subject to remeasurement at each reporting period and any change in fair value is recognized as warrant liabilities fair value adjustment in the consolidated statements of operations and comprehensive loss.

Interest expense

Interest expense is primarily incurred from our outstanding debt obligations, including those under the October 2022 Convertible Notes, the Bridge Financing Notes, the Convertible Securities Notes, and the SVB Term Loan (as defined below).

Interest Income

Interest income consists primarily of interest earned on our cash, cash equivalents, and money market accounts.

Other (expense) income, net

Other (expense) income, net primarily consists of foreign currency unrealized and realized gain / loss, and other income related to our research and development ("R&D") tax credit.

Results of Operations

Comparison for the periods from January 1, 2024 to July 30, 2024 (Predecessor), from July 31, 2024 to December 31, 2024 (Successor), to the year ended December 31, 2023 (Predecessor)

The following table sets forth a summary of our results of operations, expressed as percentages of net revenue (in thousands):

	For the years ended December 31,				
	2024		2023		
	Successor	Predecessor	Predecessor	Change	
	July 31 to December 31	January 1 to July 30	January 1 to December 31	$	%
Revenue	$ 269	$ 333	$ 300	$ 302	101%
Cost of revenue and operating expenses:					
Cost of revenue	1,937	1,381	1,306	2,012	154
Research and development	4,634	7,585	15,399	(3,180)	(21)
Selling, general, and administrative	6,976	13,047	11,537	8,486	74
Impairment - Goodwill	30,324	—	—	30,324	—
Impairment - Intangible assets, net	18,878	—	—	18,878	—
Total cost of revenue and operating expenses	62,749	22,013	28,242	56,520	207
Loss from operations	(62,480)	(21,680)	(27,942)	(56,218)	201
Other income (expense):					
Convertible notes fair value adjustment	929	2,059	(6,930)	9,918	(143)
Warrant liabilities fair value adjustment	6,576	191	(42)	6,809	n.m
Interest expense	(1,105)	(1,818)	(1,659)	(1,264)	76
Interest income	420	3	3	420	n.m
Other (expense) income, net	1,897	(33)	(20)	1,884	(9,420)
Total other income (expense), net	8,717	402	(8,648)	17,767	(205)
Net loss	$ (53,763)	$ (21,278)	$ (36,590)	$ (38,451)	105
Other comprehensive loss:					
Foreign currency translation adjustment	1	3	(11)	15	n.m
Comprehensive loss	$ (53,762)	$ (21,275)	$ (36,601)	$ (38,436)	105

n.m. = not meaningful

Revenue

Our revenues were $0.3 million and $0.3 million for the periods from July 31, 2024 to December 31, 2024 (Successor) and from January 1, 2024 to July 30, 2024 (Predecessor), respectively, and $0.3 million for the year ended December 31, 2023 (Predecessor). The increase of $0.3 million, or 101%, is due to the increase of consumable sales. For the year ended December 31, 2024, and 2023, revenue was generated only in European markets.

Costs of revenue and operating expenses

Cost of revenue

Cost of revenue was $1.9 million and $1.4 million for the period from July 31, 2024 to December 31, 2024 (Successor) and from January 1, 2024 to July 30, 2024 (Predecessor), respectively, and was $1.3 million for the year ended December 31, 2023 (Predecessor). The increase of $2.0 million, or 154%, primarily resulted from a $1.4 million increase in cost of goods sold related to increased sales of $0.6 million, an increase of $0.8 million related to the write off of obsolete inventory, a $0.5 million increase in the depreciation of Consoles, and $0.1 million increase in employee benefits.

Research and development expenses

Research and development expenses were $4.6 million and $7.6 million for the period from July 31, 2024 to December 31, 2024 (Successor) and from January 1, 2024 to July 30, 2024 (Predecessor), respectively, and was $15.4 million for the year ended December 31, 2023. The $3.2 million decrease, or 21%, was primarily related to a $2.0 million decrease of manufacturing absorption costs, $1.7 million decrease in product manufacturing costs, $1.0 million decrease in clinical trial expense, $0.4 million decrease in animal testing cost, $0.3 million decrease in costs related to consulting and prototypes, $0.1 million decrease in travel, and $0.8 million decrease in payroll. The decrease in research and development expenses results from Legacy Adagio receiving CE Marking on VT Cryoablation in March 2024.

The following is a breakdown of our research and development costs by type of expense:

	Years ended December 31,		
	2024		2023
	Successor	Predecessor	Predecessor
	July 31 to December 31,	January 1 to July 30	January 1 to December 31,
Pre-clinical trial costs and other research and development costs	$ 1,677	$ 1,732	$ 4,147
Clinical trial costs	1,920	2,619	5,504
Quality assurance costs	981	1,764	2,957
Operational costs	56	1,470	2,791
Total research and development expenses	$ 4,634	$ 7,585	$ 15,399

Our clinical trial expenses relate to trials for our iCLAS atrial ULTC catheter and system (CYROCURE-2), iCLAS atrial ULTC catheter and system (iCLAS for PsAF), vCLAS ventricular ULTC catheter (CYROCURE-VT), vCLAS ventricular ULTC catheter (FULCRUM-VT), and PFCA catheter. Clinical trial costs include the expenses related to clinical trial studies and other related expenses. Quality assurance includes regulatory fees and third-party service fees. Pre-clinical trial costs and other research and development costs include the expenses resulting from professional fees, prototypes, and animal testing. Operational costs include expenses related to product manufacturing.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $7.0 million and $13.0 million for the period from July 31, 2024 to December 31, 2024 (Successor) and from January 1, 2024 to July 30, 2024 (Predecessor), respectively, and $11.5 million for the year ended December 31, 2023 (Predecessor). The increase in selling, general and administrative expenses of $8.5 million, or 74%, is primarily due to an increase of $5.2 million in professional fees which include legal and accounting fees related to the transaction costs associated with the Business Combination, an increase in payroll and personnel expense of $3.0 million, and an increase in building and maintenance costs of $0.3 million.

Impairment - Goodwill

We recorded a $30.3 million Goodwill impairment charge in 2024, with no comparable charges in 2023. Refer to *Note 7-Goodwill and Intangible Assets, net* in our consolidated financial statements for additional details.

Impairment - Intangible assets, net

We recorded intangible asset impairment charges of $18.9 million in 2024, with no comparable charges in 2023. Refer to *Note 7-Goodwill and Intangible Assets, net* in our consolidated financial statements for additional details.

Convertible notes fair value adjustment

The convertible notes fair value increased $0.9 million and $2.1 million for the period from July 31, 2024 to December 31, 2024 (Successor) and from January 1, 2024 to July 30, 2024 (Predecessor), respectively, and decreased $6.9 million for the year ended December 31, 2023 (Predecessor). The increase of $0.9 million for the period from July 31, 2024 to December 31, 2024 (Successor) is due to an increase in the fair value of the Convertible Securities Notes. The net decrease of $2.1 million January 1, 2024 to July 30, 2024 (Predecessor) is related to decreases in the October 2022 Convertible Notes, November 2023 Convertible Notes, and February 2024 Convertible Notes of $4.3 million, $2.4 million, and $0.3 million, respectively. These decreases were offset by increases in the April 2023 Convertible Notes, May 2024 Convertible Notes, June 2024 Convertible Notes, July 2024 Convertible Notes of $3.4 million, $0.7 million, $0.6 million, and $0.2 million, respectively. The decrease of $6.9 million for the year ended December 31, 2023 (Predecessor) is due to a fair value decrease of the October 2022 Convertible Notes and the April 2023 Convertible Notes.

Warrant liabilities fair value adjustment

The warrant liabilities fair value decreased $6.6 million and $0.2 million for the period from July 31, 2024 to December 31, 2024 (Successor) and from January 1, 2024 to July 30, 2024 (Predecessor), respectively, and increased $42.0 thousand for the year ended December 31, 2023 (Predecessor). The decrease of $6.6 million from July 31, 2024 to December 31, 2024 (Successor) is related to a decrease in the fair value of the PIPE Pre-funded Warrants and the Convert Warrants of $3.7 million and $2.8 million, respectively. The decrease of $0.2 million from January 1, 2024 to July 30, 2024 (Predecessor) is related to a decrease in the fair value of SVB Warrants (as defined herein) and Series E Pre-funded Warrants of $77.6 thousand and $0.1 million, respectively. The increase of $42.0 thousand for the year ended December 31, 2023 (Predecessor) is due to a fair value increase of the SVB Warrants.

Interest expense

Interest expense was $1.1 million and $1.8 million for the period from July 31, 2024 to December 31, 2024 (Successor) and from January 1, 2024 to July 30, 2024 (Predecessor), respectively, and was $1.7 million for the year ended December 31, 2023 (Predecessor). The increase of $1.3 million, or 76%, was related to additional interest incurred from the Bridge Financing Notes and the Convertible Securities Notes.

Interest income

Interest income was $0.4 million and $3.0 thousand for the period from July 31, 2024 to December 31, 2024 (Successor) and from January 1, 2024 to July 30, 2024 (Predecessor), respectively, and was $3 thousand for the year ended December 31, 2023 (Predecessor). The increase in interest income of $0.4 million is primarily due to the increase of cash balances in an asset management account.

Other income (expense), net

Other income was $1.9 million and other expense was $33.0 thousand for the period from July 31, 2024 to December 31, 2024 (Successor) and from January 1, 2024 to July 30, 2024 (Predecessor), respectively, compared to other expense of $20 thousand for the year ended December 31, 2023 (Predecessor). This net increase in other income of $1.9 million was primarily attributable to a tax benefit of $1.9 million as a result of the reversal of a portion of the deferred tax liability associated with the impairment of certain of our indefinite-lived intangibles in the period from July 31, 2024 to December 31, 2024 (Successor).

Liquidity and Capital Resources

Sources of Liquidity

To date, we have financed our operations primarily through the sale of equity securities, convertible promissory notes and the SVB Term Loan. Since inception we have incurred operating losses and negative cash flows and anticipate continuing to do so for at least the next several years.

As of December 31, 2024 and December 31, 2023, the Successor had cash and cash equivalents of $20.6 million and Predecessor had $1.4 million, respectively. For the period from July 31, 2024 to December 31, 2024 (Successor) and from January 1, 2024 to July 30, 2024 (Predecessor), net (losses) were $(53.8) million and $(21.3) million, respectively, and was $(36.6) million for the year ended December 31, 2023 (Predecessor). For the period from July 31, 2024 to December 31, 2024 (Successor), the period from January 1, 2024 to July 30, 2024 (Predecessor), and for the year ended December 31, 2023 (Predecessor) net cash used in operating activities was $13.6 million, $16.0 million, and $25.7 million, respectively.

For the 12 months after the issuance date of our consolidated financial statements (e.g., April 2025 – March 2026), we project our cash burn to be $20.0 million. We do not require significant cash reserve to meet short term and long-term obligations with a balance of approximately $2.8 million for accounts payable, $3.7 million for accrued liabilities, and $1.1 million for other accrued liabilities as of December 31, 2024 (Successor). We have a balance of $20.6 million in cash as of December 31, 2024 after the Closing of the Business Combination (refer to the "*Description of the Merger"* for additional details), and we do not believe our current cash and cash equivalents are sufficient to fund operations for at least the next 12 months from the issuance date of the consolidated financial statements. We believe that this raises substantial doubt about our ability to continue as a going concern.

We intend to mitigate the conditions and events that raise substantial doubt about our ability to continue as a going concern entity by (i) negotiate other cash equity or debt financing in the short-term, (ii) continue to pursue the necessary regulatory approvals to launch commercially in the U.S. market, and (iii) execute cost-cutting measures to manage cash burn. However, there can be no assurances that the current plans will generate any liquidity to us or be available on terms acceptable to us.

Future Funding Requirements

In the future, we may need to raise additional funds through the issuance of debt and/or equity securities or otherwise. Until such time, if ever, that we can generate revenue sufficient to achieve profitability, we expect to finance our operations through equity or debt financings, which may not be available to us on the timing needed or on terms that we deem to be favorable. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we are unable to maintain sufficient financial resources, our business, financial condition and results of operations will be materially and adversely affected. We may be required to delay, limit, reduce or terminate our product discovery and development activities or future commercialization efforts.

Our future liquidity and capital funding requirements will depend on numerous factors, including:

- our revenue growth;
- our research and development efforts;
- our sales and marketing activities;
- our ability to raise additional funds to finance our operations;

- the outcome, costs and timing of any clinical trial results for our current or future products;
- the emergence and effect of competing or complementary products;
- the availability and amount of reimbursement for procedures using our products;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our ability to retain our current employees and the need and ability to hire additional management and sales, scientific and medical personnel;
- the terms and timing of any collaborative, licensing or other arrangements that we have or may establish;
- debt service requirements; and
- the extent to which we acquire or invest in businesses, products or technologies;

Our primary uses of capital are, and we expect will continue to be, investment in our commercial organization and related expenses, clinical research and development services, and related supplies, legal and other regulatory expenses, general administrative costs and working capital.

Debt Obligations (Predecessor)

October 2022 Convertible Notes

In October 2022, we entered into a Note Purchase Agreement with investors for the issuance and sale of convertible promissory notes (the "October 2022 Convertible Notes") with an aggregate principal amount of $9.5 million at an interest rate of eight percent (8.0%) per year. The October 2022 Convertible Notes had an original maturity date of October 27, 2023, which was subsequently extended to the latest of (i) January 5, 2024, (ii) termination of agreements between Legacy Adagio and ARYA in connection with a non-binding summary of certain proposed terms and conditions of the Business Combination, or (iii) the termination or lapse of the exclusivity period as defined in the non-binding term sheet as mentioned above.

The October 2022 Convertible Notes were also amended to be subordinate to the April 2023 Convertible Notes (as described below) and provide for the conversion of all principal and accrued interest in respect of all the October 2022 Convertible Notes into shares of Series E Preferred Stock of Legacy Adagio in connection with the Business Combination. (refer to *Note 9-Debt* in our consolidated financial statements for additional details).

In November 2023 and February 2024, the October 2022 Convertible Notes were further amended to also subordinate the November 2023 Convertible Notes and the February 2024 Convertible Notes. Upon the consummation of the Business Combination, all principal and accrued interest in respect of the October 2022 Convertible Notes were converted into shares of Legacy Adagio common stock when multiplied by the exchange ratio applicable to the Legacy Adagio common stock in the Business Combination, which entitled the holder of this note to receive a number of shares of the same class of common stock that were issued in the PIPE Financing equal to the then outstanding principal amount and any accrued and unpaid interest under this note, divided by 75% of the effective price of each share of common stock sold in the PIPE Financing. Further, on the Closing Date, Legacy Adagio common stocks were converted to the Company's common stock based on the exchange ratio set forth in the Business Combination Agreement.

Upon the consummation of the Business Combination, the October 2022 Convertible Notes automatically converted into 1,444,899 shares of the Company's common stock.

Bridge Financing Notes

April 2023 Convertible Notes

In April 2023, we issued a $5.0 million convertible promissory note that would mature on the latest of (i) January 5, 2024, (ii) termination of agreements between Legacy Adagio and ARYA in connection with the Business Combination, or (iii) the termination or lapse of the exclusivity period as defined in the non-binding term sheet as mentioned above, and accrued simple interest at eight percent (8.0%) per annum (the "April 2023 Convertible Notes"). Additionally, we obtained the right to issue up to $10.0 million in additional convertible promissory notes available beginning one month after April 4, 2023 through the occurrence of an ARYA stockholder vote with regard to the Business Combination.

In November 2023, the April 2023 Notes were amended to align certain terms to the November 2023 Notes (refer to *Note 9-Debt* in our consolidated financial statements for the year ended December 31, 2024, and December 31, 2023, for additional details).

November 2023 Convertible Notes

On November 28, 2023, Legacy Adagio issued to Perceptive Life Sciences Master Fund, Ltd. (the "Perceptive PIPE Investor"), a $2.0 million convertible promissory note that would mature on the latest of (i) January 5, 2024, (ii) termination of agreements between Legacy Adagio and ARYA in connection with a non-binding summary of the Business Combination, or (iii) the termination or lapse of the exclusivity period as defined in the non-binding term sheet as mentioned above (the "November 2023 Convertible Notes"). The November 2023 Notes accrued simple interest at eight percent (8.0%) per annum. Additionally, Legacy Adagio obtained the right to issue up to $6.0 million of Delayed Draw Commitment available beginning one month after November 28, 2023, through the occurrence of an ARYA stockholder vote with regard to the Business Combination.

In December 2023, the November 2023 Notes were amended to permit the issuance of a Delayed Draw Commitment in the original amount of $6.0 million. On December 13, 2023, and December 28, 2023, Legacy Adagio drew the principal amount of $1.0 million and $2.0 million, respectively. As of December 31, 2024, Legacy Adagio drew the remaining principal amount of $3.0 million. The combined $3.0 million convertible promissory notes were issued pursuant to the clause and terms in the November 2023 Notes agreement (refer to *Note 9- Debt* in our consolidated financial statements for additional details).

May 2024 Convertible Notes

On May 21, 2024, Legacy Adagio issued a $3.0 million convertible promissory note ("May 2024 Convertible Notes") to Perceptive PIPE Investor that matures upon the termination of the Business Combination Agreement in accordance with its terms. It accrues simple interest at eight percent (8.0%) per annum.

June 2024 Convertible Notes

On June 25, 2024, Legacy Adagio issued a $2.5 million convertible promissory note ("June 2024 Convertible Notes") to Perceptive PIPE Investor that matures upon the termination of the Business Combination Agreement in accordance with its terms. It accrues simple interest at eight percent (8.0%) per annum.

July 2024 Convertible Notes

On July 23, 2024, Legacy Adagio issued a $1.0 million convertible promissory note ("July 2024 Convertible Notes") to Perceptive PIPE Investor that matures upon the termination of the Business Combination Agreement in accordance with its terms. It accrues simple interest at eight percent (8.0%) per annum.

Pursuant to the Business Combination Agreement, the outstanding $29.5 million principal along with the accrued but unpaid interest of the Bridge Financing Notes, was converted in exchange for 4,372,607 shares of the Company's common stock and 3,540,000 Base Warrants as part of the PIPE Financing.

February 2024 Convertible Notes

On February 13, 2024, the Legacy Adagio issued to Perceptive PIPE Investor a principal of $7.0 million convertible promissory note that matures upon the termination of the Business Combination Agreement in accordance with its terms. The February 2024 Convertible Notes accrues simple interest at eight percent (8.0%) per annum.

Upon the consummation of the Business Combination, the February 2024 Convertible Notes was automatically transferred to the Company in connection with the issuance of the Convertible Securities Notes to Perceptive PIPE Investor, pursuant to, and in accordance with, the note purchase agreement and the Convertible Security Subscription Agreement. Any interest accrued on the principal amount of the February 2024 Convertible Notes was forfeited in connection with the transfer of the notes to the Company.

On the Closing Date, the $7.0 million of February 2024 Convertible Notes were converted into $7.0 million Convertible Securities Notes and 525,000 Convert Warrants.

SVB Term Loan

In February 2023, Legacy Adagio entered into an agreement with Silicon Valley Bank to borrow an initial term loan advance of $3.0 million and a right to borrow a subsequent term loan advance of $2.0 million ("SVB Term Loan"). The loans matured on January 1, 2025. In conjunction with the SVB Term Loan, Legacy Adagio issued warrants to acquire 32,720 shares of common stock in February 2023 and distributed additional warrants to acquire 16,360 shares of common stock as of December 31, 2023 ("SVB Warrants"). Prior to the Closing of the Business Combination, the existing SVB Term Loan of Legacy Adagio as on July 30, 2024 had a net balance of $1.0 million, including $1.0 million of principal payment due within twelve months with an unamortized debt discount of $9.7 thousand. The unpaid principal and accrued interest were carried as assumed liabilities to the Company and paid at the Closing. (Refer to *Note 9-Debt* in our consolidated financial statements for additional details).

Debt Obligations (Successor)

Convertible Securities Notes

In connection with the execution of the Business Combination Agreement, Convert Investors executed the Convertible Security Subscription Agreement dated February 13, 2024, which was amended on June 20, 2024, with ListCo. In accordance with the agreement, ListCo issued on the Closing Date to the Convert Investors $20.0 million of Convertible Securities Notes and 1,500,000 Convert Warrants.

The total of $20.0 million Convertible Securities Notes will be convertible into shares of the Company's common stock at a conversion price of $10.00 per share, subject to adjustment per the terms of the agreement, and the total of 1,500,000 warrants, each of which will be exercisable on a cashless basis or for one share of the Company's common stock at $24.00 per share, subject to adjustment. The Convertible Securities Notes have a maturity of three years and nine months after the Closing and interest will be payable in cash or compound as additional principal outstanding which accrues on an annual basis.

The conversion of the February 2024 Convertible Notes was carried out on the same terms as the other Convert Investors executing the Convertible Security Subscription Agreement.

Cash Flows

The following table shows a summary of our cash flows for each of the periods shown below:

	Years ended December 31,		
	2024		2023
	Successor	Predecessor	Predecessor
	July 31 to December 31,	January 1 to July 30	January 1 to December 31,
Net cash used in operating activities	$ (13,469)	$ (15,990)	$ (25,652)
Net cash used in investing activities	(1,280)	(368)	(340)
Net cash provided by financing activities	—	15,633	21,875
Effect of foreign currency translation on cash	181	24	(47)
Net change in cash and cash equivalents	$ (14,568)	$ (701)	$ (4,164)

Comparison for the periods from January 1, 2024 to July 30, 2024 (Predecessor), from July 31, 2024 to December 31, 2024 (Successor), to the year ended December 31, 2023 (Predecessor)

Cash Flows Used in Operating Activities

Net cash used in operating activities for the period from July 31, 2024 to December 31, 2024 (Successor) was $13.5 million, consisting primarily of a net loss of $53.8 million, net by non-cash items of $42.5 million, and net by change in our net operating assets and liabilities of $2.2 million. Non-cash items primarily consisted of a $30.3 million impairment charge to goodwill, a $18.9 million impairment charge to intangible assets and $0.7 million in depreciation and amortization; offset by offset by a gain of $0.9 million from the change in fair value of convertible notes payable, and a gain of $6.6 million from the change in fair value of warrant liabilities. Changes in our net operating assets and liabilities were primarily due to a $1.4 million increase in inventory, offset by $1.9 million decrease in accounts payable, a $0.9 million increase in prepaid expenses and other current assets.

Net cash used in operating activities for the period from January 1, 2024 to July 30, 2024 (Predecessor) was $16.0 million consisting primarily of a net loss of $21.3 million, adjusted by non-cash items of $0.8 million, and net with the change in our net operating assets and liabilities of $6.1 million. Non-cash items primarily consisted of $0.6 million in depreciation and amortization, $0.6 million in stock-based compensation, noncash operating lease expense of $0.1 million, and loss on disposal of property and equipment of $0.1 million; offset by a gain of $2.1 million from the change in fair value of convertible notes payable, and a gain of $0.2 million from the change in fair value of warrant liabilities. Changes in our net operating assets and liabilities were primarily due to a $7.4 million increase in accrued transaction costs, the increase in accrued liabilities of $0.5 million and a $1.7 million increase in other accrued liabilities, which were primarily driven by the increase in transaction costs related to the Business Combination, the increase in accrued variable compensation related to the Business Combination, and the increase in interest related the convertible notes; offset by a $2.6 million decrease in accounts payable, $0.8 million increase in inventory, which were primarily driven by the payment of accounts payable related to the Business combination and an increase in inventory purchases.

