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, 2025

OR

☐ **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 001-42801

PICARD MEDICAL, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**86-3212894**
(State or other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification Number)**

1992 E Silverlake
Tucson, AZ 85713
(Address of Principal Executive Offices) (Zip Code)

(520) 545-1234
(Telephone Number, Including Area Code)

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common stock, par value $0.0001 per share	PMI	NYSE American LLC

Securities Registered Pursuant to Section 12(b) of the Act: None

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 ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 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, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the 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 (15 U.S.C. 7262(b)) 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 Act). Yes ☐ No ☒

The aggregate market value of the shares of common stock of the registrant held by non-affiliates of the registrant was approximately $130,820,904 as of September 2, 2025. Note that September 2, 2025, the closing date of the Registrant's initial public offering, is used to calculate the aggregate market value held by non-affiliates since the Registrant was not publicly traded on June 30, 2025.

Number of common shares outstanding as of March 23, 2026: 75,178,535

DOCUMENTS INCORPORATED BY REFERENCE

None

Auditor Firm Id: 206	Auditor Name: MaloneBailey, LLP	Auditor Location: Houston, Texas

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K ("Annual Report") contains forward-looking statements which are made pursuant to safe harbor provisions of Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements including, without limitation, statements regarding our business strategy, expected expansion of our research and development, investments, and our operations and expected financial performance and condition. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "potential," "positioned," "seek," "should," "target," "will," "would," or other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms, although not all forward-looking statements contain these words.

Forward-looking statements are based on management's current expectations, estimates, forecasts, and projections about our business and the industry in which we operate, and management's beliefs and assumptions are not guarantees of future performance or development and involve known and unknown risks, uncertainties, and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this Annual Report may turn out to be inaccurate. Furthermore, if the forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and/or plans in any specified time frame, or at all. Factors that may cause actual results to differ materially from current expectations include, among other things, those described in "Part I, Item 1A. Risk Factors." You are urged to consider these factors carefully by evaluating these forward-looking statements. The factors described herein should not be construed as exhaustive. In addition to other factors, new risks emerge from time to time, and it is not possible for us to predict all risks. These forward-looking statements speak only as of the date hereof. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

We are subject to many risks, including risks that may prevent us from achieving our business objectives or that may adversely affect our business, results of operations, financial condition, and cash flows. You should carefully consider the risks discussed in the section entitled "Part I, Item 1A. Risk Factors," including the following principal risks:

- Loss of, reduced purchases by, or delayed payments from any of our customers, which are concentrated among a limited number of heart transplant centers, hospitals, surgeons, and their distributors;
- Our concentration risk due to reliance on a limited number of products, and the material impact that any disruption in production, quality, regulator status, safety, or market acceptance of these products could have on our business;
- Manufacturing of our products is complex, highly manual, and concentrated, which exposes us to risks related to workforce constraints, training timelines, equipment failures, natural disasters, or noncompliance with U.S. Food and Drug Administration ("FDA") regulation;
- Our reliance on single- or limited-source suppliers for many critical components, including valves and drive parts, and lack of secondary sources, which could cause shortages and/or require new regulatory clearances or approvals;
- Changes in regulatory policy, including new requirements, could lead to delays or denials for new research, expansions, or product upgrades;
- Delays or failure to obtain certification under EU Medical Devices Regulation would limit or prevent our growth in European markets;
- Clinical studies necessary for approvals, expansions, and updates are costly, lengthy, and uncertain; difficulties with site qualification, enrollment, protocol adherence, adverse events or inconclusive results may prevent or delay approvals;
- Device malfunctions or quality issues could lead to field actions, corrections, recalls, investigations, enforcement, reputational harm, and substantial costs, which we may be unable to remediate promptly or effectively;
- We could face significant penalties, sanctions, litigation exposure, and reputational damage if our products are misused;
- Physician adoption requires education, clinical evidence, and perceived advantages over alternatives; reluctance to adopt total artificial heart therapy may limit demand and financial support;
- Competitive products that are more effective, convenient, or less costly from larger companies with greater resources and relationships could reduce demand for our products;
- Profit margin improvement depends on successful product enhancements, and delays or setbacks could constrain profitability even if revenues grow;