Net cash used in operating activities for the year ended December 31, 2023 (Predecessor), was $25.7 million, consisting primarily of a net loss of $36.6 million net by non-cash items of $8.1 million, and net by the change in our net operating assets and liabilities of $2.8 million. Non-cash items primarily consisted of a loss of $7.0 million related to the change in fair value of convertible notes payables, $532 thousand in depreciation and amortization, $442 thousand in stock-based compensation, and $159 thousand in noncash operating lease expenses. Changes in our net operating assets and liabilities, were primarily due to a $3.0 million increase in inventory, a $886 thousand increase in accrued liabilities, $161 thousand increase in operating leases liabilities, $410 thousand decrease in prepaid expenses and other current assets, a $444 thousand increase in accrued transaction costs, a $2.8 million increase in accounts payable, and a $1.4 million increase in other accrued liabilities which was primarily driven by the increase in interest related the convertible notes, and the increase in transaction costs related to the Business Combination; offset by a $70 thousand increase in accounts receivable.

Cash Flow Used in Investing Activities

Net cash used in investing activities for the period from July 31, 2024 to December 31, 2024 (Successor) and the period from January 1, 2024 to July 30, 2024 (Predecessor) was $1.2 million and $0.4 million, respectively. Net cash used in investing activities for the for the year ended December 31, 2023 (Predecessor) was $0.3 million. The increase was due to the increased purchase of property.

Cash Flow Provided by Financing Activities

Net cash provided by financing activities for the period from July 31, 2024 to December 31, 2024 (Successor) was nil.

Net cash provided by financing activities for the period from January 1, 2024 to July 30, 2024 (Predecessor) was $15.6 million. It is primarily due to receiving $16.5 million from the issuance of the $7.0 million February 2024 Convertible Notes, $3.0 million May 2024 Convertible Notes, $2.5 million June 2024 Convertible Notes, $1.0 million from the July 2024 Convertible Notes, and the draw of $3.0 million November 2023 Convertible Notes, net by a $0.9 million repayment of SVB Term Loan.

Net cash provided by financing activities for the year ended December 31, 2023 (Predecessor) was $22.0 million. It is due to receiving $20.0 million and $3.0 million from the issuance of convertible notes payable and SVB term loan, respectively, and $18 thousand related to exercise of common stock options in 2023, offset by a decrease of $1.1 million repayment of SVB Term Loan.

Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. We are, therefore, not exposed to the financing, liquidity, market, or credit risk that could arise if we had engaged in those types of relationships.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the amounts reported in our audited consolidated financial statements and accompanying notes included elsewhere in this Annual Report on Form 10-K. We base our estimates on historical experience, current business factors and various other assumptions that we believe are necessary to consider forming a basis for making judgments about the carrying values of assets and liabilities, the recorded amounts of revenue and expenses and the disclosure of contingent assets and liabilities. We are subject to uncertainties such as the impact of future events, economic and political factors, and changes in our business environment; therefore, actual results could differ from these estimates.

Accordingly, the accounting estimates used in the preparation of our consolidated financial statements will change as new events occur, as more experience is acquired, as additional information is obtained and as our operating environment changes. Changes in estimates are made when circumstances warrant. Such changes in estimates and refinements in estimation methodologies are reflected in reported results of operations; if material, the effects of changes in estimates are disclosed in the notes to our audited consolidated financial statements.

On an ongoing basis, we evaluate our estimates and assumptions. Our actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in *Note 2-Summary of Significant Accounting Policies* to our consolidated financial statements. These are the policies that we believe are the most critical to aid in fully understanding and evaluating our consolidated financial condition and results of operations.

Stock-Based Compensation

We recognize compensation expense for all stock-based awards issued to employees and non-employees based on the estimated grant-date fair value, which is recognized as expense on a straight-line basis over the requisite service period. We have elected to recognize forfeitures as they occur. The fair value of stock options is determined using the Black-Scholes-Merton option-pricing model. The determination of fair value for stock-based awards on the date of grant using an option-pricing model requires management to make certain assumptions including expected volatility, expected term, risk-free interest rate and expected dividends in addition to our common stock valuation. The assumptions used in calculating the fair value of stock-based awards represent our best estimates and involve inherent uncertainties and the application of our judgment.

All stock-based compensation costs are recorded in cost of products sold, research and development expense or selling, general, and administrative expense in the consolidated statements of operations and comprehensive loss based upon the respective employee's or non-employee's roles.

Impairment of Intangible Assets

Our definite lived intangible assets subject to amortization are reviewed for impairment in accordance with ASC 360, *Property, Plant and Equipment*, which requires that companies consider whether events or changes in facts and circumstances, both internally and externally, may indicate that an impairment of definite lived intangible assets held for use are present. We review definite lived intangible assets for impairment at least annually or whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the asset, the assets are written down to their estimated fair values and the loss is recognized in the consolidated statements of operations.

For the period from January 1, 2024 to July 30, 2024 (Predecessor) and for the year ended December 31, 2023 (Predecessor), we determined that there was no impairment of definite-lived intangible assets. We determined that as of December 31, 2024, the fair value of our definite lived intangible assets was less than the carrying amount. As a result, we recorded a $3.8 million impairment charge during the period from July 31, 2024 to December 31, 2024 (Successor). The impairment was driven by a sustained decline in our share price and market capitalization.

Indefinite-lived intangible assets consist of In-Process Research and Development ("IPR&D"). In accordance with ASC 350, Intangibles – Goodwill and Other Intangible, assets with indefinite lives are tested for impairment if impairment indicators arise and, at a minimum, annually. However, an entity is permitted to first assess qualitative factors to determine if a quantitative impairment test is necessary. Further testing is only required if the entity determines, based on the qualitative assessment, that it is more likely than not that an indefinite-lived intangible asset's fair value is less than its carrying amount. Otherwise, no further impairment testing is required. The indefinite-lived intangible asset impairment test consists of a one-step analysis that compares the fair value of the intangible asset with its carrying amount. If the carrying amount of an intangible asset exceeds its fair value, an impairment loss is recognized in an amount equal to that excess.

For the period from January 1, 2024 to July 30, 2024 (Predecessor) and for the year ended December 31, 2023 (Predecessor), we determined that there was no impairment of indefinite-lived intangible assets. We determined that as of December 31, 2024, the fair value of our indefinite-lived intangible assets was less than the carrying amount. As a result, we recorded a $15.1 million impairment charge during the period from July 31, 2024 to December 31, 2024 (Successor). The impairment was driven by a sustained decline in our share price and market capitalization.

Impairment of Goodwill

In accordance with ASC 350, Intangibles – Goodwill and Other, we test goodwill for impairment at the reporting unit level. We have one reporting unit for the goodwill impairment testing purposes. Goodwill is tested for impairment on an annual basis in the fourth quarter, or more frequently if events or changes in circumstances indicate the carrying value of goodwill may not be recoverable (a "triggering event"). On the occurrence of a triggering event, an entity has the option to first assess qualitative factors to determine whether a quantitative impairment test is necessary. If it is more likely than not that goodwill is impaired, the fair value of the reporting unit (the Company) is compared with its carrying value. An impairment charge is recognized for the amount by which the carrying amount exceeds the fair value, provided, the loss recognized cannot exceed the total amount of goodwill.

For the period from January 1, 2024 to July 30, 2024 (Predecessor) and for the year ended December 31, 2023 (Predecessor), we determined that there was no goodwill impairment. We determined that as of December 31, 2024, our fair value was less than our carrying amount. As a result, we recorded a $30.3 million goodwill impairment charge during the period from July 31, 2024 to December 31, 2024 (Successor). The impairment was driven by a sustained decline in our share price and market capitalization.

Common Stock Valuations (Predecessor)

Due to the absence of a public trading market, we determined the fair value of our common stock by considering numerous objective and subjective factors. The factors considered include, but are not limited to:

(i) the results of contemporaneous independent third-party valuations of our common stock;

(ii) the prices, rights, preferences and privileges of our preferred stock relative to those of our common stock;

(iii) the lack of marketability of our common stock;

(iv) actual operating and financial results;

(v) current business conditions and projects; and

(vi) the likelihood of achieving a liquidity event.

As of December 31, 2023, the fair value of our common stock was determined with the probability weighted expected return method ("PWERM"), which assessed the probability weighted depending on different scenarios. As of June 30, 2024, the valuation was based on the scenario (i) bankruptcy/suboptimal sale scenario reflecting a zero return to common shareholders, with 0% probability, (ii) an "as converted" merger with a 95% probability, and (iii) a delayed but successful liquidity event per the option pricing method, with 5% probability. As of December 31, 2023, the valuation was based on the scenario (i) the bankruptcy/suboptimal sale scenario reflecting a zero return to common shareholders, with 20% probability (ii) a consummation of a business combination transaction with a special purpose acquisition company ("SPAC"), with 40% probability, and (iii) a delayed but successful liquidity event per the option pricing method, with 40% probability. As of December 31, 2023, in determining the value under the consummation of a business combination transaction with a SPAC scenario, we utilized the preliminary terms of the letter of intent with such SPAC that (i) the transaction based on diluted equity value of $38.8 million and (ii) all dilutive instruments are expected to convert or be exercised resulting in 6,369,633 total common shares outstanding.

The valuation under the scenario of a delayed but successful liquidity event per the option pricing method was determined by the fair value per share at a marketable basis applied by a discount for lack marketability ("DLOM"). The fair value per share at a marketable basis was determined using the interval option value allocation approach. The DLOM was determined based on Finnerty put option model, marketability factors and restricted stock studies.

The significant unobservable inputs into the valuation model include:

- the timing of potential events (for example, a consummation of a business combination transaction with a SPAC) and their probability of occurring;
- the selection of guideline public company multiples; and
- a discount for the lack of marketability of the common stock.

An increase or decrease in any of the unobservable inputs in isolation could result in a material change. In the future, depending on the weight of evidence and valuation approaches used, these or other inputs may have a more significant impact on the estimated fair value.

Convertible Notes Valuation (Predecessor)

As permitted under ASC 825, Financial Instruments ("ASC 825"), the Company elected the fair value option to account for the October 2022 Convertible Notes, and the Bridge Financing Notes in order to measure those liabilities at amounts that more accurately reflect the current economic environment in which Legacy Adagio operates.

The change in fair value of the Convertible Securities Notes, excluding amounts related to interest, is recorded in "Convertible notes fair value adjustment," while amounts related to interest are recorded as interest expense in the consolidated statements of operations and comprehensive loss. As a result of applying the fair value option, direct costs and fees related to the issuance of the convertible notes were expensed as incurred (i.e., not recognized as deferred costs). Refer to *Note 3-Fair Value Measurements* in our consolidated financial statements for additional detail.

As of December 31, 2023, Adagio calculated the value of the convertible notes based on the equity value from 409(a) valuations, considering the expected payoff of the convertible notes upon different types of events.

Utilizing the PWERM, Adagio assessed the probability that the October 2022 Convertible Notes would be converted to common stock through the result of mandatory prepayment, private investment in PIPE Financing, or no PIPE Financing and no Qualified Financing, weighted with a probability of 20%, 40% and 40%, respectively, as of December 31, 2023.

Utilizing the PWERM, Adagio assessed the probability that the April 2023 Notes and the November 2023 Notes would be converted to common stock as a result of a liquidation event, PIPE Financing, or no PIPE Financing and no Qualified Financing, weighted with a probability of 20%, 40% and 40% as of December 31, 2023. Adagio also implied a credit spread by calibrating the value of the April 2023 Notes at issuance to the par value and then adjusted the calibrated credit spread for seniority difference and the market related movements as appropriate.

Additional assumptions used to estimate the fair value include: (i) the expected timing of the conversion, (ii) the amount subject to equity conversion, the sum of the notes' principal and unpaid accrued interest, (iii) expected volatility, (iv) risk-free interest rate, and (v) the discount rate, based on the observed option-adjusted spread (OAS) data of traded bonds rated CCC-.

In determining the fair value of the convertible notes as of July 31, 2024, prior to the Closing, the Company used the observed closing stock price of ARYA as of July 31, 2024 multiplied by the actual number of shares that the convertible notes converted into.

SVB Term Loan (Predecessor)

Legacy Adagio accounts for the SVB Term Loan at residual value on the date of issuance. The expected life of the SVB Term Loan is the contractual term ending on the maturity date. Legacy Adagio classifies the term loan as current liabilities within twelve months of the maturity date or when otherwise due. Interest expense is recognized in the consolidated statements of operations and comprehensive loss over the contractual term of the loan. See *Note 9- Debt* in our consolidated financial statements for additional information related to the SVB Term Loan.

SVB Warrants (Predecessor)

Adagio accounts for SVB Warrants outstanding as warrant liabilities at fair value, determined using the Black-Scholes-Merton option pricing model based on the common stock value from 409(a) valuation. The assumption used to estimate the fair value include: (i) expected volatility, (ii) risk-free interest rate, (iii) expected dividend yield, and (iv) expected term.

The liability is subject to remeasurement at each reporting period and any change in fair value is recognized in the consolidated statements of operations and comprehensive loss. See *Note 10-Warrants* in our consolidated financial statements for additional information related to the warrants.

Series E Pre-funded Warrants (Predecessor)

On June 25, 2024, Legacy Adagio issued to a certain investor the pre-funded warrants to purchase Legacy Adagio's Series E Preferred Stock ("Series E Pre-funded Warrants"), in exchange of the investor's existing holding of Series E Preferred Stock. The exercise price of the pre-funded warrants is $0.001 per warrant share. Legacy Adagio measured the Series E Pre-funded Warrants at fair value based on the indicated fair value of Series E Preferred Stock, which is not observable in the market.

Convertible Preferred Stock (Predecessor)

Prior to the Closing, Legacy Adagio recorded convertible preferred stock at fair value on the dates of issuance, net of issuance costs. Upon the occurrence of certain events that are outside our control, including a deemed liquidation event, holders of the convertible preferred stock can cause redemption for cash. As the preferred stock is considered to be contingently redeemable, the preferred stock has been classified outside of permanent equity. The preferred stock will be accreted to its redemption value if the deemed liquidation events are considered probable of occurring. Upon the consummation of the Business Combination, the Legacy Adagio's convertible preferred stocks was converted into shares of Legacy Adagio's common stock on a one-to-one basis prior to Adagio Merger Effective Time and then converted into the Company's common stock at the Closing based on the exchange ratio set forth in the Business Combination Agreement.

Convertible Securities Notes (Successor)

The Company measures the Convertible Securities Notes at fair value based on significant inputs not observable in the market, which caused them to be classified as Level 3 measurements within the fair value hierarchy. The change in fair value of the Convertible Securities Notes, excluding amounts related to interest, is recorded in "Convertible notes fair value adjustment," while amounts related to interest are recorded as interest expense in the consolidated statements of operations and comprehensive loss.

The Company utilized the binomial lattice model to value the Convertible Securities Notes at the Closing Date and as of December 31, 2024. See *Note 9- Debt* in our consolidated financial statements for additional information related to the SVB Term Loan.

Convert Warrants (Successor)

On July 31, 2024, the Company issued 1,500,000 Convert Warrants in connection with the issuance of the $20.0 million Convertible Securities Notes.

As set forth in the agreement of the Convertible Securities Notes, the Convert Warrants are exercisable on a cashless basis or on a gross basis for one share of the Company's common stock at $24.0 per share, subject to adjustments. The Company may be required to cash settle the Convert Warrants when it fails to timely deliver shares to the holder who exercises the Convert Warrants or upon the occurrence of a fundamental transaction. It is determined that the Convert Warrants do not meet the equity classification requirements under ASC 815 as the Covert Warrants may require cash settlement outside of the Company's control upon a failure of timely delivery of shares or a fundamental transaction, and therefore the Convert Warrants are accounted for as derivative liabilities, and measured at fair value both initially and subsequently with changes in fair value recognized as warrant liabilities fair value adjustment within the consolidated statements of operations and comprehensive loss.

The Convert Warrants are classified as Level 3 measurements within the fair value hierarchy. The Company utilized the Black-Scholes-Merton option model to value the Convertible Securities Notes at the Closing Date and as of December 31, 2024.

PIPE Base Warrants (Successor)

On the Closing Date, the Company issued Base Warrants ("PIPE Base Warrants") along with the Company's common stock in connection with the PIPE Financing.

The Base Warrants can be exercised to the Company's common stock at any time during the period from the issuance date to the expiration date which is the fifth anniversary from the date of issuance. The warrants can be exercised on a gross or net basis at an exercise price of $10 per share.

The Base Warrants were fair valued at $2.41 per unit on the date of issuance based on the assumptions including (i) the value of the Company's common stock is $6.64 per share; (ii) a risk-free rate at 3.93%; (iii) zero dividend yield; (iv) the common stock volatility at 84.0% and a volatility haircut of 10%; (v) the remaining term is 5 years.

According to ASC 815, it is determined that the Base Warrants associated with the PIPE Financing are indexed to the Company's common stock and are accounted for as equity, which is initially measured at fair value. The Base Warrants are classified as equity in the consolidated financial statements because they meet the ASC 815-40 indexation guidance. Specifically, 1) the Base Warrants can be exercised at any time during the exercise period without contingencies; 2) the Base Warrants can be settled in a fixed number of shares upon exercise with any adjustments, such as antidilution and alternative issuance adjustments, consistent with ASC 815 guidance, which does not preclude equity classification. Additionally, the Company has sufficient authorized shares available to settle the Base Warrants, and all the adjustments are in the control of the Company, further supporting the equity classification.

Sponsor Earnout (Successor)

In September 2024, the Company issued 1,147,500 shares of the Company's common stock (such issuance, the "Sponsor Earnout") to the ARYA Sciences Holdings IV ("AYRA Sponsor") under the Sponsor Letter Agreement dated February 13, 2024 ("the Sponsor Letter Agreement"). Pursuant to the agreement, the Sponsor Earnout shall be unvested and vests upon the earlier of: i) During the period from the effective time to the 10th anniversary of the Closing Date (the "Earn-Out Period"), the stock price of the Company's common stock equals or exceeds $24.00 per share (the "Trigger Price") for any 20 trading days within any 30 trading day period from and after the Closing Date (the "Earn-Out Target"), and ii) immediately prior to the consummation of a company sale during the Earn-Out Period.

As of the reporting date, the vesting of the Sponsor Earnout was not considered probable.

According to ASC 815, it is determined that the Sponsor Earnout is indexed to the Company's common stock and classified as equity and is initially measured at fair value and not subsequently remeasured. The Sponsor Earnout vests when the Company's stock price meets a stated price or there is a company sale during the earnout period. Upon meeting either vesting condition, the same number of the Company's common stock would be issued and no longer subject to forfeiture or cancellation. The Sponsor Earnout meets the ASC 815-40 indexation guidance. Specifically, the stated stock price and company sale, as the exercise contingencies, do not preclude equity indexation and there is no variability in the number of shares issuable under the Sponsor Earnout. Additionally, the Sponsor Earnout at the issuance meets the ASC 815-40 equity classification criterion as the Company has sufficient authorized shares available to settle the Sponsor Earnout and all the antidilution adjustments are in the control of the Company.

PIPE Pre-funded Warrants (Successor)

On July 31, 2024, the Company issued 670,000 pre-funded warrants in exchange for cash proceeds in PIPE Financing to certain Other PIPE Investors ("PIPE Pre-funded Warrants").

As set forth in the agreement of the PIPE Pre-funded Warrants, the PIPE Pre-funded Warrants are exercisable on a cashless basis or on a gross basis for one share of the Company's common stock at $0.01 per share, subject to adjustments. The Company may be required to cash settle the PIPE Pre-funded Warrants when it fails to timely deliver shares to the holder who exercises the PIPE Pre-funded Warrants or upon the occurrence of a fundamental transaction. It is determined that the PIPE Pre-funded Warrants do not meet the equity classification requirements under ASC 815 as the PIPE Pre-funded Warrants may require cash settlement outside of the Company's control upon a failure of timely delivery of shares or a fundamental transaction, and therefore the PIPE Pre-funded Warrants are accounted for as derivative liabilities, and measured at fair value both initially and subsequently with changes in fair value recognized as warrant liabilities fair value adjustment within the consolidated statements of operations and comprehensive loss.

The PIPE Pre-funded Warrants are classified as Level 3 measurements within the fair value hierarchy. The fair value of the PIPE Pre-funded Warrants is based on the fair value of the Company's common stock minus the exercise price.

On December 26, 2024, a total of 670,000 pre-funded warrant shares were exercised on a cashless basis for 663,096 shares of the Company's common stock. The exercise price for the pre-funded warrants was $0.9705 per share.

Strategic Realignment of Resources and Corporate Restructuring

On December 1, 2023, Legacy Adagio approved a strategic realignment of resources and corporate restructuring (the "RIF") designed to reallocate capital, conformant to its business focus for the next two years.

As part of the RIF, Legacy Adagio initiated a reduction in its workforce of 20 employees, representing approximately 19% of Legacy Adagio's employees, which was completed on December 15, 2023. Legacy Adagio made no payment for severance or related benefit costs. Legacy Adagio made no payment of retention bonuses.

Emerging Growth Company Status

We are an emerging growth company ("EGC"), as defined in the JOBS Act. The JOBS Act permits companies with EGC status to take advantage of an extended transition period to comply with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies. We have elected to use this extended transition period to enable us to comply with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting standards as of public company effective dates.

In addition, we intend to rely on the other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, if, as an EGC, we intend to rely on such exemptions, we are not required to, among other things: (i) provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act; (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act; (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis); and (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the Chief Executive Officer's compensation to median employee compensation.

We will remain an EGC under the JOBS Act until the earliest of (i) the last date of our fiscal year in which we have total annual gross revenue of at least $1.235 billion, (ii) the date on which we are deemed to be a "large accelerated filer" under the rules of the SEC with at least $700.0 million of outstanding securities held by non-affiliates, or (iii) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the previous three-years.

Recent Accounting Pronouncements

See *Note 2- Summary of Significant Accounting Policies* in our consolidated financial statements for a description of recent accounting pronouncements applicable to our financial statements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We have operations primarily within the United States and we are exposed to market risk in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. We do not believe that inflation has had a material effect on our business, results of operations or financial condition. Nonetheless, if our costs were to become subject to significant inflationary pressures, we may not be able to fully offset such higher costs. Our inability or failure to do so could harm our business, results of operations or financial condition.

Our revenue generated in Europe, as well as costs and expenses denominated in Euro, expose us to the risk of fluctuations in foreign currency exchange rates against the U.S. dollar. We are exposed to foreign currency risks related to our revenue and operating expenses, along with certain intercompany transactions, denominated in Euro. Accordingly, changes in exchange rates may negatively affect our future revenue and other operating results as expressed in U.S. dollars. We do not believe that foreign currency exchange risk has had a material effect on our business, results of operations or financial condition.

Item 8. Financial Statements And Supplementary Data

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of
Adagio Medical Holdings, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Adagio Medical Holdings, Inc. (the "Company") as of December 31, 2024 (Successor) and 2023 (Predecessor), and the related consolidated statements of operations and comprehensive loss, consolidated statements of convertible preferred stock and stockholders' equity (deficit), and consolidated statements of cash flows for the periods July 31 to December 31, 2024 (Successor), January 1 to July 30, 2024 (Predecessor) and January 1 to December 31, 2023 (Predecessor), and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for the periods July 31 to December 31, 2024 (Successor), January 1 to July 30, 2024 (Predecessor) and January 1 to December 31, 2023 (Predecessor), in conformity with accounting principles generally accepted in the United States of America.

Going concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans regarding these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ WithumSmith+Brown, PC

We have served as Company's auditor since 2023.

Whippany, New Jersey

March 27, 2025

PCAOB ID No. 100

Adagio Medical Holdings Inc.
Consolidated Balance Sheets
(in thousands, except share and per share data)

	Successor	Predecessor
	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 20,586	$ 1,383
Accounts receivable, net	35	71
Inventory, net	2,566	3,322
Prepaid expenses	1,940	232
Other current assets	222	177
Total current assets	25,349	5,185
Property and equipment, net	1,961	1,487
Right-of-use assets, net	188	130
Intangible assets, net	6,969	—
Goodwill, net	13,967	—
Other assets	14	23
Total assets	$ 48,448	$ 6,825
Liabilities, convertible preferred stock, and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 2,840	$ 3,830
Accrued liabilities	3,673	3,048
Operating lease liabilities, current	143	79
Convertible notes payable, current	—	36,430
Warrant liabilities	—	78
Term loan, current	—	1,695
Accrued transaction costs	3	444
Other accrued liabilities	1,104	1,572
Total current liabilities	7,763	47,176
Operating lease liabilities, long-term	46	52
Convertible notes payable, non-current	16,076	—
Warrant liabilities	152	—
Deferred tax liabilities, net	883	—
Term loan, long-term	—	143
Other long-term liabilities	3,616	8
Total liabilities	28,536	47,379
Commitments and contingencies (Note 12)		
Legacy Adagio's Convertible preferred stock, $0.001 par value; 4,939,946 shares authorized as of December 31, 2023; 4,939,946 shares issued and outstanding as of December 31, 2023, with aggregate liquidation preference of $91,637 as of December 31, 2023	—	91,469
Stockholders' equity (deficit):		
Legacy Adagio's common stock, $0.001 par value; 6,594,946 shares authorized as of December 31, 2023; 786,510 shares issued as of December 31, 2023; 779,908 shares outstanding as of December 31, 2023	—	1
Common stock, $0.0001 par value; 210,000,000 shares authorized as of December 31, 2024; 15,198,232 shares issued and outstanding as of December 31, 2024	2	—
Additional paid-in capital	90,495	1,608
Accumulated other comprehensive income	1	17
Accumulated deficit	(70,586)	(133,649)
Total stockholders' equity (deficit)	19,912	(132,023)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	$ 48,448	$ 6,825

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

Adagio Medical Holdings Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Years Ended December 31		
	2024		2023
	Successor	Predecessor	Predecessor
	July 31 to December 31	January 1 to July 30	January 1 to December 31
Revenue	$ 269	$ 333	$ 300
Cost of revenue and operating expenses:			
Cost of revenue	1,937	1,381	1,306
Research and development	4,634	7,585	15,399
Selling, general, and administrative	6,976	13,047	11,537
Impairment - Goodwill	30,324	—	—
Impairment - Intangible assets, net	18,878	—	—
Total cost of revenue and operating expenses	62,749	22,013	28,242
Loss from operations	(62,480)	(21,680)	(27,942)
Other income (expense):			
Convertible notes fair value adjustment	929	2,059	(6,930)
Warrant liabilities fair value adjustment	6,576	191	(42)
Interest expense	(1,105)	(1,818)	(1,659)
Interest income	420	3	3
Other (expense) income, net	1,897	(33)	(20)
Total other income (expense), net	8,717	402	(8,648)
Net loss	$ (53,763)	$ (21,278)	$ (36,590)
Other comprehensive loss:			
Foreign currency translation adjustment	1	3	(11)
Comprehensive loss	$ (53,762)	$ (21,275)	$ (36,601)
Basic net loss per share (Note 15)	$ (3.38)	$ (26.08)	$ (48.16)
Diluted net loss per share (Note 15)	$ (3.70)	$ (26.08)	$ (48.16)

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

Adagio Medical Holdings Inc.
Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2022 (Predecessor)	**4,939,946**	**$ 91,469**	**756,160**	**$ 1**	**$ 1,153**	**$ (97,059)**	**$ 28**	**$ (95,877)**
Foreign currency translation adjustment	—	—	—	—	—	—	(11)	(11)
Stock option exercises	—	—	23,748	—	13	—	—	13
Stock-based compensation	—	—	—	—	442	—	—	442
Net loss	—	—	—	—	—	(36,590)	—	(36,590)
Balance, December 31, 2023 (Predecessor)	**4,939,946**	**$ 91,469**	**779,908**	**$ 1**	**$ 1,608**	**$ (133,649)**	**$ 17**	**$ (132,023)**
Foreign currency translation adjustment	—	—	—	—	—	—	3	3
Exchange preferred stock for pre-funded warrants	(207,902)	(4,686)	—	—	4,332	—	—	4,332
Stock option exercises	—	—	305	—	9	—	.	9
Stock-based compensation	—	—	—	—	642	—	—	642
Net loss	—	—	—	—	—	(21,278)	—	(21,278)
Balance as of July 30, 2024 (Predecessor)	**4,732,044**	**$ 86,783**	**780,213**	**$ 1**	**$ 6,591**	**$ (154,927)**	**$ 20**	**$ (148,315)**
Balance as of July 31, 2024 (Successor)	**—**	**$ —**	**13,387,636**	**$ 1**	**$ 89,786**	**$ (16,823)**	**$ —**	**$ 72,964**
Foreign currency translation adjustment	—	—	—	—	—	—	1	1
Exercise of pre-funded warrants	—	—	663,096	1	709	—	—	710
Issuance of earn-out shares	—	—	1,147,500	—	—	—	—	—
Net loss	—	—	—	—	—	(53,763)	—	(53,763)
Balance, December 31, 2024 (Successor)	**—**	**$ —**	**15,198,232**	**$ 2**	**$ 90,495**	**$ (70,586)**	**$ 1**	**$ 19,912**

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

Adagio Medical Holdings Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Years Ended December 31		
	2024		2023
	Successor	Predecessor	Predecessor
	July 31 to December 31	January 1 to July 30	January 1 to December 31
Cash flows from operating activities:			
Net loss	$ (53,763)	$ (21,278)	$ (36,590)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	740	646	532
Non-cash operating lease expense	56	98	159
Stock-based compensation	—	642	442
Provision for inventory impairment	(4)	15	25
Amortization of term loan discount	—	10	16
Loss on disposal of property and equipment	—	62	3
Impairment - Goodwill	30,324	—	—
Impairment - Intangible assets, net	18,878	—	—
Change in fair value of convertible notes payable	(929)	(2,059)	6,930
Change in fair value of warrant liabilities	(6,576)	(191)	42
Net change in operating assets and liabilities:			
Accounts receivable, net	67	(32)	(70)
Inventory, net	1,399	(773)	(2,976)
Prepaid expenses and other current assets	(886)	(95)	410
Accounts payable	(1,933)	(2,628)	2,821
Accrued liabilities	127	511	886
Accrued transaction costs	3	7,446	444
Other accrued liabilities	1,001	1,734	1,435
Operating lease liabilities	(56)	(98)	(161)
Other long-term liabilities	—	—	—
Deferred taxes	(1,917)	—	—
Net cash used in operating activities	(13,469)	(15,990)	(25,652)
Cash flows from investing activities:			
Purchases of property and equipment	(1,280)	(368)	(333)
Purchases of software	—	—	(7)
Net cash used in investing activities:	(1,280)	(368)	(340)
Cash flows from financing activities:			
Proceeds from exercise of common stock options	—	—	18
Proceeds from issuance of convertible notes payable	—	16,500	20,000
Proceeds from term loan	—	—	3,000
Repayment of non-convertible term loan	—	(867)	(1,143)
Net cash provided by financing activities	—	15,633	21,875
Effect of foreign currency translation on cash and cash equivalents	181	24	(47)
Net change in cash and cash equivalents	(14,568)	(701)	(4,164)
Cash and cash equivalents, at beginning of period	35,154	1,383	5,547
Cash and cash equivalents, at end of period	$ 20,586	$ 682	$ 1,383
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ —	$ 85	$ 208
Supplemental disclosure of noncash investing and financing activities:			
Right-of-use assets obtained in exchange for lease liabilities	$ —	$ (216)	$ —
Lease liabilities recorded for operating lease right-of-use assets	$ —	$ 216	$ —
Amount of term loan proceeds allocated to warrant liabilities	$ —	$ —	$ 36
Exchange preferred stock for pre-funded warrants	$ —	$ 4,332	$ —

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

Adagio Medical Holding, Inc.
Notes to Consolidated Financial Statements
(audited)

Note 1 - Description of Organization and Business Operations

Our Company

Adagio Medical Holding, Inc. (formerly known as Aja Holdco, Inc.) and its wholly-owned subsidiaries (collectively, the "Company", the "Successor") is medical device company focused on developing and commercializing products for the treatment of cardiac arrhythmias. The Company's unique, proprietary technology portfolio consists of Ultra-Low Temperature Cryoablation ("ULTC") both alone and in combination with Pulsed Field Ablation (also known as Pulsed Field Cryoablation or "PFCA"), along with associated catheters and consoles. Legacy Adagio (as defined below) received CE Marking in Europe for its VT Cryoablation System in March 2024 and has commercially launched in the EU. The Company has not launched commercially in the U.S. but is working towards obtaining the necessary regulatory approvals to do so. The Company is headquartered in Laguna Hills, California.

On July 31, 2024 (the "Closing Date"), ARYA Sciences Acquisition Corp IV, a Cayman Islands exempted company ("ARYA"), Aja Holdco, Inc. ("ListCo"), a Delaware corporation and wholly-owned subsidiary of ARYA, Aja Merger Sub 1, a Cayman Islands exempted company and wholly-owned subsidiary of ListCo ("ARYA Merger Sub"), Aja Merger Sub 2, Inc., a Delaware corporation and wholly-owned subsidiary of ListCo ("Company Merger Sub"), and Adagio Medical, Inc., a Delaware corporation ("Legacy Adagio", the "Predecessor"), consummated the business combination (the "Business Combination") pursuant to the terms of the Business Combination Agreement, dated February 13, 2024, by and among the foregoing parties, as amended by the Consent and Amendment No. 1 to Business Combination Agreement, dated as of June 25, 2024, by and between ARYA and Adagio (the "Business Combination Agreement").

Pursuant to the Business Combination Agreement, on the Closing Date, (i) ARYA Merger Sub merged with and into ARYA (the "ARYA Merger") and Company Merger Sub merged with and into Legacy Adagio (the "Adagio Merger" and, together with the ARYA Merger, the "Mergers"), with ARYA and Legacy Adagio surviving the Mergers and, after giving effect to such Mergers, each of ARYA and Legacy Adagio becoming a wholly-owned subsidiary of ListCo (the time that the ARYA Merger becomes effective being referred to as the "ARYA Merger Effective Time," the time that the Adagio Merger becomes effective being referred to as the "Adagio Merger Effective Time," the time after which both Mergers become effective being referred to as the "Closing," and the date on which the Closing occurs being referred to as the "Closing Date"), (ii) ListCo filed with the Secretary of State of the State of Delaware an amended and restated certificate of incorporation of ListCo, and the board of directors of ListCo approved and adopt amended and restated bylaws of ListCo, and (iii) ListCo changed its name to Adagio Medical Holdings, Inc.

Refer to *Note 3- Forward Merger* for details of the Business Combination.

The Company's common stock (as defined below) began trading on August 1, 2024, under the symbol ADGM on the Nasdaq Capital Market (NASDAQ: ADGM).

Liquidity and Going Concern

The accompanying consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern. The Company has limited revenue and has experienced recurring operating losses and negative cash flows from operations since its inception and anticipates that it will continue to do so for at least the next several years.

As of December 31, 2024, the Successor reported cash and cash equivalents of $20.6 million, and an accumulated deficit of $70.6 million. For the period from July 31, 2024 to December 31, 2024 (Successor), from January 1, 2024 to July 30, 2024 (Predecessor), and for the year ended December 31, 2023 (Predecessor), net loss was $(53.8) million, $(21.3) million, and $(36.6) million, respectively. The net cash used in operating activities was $13.5 million, $16.0 million, and $25.7 million, respectively.

Management does not believe the Company's current cash and cash equivalents are sufficient to fund operations for at least the next 12 months from the issuance date of the consolidated financial statements. Management believes that this raises substantial doubt about the Company’s ability to continue as a going concern.

Management intends to mitigate the conditions and events that raise substantial doubt about its ability to continue as a going concern entity by (i) negotiate other cash equity or debt financing in the short-term, (ii) continue to pursue the necessary regulatory approvals to launch commercially in the U.S. market, and (iii) execute cost-cutting measures to manage cash burn. However, there can be no assurances that the current plans will generate any liquidity to the Company or be available on terms acceptable to the Company.

If the Company is unable to maintain sufficient financial resources, its business, financial condition, and results of operations will be materially and adversely affected. The Company may be required to delay, limit, reduce or terminate its product discovery and development activities or future commercialization efforts. The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern and do not include adjustments that might result from the outcome of this uncertainty. This basis of accounting contemplates the recovery of the Company’s assets and the satisfaction of liabilities in the normal course of business.

Strategic Realignment of Resources and Corporate Restructuring

On December 1, 2023, Legacy Adagio approved a strategic realignment of resources and corporate restructuring (the “RIF”) designed to reallocate capital, conformant to its business focus for the next two years.

As part of the RIF, Legacy Adagio initiated a reduction in its workforce of 20 employees, representing approximately 19% of Legacy Adagio’s employees, which was completed on December 15, 2023. Legacy Adagio made no payment for severance or related benefit costs. Legacy Adagio made no payment of retention bonuses.

Note 2 - Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

As a result of the Business Combination, for accounting purposes, ListCo is the acquirer and Legacy Adagio is the accounting acquiree and predecessor. The financial statement presentation includes the financial statements of Legacy Adagio as "Predecessor" for the periods prior to the Closing Date (the "Predecessor Period(s)"), and of the Company as "Successor" for the periods after the Closing Date (the "Successor Period(s)"), including the consolidation of Legacy Adagio and ARYA. The Successor Period includes results of operations and cash flows for the period from July 31, 2024 through December 31, 2024.

As a result of the application of the acquisition method of accounting as of the Closing Date of the Business Combination, the accompanying consolidated financial statements include a black line division that indicates that the Predecessor and Successor reporting entities shown are presented on a different basis and are therefore, not comparable.

Emerging Growth Company Status

The Company is an "emerging growth company," as defined in Section 2(a) of the Securities Act of 1933, as amended, (the "Securities Act"), as modified by the Jumpstart our Business Startups Act of 2012 (the "JOBS Act").

Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. The Company has elected not to opt out of such extended transition period which means that when an accounting standard is issued or revised and it has different application dates for public or private companies, the Company, as an emerging growth company, can adopt the new standard at the time private companies adopt the new or revised standard.

Principles of Consolidation

The consolidated financial statements include the accounts of Adagio Medical Holdings, Inc., and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates and Assumptions

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, expenses and disclosures of contingent assets and liabilities. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of revenue and expenses that are not readily apparent from other sources. Actual results could differ from those estimates.

Segments

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Operating Decision Maker ("CODM") in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is its Chief Executive Officer. The Company has determined that it operates as one reportable segment, as the CODM reviews financial information presented on a consolidated basis for purposes of making operating decisions, allocating resources, and evaluating financial performance.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less from the date of purchase, including its money market account, to be cash equivalents. All of the Company's cash equivalents have liquid markets. Cash deposits held in accounts at each United States financial institution are insured up to $0.25 million by the Federal Deposit Insurance Corporation ("FDIC"). Cash deposits held in accounts at each European Union financial institution are insured up to €0.1 million by the Deposit Guarantee Scheme. The Company maintains its cash in bank deposit accounts that, at times, may exceed the stated insured limits. Any loss incurred or lack of access to uninsured funds could have a significant adverse impact on the Company's financial condition, results of operations and cash flows. Management does not expect any losses on such accounts.

Concentrations of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially subject the Company to credit risk consist principally of cash and cash equivalents. The Company deposits its cash and cash equivalents with major financial institutions; however, at times, deposits may exceed the amount of insurance provided. The Company has not experienced any losses on its deposits since inception.

Revenue Recognition

The Company generates product revenue primarily from the sale of cryoablation catheters (collectively, the "Consumables") used with the Company's cryoablation consoles ("Consoles"). The Company sells its products directly to hospitals and medical centers. To a lesser extent, the Company also generates lease revenue from the implied rental of Consoles loaned to customers at no charge.

The Company accounts for revenue earned from contracts with customers under ASC 606, Revenue from Contracts with Customers ("ASC 606"). The core principle of ASC 606 is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. The Company recognizes revenue from sales to customers applying the following five steps:

- Step 1: Identify the contract with the customer.
- Step 2: Identify the performance obligations in the contract.
- Step 3: Determine the transaction price.
- Step 4: Allocate the transaction price to the performance obligations in the contract.
- Step 5: Recognize revenue when, or as, the Company satisfies a performance obligation.

The Company's customer contracts generally have performance obligations that contain deliverables consisting of the Consumables and may also include Consoles loaned to customers. The Company evaluates each promise within a multiple-performance obligation arrangement to determine whether it represents a distinct performance obligation. The primary performance obligations in the Company's customer arrangements from which it derives revenue, is the sale of the Consumables.

When the Company loans the Console to the customer, it retains title to the Console at all times and does not require minimum purchase commitments from the customer related to any Consumables. In such cases, the Company invoices the customer for the Consumables based on customer orders received. Over time, the Company expects to recover the cost of the loaned Console through the customer's continued purchasing and use of additional Consumables. For these reasons, the Company has determined that part of the arrangement consideration for the Consumables is an implied rental payment for use of the Console. Therefore, the Company allocates the arrangement consideration between the lease components (i.e., the Console) and non-lease components (i.e., the Consumables) based on the relative estimated standalone selling price of each distinct performance obligation consistent with ASC 842, Leases and ASC 606. Revenue allocated to the lease components was not material for the periods from January 1, 2024 to July 30, 2024 (Predecessor), from July 31, 2024 to December 31, 2024 (Successor) and for the year ended December 31, 2023 (Predecessor).

Revenue from sales to customers of the Consumables is classified as revenue in the Company's consolidated statements of operations and comprehensive loss. The delivery of the Consumables are performance obligations satisfied at a point in time, when the control of the goods is transferred to the customer (i.e., FOB Shipping Point). Revenue is recognized when control is transferred to the customer in an amount that reflects the consideration the Company expects to be entitled to in exchange for the product.

Other Revenue Considerations

Revenue is reported net of sales tax. The Company has made the accounting policy election not to recognize a separate performance obligation for the shipment of products to the customer but to account for it as fulfillment cost.

The Company's contracts primarily include fixed consideration. The Company only includes estimated variable amounts in the transaction price to the extent it is probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is resolved. Customers are generally required to pay within 30 days.

Any incremental costs to obtain contracts are recorded as selling, general and administrative expense as incurred due to the short duration of the Company's contracts.

The Company does not assess whether promised goods or services are performance obligations if they are deemed immaterial in the context of the contract with the customer. Additionally, the Company does not assess whether a contract has a significant financing component if the expectation at contract inception is that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

For the periods from January 1, 2024 to July 30, 2024 (Predecessor), from July 31, 2024 to December 31, 2024 (Successor), and for the year ended December 31, 2023 (Predecessor), revenue was generated only from European markets.

Inventory

Inventory consists of raw materials, work-in-process, and finished products and is valued at the lower of cost or net realizable value. The method by which that amounts are removed from the inventory is first-in first-out ("FIFO"). Cost may include materials, labor, and manufacturing overhead. The carrying value of inventory is reviewed for potential impairment whenever indicators suggest that the cost of inventory exceeds the carrying value and management adjusts the inventory to its net realizable value. The Company also periodically evaluates inventory for estimated losses from excess quantities and obsolescence and writes down the cost of inventory to net realizable value at the time such determinations are made. Net realizable value is determined using the estimated selling price, in the ordinary course of business, less estimated costs to complete and dispose. Inventory used in research and development activities is expensed when incurred.

Property and Equipment

Property and equipment are recorded at cost, less accumulated depreciation. Depreciation and amortization are provided using the straight-line method over the estimated useful lives of the related assets, generally three to five years, or, in the case of leasehold improvements, over the remaining life of the lease term. Specifically, Consoles had a five-year useful life as of December 31, 2023, and effective on January 1, 2024, the useful life of Consoles was changed to three years to better reflect the estimated periods during which these Consoles will remain in service. The impact of the change in the estimated useful life of Consoles is not material to the Predecessor Periods or Successor Periods, nor to the future remaining life of the Consoles.

Property and equipment include equipment that is loaned to customers and located at customer premises. The Company retains ownership of the equipment held for evaluation by customers and has the right to remove the equipment if it is not being utilized according to expectations.

Intangible Assets

Intangible assets with finite useful lives are amortized on a straight-line basis over their estimated useful lives. In determining the estimated useful lives of definite-lived intangibles, the Company considers the nature, competitive position, life cycle position and expected future operating cash flows of the acquired asset, as well as its commitment to support these assets through continued investment and legal infringement protection.

The Company's intangible assets subject to amortization and other long-lived assets, are reviewed for impairment in accordance with ASC 360, *Property, Plant and Equipment*, which requires that companies consider whether events or changes in facts and circumstances, both internally and externally, may indicate that an impairment of long-lived assets held for use are present. The Company reviews long-lived assets for impairment at least annually or whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the asset, the assets are written down to their estimated fair values and the loss is recognized in the consolidated statements of operations.

For the period from January 1, 2024 to July 30, 2024 (Predecessor) and for the year ended December 31, 2023 (Predecessor), the Company determined that there was no impairment of definite-lived intangible assets. The Company determined that as of December 31, 2024, the fair value of its definite lived intangible assets was less than the carrying amount. As a result, the Company recorded a $3.8 million impairment charge during the period from July 31, 2024 to

December 31, 2024 (Successor). The impairment was driven by a sustained decline in the Company's share price and market capitalization.

Indefinite-lived intangible assets consist of In-Process Research and Development ("IPR&D"). Intangible assets with indefinite lives are tested for impairment if impairment indicators arise and, at a minimum, annually. However, an entity is permitted to first assess qualitative factors to determine if a quantitative impairment test is necessary. Further testing is only required if the entity determines, based on the qualitative assessment, that it is more likely than not that an indefinite-lived intangible asset's fair value is less than its carrying amount. Otherwise, no further impairment testing is required. The indefinite-lived intangible asset impairment test consists of a one-step analysis that compares the fair value of the intangible asset with its carrying amount. If the carrying amount of an intangible asset exceeds its fair value, an impairment loss is recognized in an amount equal to that excess.

For the period from January 1, 2024 to July 30, 2024 (Predecessor) and for the year ended December 31, 2023 (Predecessor), the Company determined that there was no impairment of indefinite-lived intangible assets. The Company determined that as of December 31, 2024, the fair value of its indefinite-lived intangible assets was less than the carrying amount. As a result, the Company recorded a $15.1 million impairment charge during the period from July 31, 2024 to December 31, 2024 (Successor). The impairment was driven by a sustained decline in the Company's share price and market capitalization.

Goodwill

In accordance with ASC 350, Intangibles – Goodwill and Other, the Company tests goodwill for impairment at the reporting unit level. The Company has one reporting unit for the goodwill impairment testing purposes.