- Insurance coverage and reimbursements are uncertain and vary by payer and country; insufficient coverage would adversely affect utilization and revenues;
- Our industry is heavily regulated and subjects us to evolving and complex healthcare, privacy, and other laws, in addition to the compliance and obligations of being a public company, and can result in civil, criminal, and administrative penalties or business restrictions;
- International expansion exposes us to risks including political and economic instability, sanctions, tariffs, export controls, currency fluctuations, local regulatory requirements, limited recourse to protect intellectual property, and challenges overseeing distributors;
- Significant product-liability risk is inherent in life-sustaining implantable medical devices, and our insurance coverage may be insufficient or unavailable on acceptable terms, and adverse claims could materially impact our financial condition;
- Our reliance on information technology systems and third-party service exposes us to cybersecurity risks, which could disrupt operations, compromise sensitive data, trigger regulatory scrutiny, and lead to significant costs;
- Many aspects of our technology are no longer protected by patents and rely on trade secrets and contractual protections, which may be breached or independently developed by others;
- Intellectual property disputes could be costly, divert management attention, require licenses or redesigns, or restrict our ability to market products;
- Acquisitions, if pursued, involve integration, operational, and financial risks and may not achieve anticipated benefits, which could dilute stockholders, increase leverage, or require significant management attention and resources;
- Exposure to credit risk from hospital and distributor receivables, particularly in certain international markets, can increase bad-debt expense and reduce cash collections;
- Tax laws could limit our net operating loss carryforwards and increase our cash tax liabilities in future profitable periods;
- Significant volatility in our financial results as a result of the Company's election to account for its senior secured note at fair value, as well as the classification of associated warrants as liabilities;
- As a newly public company, emerging growth company, and smaller reporting company, we face increased costs to establish effective internal controls and comply with evolving disclosure and governance requirements, which may result in our inability to maintain the Company's NYSE American listing. Furthermore, compliance failures could harm our reputation and stock price;
- The market price of our common stock may be volatile, an active trading market may not develop or be sustained, and/or future equity or debt financings, conversions, or other securities issuances could cause substantial dilution and further volatility;
- Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements; and
- We have been, and may in the future be, subject to securities class action or derivative litigation.

PART I

ITEM 1. BUSINESS

OVERVIEW OF BUSINESS

General

Picard Medical, Inc. ("PMI") was incorporated in the state of Delaware on April 8, 2021. Unless the context requires otherwise, in this Annual Report, the terms "we," "us," "our," the "Company," "Picard," the "Registrant," and similar references refer to the combined operations of PMI and its consolidated subsidiaries and affiliates, including SynCardia Systems, LLC ("SynCardia").

PMI functions as a holding company and owns 100% of the membership interests of SynCardia. Business operations are carried out by and through SynCardia, and accordingly most of the information in this Annual Report pertains to SynCardia's business. SynCardia is a medical technology company that manufactures and sells the only U.S. Food and Drug Administration ("FDA") and Health Canada approved Total Artificial Heart ("TAH"), which fully replaces the function of a failing human heart. To date, more than 2,100 SynCardia TAHs have been implanted in patients across 27 countries, and the SynCardia TAH is an established bridge to heart transplantation ("BTT") for patients with biventricular heart failure, also referred to as end-stage heart failure, in the United States and around the globe. SynCardia is also pursuing additional research and advancements in medical technology, including the next-generation, fully implantable and driver-less heart, the Emperor TAH. Both the SynCardia and Emperor TAH are subject to additional development and regulatory review.

The currently approved SynCardia TAH System consists of an implant including left and right artificial ventricles, external pneumatic drivers that power the implant, and drivelines that connect the external driver to the implant. The implantation procedure follows routine surgical techniques used by cardiothoracic surgeons performing heart transplantation. The system provides immediate and complete cardiac output by replacing both ventricles and all four heart valves. The SynCardia TAH is powered by pneumatic drivers available for in-hospital use, the Companion 2 Driver ("C2 Driver"), and for in-home use, the Freedom Driver. These systems generate true pulsatile flow using a redundant pneumatic pump assembly, restoring full hemodynamics and giving patients time to stabilize, recover, and ultimately receive a heart transplant. Patients supported by the SynCardia TAH may be discharged from the hospital using the portable Freedom Driver.

Implantation of the SynCardia TAH is covered by the U.S. Centers for Medicare and Medicaid Services (”CMS”) under National Coverage Determination 20.9.1 and is generally reimbursed under Diagnosis Related Group (“DRG”) 001, the highest reimbursement category for cardiac procedures. Hospital reimbursement varies based on case complexity and institutional adjustments. Because reimbursement is determined primarily by the procedure rather than the specific device used, hospitals evaluate mechanical circulatory support technologies based on clinical suitability and overall cost effectiveness within the applicable reimbursement framework. Additional information regarding reimbursement is described below.

Market

The SynCardia TAH is, to PMI's knowledge, is currently the only TAH approved for commercial use in the United States and Canada. Other companies are developing TAH systems or have obtained regulatory authorizations in certain jurisdictions outside the United States, while others are conducting clinical studies under investigational device exemptions in the United States. The competitive landscape also includes alternative mechanical circulatory support (“MCS”) therapies, including left ventricular assist devices (“LVAD”), extracorporeal membrane oxygenation (“ECMO”) systems, percutaneous axial flow ventricular assist devices such as the Impella system, and other temporary circulatory support modalities used in different clinical settings. To date, there have been no head-to-head randomized clinical trials comparing TAH systems.