Goodwill is tested for impairment on an annual basis in the fourth quarter, or more frequently if events or changes in circumstances indicate the carrying value of goodwill may not be recoverable (a "triggering event"). On the occurrence of a triggering event, an entity has the option to first assess qualitative factors to determine whether a quantitative impairment test is necessary. If it is more likely than not that goodwill is impaired, the fair value of the reporting unit (the Company) is compared with its carrying value. An impairment charge is recognized for the amount by which the carrying amount exceeds the fair value, provided, the loss recognized cannot exceed the total amount of goodwill.

For the period from January 1, 2024 to July 30, 2024 (Predecessor) and for the year ended December 31, 2023 (Predecessor), the Company determined that there was no goodwill impairment. The Company determined that as of December 31, 2024, its fair value was less than the carrying amount. As a result, the Company recorded a $30.3 million goodwill impairment charge during the period from July 31, 2024 to December 31, 2024 (Successor). The impairment was driven by a sustained decline in the Company's share price and market capitalization.

Concentrations

The Company had two suppliers each exceed 10% of total accounts payable as of December 31, 2024 (Successor), representing 55% of accounts payable. As of December 31, 2023 (Predecessor), Legacy Adagio has three suppliers each exceed 10% of total accounts payable, representing 72% of accounts payable.

The Company's five and ten largest suppliers accounted for approximately 47% and 65%, respectively, of the Company's expenditures for the period from July 31, 2024 to December 31, 2024 (Successor). Legacy Adagio's five and ten largest suppliers accounted for approximately 45% and 54%, respectively, of Legacy Adagio's expenditures for the year ended December 31, 2023 (Predecessor).

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property and equipment and finite-lived intangible assets, for impairment annually or whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss is recognized when the asset's carrying value exceeds the total undiscounted cash flows expected from its use and eventual disposition. The amount of the impairment loss is determined as the excess of the carrying value of the asset over its fair value.

For the periods from January 1, 2024 to July 30, 2024 (Predecessor), July 31, 2024 to December 31, 2024 (Successor), and for the year ended December 31, 2023 (Predecessor), the Company determined that there was no impairment of long-lived assets.

Foreign Currency Translation and Transactions

The assets, liabilities, and results of operations of Adagio Medical GmbH are recorded using the Euro as the designated functional currency, which is the currency of the primary economic environment in which Adagio Medical GmbH operates. Consequently, transactions in currencies other than Euro are measured and recorded in Euro. Upon consolidation with the Company, its assets and liabilities are translated to U.S. Dollars at currency exchange rates as of the consolidated balance sheet date and its revenues and expenses are translated at the weighted-average currency exchange rates during the applicable reporting periods. Translation adjustments resulting from the process of translating this entity's financial statements are reported in accumulated other comprehensive loss in the consolidated balance sheets and foreign currency translation adjustment in the consolidated statements of operations and comprehensive loss.

Leases

The Company accounts for its lease property under ASC 842. Under this guidance, arrangements meeting the definition of a lease are classified as operating or financing leases, and are recorded on the consolidated balance sheets as both a right-of-use asset and a lease liability, calculated by discounting fixed lease payments over the lease term at the rate implicit in the lease or the Company's incremental borrowing rate, which is the rate for collateralized borrowings based on the current economic environment, current borrowings, value of leases, currency in which the lease obligation is satisfied, rate sensitivity, lease term and materiality. Lease liabilities are increased by interest and reduced by payments each period, and the right-of-use asset is amortized over the lease term. For operating leases, interest on the lease liability and the amortization of the right-of-use asset results in straight-line rent expense over the lease term. Variable lease expenses are recorded when incurred.

The Company determines whether a contract is or contains a lease at the inception of the contract. A contract will be deemed to be or contain a lease if the contract conveys the right to control and direct the use of identified property or equipment for a period of time in exchange for consideration. The Company generally must also have the right to obtain substantially all of the economic benefits from the use of the property and equipment.

In calculating the right-of-use asset and lease liability, the Company elected to combine lease and non-lease components for its real estate leases. The Company adopted the policy election to exclude short-term leases having initial terms of twelve months from the initial recognition provisions of ASC 842. Refer to *Note 11- Operating Leases* for additional details.

The Company's implied rental agreements for its Consoles qualify as operating leases and as such, revenue is recognized in accordance with ASC 842, Leases and ASC 606, Revenue from Contracts with Customers. Revenue allocated to the lease components were not significant for the periods from January 1, 2024 to July 30, 2024 (Predecessor), from July 31, 2024 to December 31, 2024 (Successor), and for the year ended December 31, 2023 (Predecessor).

Cost of Revenue

Cost of revenue includes raw materials, direct labor, manufacturing overhead, shipping and receiving costs and other less significant indirect costs related to the production of the Company's products.

Cost of revenue also includes the depreciation expense of Consoles loaned to the customers.

Research and Development

Research and development expenses consist primarily of salaries, consulting fees, and employee-related costs (including stock-based compensation) for personnel directly engaged in research and development activities, clinical trial expenses, equipment costs, material costs, allocated rent and facilities costs, and depreciation. Research and development expenses relating to possible future products are expensed as incurred. The Company also accrues and expenses costs for activities associated with clinical trials performed by third parties as incurred.

Selling, General and Administrative

Selling, general and administrative expenses consist primarily of salaries, and employee-related costs (including stock-based compensation) for personnel in executive, finance and other administrative functions, allocated rent and facilities costs, legal fees relating to intellectual property and corporate matters, professional fees for accounting and consulting services, marketing costs and insurance costs. The Company expenses all selling, general, and administrative costs as incurred. The incurred transaction costs are recorded in selling, general, and administrative costs.

Accrued Transaction Costs (Predecessor)

In connection with the Business Combination, Legacy Adagio accrued transaction costs, consisting primarily of legal, accounting and other professional fees, which were incurred and expensed, but not yet paid. The accrued expenses as of December 31, 2023 (Predecessor) are recorded in accrued transaction costs on the consolidated balance sheets.

Fair Value Measurements

Fair value measurements are based on the premise that fair value is an exit price representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the following three-tier fair value hierarchy is used in determining the inputs for measuring fair value:

- Level 1-Quoted prices in active markets for identical assets or liabilities.

- Level 2-Observable inputs other than Level 1 prices for similar assets or liabilities that are directly or indirectly observable in the marketplace.

- Level 3-Unobservable inputs which are supported by little or no market activity and consist of financial instruments valued using pricing models, discounted cash flow methodologies or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

Financial instruments measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. Management's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment and considers factors specific to the asset or liability. The use of different assumptions and/or estimation methodologies may have a material effect on estimated fair values. Accordingly, the fair value estimates disclosed, or initial amounts recorded may not be indicative of the amount that the Company or holders of the instruments could realize in a current market exchange. The fair value of the convertible notes payable and warrant liabilities may be impacted by certain unobservable inputs, most significantly with regard to discount rates, expected volatility and historical and projected performance. Significant changes to these inputs in isolation could result in a significantly different fair value measurement.

Fair Value Option for Convertible Notes

As permitted under ASC 825, Financial Instruments ("ASC 825"), Legacy Adagio elected the fair value option to account for the Convertible Securities Notes issued in October 2022 (the "October 2022 Convertible Notes"), April 2023 (the "April 2023 Convertible Notes"), November 2023 (the "November 2023 Convertible Notes"), February 2024 (the "February 2024 Convertible Notes", or the "2024 Bridge Financing Notes"), May 2024 (the "May 2024 Convertible Notes"), June 2024 (the "June 2024 Convertible Notes"), and July 2024 (the "July 2024 Convertible Notes") (collectively, "Legacy Adagio Convertible Notes"), and the Company elected the fair value option to account for the Convertible Securities Notes (as defined below), in order to measure those liabilities at amounts that more accurately reflect the current economic environment in which the Legacy Adagio and the Company operated.

The Convertible Securities Notes mentioned above were recorded at fair value at issuance and subsequently were remeasured to fair value at the end of each reporting period. The change in fair value of the Convertible Securities Notes, excluding amounts related to interest, is recorded in "Convertible notes fair value adjustment", while amounts related to interest are recorded as interest expense in the consolidated statements of operations and comprehensive loss.

As a result of applying the fair value option, direct costs and fees related to the issuance of the Convertible Securities Notes were expensed as incurred (i.e., not recognized as deferred costs). Refer to *Note 4- Fair Value Measurements* for further detail.

Warrants

The Company has Convert Warrants (as defined below) issued along with the Convertible Securities Notes, and PIPE Pre-funded Warrants (as defined below) issued in PIPE Financing (as defined below), which are classified as liabilities. The Company also has PIPE Base Warrants (as defined below) issued in PIPE Financing, which is classified as equity. Legacy Adagio has certain common stock warrants ("SVB Warrants") issued along with the SVB Term Loan (as defined below) and pre-funded warrants to purchase Series E preferred stock ("Series E Pre-funded Warrants"), which were both classified as liabilities.

The Company and Legacy Adagio determine the classification of warrants based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC 480 and ASC 815. The assessment considers whether the warrants are freestanding financial instruments and meet all of the requirements for equity classification, including whether the warrants are indexed to the Company's own shares of common stock, among other conditions for equity classification. This assessment is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding. For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are classified as liabilities and are required to be recorded at their initial fair value on the date of issuance, and each balance sheet date thereafter until settlement. Changes in the estimated fair value of the liability-classified warrants are recognized in warrant liabilities fair value adjustment in the consolidated statements of operations and comprehensive loss.

The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is reassessed at the end of each reporting period. Equity instruments that are initially classified as equity that become subject to reclassification are reclassified to a liability at the fair value of the instrument on the reclassification date. Derivative instrument liabilities are classified in the consolidated balance sheets as current or non-current based on whether or not net-cash settlement of the derivative instrument could be required within twelve months of the consolidated balance sheet date.

See *Note 10- Warrants* for additional information related to the warrants.

Term Loan (Predecessor)

The Company accounts for the Predecessor term loan at residual value on the date of issuance. The expected life of the term loan is the contractual term ending on the maturity date. The Company classifies the term loan as current liabilities within twelve months of the maturity date or when otherwise due. Interest expense is recognized in the consolidated statements of operations and comprehensive loss over the contractual term of the loan. See *Note 9- Debt* for additional information related to the term loan.

Convertible Preferred Stock (Predecessor)

The Company records the Legacy Adagio convertible preferred stock at fair value on the dates of issuance, net of issuance costs. Upon the occurrence of certain events that are outside the Legacy Adagio's control, including a deemed liquidation event, holders of the convertible preferred stock can cause redemption for cash. Each share of preferred stock would automatically be converted into shares of Legacy Adagio common stock at the then effective conversion rate immediately upon the earlier of (i) the election of the holders of a majority of the outstanding shares of preferred stock, voting as a separate class on an as-converted to common stock basis, or (ii) the closing of the sale of the Legacy Adagio's common stock in a firm commitment, underwritten public offering registered under the Securities Act of 1933, as amended, with aggregate offering proceeds to Legacy Adagio (before deduction for underwriters' discounts and expenses relating to the issuance) of at least $75.0 million and a public offering price per share equal to at least $67.83 (subject to adjustments for stock dividends, splits, combinations and similar events).

As the Legacy Adagio preferred stock is considered to be contingently redeemable, the Legacy Adagio preferred stock has been classified outside of permanent equity.

Stock-Based Compensation

The Company recognizes compensation expense for all stock-based awards issued to employees and non-employees based on the estimated grant-date fair value, which is recognized as expense on a straight-line basis over the requisite service period. The Company has elected to recognize forfeitures as they occur. The fair value of stock options is determined using the Black-Scholes-Merton option-pricing model. The determination of fair value for stock-based awards on the date of grant using an option-pricing model requires management to make certain assumptions including expected volatility, expected term, risk-free interest rate and expected dividends in addition to the Company's common stock valuation. Refer to *Note 14- Stock-Based Compensation*.

Due to the absence of an active market for Legacy Adagio common stock, the Company utilized methodologies, approaches, and assumptions consistent with the American Institute of Certified Public Accountants Audit and Accounting Practice Aid Series: Valuation of Privately Held Company Equity Securities Issued as Compensation to estimate the fair value of Legacy Adagio common stock. In determining the exercise prices for options granted, the Company considered the fair value of the common stock as of the grant date. The fair value of the common stock is determined based upon a variety of factors, including the Company's financial position, historical performance and operating results, the Company's stage of development, the progress of the Company's research and development programs, the prices at which the Company sold its convertible preferred stock, the superior rights, preferences and privileges of the Company's convertible preferred stock relative to its common stock, external market conditions affecting the medical technologies industry, the lack of marketability of the Legacy Adagio common stock, prospects of a transaction and market performance of peer companies. Significant changes to the key assumptions underlying the factors used could result in different fair values of Legacy Adagio at each valuation date.

Income Taxes

Income taxes are recorded in accordance with ASC 740, Income Taxes ("ASC 740"), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements. Deferred tax assets and liabilities are determined based on the difference between the consolidated financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse and include NOL carryforwards and Research and Development ("R&D") tax credit carryforwards. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit would more likely than not be realized assuming examination by the taxing authority. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances.

ASU 2019-12, Simplifying the Accounting for Income Taxes was adopted in the first quarter of 2021 and the Company has recorded franchise taxes not based on income outside of income tax expense. The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest and penalties on its consolidated balance sheets and has not recognized interest and/or penalties in the consolidated statements of operations and comprehensive loss for the periods from January 1, 2024 to July 30, 2024 (Predecessor), July 31, 2024 to December 31, 2024 (Successor), and for the year ended December 31, 2023 (Predecessor), respectively.

To date, there have been no interest or penalties charged in relation to the unrecognized tax benefits. Refer to *Note 16- Income Taxes* for additional details.

Recent Accounting Pronouncements

In *November 2024,* the FASB issued ASU *2024-03, Disaggregation of Income Statement Expenses*, which requires annual and interim disclosure of disaggregated disclosures of certain costs and expenses on the income statement. The standard is effective for fiscal years beginning after *December 15, 2026,* and interim periods within fiscal years beginning after *December 15, 2027,* with early adoption permitted. Amendments are applied on a prospective basis with retrospective application permitted. The Company is currently evaluating the impact of this guidance.

Recently Adopted Accounting Pronouncements

The Company adopted ASU *2023-07,* Segment Reporting (Topic *280*): *Improvements to Reportable Segment Disclosures*, in the *fourth* quarter of *2024.* The amendments in this update require public entities to disclose, on an annual and interim basis, significant segment expenses that are regularly provided to the chief operating decision maker (the "CODM") and which are included within each reported measure of segment profit or loss as well as disclosure of other segment items and a description of their composition. The amendments also require public entities to disclose the title and position of the CODM and an explanation of how the CODM uses the reported measure(s) of segment profit or loss in assessing segment performance and deciding how to allocate resources. The adoption of this guidance resulted in incremental disclosures in the Company's consolidated financial statements. Refer to *Note 18- Segment Reporting* for additional details.

Note 3 – Forward Merger

On February 13, 2024, ARYA, ListCo, ARYA Merger Sub, and Company Merger Sub, entered into a Business Combination Agreement, which was amended by the Consent and Amendment No. 1 to the Business Combination Agreement, dated as of June 25, 2024.

Prior to the annual general meeting, holders of 2,707,555 shares of ARYA's redeemable Class A ordinary shares exercised their right to redeem such shares for cash at a redemption price of approximately $11.56 per share, for an aggregate redemption amount of approximately $31.3 million.

Description of the Transaction

Upon the consummation of the Business Combination,

a) Each issued and outstanding Class A ordinary share of ARYA, par value $0.0001 per share, were automatically cancelled, extinguished and converted into one share of common stock, par value $0.0001 per share, of the Company ("Company's common stock").

b) Each issued and outstanding Class B ordinary share of ARYA, par value $0.0001 per share, are automatically cancelled, extinguished and converted into the right to receive one share of the Company's common stock, other than (i) 1,000,000 Class B ordinary shares that are forfeited by the Sponsor, and issued to the PIPE Investors (as defined below), including the Perceptive PIPE Investor (as defined below); (ii) 1,147,500 shares of the Company's common stock issuable to the Sponsor are subject to share trigger price vesting and will vest if, prior to the tenth anniversary of the Closing, the post-closing share price of the Company equals or exceeds $24.00 per share for any 20 trading days within any 30 trading day period (the "Share Trigger Price Vesting").

c) Each warrant of Legacy Adagio (other than the Series E Pre-funded Warrants) was terminated in accordance with the terms of the applicable warrant agreement.

d) All issued and outstanding convertible promissory notes of Legacy Adagio (excluding the Bridge Financing Notes and the 2024 Bridge Financing Notes), including any accrued and unpaid interest thereon, are automatically and fully converted into shares of Legacy Adagio common stock in accordance with the terms of such convertible promissory notes, and such convertible promissory notes are cancelled, satisfied, extinguished, discharged and retired in connection with such conversion.

e) Each share of Legacy Adagio preferred stock, par value $0.001 per share, that is issued and outstanding are automatically converted into shares of Legacy Adagio common stock on a one-to-one basis.

f) All issued and outstanding shares of Legacy Adagio common stock including Series E Pre-funded Warrants that had been issued and outstanding are automatically cancelled and extinguished and converted into shares of the Company's common stock based on the exchange ratio set forth in the Business Combination Agreement.

g) Each issued, outstanding and unexercised option to purchase Legacy Adagio common stock ("Legacy Adagio Option") that had been vested prior to the Closing with an aggregate value that exceeds the aggregate exercise price of such Legacy Adagio Option (each an "In-the-Money Adagio Options") are cancelled and extinguished in exchange for options to purchase shares of the Company's common stock, and each issued and outstanding Legacy Adagio equity award (other than an In-the-Money Adagio Options) are automatically cancelled and extinguished for no consideration, and each holder thereof will cease to have any rights with respect thereto.

h) $7.0 million of 2024 Bridge Financing Notes is converted into Convertible Securities Notes and Convert Warrants (as defined below).

In connection with the execution of the Business Combination Agreement, ListCo and ARYA entered into Subscription Agreements (the "Initial Subscription Agreements"), with Perceptive Life Sciences Master Fund, Ltd, a Cayman Islands exempted company (the "Perceptive PIPE Investor") and certain other investors (the "Initial Other PIPE Investors", and together with the Perceptive PIPE Investor, the "Initial PIPE Investors"). In June 2024, ListCo and ARYA entered into additional Subscription Agreements (the "June Subscription Agreements" and, together with the Initial Subscription Agreements, the "Subscription Agreements") with certain additional investors, (the "June PIPE Investors", and together with the Initial Other PIPE Investors, the "Other PIPE Investors", and the Other PIPE Investors, together with the Perceptive PIPE Investor, the "PIPE Investors").

Pursuant to the subscription agreements, the PIPE Investors have committed financing valued at $64.5 million (the "PIPE Financing").

The PIPE Financing included:

(i) Commitments by certain Other PIPE Investors to purchase $2.5 million in Class A shares of ARYA in the open market and not to redeem such shares before the Closing, resulting in the issuance of 355,457 shares of Company's common stock and 299,902 warrants exercisable for shares of the Company's common stock (the "Base Warrants").

(ii) Commitments by certain Other PIPE Investors that were shareholders of ARYA to not to redeem 247,700 Class A shares of ARYA, resulting in the issuance of 405,772 shares of Company's common stock and 343,756 Base Warrants.

(iii) Agreements to purchase 1,036,666 shares of Company's common stock, 1,440,000 Base Warrants, and 670,000 PIPE Pre-funded Warrants for a cash investment of $12 million in the Company.

(iv) Contribution of total $29.5 million in April 2023 Convertible Notes, November 2023 Convertible Notes, May 2024 Convertible Notes, June 2024 Convertible Notes, and July 2024 convertible Notes (collectively, "Bridge Financing Notes"), and accrued interest of $1.7 million by the Perceptive PIPE Investor.

(v) An additional cash investment of $15.9 million by the Perceptive PIPE Investor.

In return for the investment specified in (iv) and (v) above, the Perceptive PIPE Investor received 6,622,959 shares of the Company's common stock and 5,445,069 Base Warrants.

Further, in connection with the execution of the Business Combination Agreement, certain investors ("Convert Investors") executed a securities purchase agreement, dated February 13, 2024, with ListCo (the "Convertible Security Subscription Agreement"), pursuant to which ListCo issued on the Closing Date to the Convert Investors $20.0 million of 13% senior secured convertible notes (the "Convertible Securities Notes"), which will be convertible into shares of the Company's common stock at a conversion price of $10.00 per share, subject to adjustment, and 1,500,000 warrants (the "Convert Warrants"), each Convert Warrant being exercisable on a cashless basis or for cash at a price of $24.00 per share, subject to adjustment. Such $20.0 million of financing in the form of Convertible Securities Notes includes the conversion of the 2024 Bridge Financing Notes into Convertible Securities Notes and Convert Warrants at Closing, as further described in *Note 9- Debt*.

Acquisition Method of Accounting

The Business Combination has been accounted for as a forward-merger in accordance with U.S. GAAP. Under this method of accounting, ListCo has been treated as the "accounting acquirer" and Legacy Adagio as the "accounting acquiree" for financial reporting purposes. Accordingly, for accounting purposes, the Business Combination has been accounted for using the acquisition method of accounting. The acquisition method of accounting is based on ASC 805 and uses the fair value concepts defined in ASC 820. ASC 805 requires, among other things, that assets acquired, and liabilities assumed be recognized at their fair values as of the acquisition date, with limited exceptions per ASC 805-20-30-12 through 30-23. As such, under the acquisition method of accounting, ListCo's assets and liabilities retain their carrying amounts, and the assets and liabilities of Legacy Adagio, including any intangible assets recognized in connection with the Business Combination, are recorded at their fair values as of the acquisition date, except as otherwise required. The excess of the purchase price over the estimated fair values of net assets acquired is recorded as goodwill.

Under the acquisition method of accounting, ListCo was considered to be the accounting acquirer based on the terms of the Business Combination. Upon consummation of the Business Combination, the cash on hand resulted in the equity at risk being considered insufficient for Legacy Adagio to finance its activities without additional subordinated financial support. Therefore, Legacy Adagio was considered a Variable Interest Entity ("VIE") and the primary beneficiary of Legacy Adagio was treated as the accounting acquirer.

ListCo is the primary beneficiary of Legacy Adagio. ListCo will hold 100% of the voting rights of Legacy Adagio and will control the Board of Directors of Legacy Adagio. Therefore, ListCo will have the sole power to control the significant activities that will impact Legacy Adagio's economic performance. ListCo's equity interest in Legacy Adagio will result in the right to receive benefits and the obligation to absorb the losses of Legacy Adagio that could be significant to ListCo.

The following is a summary of the purchase price calculation (in thousands except share and per share data):

Number of the Company's common stock issued		6,771,769
Number of replacement stock options granted to Legacy Adagio's option holders by the Company		7,587
Total shares and stock options		6,779,356
Multiplied by the Company's common stock price at the Closing	$	6.64
Total	$	45,015
Number of PIPE Base Warrants issued in lieu of settling Bridge Financing Notes		3,540,000
Multiplied by estimated value of PIPE Base Warrants at the Closing	$	2.41
Estimated fair value of PIPE Base Warrants issued in lieu of settling Bridge Financing Notes	$	8,531
Total purchase price	$	53,546

The allocation of the purchase price was as follows (in thousands):

Assets Acquired:		
Cash	$	681
Accounts receivable, net		102
Inventories, net		4,077
Prepaid expenses		308
Other current assets		195
Property and equipment, net		1,133
Intangible assets, net		26,200
Goodwill		44,291
Right-of-use asset, net		247
Other assets		18
Tota assets acquired	$	77,252
Liabilities Assumed:		
Accounts payable	$	10,103
Accrued liabilities		3,556
Operating lease liabilities, current		138
Convertible notes payable, long-term		5,951
Warrant liabilities		1,049
Operating lease liabilities, long-term		109
Deferred tax liabilities		2,800
Total liabilities assumed	$	23,706
Net total	$	53,546

Goodwill represents the excess of the total purchase consideration over the fair value of the underlying net assets and captures the value attributable to future economic benefits arising from future technology development beyond the existing pipeline of identified IPR&D projects.

The acquired intangible assets consist of developed technology and IPR&D, which were valued at $26.2 million at the Closing using the cost approach. This approach considers an asset's replacement cost (direct and indirect) adjusted, where applicable, for obsolescence to estimate the replacement cost of the asset's current service potential (i.e., remaining useful life and cash-flow generating capacity). Obsolescence for an acquired intangible asset may include functional (technological) obsolescence and economic (external) obsolescence. The Company has determined the estimated useful life of 5 years for developed technology based on consideration of the economic benefit of the asset. Refer to *Note 7- Goodwill and Intangible Assets* for details.

In connection with the Business Combination, the transactions that occurred concurrently with the Closing Date of the Business Combination were reflected "on the line". "On the line" describes those transactions triggered by the consummation of the Business Combination that are not recognized in the consolidated financial statements of the Predecessor nor the Successor as they are not directly attributable to either period but instead were contingent on the Business Combination.

The number of shares of common stock issued and amounts recorded on the line within stockholders' equity (deficit) are reflected below to arrive at the opening consolidated balance sheet of the Successor.

	Number of Shares	Common Stock	APIC	Accumulated Deficit
ListCo closing equity as of July 30, 2024	—	—	$ 2,729	$ (2,734)
Accumulated deficit carried over from ARYA	—	—	—	(14,089)
Contribution of cash proceeds in PIPE Financing	3,287,018	—	23,433	—
Conversion of ARYA convertible promissory Notes	355,100	—	3,551	—
Conversion of ARYA Class A ordinary shares and Class B ordinary shares	2,089,000	—	—	—
Conversion of Class A ordinary shares subject to redemption	123,520	—	1,361	—
Shares issued for acquisition of Legacy Adagio	6,771,769	1	53,546	—
Additional shares issued and reclassification of Class A ordinary shares subject to non-redemption agreements and open market subscription agreements	761,229	—	5,166	—
Successor's opening equity as of July 31, 2024 (Successor)	13,387,636	1	$ 89,786	$ (16,823)

In conversion of the ARYA's equity outstanding prior to the Closing Date, for each issued and outstanding Class B ordinary share of ARYA at par value $0.0001 per share, a total of 1,147,500 shares ("Earn-out Shares") of the Company's common stock are issuable to the Sponsor, which are subject to vesting based on a share price trigger. These shares will vest if, within ten years of the Closing, the share price of the Company's Common Stock reaches or exceeds $24.00 per share for at least 20 trading days within a 30-day period. As of the reporting date, the vesting of these shares was not considered probable.

Pro Forma Financial Information (Unaudited)

The following unaudited pro forma financial information summarizes the results of operations for the Company as though the Business Combination had occurred on January 1, 2023 and has been derived from the historical consolidated financial statements of the Company's Predecessor Periods and the Successor Period. The Successor and Predecessor Periods for the years ended December 31, 2024 and 2023 have been combined. The unaudited pro forma financial information has been presented for illustrative purposes only and is not necessarily indicative of results of operations that would have been achieved had the acquisition taken place on the date indicated, or the future consolidated results of operations of the Company.

	Nine Months Ended September 30,	
	2024	2023
Revenue	$ 465	$ 222
Net loss	(28,987)	(26,113)

The unaudited pro forma results reflect the adjustments for recording the step-up amortization adjustments for the fair value of intangible assets acquired, reversal of change in fair value of Legacy Adagio Convertible Notes and warrants, reversal of interest on Legacy Adagio Convertible Notes, reversal of interest on Legacy Adagio's SVB Term Loan, and recording interest on Convertible Securities Notes.

Note 4 – Fair Value Measurements

The Company's financial instruments include its money market accounts (included as part of cash and cash equivalents), accounts receivable, accounts payable, common stock warrant liabilities (i.e. Convert Warrants and SVB Warrants), pre-funded warrant liabilities (i.e. PIPE Pre-funded Warrants), and convertible notes payables (i.e. Convertible Securities Notes and Legacy Adagio Convertible Notes). The recorded carrying amounts of cash and equivalents, accounts receivable and accounts payable approximates fair value due to their short-term nature. The convertible notes, common stock warrant liabilities, and pre-funded warrant liabilities are carried at fair value.

Assets and liabilities recognized at fair value on a recurring basis in the consolidated balance sheets consists of cash equivalents, common stock warrant liabilities, pre-funded warrant liabilities, and convertible notes payables. These items are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

The following tables summarize the Company's financial instruments at fair value based on the fair value hierarchy for each class of instrument (in thousands):

December 31, 2024 (Successor)	Level 1	Level 2	Level 3
Assets:			
Money market account	$ 19,014	$ —	$ —
Liabilities:			
Convertible Securities Notes	$ —	$ —	$ 16,076
Convert Warrants	$ —	$ —	$ 152
PIPE Pre-funded Warrants	$ —	$ —	$ —

December 31, 2023 (Predecessor)	Level 1	Level 2	Level 3
Assets:			
Money market account	$ 24	$ —	$ —
Liabilities:			
Legacy Adagio Convertible Notes	$ —	$ —	$ 36,430
SVB Warrants	$ —	$ —	$ 78

There were no transfers made among the three levels in the fair value hierarchy for the periods from January 1, 2024 to July 30, 2024 (Predecessor), from July 31, 2024 to December 31, 2024 (Successor) and for the year ended December 31, 2023 (Predecessor).

Legacy Adagio Convertible Notes (Predecessor)

On October 27, 2022, Legacy Adagio entered into a note purchase agreement with investors for the issuance and sale of convertible promissory notes with an aggregate principal amount of $9.5 million at an interest rate of eight percent (8.0%) per annum. On April 4, 2023, November 28, 2023, and February 13, 2024, the October 2022 Convertible Notes were amended. Upon the consummation of the Business Combination, the principal and the accrued interest of the October 2022 Convertible Notes were converted into shares of Legacy Adagio common stock. Further, on the Closing Date, Legacy Adagio common stock was converted to the Company's Common Stock based on the exchange ratio set forth in the Business Combination Agreement. Refer to *Note 9- Debt* for details.

On April 4, 2023, Legacy Adagio issued a $5.0 million convertible promissory note to Perceptive PIPE Investor that matured upon the termination of the Business Combination Agreement in accordance with its terms. The April 2023 Convertible Notes accrues simple interest at eight percent (8.0%) per annum. Additionally, Legacy Adagio obtained the right to issue up to $10.0 million in additional convertible promissory notes. On February 13, 2023, November 28, 2023 and February 13, 2024, the April 2023 Convertible Notes were amended. Prior to the Closing Date, the total of $15.0 million convertible promissory note has been drawn by Legacy Adagio.

On November 28, 2023, Legacy Adagio issued a $2.0 million convertible promissory note to Perceptive PIPE Investor that matured upon the termination of the Business Combination Agreement in accordance with its terms. The November 2023 Convertible Notes accrues simple interest at eight percent (8.0%) per annum. Additionally, Legacy Adagio obtained the right to issue up to $6.0 million in additional convertible promissory notes ("Delayed Draw Commitment"). On December 13, 2023, December 28, 2023, and February 13, 2024, the November 2023 Convertible Notes were amended. Prior to the Closing Date, the total of $8.0 million convertible promissory note has been drawn by Legacy Adagio.

On February 13, 2024, Legacy Adagio issued a $7.0 million convertible promissory note to Perceptive PIPE Investor that matured upon the termination of the Business Combination Agreement in accordance with its terms. The 2024 Bridge Financing Note accrues simple interest at eight percent (8.0%) per annum. Prior to the Closing Date, the total of $7.0 million convertible promissory note has been drawn by Legacy Adagio. Upon the consummation of the Business Combination, the 2024 Bridge Financing Note of $7.0 million converted into $7.0 million of the Company's Convertible Securities Notes and 525,000 Convert Warrants. Refer to *Note 9- Debt* for details.

On May 21, 2024, Legacy Adagio issued a $3.0 million convertible promissory note to Perceptive PIPE Investor that matured upon the termination of the Business Combination Agreement in accordance with its terms. The May 2024 Convertible Notes accrues simple interest at eight percent (8.0%) per annum. Prior to the Closing Date, the total of $3.0 million convertible promissory note has been drawn by Legacy Adagio.

On June 25, 2024, Legacy Adagio issued a $2.5 million convertible promissory note to Perceptive PIPE Investor that matured upon the termination of the Business Combination Agreement in accordance with its terms. The June 2024 Convertible Notes accrues simple interest at eight percent (8.0%) per annum. Prior to the Closing Date, the total of $2.5 million convertible promissory note has been drawn by Legacy Adagio.

On July 23, 2024, Legacy Adagio issued a $1.0 million convertible promissory note to Perceptive PIPE Investor that matured upon the termination of the Business Combination Agreement in accordance with its terms. It accrues simple interest at eight percent (8.0%) per annum. Prior to the Closing Date, the total of $1.0 million convertible promissory note has been drawn by Legacy Adagio.

Upon the consummation of the Business Combination, the principal of Bridge Financing Notes along with its accrued but unpaid interest, was converted into the shares of the Company's Common Stock and Base Warrants as part of the PIPE Financing. Refer to *Note 9- Debt* for details.

The Company measures Legacy Adagio Convertible Notes at fair value based on significant inputs not observable in the market, which caused them to be classified as Level 3 measurements within the fair value hierarchy.

In determining the fair value of the Legacy Adagio Convertible Notes as of December 31, 2023, the Company applied the probability-weighted expected return method ("PWERM"). The PWERM determines the value of an instrument based upon an analysis of future values for the potential instrument payouts under different future outcomes. The instrument value is based upon the present value of the probability of each future outcome becoming available to the instrument holders, and the rights of each security.

The Company calculated the estimated fair value of convertible promissory notes as of December 31, 2023 using the following assumptions:

As of December 31, 2023 (Predecessor)	Discount rate	Expected Term (years)	Risk-Free interest rate	Volatility
October 2022 Convertible Notes	36.8 %	0.33	5.4 %	110 %
April 2023 Convertible Notes	30.6 %	0.33	5.4 %	110 %
November 2023 Convertible Notes	30.6 %	0.33	5.4 %	110 %

In determining the fair value of the Legacy Adagio Convertible Notes as of July 31, 2024, prior to the Closing, the Company used the observed closing stock price of ARYA as of July 31, 2024, multiplied by the actual number of shares that the Legacy Adagio Convertible Notes converted into.

The following table presents changes in the Level 3 convertible promissory notes measured at fair value for the year ended December 31, 2023 (Predecessor) (in thousands):

Year ended December 31, 2023 (Predecessor)	Balance (beginning of year)	Additions	Fair value measurement adjustments	Balance (end of year)
October 2022 Convertible Notes	$ 9,500	$ —	$ 3,061	$ 12,561
April 2023 Convertible Notes	—	15,000	(243)	14,757
November 2023 Convertible Notes	—	5,000	4,112	9,112

The following table presents changes in the Level 3 convertible promissory notes measured at fair value for the period from January 1, 2024 to July 30, 2024 (Predecessor) (in thousands):

Period from January 1 to July 30, 2024 (Predecessor)	Balance (beginning of year)	Additions	Fair value measurement adjustments	Balance (end of period)
October 2022 Convertible Notes	$ 12,561	$ —	$ (4,304)	$ 8,257
April 2023 Convertible Notes	14,757	—	3,378	18,135
November 2023 Convertible Notes	9,112	3,000	(2,373)	9,739
February 2024 Convertible Notes	—	7,000	(256)	6,744
May 2024 Convertible Notes	—	3,000	685	3,685
June 2024 Convertible Notes	—	2,500	577	3,077
July 2024 Convertible Notes	—	1,000	233	1,233

Convertible Securities Notes (Successor)

On July 31, 2024, the Company issued the $20.0 million Convertible Securities Notes to Convert Investor having a maturity of three years and nine months after the Closing. The interest is accrued by quarterly compounding based on a 13% interest rate per annum. The Company received the funding from the Convertible Securities Notes as at the Closing. Refer to *Note 9- Debt* for details.

The Company measures the Convertible Securities Notes at fair value based on significant inputs not observable in the market, which caused them to be classified as Level 3 measurements within the fair value hierarchy.

The Company utilized the binomial lattice model to value the Convertible Securities Notes at the Closing Date and as of December 31, 2024. The following table summarizes the significant inputs as of the valuation dates:

	Predecessor	Successor
Convertible Securities Notes	**July 31, 2024**	**December 31, 2024**
Stock price	$ 6.64	$ 1.05
Discount rate	25.8 %	20.6 %
Expected term (years)	3.75	3.33
Risk-free interest rate	4.01 %	4.20 %
Volatility	60 %	60 %

The following table presents changes in the Level 3 convertible promissory notes measured at fair value for the period from July 31, 2024 to December 31, 2024 (Successor) (in thousands):

Convertible Securities Notes - July 31, 2024 to December 31, 2024 (Successor)	
Balance (beginning of period)	$ 17,005
Additions	—
Fair value measurement adjustments	(929)
Balance (end of period)	$ 16,076

Warrant Liabilities (Predecessor)

i. Series E Pre-funded Warrants

On June 25, 2024, the Legacy Adagio issued to certain investor the Series E Pre-funded Warrants to purchase the Legacy Adagio's Series E Preferred Stock, in exchange of the investor's existing holding of Series E Preferred Stock. The exercise price of the pre-funded warrants is $0.001 per warrant share. The Company measured the pre-funded warrants at fair value based on the indicated fair value of Series E Preferred Stock, which is not observable in the market. The measurement caused the pre-funded warrant to be classified as Level 3 measurements within the fair value hierarchy. Changes in the fair value of the pre-funded warrants were recognized as warrant liabilities fair value adjustment within the consolidated statements of operations and comprehensive loss. Refer to *Note 10-Warrants* for additional information.

The fair value of the Series E Pre-funded Warrants is based on the fair value of the Series E Preferred Stock minus the exercise price. As of June 30, 2024, the Company estimated the fair value of the Series E Preferred Stock by applying a conversion factor of 1.08 to the indicated fair value of Legacy Adagio common stock.

As of July 31, 2024, prior to the Closing, the Company estimated the fair value of Series E Pre-funded Warrants based on the observed closing stock price of ARYA as of July 31, 2024, multiplied by the actual number of shares that the Series E Pre-funded Warrants converted into. The estimated fair value of the Series E Pre-funded Warrants as of June 30, 2024 and July 31, 2024 prior to the Closing is $0.3 million and $0.2 million, respectively.

Upon the consummation of the Business Combination, the Series E Pre-funded Warrants were automatically cancelled and extinguished and converted into shares of the Company's common stock based on the exchange ratio set forth in the Business Combination Agreement.

ii. SVB Warrants

On February 3, 2023, in conjunction with the Loan and Security Agreement ("LSA") with Silicon Valley Bank ("SVB Term Loan"), Legacy Adagio issued Initial Warrants to purchase shares of common stock of the Company, and a contingent right to obtain an additional share of the common stock upon the non-occurrence of the Interest Only Milestone (as defined below). The Company measured SVB Warrants at fair value based on significant inputs not observable in the market, which caused them to be classified as Level 3 measurements within the fair value hierarchy. Changes in the fair value of the common stock warrants related to updated assumptions and estimates were recognized as warrant liabilities fair value adjustment within the consolidated statements of operations and comprehensive loss.

The SVB Warrants were not material as of December 31, 2023 (Predecessor) and there were no material changes in fair value for the periods from January 1, 2024 to July 30, 2024 (Predecessor), and the period from July 31, 2024 to December 31, 2024 (Successor).

The SVB Warrants were terminated prior to the consummation of the Business Combination as the fair market value of Legacy Adagio common stock is lower than the warrant exercise price before the Closing. Refer to *Note 10- Warrants* for additional information.

Warrant Liabilities (Successor)

i. Convert Warrants

On July 31, 2024, the Company issued 1,500,000 Convert Warrants in connection with the issuance of the $20.0 million Convertible Securities Notes. Refer to *Note 10- Warrants* for additional information.

As set forth in the agreement of the Convertible Securities Notes, the Convert Warrants are exercisable on a cashless basis or on a gross basis for one share of the Company's common stock at $24.0 per share, subject to adjustments. The Company may be required to cash settle the Convert Warrants when it fails to timely deliver shares to the holder who exercises the Convert Warrants or upon the occurrence of a fundamental transaction. It is determined that the Convert Warrants do not meet the equity classification requirements under ASC 815 as the Covert Warrants may require cash settlement outside of the Company's control upon a failure of timely delivery of shares or a fundamental transaction, and therefore the Convert Warrants are accounted for as derivative liabilities, and measured at fair value both initially and subsequently with changes in fair value recognized as warrant liabilities fair value adjustment within the consolidated statements of operations and comprehensive loss.

The Convert Warrants are classified as Level 3 measurements within the fair value hierarchy. The Company utilized the Black-Scholes-Merton option model to value the Convertible Securities Notes at the Closing Date and as of December 31, 2024. The following table summarizes the significant inputs as of the valuation dates:

	Predecessor	Successor
Convert Warrants	**July 31, 2024**	**December 31, 2024**
Common stock price	$ 6.64	$ 1.05
Expected volatility	55.0 %	65.0 %
Risk free rate	3.96 %	4.36 %
Expected dividend yield	— %	— %
Expected term (years)	7.0	6.58

The following table presents changes in the Level 3 Convert Warrants measured at fair value for the period from July 31, 2024 to December 31, 2024 (Successor) (in thousands):

Convert Warrants - July 31, 2024 to December 31, 2024 (Successor)	
Balance (beginning of period)	$ 2,996
Additions	—
Fair value measurement adjustments	(2,844)
Balance (end of period)	$ 152

ii. PIPE Pre-funded Warrants

On July 31, 2024, the Company issued 670,000 pre-funded warrants in exchange for cash proceeds in PIPE Financing to certain Other PIPE Investors ("PIPE Pre-funded Warrants"). Refer to *Note 10-Warrants* for additional information.

As set forth in the agreement of the PIPE Pre-funded Warrants, the PIPE Pre-funded Warrants are exercisable on a cashless basis or on a gross basis for one share of the Company's common stock at $0.01 per share, subject to adjustments. The Company may be required to cash settle the PIPE Pre-funded Warrants when it fails to timely deliver shares to the holder who exercises the PIPE Pre-funded Warrants or upon the occurrence of a fundamental transaction. It is determined that the PIPE Pre-funded Warrants do not meet the equity classification requirements under ASC 815 as the PIPE Pre-funded Warrants may require cash settlement outside of the Company's control upon a failure of timely delivery of shares or a fundamental transaction, and therefore the PIPE Pre-funded Warrants are accounted for as derivative liabilities, and measured at fair value both initially and subsequently with changes in fair value recognized as warrant liabilities fair value adjustment within the consolidated statements of operations and comprehensive loss.

The PIPE Pre-funded Warrants are classified as Level 3 measurements within the fair value hierarchy. The fair value of the PIPE Pre-funded Warrants is based on the fair value of the Company's common stock minus the exercise price.

On December 26, 2024, a total of 670,000 pre-funded warrant shares were exercised on a cashless basis for 663,096 shares of the Company's common stock. The exercise price for the pre-funded warrants was $0.9705 per share.

The following table presents changes in the Level 3 PIPE Pre-funded Warrants measured at fair value for the period from July 31, 2024 to December 31, 2024 (Successor) (in thousands):

PIPE Pre-funded Warrants - July 31, 2024 to December 31, 2024 (Successor)		
Balance (beginning of period)	$	4,442
Exercises		(710)
Additions		—
Fair value measurement adjustments		(3,732)
Balance (end of period)	$	—

Note 5 - Inventory, net

Inventory as of December 31, 2024 and December 31, 2023 consists of the following (in thousands):

	Successor	Predecessor
	December 31, 2024	December 31, 2023
Raw materials	$ 1,683	$ 2,211
Work-in-Process	388	197
Finished goods	495	914
Total inventory	$ 2,566	$ 3,322

Obsolete and expired inventory are expensed as incurred. Inventory is recorded net of obsolescence and manufacturing scrap of $0.8 million, $58.0 thousand, and $93.6 thousand for the periods from January 1, 2024 to July 30, 2024 (Predecessor), from July 31, 2024 to December 31, 2024 (Successor), and the year ended December 31, 2023 (Predecessor), respectively.

Note 6 - Property and Equipment

The Company's property and equipment, net, as of December 31, 2024 and December 31, 2023 consists of the following (in thousands):

	Successor	Predecessor
	December 31, 2024	December 31, 2023
Consoles	$ 3,060	$ 1,565
Machinery and equipment	709	772
Leasehold improvements	306	305
Tools and molds	257	221
Computer equipment	205	193
Demo equipment	66	66
Furniture and fixtures	49	49
Construction in process	—	54
Vehicles	39	39
Total property and equipment	4,691	3,264
Less: accumulated depreciation	(2,730)	(1,777)
Property and equipment, net	$ 1,961	$ 1,487

Depreciation expense was $0.7 million, $0.3 million and $0.5 million for the periods from January 1, 2024 to July 30, 2024 (Predecessor), from July 31, 2024 to December 31, 2024 (Successor), and the year ended December 31, 2023 (Predecessor), respectively.

Note 7 – Goodwill, net and Intangible Assets, net

The Company's intangible assets, net consists of the following (in thousands):

		Successor			
		December 31, 2024			
	Useful Life (years)	Gross Carrying Amount	Accumulated Amortization	Impairment	Net Carrying Amount
IPR&D	Indefinite	$ 22,100	$ —	(15,131)	$ 6,969
Developed technology	5.0	4,100	(353)	(3,747)	—
Total		$ 26,200	$ (353)	$ (18,878)	$ 6,969

Amortization of intangible assets was $0.4 million for the period from July 31, 2024 to December 31, 2024 (Successor). There was no amortization of intangible assets for the period from January 1, 2024 to July 30, 2024 (Predecessor).

For the period from January 1, 2024 to July 30, 2024 (Predecessor) and for the year ended December 31, 2023 (Predecessor), the Company determined that there was no impairment of indefinite-lived intangible assets. During the fourth quarter of 2024, the Company performed an impairment assessment on its indefinite lived intangible assets, and determined that as of December 31, 2024, the fair value of its intangible assets was less than the carrying amount. As a result, the Company recorded an $18.9 million impairment charge during the period from July 31, 2024 to December 31, 2024 (Successor). The impairment was driven by a sustained decline in the Company's share price and market capitalization.

There were no intangible assets as of December 31, 2023 (Predecessor).

The following table presents the changes in goodwill (in thousands):

	Successor		
	December 31, 2024		
	Carrying Amount	Impairment	Net Carrying Amount
Goodwill	$ 44,291	$ (30,324)	$ 13,967

For the period from January 1, 2024 to July 30, 2024 (Predecessor) and for the year ended December 31, 2023 (Predecessor), the Company determined that there was no goodwill impairment. During the fourth quarter of 2024, the Company conducted its annual assessment of goodwill. During its assessment, the Company determined that as of December 31, 2024, its fair value was less than the carrying amount. As a result, the Company recorded a $30.3 million goodwill impairment charge during the period from July 31, 2024 to December 31, 2024 (Successor). The impairment was driven by a sustained decline in the Company's share price and market capitalization.

There was no goodwill as of December 31, 2023 (Predecessor).

Note 8 - Accrued Liabilities

The following table presents details of accrued liabilities as of December 31, 2024 and December 31, 2023 (in thousands):

	Successor	Predecessor
	December 31, 2024	December 31, 2023
Compensation and related expenses	$ 2,622	$ 1,566
Research and development expenses	775	1,191
Other	276	291
Total accrued liabilities	$ 3,673	$ 3,048

Note 9 - Debt

Outstanding debt as of December 31, 2024 and December 31, 2023 consists of the following (in thousands):

	Successor	Predecessor
	December 31, 2024	December 31, 2023
Convertible Securities Notes	$ 16,076	$ —
October 2022 Convertible Notes measured at fair value	—	12,561
April 2023 Convertible Notes measured at fair value	—	14,757
November 2023 Convertible Notes measured at fair value	—	9,112
SVB term loan	—	1,838
Total outstanding debt	$ 16,076	$ 38,268

October 2022 Convertible Notes (Predecessor)

On October 27, 2022, the Legacy Adagio entered into the October 2022 Convertible Notes with investors for the issuance and sale of convertible promissory notes with an aggregate principal amount of $9.5 million at an interest rate of eight percent (8.0%) per annum.

On April 4, 2023, the October 2022 Convertible Notes, which had an original maturity date of October 27, 2023, were amended to extend the maturity date to the latest of (i) January 5, 2024, (ii) termination of agreements between the Legacy Adagio and ARYA in connection with a non-binding summary of certain proposed terms and conditions of a potential business combination, or (iii) the termination or lapse of the exclusivity period as defined in the non-binding term sheet as mentioned above. The October 2022 Convertible Notes agreement was also amended to subordinate the October 2022 Convertible Notes to the April 2023 Convertible Notes (as described below) and provide for the conversion of all principal and accrued interest in respect of all the October 2022 Convertible Notes into shares of Series E Preferred Stock of the Legacy Adagio in connection with the Business Combination.

On November 28, 2023, the October 2022 Convertible Notes agreement was further amended to subordinate the October 2022 Convertible Notes to the April 2023 Convertible Notes and the November 2023 Convertible Notes (as described below). Upon the consummation of the Business Combination, all principal and accrued interest in respect of the October 2022 Convertible Notes was converted into shares of the Legacy Adagio common stock, when multiplied by the exchange ratio applicable to the Legacy Adagio common stock in the Business Combination, entitled the holder of this note to receive a number of shares of the same class of common stock that are issued in the Private Investment in Public Equity Financing ("PIPE Financing") equal to the then outstanding principal amount and any accrued and unpaid interest under this note, divided by 75% of the effective price of each share of common stock sold in the PIPE Financing.

On February 13, 2024, the October 2022 Convertible Notes agreement was further amended to extend the maturity date to the termination of the Business Combination Agreement, and subordinate the October 2022 Convertible Notes to the April 2023 Convertible Notes, the November 2023 Convertible Notes, and February 2024 Convertible Notes (as described below).

The total of $9.5 million principal was received by the Legacy Adagio as of December 31, 2022. As of December 31, 2023 (Predecessor), the principal amount outstanding was $9.5 million.

For the period from January 1, 2024 to July 30, 2024 (Predecessor) and the year ended December 31, 2023 (Predecessor), Legacy Adagio has recognized the interest expense of $0.4 million and $0.8 million, respectively.

Upon the consummation of the Business Combination, all principal and accrued interest in respect to the October 2022 Convertible Notes were converted into 8,661,985 shares of Legacy Adagio common stock. Further, on Closing Date, the 8,661,985 Legacy Adagio common stocks were converted to 1,444,899 Company's common stock based on the exchange ratio set forth in the Business Combination Agreement.

Bridge Financing Notes (Predecessor)

April 2023 Convertible Notes

On April 4, 2023, Legacy Adagio issued a $5.0 million convertible promissory note that matures on the latest of (i) January 5, 2024, (ii) termination of agreements between Legacy Adagio and ARYA in connection with a non-binding summary of the Business Combination, or (iii) the termination or lapse of the exclusivity period as defined in the non-binding term sheet as mentioned above. The April 2023 Convertible Notes accrue simple interest at eight percent (8.0%) per annum. Additionally, Legacy Adagio obtained the right to issue up to $10.0 million in additional convertible promissory notes available beginning one month after April 4, 2023 through the occurrence of an ARYA stockholder vote with regard to a transaction. During the period from April 4, 2023 to December 31, 2023, Legacy Adagio issued the additional $10.0 million.

On November 28, 2023, the April 2023 Convertible Notes were amended to align certain terms of the April 2023 Convertible Notes with the November 2023 Convertible Notes.

Upon the consummation of the Business Combination, this note was automatically converted into the type of securities that are issued in the PIPE Financing in an amount equal to the then-outstanding principal amount and any accrued and unpaid interest, divided by the effective price of the securities sold in the PIPE Financing.

As of December 31, 2023 (Predecessor), the principal amount outstanding was $15.0 million.

For the period from January 1, 2024 to July 30, 2024 (Predecessor) and the year ended December 30, 2023 (Predecessor), Legacy Adagio has recognized the interest expense of $0.6 million and $0.6 million, respectively.

November 2023 Convertible Notes

On November 28, 2023, Legacy Adagio issued to Perceptive PIPE Investor a $2.0 million convertible promissory note that matures on the latest of (i) January 5, 2024, (ii) termination of agreements between Legacy Adagio and ARYA in connection with a non-binding summary of the Business Combination, or (iii) the termination or lapse of the exclusivity period as defined in the non-binding term sheet as mentioned above. The November 2023 Convertible Notes accrues simple interest at eight percent (8.0%) per annum. Additionally, Legacy Adagio obtained the right to issue up to $6.0 million of Delayed Draw Commitment.

Upon the consummation of the Business Combination, this note was automatically converted into the type of securities that are issued in the PIPE Financing in an amount equal to the then-outstanding principal amount and any accrued and unpaid interest, divided by the effective price of the securities sold in the PIPE Financing.

In December 2023, the November 2023 Convertible Notes were amended to permit the issuance of a Delayed Draw Commitment in the principal amount of $1.0 million and $2.0 million on December 13, 2023 and December 28, 2023, respectively. The combined $3.0 million convertible promissory notes were issued pursuant to the clause and terms in the November 2023 Convertible Notes agreement.

As of December 31, 2023 (Predecessor), the principal amount outstanding was $5.0 million.

For the period from January 1, 2024 to July 30, 2024 (Predecessor) Legacy Adagio has recognized the interest expense of $0.3 thousand.

May 2024 Convertible Notes

On May 21, 2024, Legacy Adagio issued to Perceptive PIPE Investor a $3.0 million convertible promissory note that matures upon the termination of the Business Combination Agreement in accordance with its terms. The May 2024 Convertible Notes accrues simple interest at eight percent (8.0%) per annum.

Upon the consummation of the Business Combination, this note was automatically converted into the type of securities that are issued in the PIPE Financing in an amount equal to the then-outstanding principal amount and any accrued and unpaid interest, divided by the effective price of the securities sold in the PIPE Financing.

For the period from January 1, 2024 to July 30, 2024 (Predecessor) Legacy Adagio has recognized interest expense of $46.0 thousand.

June 2024 Convertible Notes

On June 25, 2024, Legacy Adagio issued to Perceptive PIPE Investor a $2.5 million convertible promissory note that matures upon the termination of the Business Combination Agreement in accordance with its terms. The June 2024 Convertible Notes accrues simple interest at eight percent (8.0%) per annum.

Upon the consummation of the Business Combination, this note was automatically converted into the type of securities that are issued in the PIPE Financing in an amount equal to the then-outstanding principal amount and any accrued and unpaid interest, divided by the effective price of the securities sold in the PIPE Financing.

For the periods from January 1, 2024 to July 30, 2024 (Predecessor) Legacy Adagio has recognized the interest expense of $19.2 thousand.

July 2024 Convertible Notes

On July 23, 2024, Legacy Adagio issued a $1.0 million convertible promissory note to Perceptive PIPE Investor that matures upon the termination of the Business Combination Agreement in accordance with its terms. It accrues simple interest at eight percent (8.0%) per annum.

Upon the consummation of the Business Combination, this note was automatically converted into the type of securities that are issued in the PIPE Financing in an amount equal to the then-outstanding principal amount and any accrued and unpaid interest, divided by the effective price of the securities sold in the PIPE Financing.

For the period from July 31, 2024 to December 31, 2024 (Successor), Legacy Adagio has recognized the interest expense of $0.0 thousand.

Pursuant to the Business Combination Agreement, the outstanding $29.5 million principal along with the accrued but unpaid interest of the Bridge Financing Notes, was converted in exchange for 4,372,607 shares of the Company’s common stock and 3,540,000 Base Warrants as part of the PIPE Financing.

February 2024 Convertible Notes (Predecessor)

On February 13, 2024, the Legacy Adagio issued to Perceptive PIPE Investor a principal of $7.0 million convertible promissory note that matures upon the termination of the Business Combination Agreement in accordance with its terms. The February 2024 Convertible Notes accrues simple interest at eight percent (8.0%) per annum.

Upon the consummation of the Business Combination, the February 2024 Convertible Notes was automatically transferred to the Company in connection with the issuance of the Convertible Securities Notes to Perceptive PIPE Investor, pursuant to, and in accordance with, the note purchase agreement and the Convertible Security Subscription Agreement (as defined below), dated February 13, 2024, by and among the Company, ARYA, Legacy Adagio and Perceptive PIPE Investor. Any interest accrued on the principal amount of the February 2024 Convertible Notes will be forfeited in connection with the transfer of the notes to the Company.

For the period from January 1, 2024 to July 30, 2024 (Predecessor) Legacy Adagio has recognized the interest expense of $0.3 million.

On the Closing Date, the $7.0 million of February 2024 Convertible Notes were converted into $7.0 million Convertible Securities Notes and 525,000 Convert Warrants.

SVB Term Loan (Predecessor)

On February 3, 2023, Legacy Adagio entered into an agreement to obtain an initial term loan advance of $3.0 million and a right to issue a subsequent term loan advance of $2.0 million pursuant to the LSA. The loans mature on January 1, 2025 and Legacy Adagio must make monthly payments at a floating rate per annum equal to the greater of (1) seven percent (7.0%) and (2) the market prime rate plus one and one half of one percent (1.5%).

In connection with the issuance of the SVB Term Loan, Legacy Adagio issued liability - classified warrants with a fair value of $28.5 thousand to purchase 32,720 shares of common stock of Legacy Adagio (“Initial Warrants”), and a contingent right, with a fair value of $7.1 thousand, to obtain an additional 16,360 shares of the common stock (“Additional Warrants”) upon the nonoccurrence of the Interest Only Milestone. The Interest Only Milestone (“Milestone”) refers to a specific condition that is met on or before April 30, 2023. To satisfy this Milestone, Legacy Adagio must ensure that no event of default has occurred. If this condition is met, Legacy Adagio must provide SVB (i) the intent for the sale of all capital stock of Legacy Adagio, or (ii) an executed term sheet for a priced equity financing of at least $40.0 million from the sale of Legacy Adagio’s capital stock.

The initial recognition of the warrant liabilities and the contingent right resulted in a discount of $35.6 thousand to the SVB Term Loan. The discount is being amortized to interest expense over the term of the LSA.

As of December 31, 2023, the outstanding principal of SVB Term Loan was $1.9 million and the unamortized debt discount was $19.4 thousand.

For the periods from January 1, 2024 to July 30, 2024 (Predecessor) and the year ended December 31, 2023 (Predecessor), Legacy Adagio has recognized the interest expense was $87.3 thousand and $0.2 million, respectively.

Prior to the Closing, the existing SVB Term Loan of Legacy Adagio has a net balance of $1.0 million, including $1.0 million of principal and accrued interest, and an unamortized debt discount of $9.7 thousand. The unpaid principal and accrued interest were carried as assumed liabilities to the Company and paid at the Closing.

Convertible Securities Notes (Successor)

In connection with the execution of the Business Combination Agreement, Convert Investors executed the Convertible Security Subscription Agreement dated February 13, 2024, which was amended on June 20, 2024, with ListCo. In accordance with the agreement, ListCo issued on the Closing Date to the Convert Investors $20.0 million of Convertible Securities Notes and 1,500,000 Convert Warrants.

The total of $20.0 million Convertible Securities Notes will be convertible into shares of the Company's common stock at a conversion price of $10.00 per share, subject to adjustment per the terms of the agreement. In the event of default, the Company may irrevocably elect in the event of default notice to permit the holder to effect alternate conversion, for which the conversion calculation and price are specified in the agreement.

The total of 1,500,000 Convert Warrants, each of which will be exercisable on a cashless basis or for one share of the Company's common stock at $24.00 per share, subject to adjustment. The Convertible Securities Notes have a maturity of three years and nine months after the Closing and interest will be payable in cash or compound as additional principal outstanding which accrues on a quarterly basis.

The conversion of the February 2024 Convertible Notes was carried out on the same terms as the other Convert Investors executing the Convertible Security Subscription Agreement.

For the period from July 31, 2024 to December 31, 2024 (Successor), the Company has recognized interest expense of $1.1 million.

Note 10 - Warrants

SVB Warrants (Predecessor)

On February 3, 2023, in conjunction with the LSA, the Legacy Adagio issued Initial Warrants to purchase 32,720 shares of common stock of the Company, and a contingent right to obtain an additional 16,360 shares of the common stock upon the non-occurrence of the Interest Only Milestone as mentioned above. The Additional Warrants are subject to the same terms as the Initial Warrants (collectively "SVB Warrants").

The exercise price of the SVB Warrants is $7.97 per share. The warrants are fully exercisable and will expire on February 3, 2033.

The SVB Warrants were terminated prior to the consummation of the Business Combination as the fair market value of Legacy Adagio common stock is lower than the exercise price of the SVB Warrants before the Closing.

Series E Pre-funded Warrants (Predecessor)

On June 25, 2024, in conjunction with the Series E Preferred Stock exchange agreement (refer to *Note 13-Mezzanine Equity and Stockholders' Equity (Deficit))*, Legacy Adagio issued to a certain investor 207,902 shares of pre-funded warrants to purchase 207,902 shares of Series E Preferred Stock, in exchange of the investor's existing holding of 207,902 shares of Series E Preferred Stock.

The exercise price of the pre-funded warrants is $0.001 per share. The pre-funded warrants are exercisable, at the option of the holder, on any day on or after the issuance date, in whole or in part. As an alternative to immediate cash payment, the investor may elect to exercise the pre-funded warrant through a cashless exercise.

Upon the consummation of the Business Combination, the 207,902 Series E Pre-funded Warrants were converted in exchange for 34,680 shares of the Company's common stock.

Convert Warrants (Successor)

As mentioned in *Note 9- Debt*, the Company issued $20.0 million of Convertible Securities Notes and 1,500,000 Convert Warrants at the Closing. Each of the Convert Warrants is exercisable on a cashless basis or for one share of the Company's common stock at an exercise price of $24.00 per share, subject to adjustment. The Convert Warrants expire on the seventh anniversary from the issuance date.

PIPE Pre-funded Warrants (Successor)

The Company issued 670,000 PIPE Pre-funded Warrants, along with 681,111 shares of the Company's Common Shares and 1,140,000 Base Warrants to certain Other PIPE Investor in exchange for cash proceeds of $9.5 million in PIPE Financing.

As set forth in the agreement of the PIPE Pre-Funded Warrants, the PIPE Pre-Funded Warrants are exercisable on a cashless basis or on a gross basis for one share of the Company's Common Stock at an exercise price of $0.01 per share, subject to adjustments. The Company may be required to cash settle the PIPE Pre-funded Warrants when it fails to timely deliver shares to the holder who exercises the PIPE Pre-funded Warrants or upon the occurrence of a fundamental transaction. The PIPE Pre-funded Warrants expires when it is exercised in full.

On December 26, 2024, a total of 670,000 pre-funded warrant shares were exercised on a cashless basis to acquire 663,096 shares of the Company's Common Stock. The exercise price for the pre-funded warrants was $0.9705 per share.

As of December 31, 2024, there were no prefunded warrants outstanding.

PIPE Base Warrants (Successor)

On the Closing Date, the Company issued 3,540,000 Base Warrants along with 4,372,607 shares of the Company's Common Shares to settle the outstanding principal and accrued interest of the Bridge Financing Notes.

The Company also issued 3,345,069 Base Warrants along with 3,287,018 shares of the Company's Common Stock and 670,000 PIPE Pre-Funded Warrants to PIPE Investors for cash proceeds received in PIPE Financing.

Further, in connection with the non-redemption agreements entered with certain Other PIPE Investors holding 468,941 shares of ARYA's Class A ordinary shares, the Company issued 643,658 units of Base Warrants along with 761,229 shares of the Company's Common stock in exchange for the non-redeemable 468,941 shares of ARYA's Class A ordinary shares.

The Base Warrants can be exercised to the Company's Common Stock at any time during the period from the issuance date to the expiration date which is the fifth anniversary from the date of issuance. The warrants can be exercised on a gross or net basis at an exercise price of $10 per share.

The Base Warrants were fair valued at $2.41 per unit on the date of issuance based on the assumptions including (i) the value of the Company's Common Stock is $6.64 per share; (ii) a risk-free rate at 3.93%; (iii) zero dividend yield; (iv) the common stock volatility at 84.0% and a volatility haircut of 10%; (v) the remaining term is five years.

According to ASC 815, it is determined that the Base Warrants associated with the PIPE Financing are indexed to the Company's Common Stock and are accounted for as equity, which is initially measured at fair value. The Base Warrants are classified as equity in the consolidated financial statements because they meet the ASC 815-40 indexation guidance. Specifically, 1) the Base Warrants can be exercised at any time during the exercise period without contingencies; 2) the Base Warrants can be settled in a fixed number of shares upon exercise with any adjustments, such as antidilution and alternative issuance adjustments, consistent with ASC 815 guidance, which does not preclude equity classification. Additionally, the Company has sufficient authorized shares available to settle the Base Warrants, and all the adjustments are in the control of the Company, further supporting the equity classification.

Note 11 - Operating Leases

The Company leases distribution and research and development facilities as well as sub-leases office and manufacturing space from third parties and related parties (refer to *Note 17-Related Party Transactions*) under its operating leases. The leases have expirations ranging from March 2024 to June 2026, some of which include rent escalations or an option to extend the lease for up to three years per renewal. The exercise of lease renewal options is at the sole discretion of the Company. Where leases contain an option to renew, any period beyond the option date is only included as part of the lease term if the Company is reasonably certain to exercise the option.

As of December 31, 2024 and December 31, 2023, the Company does not have any finance or short-term leases and has not entered into leases which have not yet commenced that would entitle the Company to significant rights or create additional obligations as of December 31, 2024 and December 31, 2023.

The following table summarizes quantitative information of the Company's operating leases for the periods from January 1, 2024 to July 30, 2024 (Predecessor), from July 31, 2024 to December 31, 2024 (Successor), and the year ended December 31, 2023 (Predecessor):

	Years Ended December 31,		
	2024		2023
	Successor	Predecessor	Predecessor
In thousands, unaudited	July 31 to December 31,	January 1 to July 30	January 1 to December 31,
Operating cash flows paid for operating leases	$ 63	$ 108	$ 178
Weighted average remaining lease term (years)	1.3	1.7	1.7
Weighted average discount rate	8 %	8 %	8 %

Operating lease cost was $0.1 million, $78.0 thousand, and $0.2 million for the periods from January 1, 2024 to July 30, 2024 (Predecessor), from July 31, 2024 to December 31, 2024 (Successor), and the year ended December 31, 2023 (Predecessor), respectively. There has been no variable lease cost for the periods from January 1, 2024 to July 30, 2024 (Predecessor), from July 31, 2024 to December 31, 2024 (Successor) and the year ended December 31, 2023 (Predecessor).

The following table presents the future minimum payments under the non-cancellable operating leases as of December 31, 2024 (in thousands):

Year ending December 31,	
2025	$ 154
2026	48
Total undiscounted future cash flows	202
Less: imputed interest	(13)
Total operating lease liability	$ 189

Note 12 - Commitments and Contingencies

Litigation

The Company is not currently party to any legal proceedings. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses as incurred the costs related to such legal proceedings, if any.

Note 13 - Mezzanine Equity and Stockholders' Equity (Deficit)

Authorized Shares (Predecessor)

The Legacy Adagio's Amended and Restated Articles of Incorporation authorize the issuance of two classes of stock designated as common and preferred stock, each having a par value of $0.001 per share. The number of shares authorized as of July 30, 2024 is 11,534,892 consisting of 6,594,946 shares of common stock and 4,939,946 shares of preferred stock, designated as Series A, Series B, Series C, Series D, and Series E preferred stock in the amounts included in the table below.

Convertible Preferred Stock (Predecessor)

Legacy Adagio classifies convertible preferred stock as temporary equity on the accompanying consolidated balance sheets, as all such preferred stock is redeemable either at the option of the holder or upon an event outside the control of Legacy Adagio. The requirements of a deemed liquidation event, as defined within its amended and restated certificate of incorporation filed in November 2020, are not entirely within Legacy Adagio's control. In the event of such a deemed liquidation event, the proceeds from the event are distributed in accordance with the liquidation preferences, provided that the holders of preferred stock have not converted their shares into common stock. Legacy Adagio records the issuance of preferred stock at the issuance price less related issuance costs. Legacy Adagio has not adjusted the carrying value of outstanding preferred stock to its liquidation preference because a deemed liquidation event is not probable of occurring as of the end of the reporting period.

During the period from January 1, 2024 to July 30, 2024 (Predecessor), the following transactions have been executed:

- On June 25, 2024, 207,902 shares of Series E Preferred Stock were extinguished and exchanged for 207,902 shares of pre-funded warrants to purchase Series E Preferred Stock. See *Note 10- Warrants* for additional information regarding the Series E Pre-funded Warrants. The difference between the carrying value of the extinguished Series E Preferred Stock and the fair value of the issued Series E Pre-funded Warrants is recorded in additional paid-in capital.

On the Closing Date, the Legacy Adagio's 4,732,044 convertible preferred stocks were converted into shares of Legacy Adagio common stock on a one-to-one basis prior to Adagio Merger Effective Time and then converted into 789,337 shares of the Company's Common Stock and additional paid in capital at the Closing based on the exchange ratio set forth in the Business Combination Agreement.

There were no preferred stock transactions during the year ended December 31, 2023 (Predecessor).

The following table summarizes information related to issuance of the Company's preferred stock as of December 31, 2023 (Predecessor) (in thousands, except share and per share data):

Preferred Stock Class	Number of Shares Authorized	Shares Issued and Outstanding	Carrying Value (1)	Conversion Price Per Share	Number of Common Stock Equivalent Shares	Liquidation Preference
Series A	270,856	270,856	$ 2,500	$ 9.23	270,856	$ 2,500
Series B	815,730	815,730	10,626	13.04	815,730	10,637
Series C	981,596	981,596	15,988	16.30	981,596	16,000
Series D	992,064	992,064	19,990	20.16	992,064	20,000
Series E	1,879,700	1,879,700	42,365	22.61	1,879,700	42,500
	4,939,946	4,939,946	$ 91,469		4,939,946	$ 91,637

(1) The carrying value reflects the gross proceeds received from the sale of the preferred stock less issuance costs.

The relative rights, terms, privileges, and restrictions granted to or imposed upon preferred stockholders are described below:

Preferred Stock - Dividends

Prior and in preference to any declaration or payment of any dividends to the holders of common stock, the holders of preferred stock shall be entitled to receive dividends out of any assets legally available therefor, at the rate of eight percent (8%) of the original issue price per share per annum. The original issue price of Series A, Series B, Series C, Series D, and Series E is $9.23, $13.04, $16.30, $20.16, and $22.61, respectively. The dividends shall not be cumulative.

In the event that the dividend amount declared by the Board of Directors of Legacy Adagio is insufficient to permit payment of the full aforesaid dividends, such dividends will be paid ratably to each holder of preferred stock in proportion to the dividend amounts to which each holder of preferred stock is entitled. After payment of the full amount of the aforesaid dividends, any additional dividends declared shall be distributed to the holder of common stock and preferred stock in proportion to the number of shares of common stock that would be held by such holder on an as-converted to common stock basis.

No dividends on preferred stock or common stock have been declared by the Board of Directors as of December 31, 2023 (Predecessor) or as of December 31, 2024 (Successor).

Liquidation Preference

In the event of liquidation of Legacy Adagio, including a merger, acquisition, or sale of all or substantially all the assets of Legacy Adagio, holders of preferred stock are entitled to receive an amount equal to the original issue price of each share of preferred stock held plus any dividends declared but not yet paid, prior to any distribution of assets or surplus funds of Legacy Adagio to common stock shareholders. After payment has been made to the holders of the preferred stock of the full amounts to which they are entitled as noted above, the remaining assets would be distributed among the holders of the common stock pro rata based on the number of shares of common stock held by each holder.

If, at the time of liquidation, the assets are insufficient to permit full payment of the liquidation preferences of the series listed in the order above, the assets must be distributed ratably among the holders of the series in proportion to the full preferential amount each such holder is otherwise entitled to receive in respect to such shares.

Voting Rights

So long as the shares of preferred stock that are convertible into at least 1,000,000 shares of common stock (subject to appropriate adjustment in the event of any stock dividends, stock split, combination or other similar recapitalization with respect to the common stock) are issued and outstanding, the holders of preferred stock, voting as a separate class on an as-converted to common stock basis, shall have the right to elect four members of the Board of Directors of Legacy Adagio. The holders of common stock, voting as a separate class, shall have the right to elect one member of the Board of Directors. The remaining directors shall be elected by the holders of the common stock and the preferred stock, voting together as a single class on an as-converted to common stock basis.

On all other matters, the holders of the preferred stock shall have full voting rights and powers equal to the voting rights and powers of the holders of common stock.

Fractional votes by the holders of preferred stock shall not be permitted and any fractional voting rights shall be rounded to the nearest whole number.

Conversion Rights

Each share of preferred stock shall be convertible, at the option of the holder, into shares of common stock without the payment of any additional consideration. The preferred stock shall be convertible into the number of fully paid and nonassessable shares of common stock which results from dividing the conversion price per share in effect for the preferred stock at the time of conversion into the per share conversion value. The initial per share conversion price of Series A, Series B, Series C, Series D, and Series E is $9.23, $13.04, $16.30, $20.16, and $22.61, respectively. The initial conversion price is subject to adjustment for antidilution provisions, as defined. The per share conversion value of Series A, Series B, Series C, Series D, and Series E is $9.23, $13.04, $16.30, $20.16, and $22.61, respectively.

Each share of preferred stock shall automatically be converted into shares of common stock at the then effective conversion rate immediately upon the earlier of (i) the election of the holders of a majority of the outstanding shares of preferred stock, voting as a separate class on an as-converted to common stock basis, or (ii) the closing of the sale of the Legacy Adagio common stock in a firm commitment, underwritten public offering registered under the Securities Act of 1933, as amended, with aggregate offering proceeds to Legacy Adagio (before deduction for underwriters' discounts and expenses relating to the issuance) of at least $75 million and a public offering price per share equal to at least $67.83 (subject to adjustments for stock dividends, splits, combinations and similar events).

Protective Provisions

So long as there are at least 1,000,000 shares of preferred stock outstanding, Legacy Adagio shall not (by merger, reclassification, amendment or otherwise), without first obtaining the approval of the holders of at least seventy percent (70%) of the then outstanding shares of preferred stock, voting separately as a class, to, among other things: (i) amend the certificate of incorporation or bylaws; (ii) adversely alter or change the rights, preferences or privileges of the preferred stock; (iii) increase or decrease the aggregate number of authorized shares of any class of the capital stock of Legacy Adagio.

So long as shares of Series E preferred stock that are convertible into at least 500,000 shares of common stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the common stock) are issued and outstanding, Legacy Adagio shall not directly or indirectly (by merger, reclassification, amendment or otherwise), without first obtaining the approval of the holders of at least a majority of the voting power of the then outstanding shares of Series E preferred stock, voting separately as a class, to, among other things: (i) amend, alter, repeal or waive any provision of the certificate of incorporation or bylaws of Legacy Adagio in a manner that adversely affects the holders of the Series E preferred stock in a manner different from any other series of preferred stock; (ii) create or authorize the creation of or issue any other security convertible into to exercisable for any equity security having rights, preferences or privileges senior to the Series E preferred stock; (iii) increase or decrease the authorized number of shares of Series E preferred stock.

Common Stock (Predecessor)

Each share of common stock is entitled to one vote. As of December 31, 2023 (Predecessor), Legacy Adagio was authorized to issue up to 6,594,946 of common stock at a par value of $0.001 per share out of which 786,510 shares issued and 779,908 shares outstanding.

On the Closing Date, as explained in *Note 3- Forward Merger*, each share of Legacy Adagio issued and outstanding prior to the Closing Date was converted into the Company's Common Stock based on the exchange ratio set forth in the Business Combination Agreement.

Common Stock (Successor)

As of December 31, 2024 (Successor), the Company's certificate of incorporation, as amended and restated, authorized the Company to issue up to 210,000,000 of common stock at a par value of $0.0001 per share, and 20,000,000 shares of preferred stock, par value $0.0001 per share. As of December 31, 2024 (Successor), 15,198,232 shares were issued and outstanding, including 1,147,500 Sponsor Earnout (as defined below).

In September 2024, the Company issued 1,147,500 shares of the Company's Common Stock (such issuance, the "Sponsor Earnout") to ARYA Sciences Holdings IV under the Sponsor Letter Agreement dated February 13, 2024 ("the Sponsor Letter Agreement"). Pursuant to the agreement, the Sponsor Earnout shall be unvested and vests upon the earlier of: i) During the period from the effective time to the 10th anniversary of the Closing Date (the "Earn-Out Period"), the stock price of the Company's Common Stock equals or exceeds $24.00 per share (the "Trigger Price") for any 20 trading days within any 30 trading day period from and after the Closing Date (the "Earn-Out Target"), and ii) immediately prior to the consummation of a company sale during the Earn-Out Period.

As of the reporting date, the vesting of the Sponsor Earnout was not considered probable.

According to ASC 815, it is determined that the Sponsor Earnout is indexed to the Company's Common Stock and classified as equity and is initially measured at fair value and not subsequently remeasured. The Sponsor Earnout vests when the Company's stock price meets a stated price or there is a company sale during the earnout period. Upon meeting either vesting condition, the same number of the Company's Common Stock would be issued and no longer subject to forfeiture or cancellation. The Sponsor Earnout meets the ASC 815-40 indexation guidance. Specifically, the stated stock price and company sale, as the exercise contingencies, do not preclude equity indexation and there is no variability in the number of shares issuable under the Sponsor Earnout. Additionally, the Sponsor Earnout at the issuance meets the ASC 815-40 equity classification criterion as the Company has sufficient authorized shares available to settle the Sponsor Earnout and all the antidilution adjustments are in the control of the Company.

The holders of the Company's Common Stock are entitled to receive dividends whenever funds are legally available, when and if declared by the Company's Board of Directors. As of December 31, 2024 (Successor), no cash dividend has been declared to date. Each share of the Company's Common Stock is entitled to one vote.

Below table summarizes the number of shares of common stock outstanding immediately following the Closing:

	Number of Shares
Contribution from PIPE Financing for cash	3,287,018
Conversion of ARYA convertible promissory notes	355,100
Conversion of ARYA Class A ordinary shares and Class B ordinary shares	2,089,000
Conversion of Class A ordinary shares subject to redemption	123,520
Shares issued in purchase consideration	6,771,769
Additional shares issued and reclassification of Class A ordinary shares subject to non-redemption agreements and open market subscription agreements	761,229
Total	13,387,636

The table below summarizes the Company's reserved common stock for further issuance as of December 31, 2024 (Successor) and December 31,2023 (Predecessor):

	Successor	Predecessor
	December 31, 2024	December 31, 2023
Conversion of preferred stock	—	4,939,946
Stock options issued and outstanding under the 2012 and 2022 Plan	—	747,001
Common shares available for future grant under the 2012 and 2022 Plan	—	27,012
Base Warrants	7,528,727	
PIPE Pre-funded Warrants	—	—
Convertible Securities Notes	3,231,327	—
Convert Warrants	1,500,000	—
Company's common stock issuable upon the exercise of outstanding options Legacy Adagio's equity plans that were assumed in the Business Combination	7,587	—
Common stock reserved for future issuance under the 2024 Equity Incentive Plan	4,472,592	—
Common stock reserved for future issuance under the 2024 Key Employee Equity Incentive Plan	3,354,444	—
Common stock reserved for future issuance under the 2024 Employee Stock Purchase Plan	441,293	—
Common stock reserved for future issuance	20,535,970	5,713,959

Note 14 - Stock-Based Compensation

Predecessor Periods

2012 Stock Incentive Plan

In January 2011, Legacy Adagio's Board approved the 2012 Stock Incentive Plan (the "2012 Plan"), which permitted grants of Incentive Stock Options ("ISOs") and Non-statutory Stock Options ("NSOs") to employees, directors and consultants. The maximum number of shares that can be granted under the 2012 Plan cannot exceed 1,255,000 shares. The 2012 Plan had a maximum 10-year term and as such, terminated in January 2022.

2022 Stock Incentive Plan

In April 2022, the Legacy Adagio's Board approved, in conjunction with the termination of the 2012 Plan, the 2022 Stock Incentive Plan (the "2022 Plan"), permitting ISOs and NSOs to employees, directors and consultants. The maximum number of shares granted under the 2022 Plan cannot exceed 203,855 plus any shares subject to stock options granted under the 2012 Plan that expired or were otherwise terminated without having been exercised in full, were forfeited, or were repurchased by the Company. The 2022 Plan is intended as the successor to and continuation of the 2012 Plan (thereafter both the 2012 and 2022 Plans are referred to as the "Stock Incentive Plan").

The Stock Incentive Plan provides a means whereby participants may purchase shares of common stock pursuant to ISOs or NSOs and such persons may be granted shares of common stock for consideration consisting of cash and/or past services rendered to or on behalf of Legacy Adagio. ISOs may only be granted to employees. NSOs and stock purchase rights may be granted to employees and consultants. Generally, options awards only have service conditions that need to be met for the awards to vest, with the exception of grants to two non-employees that had performance obligations that were deemed to be immaterial.

The stock options generally vest over four years and have a ten-year contractual term. The fair value of each employee and non-employee stock option grant is estimated on the date of grant using the Black-Scholes option pricing model. As Legacy Adagio lacks company-specific historical and implied volatility information required for valuation, Legacy Adagio estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies. Due to the lack of historical exercise history, the expected life term of ISOs that were granted after 2013 was determined using the "simplified method" provided by the Securities and Exchange Commission in Staff Accounting Bulletins Number 107 and 110. The expected life term of NSOs is determined either by using the "simplified method," or by calculating the time to expiry from the grant date. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant for time periods approximately equal to the expected term of the award. Expected dividend yield is zero as Legacy Adagio has never paid nor does it expect to pay any cash dividend in the near future.

The following table summarizes stock option activity during the periods from January 1, 2024 to July 30, 2024 (Predecessor):

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2023 (Predecessor)	747,001	$ 6.17	7.45	$ 72
Forfeited	(6,592)	4.82	—	—
Outstanding, July 30, 2024 (Predecessor)	740,409	$ 6.18	—	$ —
Vested and expected to vest, July 30, 2024 (Predecessor)	—	$ —	—	$ —
Vested and exercisable, July 30, 2024 (Predecessor)	—	$ —	—	$ —

There were no stock options exercised during the period from January 1, 2024 to July 30, 2024 (Predecessor). Certain stock option grants under the Stock Incentive Plan allow the recipient to exercise the options prior to the options becoming fully vested. Under the Stock Incentive Plan, the Company retains the right to repurchase common shares that have been issued upon early exercise of options at the original issue price. Cash received for the early exercise of unvested stock options is initially recorded as a liability. At each reporting date, the vested shares are released to equity.

The fair value of awards vested was $0.3 million during the period from January 1, 2024 to July 30, 2024 (Predecessor). As of July 30, 2024 prior to the Closing (Predecessor), the total unrecognized compensation cost of $0.4 million was accelerated at the Closing, which was recognized and expensed in accordance with the terms of the 2012 Stock Incentive Plan and the 2022 Stock Incentive Plan.

Upon the consummation of the Business Combination, 45,544 In-the-Money Adagio Options were canceled and extinguished in exchange for 7,587 options to purchase the Company's Common Stock.

Stock-Based Compensation Expense

The following table summarizes the total stock-based compensation expense for the stock options expense recorded in the consolidated statements of operations and comprehensive loss for the periods from January 1, 2024 to July 30, 2024 (Predecessor), July 31 to December 31, 2024 (Successor), and the year ended December 31, 2023 (Predecessor) (in thousands):

	2024		2023
	Successor	Predecessor	Predecessor
	July 31 to December 31,	January 1 to July 30	January 1 to December 31,
Selling, general, and administration	$ —	$ 527	$ 384
Research and development	—	115	58
Total stock-based compensation expense	$ —	$ 642	$ 442

Successor *Periods*

2024 Equity Incentive Plan

The Board of Directors of the Company adopted the 2024 Equity Incentive Plan on July 26, 2024. The purpose of the plan is to promote the success and enhance the value of the Company by linking the individual interests of the members of the Board, Employees, and Consultants to those of Company stockholders and by providing such individuals with an incentive for outstanding performance to generate superior returns to Company stockholders. The 2024 Equity Incentive Plan authorizes the issuance of up to 4,472,593 shares of the Company's Common Stock, plus an annual increase on the first day of each year beginning in 2025 and ending in (and including) 2034 equal to the lesser of (A) five percent (5%) of the shares of Common Stock outstanding on a fully diluted basis on the last day of the immediately preceding fiscal year and (B) such smaller number of shares of Company's Common Stock as determined by the Board or the compensation committee thereof. The Company may grant an option, a stock appreciation right, a restricted stock award, a restricted stock unit award, a performance stock award, a performance stock unit award, or other stock- or cash-based award, or a dividend equivalent award, which may be awarded or granted under the Plan. The awards can be issued to any person who is an employee, a consultant, or a non-employee director.

The Company has not granted any awards under this plan as of December 31, 2024.

2024 Key Employee Equity Incentive Plan

The Board of Directors of the Company adopted the 2024 Key Employee Equity Incentive Plan on July 26, 2024. The purpose of the Plan is to promote the success and enhance the value of the Company by linking the individual interests of key employees of the Company to those of Company stockholders and by providing such individuals with an incentive for outstanding performance to generate superior returns to Company stockholders. The 2024 Key Employee Equity Incentive Plan authorizes the issuance of up to 3,354,444 shares of the Company's Common Stock. The Company may grant option, a stock appreciation right, a restricted stock award, a restricted stock unit award, a performance stock award, a performance stock unit award, other stock- or cash-based award, or a dividend equivalent award, which may be awarded or granted under the plan. The awards can only be issued to certain individuals as identified in the plan who are an employee, a consultant, or a non-employee director.

The Company has not granted any awards under this plan as of December 31, 2024.

2024 Employee Stock Purchase Plan

The Board of Directors of the Company adopted the 2024 Equity Incentive Plan on July 26, 2024. The 2024 Employee Stock Purchase Plan provides a means by which eligible employees of the Company and certain designated related corporations may be given an opportunity to purchase shares of the Company's Common Stock. The plan permits the Company to grant a series of purchase rights to eligible employees under an Employee Stock Purchase Plan. The 2024 Employee Stock Purchase Plan authorizes the issuance of up to 441,293 shares of the Company's Common Stock, plus an annual increase on the first day of each year beginning in 2025 and ending in (and including) 2034 equal to one percent (1%) of the share of common stock outstanding on a fully diluted basis on the last day of the immediately preceding fiscal year, provided that the Board or its compensation committee may reduce the amount of the increase in any particular year.

The Company has not granted any purchase rights under this plan as of December 31, 2024.

The following table summarizes stock option activity during the period from July 31, 2024 to December 31, 2024 (Successor):

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value (in thousands)
Outstanding, July 31, 2024 (Successor)	—	$ —	—	$ —
Options issued as part of the Business Combination	7,587	8.97	—	—
Outstanding, December 31, 2024 (Successor)	7,587	$ 8.97	—	$ —
Options vested, December 31, 2024 (Successor)	7,587	$ 8.97	—	$ —
Options vested and exercisable, December 31, 2024 (Successor)	7,587	$ 8.97	—	$ —

As discussed above, the Company has not granted any options under the 2024 Equity Incentive Plan, the 2024 Key Employee Equity Incentive Plan and the 2024 Employee Stock Purchase Plan.

Note 15 – Earnings Per Share ("EPS")

Predecessor

Basic net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period. Diluted net loss per common share excludes the potential impact of the Company's convertible preferred stock, common stock warrants, and common stock options because the Company's net losses would cause such shares to be anti-dilutive. Therefore, as the Company recorded net losses in the periods presented, basic and diluted net loss per common share are the same.

	Predecessor	
	Period from January 1 to July 30, 2024	Year ended December 31, 2023
Numerator:		
Net loss attributable to common stockholders	$ (21,278)	$ (36,590)
Denominator:		
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders - basic and diluted	815,854	759,814
Net loss per share attributable to common stockholders - basic and diluted	$ (26.08)	$ (48.16)

The following potentially dilutive securities were excluded from the computation of diluted net loss per share calculations for the periods presented because the impact of including them would be anti-dilutive:

	Predecessor	
	As of July 30, 2024	As of December 31, 2023
Convertible preferred stock	4,732,044	4,939,946
Stock options	740,409	747,001
SVB Warrants	—	49,080
Total potentially dilutive securities	5,472,453	5,736,027

Successor

After the Business Combination, the Successor calculated basic earnings-per-share ("EPS") and diluted EPS to common stockholders in conformity with the two-class method required for companies with participating securities. The Company considered (i) the Convertible Securities Notes and (ii) the earnout shares subject to vesting conditions to be participating securities as they participate in any distributions declared by the Company. The Company's Base Warrants and Convert Warrants are considered as non-participating securities, as the holders are not entitled to any shareholder right prior to the exercise of the Base Warrants and the Convert Warrants. As of the reporting date, none of the Base Warrants or the Convert Warrants were exercised to receive the Company's Common Stock.

Under the two-class method, undistributed earnings allocated to these participating securities were subtracted from net income in determining net income attributable to common stockholders. In periods of net loss, losses are allocated to the participating security only if the security has not only the right to participate in earnings, but also a contractual obligation to share in the Company's losses. As the Company incurred a net loss for the period from July 31, 2024 to December 31, 2024 (Successor), the Convertible Securities Notes were not considered participating securities, and were excluded from the two-class method EPS calculation for those periods.

Further, Basic EPS under the two-class method includes the impact of the Company's PIPE Pre-funded Warrants as the PIPE Pre-funded Warrants are exercisable for only $0.01 per share (i.e., de minimis cash consideration) without an expiration date and not subject to exercise contingencies.

The Company discloses the Diluted EPS under the if-converted method as such diluted EPS is lower than the diluted EPS calculated under the two-class method. The Earn-out shares subject to vesting conditions are not considered in the denominator for the calculation of diluted EPS as the vesting conditions for the Earn-out shares were not met during the successor reporting period.

The following table sets forth the computation of basic earnings per share attributable to common stockholders and the participating securities for the periods presented (in thousands, except share and per share data):

Basic EPS:

	July 31, 2024 to December 31, 2024 (Successor)		
(amounts in thousands, except share and per share data)	Common Shares	Convertible Securities Notes	Sponsor Earnout
Numerator:			
Net loss allocated to each class of participating securities	$ (49,888)	$ —	$ (3,875)
Denominator:			
Weighted-average shares outstanding	14,772,692	—	—
Shares issuable to Convertible Securities Notes	—	—	—
Sponsor Earnout	—	—	1,147,500
Net loss per share attributable to each class of participating securities – Basic	$ (3.38)	$ —	$ (3.38)

The following table sets forth the computation of diluted earnings per share attributable to common stockholders for the periods presented (in thousands, except share and per share data):

Diluted EPS:

(amounts in thousands, except share and per share data)	Successor July 31, 2024 to December 31, 2024
Numerator:	
Net loss – Basic	$ (53,763)
Less: Adjustment for fair value changes to convertible securities notes	(929)
Net loss attributable to common stockholders – Diluted	$ (54,692)
Denominator:	
Weighted-average shares outstanding – Basic	14,772,692
Weighted-average effect of shares issuable to Convertible Securities Notes (if-converted method)	—
Weighted-average shares outstanding – Diluted	14,772,692
Net loss per share attributable to common shares – Diluted (if-converted method)	$ (3.70)

The following potentially dilutive securities were excluded from the computation of diluted net loss per share calculations for the periods presented because the impact of including them would be anti-dilutive:

	Successor December 31, 2024
Base Warrants	7,528,727
Convert Warrants	1,500,000
Earn-out Shares, subject to vesting conditions	1,147,500
Stock options issued in connection with the Business Combination	7,587
Total potentially dilutive securities	10,183,814

Note 16 - Income Taxes

The Company accounts for income taxes in accordance with ASC 740. Under the provisions of ASC 740, management is required to evaluate whether a valuation allowance should be established against its deferred tax assets. The Company currently has a full valuation allowance against our deferred tax assets. As of each reporting date, the Company's management considers new evidence, both positive and negative, that could impact management's view with regard to future realization of deferred tax assets. For the periods from January 1, 2024 to July 30, 2024 (Predecessor) and July 31, 2024 to December 31, 2024 (Successor), there was no material change from fiscal year ended December 31, 2023 (Predecessor) in the amount of the Company's deferred tax assets that are not considered to be more likely than not to be realized in future years.

For the periods from January 1, 2024 to July 30, 2024 (Predecessor) and July 31, 2024 to December 31, 2024 (Successor), the effective tax rate for the Company's operations was 21.0%. The effective tax rate differed from the U.S. federal statutory rate primarily due to state income taxes, losses from the German subsidiary that is subject to different effective tax rates, stock-based compensation, fair value adjustments for convertible notes and warrant liabilities, and a change in the valuation allowance that offset the tax benefit on the current period pre-tax loss.

For the year ended December 31, 2023 (Predecessor), the effective tax rate for the Company's operations was 21.0%. The effective tax rate differed from the U.S. federal statutory rate primarily due to state income taxes, losses from the German subsidiary that is subject to different effective tax rates, stock-based compensation and a change in the valuation allowance that offset the tax benefit on the current period pre-tax loss.

The Company is subject to U.S. federal income tax as well as income tax of foreign and state tax jurisdictions. The tax years 2019-2024 remain open to examination by the major taxing jurisdictions to which the Company is subject, except the Internal Revenue Service for which the tax years 2020-2024 remain open.

The components of pretax loss from operations for the years ended December 31, 2024 and 2023 are as follows `(dollars in thousands):

	2024		2023
Years ended December 31,	Successor July 31 to December 31	Predecessor January 1 to July 30	Predecessor January 1 to December 31
U.S.	$ (76,889)	$ —	$ (36,517)
Foreign	(22)	—	(73)
Pretax loss from operations	$ (76,911)	$ —	$ (36,590)

There was no income tax provision for the year ended December 31, 2024 and 2023. Current income taxes are based upon the year's income taxable for federal, state and foreign tax reporting purposes. Deferred income taxes are provided for certain income and expenses which are recognized in different periods for tax and financial reporting purposes. Deferred tax assets and liabilities are computed for differences between the consolidated financial statements and tax bases of assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates applicable to the period in which the differences are expected to affect taxable income, and include NOL carryforwards and R&D tax credit carryforwards.

The following table presents a reconciliation of income tax computed at the U.S. federal statutory tax rate to the total income tax benefit for the years ended December 31, 2024 and 2023 (dollars in thousands):

	Years Ended December 31					
	2024				2023	
	Successor		Predecessor		Predecessor	
	July 31 to December 31		January 1 to July 30		January 1 to December 31	
Years ended December 31,	Amount	Tax Rate	Amount	Tax Rate	Amount	Tax Rate
Income tax benefit at federal statutory rate	$ (16,151)	21.0 %	$ —	— %	$ (7,684)	21.0 %
Adjustments for tax effects of:						
Permanent adjustments	687	(0.9)%	—	— %	448	(1.2)%
Goodwill impairment	6,368	(8.3)				
Change in FV of convertible note	(627)	0.8 %	—	— %	1,456	(4)%
Change in FV of warrant liability	(1,421)	1.8 %	—	— %	—	— %
NOL true-up adjustment	—	— %	—	— %	2,922	(8)%
Foreign rate differential	2	— %	—	— %	(11)	(0.0)%
Change in federal valuation allowance	9,230	(12.0)%	—	— %	2,869	(7.8)%
Income tax benefit	$ (1,912)	2.4 %	$ —	— %	$ —	— %

Significant components of the Company's deferred tax assets and liabilities as of December 31, 2024 and 2023 are as follows (in thousands):

	December 31, 2024	December 31, 2023
	Successor	Predecessor
Deferred tax assets:		
Net operating losses	$ 30,454	$ 25,786
Capitalized research costs	5,596	4,456
Research and development credit	1,604	1,604
Accrued compensation	482	392
Stock-based compensation	11	269
Operating lease liabilities	30	14
State taxes	130	—
Other	297	114
Total deferred tax assets	38,604	32,635
Less: Valuation allowance	(36,857)	(32,100)
Total deferred tax assets, net of valuation allowance	1,747	535
Deferred tax liabilities:		
Right-of-use assets	(29)	(14)
Intangible assets	(2,080)	—
Unrecognized tax benefit	(521)	(521)
Total deferred tax liabilities	(2,630)	(535)
Net deferred tax liabilities	$ (883)	$ —

The Company has established a valuation allowance as of December 31, 2024 and 2023 to fully offset the net deferred tax assets of $36.9 million and $32.1 million, respectively. Realization of the future tax benefits is dependent on the Company's ability to generate sufficient taxable income within the carryforward period. Management assesses the available positive and negative evidence to estimate whether sufficient future taxable income will be generated to permit use of the existing deferred tax assets. A significant piece of objective negative evidence evaluated was the cumulative loss incurred over the three-year period ended December 31, 2024. Such objective evidence limits the ability to consider other subjective evidence, such as the Company's projections for future commercialization. Management has concluded that it is more likely than not that the Company will not have sufficient foreseeable taxable income to allow for the utilization of the deferred tax assets; therefore, a full valuation allowance has been established to reduce the net deferred tax liability to $883 at December 31, 2024, and to zero net deferred tax at December 31, 2023.

As of December 31, 2024 and 2023, the Company had federal NOL carryforwards of approximately $122.3 million and $100.0 million, respectively. $19.0 million of the federal NOL carryforwards will begin to expire from 2031. Due to the enactment of the Tax Cuts and Jobs Act, federal net operating losses generated beginning in 2018 are carried forward indefinitely. Therefore, the remaining federal NOL carry forwards of $103.3 million and $81.0 million as of December 31, 2024 and 2023, respectively, have an unlimited carryover period. As of December 31, 2024 and 2023, the Company had state NOL carryforwards of $53.4 million and $53.4 million, respectively, which will begin to expire from 2031. As of December 31, 2024 and 2023, the Company had a NOL from Adagio Medical GmbH of $180.2 thousand and $249.3 thousand, respectively. The NOLs are carried forward indefinitely. As of December 31, 2024 and 2023, the Company also had net federal R&D tax credit carry-forwards of approximately $1.6 million and $1.6 million, respectively. The federal R&D tax credits will begin to expire in 2038. The Company had no state R&D credits.

The Company's tax attribute carryforwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or that could occur in the future, as required by Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), as well as similar state and foreign provisions. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be used annually to offset future taxable income and tax, respectively. In general, an "ownership change" as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50% of the outstanding stock of a company by certain stockholders. The Company has not completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since the Company's formation due to the complexity and cost associated with such study, and the fact that there may be additional such ownership changes in the future. Any limitation may result in expiration of a portion of the NOL carryforwards or R&D tax credit carryforwards before utilization; however, such limitation, if any, would not have an impact on the Company's financial statement due to the full valuation allowance.

The Company conducts intensive research and experimentation activities, generating R&D tax credits for federal purposes under Section 41 of the Code. The Company has performed a formal study validating these credits claimed in the tax returns.

The following table summarizes the changes to unrecognized tax benefits as of December 31, 2024 and 2023 (in thousands):

	2024		2023
Years ended December 31,	Successor July 31 to December 31	Predecessor January 1 to July 30	Predecessor January 1 to December 31
Balance at beginning of year	$ 521	$ —	$ 321
Gross increases – tax positions during the year	—	—	200
Balance at end of year	$ 521	$ —	$ 521

As of December 31, 2024, the Company has unrecognized tax benefits of $0.5 million of which $0.5 million will affect the effective tax rate if recognized when the Company no longer has a valuation allowance offsetting its deferred tax assets.

The Company does not anticipate that there will be a significant change in unrecognized tax benefits over the next 12 months.

The Company is subject to U.S. federal and various state tax as well as Germany tax jurisdictions. Since the Company formed in 2011, all filed tax returns are subject to examination. Generally, the tax years remain open for examination by the federal statute under a three-year statute of limitation; however, states generally keep their statutes open between three and four years. However, the Company's tax years from inception are subject to examination by the United States and various state taxing authorities due to the carry forward of unused NOLs and R&D credits.

Enacted in December 2017, the Tax Cuts and Jobs Act of 2017 ("TCJA") amended Section 174 to require capitalization of all research and experimental ("R&E") costs incurred in tax years beginning after December 31, 2021. For tax years beginning on or after January 1, 2022, R&E costs must be amortized over five years if the R&E activities are performed in the U.S., or over 15 years if the activities are performed outside of the U.S., beginning with the midpoint of the tax year in which the costs were paid or incurred. During 2024, the Company capitalized $11.8 million of R&E costs. The Company plans to refine the calculation for Section 174 and make an adjustment on the tax return.

Note 17 - Related Party Transactions

Shared Services Agreement

During the periods from January 1, 2024 to July 30, 2024 (Predecessor), from July 31, 2024 to December 31, 2024 (Successor), and the year ended December 31, 2023 (Predecessor), the Company incurred $0.9 million, $0.4 million, $1.4 million, respectively, for finance and accounting services and other general and administrative support services ("Shared Services Agreement") to Fjord Ventures ("Fjord"), a company owned and operated by the Company's CEO. The transactions are recorded as selling, general and administrative expenses on the consolidated statements of operations and comprehensive loss.

Laguna Hills Sublease (Predecessor)

In addition to the Shared Services Agreement, Legacy Adagio also sub-leases approximately 4,992 square feet of office and manufacturing space in Laguna Hills, California from Fjord. On March 31, 2024, the sub-lease with Fjord is expired.

During the periods from January 1, 2024 to July 30, 2024 (Predecessor), and the year ended December 31, 2023 (Predecessor), Legacy Adagio incurred $25.5 thousand, $0.1 million of lease expense, respectively, under the sub-lease agreement.

Refer to *Note 11-Operating Leases* for further detail.

October 2022 Convertible Notes (Predecessor)

On October 27, 2022, Legacy Adagio issued a $0.5 million convertible promissory note to Fjordinvest, LLC ("Fjordinvest"), a company owned and operated by the Legacy Adagio's CEO. On April 4, 2023, November 28, 2023 and February 13, 2024, the October 2022 Convertible Notes were amended. Refer to *Note 9-Debt* for additional information regarding the October 2022 Convertible Notes.

Convertible Securities Notes (Successor)

In connection with the Business Combination and the Convertible Securities Notes agreement, the Company issued a $7.0 million Convertible Securities Notes to Perceptive PIPE Investor, the controlling party of the Company, in exchange for Perceptive PIPE Investor's investment in Legacy Adagio in the form of the February 2024 Convertible Notes. Refer to *Note 9-Debt* for additional information regarding the Convertible Securities Notes.

PIPE Financing (Successor)

In connection with the Business Combination and the PIPE Financing, the Company issued 4,372,607 shares of the Company's Common Stock and 3,540,000 Base Warrants to Perceptive PIPE Investor, the controlling party of the Company, in exchange for Perceptive PIPE Investor's investment in Legacy Adagio in the form of Bridge Financing Notes. Refer to *Note 9-Debt* for additional information regarding the Convertible Securities Notes.

Further, in connection with the PIPE Financing, the Company issued 2,250,352 shares of the Company's Common Stock and 1,905,069 Base Warrants to Perceptive PIPE Investor, the controlling party of the Company, in exchange for Perceptive PIPE Investor's additional cash investment of approximately $15.9 million in the Company.

Note 18 – Segment Reporting

The Company adopted *ASU 2023-07* during the year ended December 31, 2024 retrospectively to all periods presented in the consolidated financial statements. The Company has one reportable segment managed on a consolidated basis by the Chief Executive Officer (CEO) who is the chief operating decision maker ("CODM"). In identifying one reportable segment, the Company considered the basis of organization for the design and development and commercialization of ablation technologies for the treatment of cardiac arrhythmias.

The accounting policies of the segment are the same as those described in the summary of significant accounting policies. The CODM assesses performance and decides how to allocate resources based on consolidated net loss as reported in the consolidated statements of operations and comprehensive loss. There are no other expense categories regularly provided to the CODM that are not already included in the consolidated statements of operations and comprehensive loss. The measure of segment assets is reported on the balance sheet as cash, cash equivalents and money market accounts.

Summary of segment net loss, including significant segment expenses were as follows:

	Years Ended December 31		
	2024		2023
	Successor	Predecessor	Predecessor
	July 31 to December 31	January 1 to July 30	January 1 to December 31
Revenue	$ 269	$ 333	$ 300
Less:			
Cost of revenue	1,937	1,381	1,306
Research and development	4,634	7,585	15,399
Selling, general, and administrative	6,976	13,047	11,537
Impairment - Goodwill	30,324	—	—
Impairment - Intangible assets, net	18,878	—	—
Other income (expense), net	8,717	402	(8,648)
Net loss	$ (53,763)	$ (21,278)	$ (36,590)

Note 19 - Subsequent Events

The Company has evaluated subsequent events occurring after the balance sheet date through the date these consolidated financial statements were issued and determined that the following material events required disclosure:

On March 20, 2025, the Company granted stock options to purchase an aggregate of 2,706,000 shares of its common stock to employees, executives, and members of the Board of Directors under its 2024 Equity Incentive Plan. The grants included Incentive Stock Options ("ISOs") and Non-statutory Stock Options ("NSOs") with an exercise price equal to the fair market value of the Company's common stock on the grant date.

On March 11, 2025, John Dahldorf, the Company's Chief Financial Officer announced his decision to resign as Chief Financial Officer, effective March 28, 2025.

Mr. Dahldorf's resignation was not the result of any dispute or disagreement with the Company on any matter related to the Company's financial reporting or accounting policies, procedures, estimates, or judgments.

On February 28, 2025, the Company announced a strategic restructuring to prioritize its FULCRUM-VT U.S. pivotal investigational device exemption clinical trial and a new product design optimization program. This restructuring includes pausing the limited European launch of the vCLAS catheter and implementing a reduction in workforce effective February 28, 2025, to reallocate resources toward these critical priorities.

On January 30, 2025, the Company provided formal notice to Fjord Ventures LLC of its intent to terminate the Facilities and Services Agreement, dated as of June 1, 2011, as amended. The notice of termination was provided in accordance with the termination provisions outlined in the Agreement. The Agreement will terminate effective July 30, 2025. The termination is due to the Company no longer needing the services provided under the Agreement. The Agreement provided for various services and facilities to be rendered by Fjord to the Company. These services included employee benefits plan administration, administrative support, IT services, and the provision of office space and supplies.

On January 3, 2025, the Company entered into Limited Waiver and Amendment agreements with certain investors to address defaults related to misstated financial statements previously disclosed on November 1, 2024. These waivers pertain to the Securities Purchase Agreement, Registration Rights Agreement, and promissory notes issued on July 31, 2024. The investors agreed to accept restricted shares in lieu of payment in cash at a price of $2.00 per share, with the Company issuing a total of 183,333 Restricted Shares for registration delay penalties.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the U.S. Securities Exchange Act of 1934, as amended (the "Exchange Act") is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the Company's reports filed or submitted under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure.

We do not expect that our disclosure controls and procedures will prevent all errors and all instances of fraud. Disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Further, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and the benefits must be considered relative to their costs. Because of the inherent limitations in all disclosure controls and procedures, no evaluation of disclosure controls and procedures can provide absolute assurance that we detected all of our control deficiencies and instances of fraud, if any. The design of disclosure controls and procedures also is based partly on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

As required by Rules 13a-15 and 15d-15 under the Exchange Act, our Chief Executive Officer and Chief Financial Officer carried out an evaluation of the effectiveness the design and operation of our disclosure controls and procedures as of December 31, 2024 and prior to the filing of this Annual Report. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2024, our disclosure controls and procedures were not effective due to the material weaknesses described below.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) of the Exchange Act. Under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer and oversight of the Board of Directors, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on criteria established in the framework set forth in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Our management, including our Chief Executive Officer and Chief Financial Officer, recognizes that disclosure internal controls over financial reporting, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls.

Identified Material Weaknesses and Remediation

A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected.

Based on our evaluation and our Chief Executive Officer and Chief Financial Officer assessment over the effectiveness of our internal control over financial reporting as of December 31, 2024, and we determined that our internal control over financial reporting was not effective as of December 31, 2024 at a reasonable assurance level due to the material weaknesses related to the inadequate design and operation of management's review controls over valuation reports prepared by third-party specialists in conjunction with the accounting for certain debt and equity instruments.

We have implemented our remediation plan to address the material weaknesses identified above. Such measures include:

1) additional review of third-party valuation reports utilized in the accounting for certain debt and equity instruments;

2) additional review of the manual journal entries based on externally generated reports and agreements with regard to accounting issues in certain debt and equity instruments;

3) enhanced oversight controls on the work performed by third-party specialists.

We will not consider the material weakness remediated until the remedial controls operate for a sufficient period of time and we have concluded, through testing, that these controls are effectively designed and operating effectively. We will continue to assess throughout 2025.

Changes in Internal Control over Financial Reporting

Other than in connection with executing upon the continued implementation of the remediation measures referenced above, there have been no changes in our internal controls over financial reporting during the year ended December 31, 2024, that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

Item 9B. Other Information.

During the three-months ended December 31, 2024, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions That Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item will be included in our Definitive Proxy Statement for the 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2024, and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this item will be included in our Definitive Proxy Statement for the 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2024, and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item will be included in our Definitive Proxy Statement for the 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2024, and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item will be included in our Definitive Proxy Statement for the 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2024, and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this item will be included in our Definitive Proxy Statement for the 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2024, and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a). The following documents are filed as a part of this report:

1. *Financial Statements: Consolidated Financial Statements filed as part of this report are listed under Item 8. Financial Statements and Supplementary Data.*

2. *Financial Statement Schedules: Not Applicable.*

3. *Exhibits: See Item 15(b) below.*

(b). Exhibits:

The following exhibits are filed as part of, or incorporated by reference into, this Annual Report on Form 10-K.

No.	Description of Exhibit
2.1	Business Combination Agreement, dated as of February 13, 2024, by and among Aja HoldCo, Inc., ARYA Sciences Acquisition Corp IV, Aja Merger Sub 1, Aja Merger Sub 2, Inc. and Adagio Medical, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the SEC on August 6, 2024).
2.2	Consent and Amendment No. 1 to the Business Combination Agreement, dated as of June 25, 2024, by and among ARYA Sciences Acquisition Corp IV and Adagio Medical, Inc. (incorporated by reference to Exhibit 2.2 to the Company's Current Report on Form 8-K filed with the SEC on August 6, 2024).
3.1	Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on August 6, 2024).
3.2	Amended and Restated By-Laws of the Company (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed with the SEC on August 6, 2024).
4.1	Form of Base Warrant Agreement (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on August 6, 2024).
4.2	Form of Pre-Funded Warrant Agreement (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on August 6, 2024).
4.3	Form of Convert Warrant Agreement (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the SEC on August 6, 2024).
4.4	Specimen Common Stock Certificate of New Adagio (incorporated by reference to Exhibit 4.4 to the Company's Current Report on Form 8-K filed with the SEC on August 6, 2024).
10.1	Form of Convertible Security Subscription Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on August 6, 2024).
10.2	Investor Rights Agreement, dated as of February 13, 2024, by and among ARYA, ListCo, the Perceptive PIPE Investor, the Sponsor and the other parties thereto (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on August 6, 2024).
10.3	Sponsor Letter Agreement, dated February 13, 2024, by and between ARYA Sciences Acquisition Corp, ARYA Sciences Holdings IV, Todd Wider, Michael Henderson, Leslie Trigg, Joseph Edelman, Adam Stone, Michael Altman, Konstantin Poukalov and Adagio Medical, Inc. (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the SEC on August 6, 2024).
10.4	Form of Adagio Stockholder Transaction Support Agreement (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed with the SEC on August 6, 2024).
10.5	Form of New Adagio 2024 Equity Incentive Plan (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed with the SEC on August 6, 2024).
10.6	Form of New Adagio 2024 Key Employee Equity Incentive Plan (incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed with the SEC on August 6, 2024).

10.7	Form of New Adagio 2024 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed with the SEC on August 6, 2024).
10.8	Form of New Adagio Indemnity Agreement (incorporated by reference to Exhibit 10.8 to the Company's Current Report on Form 8-K filed with the SEC on August 6, 2024).
10.9	Convert Guaranty, dated as of July 31, 2024, by and among Adagio and the other parties thereto (incorporated by reference to Exhibit 10.9 to the Company's Current Report on Form 8-K filed with the SEC on August 6, 2024).
10.10	Convert Security Document, dated as of July 31, 2024, by and among New Adagio, Adagio and the other parties thereto (incorporated by reference to Exhibit 10.10 to the Company's Current Report on Form 8-K filed with the SEC on August 6, 2024).
10.11	Registration Rights Agreement dated as of July 31, 2024, by and among New Adagio, Perceptive Life Sciences Master Fund, Ltd. and the other parties thereto (incorporated by reference to Exhibit 10.11 to the Company's Current Report on Form 8-K filed with the SEC on August 6, 2024).
10.23	Offer Letter, dated July 31, 2024, between Adagio Medical, Inc. and Olav Bergheim (incorporated by reference to Exhibit 10.23 to the Company's Current Report on Form 8-K filed with the SEC on August 6, 2024).
10.24*	Tenth Amendment to the Facilities and Services Agreement, dated August 1, 2024, between Fjord Ventures, LLC and Adagio Medical, Inc.
19.1*	Insider Trading Policy
23.1*	Consent of WithumSmith+Brown, PC, independent registered public accounting firm for Adagio Medical Holdings, Inc.
31.1*	Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rules 13a-14(a) and 15(d)-14(a), as adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Securities Exchange Act Rules 13a-14(a) and 15(d)-14(a), as adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1*	Policy Relating to Recovery of Erroneously Awarded Compensation
101.INS*	Inline XBRL Instance Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Labels Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Inline XBRL for the cover page of this Annual Report on Form 10-K, included in the Exhibit 101 Inline XBRL Document Set.

* Filed herewith
** Furnished herewith

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ADAGIO MEDICAL HOLDINGS, INC.

Date: March 27, 2025

/s/ Todd Usen
Name: Todd Usen
Title: Director and Chief Executive Officer

Date: March 27, 2025

/s/ John Dahldorf
Name: John Dahldorf
Title: Chief Financial Officer

Date: March 27, 2025

/s/ James L. Cox
Name: James L. Cox
Title: Director

Date: March 27, 2025

/s/ Orly Mishan
Name: Orly Mishan
Title: Director

Date: March 27, 2025

/s/ Keyvan Mirsaeedi-Farahani
Name: Keyvan Mirsaeedi-Farahani
Title: Director

Date: March 27, 2025

/s/ Timothy Moran
Name: Timothy Moran
Title: Director

Date: March 27, 2025

/s/ Sandra Gardiner
Name: Sandra Gardiner
Title: Director

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EXECUTIVE OFFICERS

Todd Usen
Chief Executive Officer

Deborah Kaster
Chief Financial Officer and Chief Business Officer

BOARD OF DIRECTORS

Orly Mishan
Chairman of the Board of Adagio Medical
Managing Director
Perceptive Advisors

Todd Usen
Chief Executive Officer
Adagio Medical

James L. Cox, M.D.
Co-Founder
Adagio Medical

Sandra Gardiner
Partner
FLG Partners

Keyvan Mirsaeedi-Farahani
Managing Director
Perceptive Advisors

Timothy Moran
Chief Business Officer
Kestra Medical Technologies

LISTING

Our common stock is listed on Nasdaq under the ticker symbols "ADGM."

TRANSFER AGENT AND REGISTRAR

Continental Stock Transfer & Trust Company
1 State Street, 30th Floor
New York, NY 10004-1561
cstmail@continentalstock.com

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

WithumSmith+Brown, PC, Whippany, New Jersey

LEGAL COUNSEL

Cooley LLP

ANNUAL MEETING

December 15, 2025, at 10:00 a.m. Pacific Time

Online at:
www.virtualshareholdermeeting.com/ADGM2025

FORM 10-K

A copy of our Form 10-K filed with the SEC will be made available to all stockholders at no charge.

The Form 10-K also can be accessed through the SEC website at **www.sec.gov**, or through our Investor website at **investors.adagiomedical.com**

To receive a copy by mail please contact:

Investor Relations
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