Strategy

PMI's strategy focuses on expanding the clinical use of the SynCardia Total Artificial Heart, developing next generation technologies, improving manufacturing efficiency, and pursuing selected international regulatory approvals.

- Develop Next Generation Fully Implantable Artificial Heart: The Company is developing the Emperor TAH, a next generation fully implantable artificial heart designed to eliminate the need for external pneumatic drivers. The Emperor system is intended to build upon PMI's existing ventricular platform while incorporating an internal driver system capable of generating pulsatile flow. Design prototypes of the Emperor system are currently undergoing non-clinical bench and animal testing. Subject to the results of nonclinical testing and regulatory review, PMI may seek FDA approval for Emperor as early as 2028.

- Expand U.S. Commercial Adoption Through Label Expansion: PMI is working with the FDA to expand the approved indications for use of the SynCardia TAH beyond the current BTT indication. These efforts include seeking approval for bridge to candidacy (“BTC”) and longer duration support. BTT supports patients with end stage heart failure who are listed or eligible for heart transplantation and require mechanical circulatory support while awaiting a donor heart. BTC supports patients whose eligibility for transplantation is still being evaluated and who require additional time for medical optimization, rehabilitation, or resolution of reversible contraindications. Expansion of these indications may increase the number of patients eligible to receive the SynCardia TAH.
- Pursue Select International Regulatory Approvals: While PMI's primary commercial focus is currently the United States and Canada, the Company is pursuing additional regulatory approvals in selected international markets. These efforts include working toward CE Mark certification in the European Union under the Medical Device Regulation ("MDR") framework and evaluating potential regulatory approval pathways with the National Medical Products Administration (NMPA) in China.
- Improve Manufacturing Efficiency and Margins: PMI is evaluating opportunities to improve manufacturing efficiency and reduce production costs. These initiatives include potential collaboration with SynCardia Medical Beijing, Inc. ("SMB") for certain pneumatic driver manufacturing activities and continued development of next generation driver technologies.
- Advance Next Generation Pneumatic Driver Technology: PMI is developing next generation of pneumatic driver technology, including the Unicorn driver, which is intended to improve portability, reliability, and patient mobility relative to existing pneumatic driver systems

Competitive Landscape

Total Artificial Hearts

The SynCardia TAH is currently the only total artificial heart approved for commercial use in the United States and Canada. CARMAT SA (“Carmat”) has developed the Aeson total artificial heart, which has received a *Conformité Européenne* (European Conformity) (“CE") mark approval in Europe. Carmat has publicly disclosed financial distress and entered insolvency and restructuring proceedings in 2025. Although the Aeson device has received regulatory approvals in certain jurisdictions and has been implanted clinically, Carmat’s ability to continue manufacturing and commercial operations remains uncertain. BiVACOR Inc ("BiVACOR") initiated early-stage human clinical testing of its total artificial heart in July 2024. BiVACOR has not received regulatory approval for commercial use in any market. To date, there have been no head-to-head clinical trials comparing total artificial heart technologies.

Alternative MCS Approaches

Clinicians have explored the use of two LVADs to provide biventricular support. In certain cases, two Abbott HeartMate 3 LVADs have been combined and informally referred to as a total artificial heart configuration. This configuration is not approved by the FDA. Other mechanical circulatory support approaches include LVADs, extracorporeal membrane oxygenation ECMO, and axial flow assist devices used to support patients with advanced heart failure. These technologies typically support only one ventricle at a time and are often limited to hospital use. In contrast, the SynCardia TAH replaces both ventricles and is designed to provide pulsatile flow and allow hospital discharge using the portable Freedom Driver.

PMI has accumulated significant clinical experience with the SynCardia TAH, with more than 2,100 implants performed worldwide. The core of the system is the artificial heart ventricles, whose blood contacting surfaces have been used across these implants. The Company intends to build upon this ventricular platform through the development of a next generation fully implantable artificial heart system designed to eliminate the need for external pneumatic drivers.

Financing Activities

Initial Public Offering

In September 2025, PMI completed an initial public offering ("IPO") of 4,887,500 shares of common stock ("Common Stock") at a public offering price of $4.00 per share for total gross proceeds of $19.6 million, before deducting underwriting discounts and offering expenses. The total shares include an additional 637,500 shares issued pursuant to the underwriters' over-allotment options. The shares of common stock are listed on the New York Stock Exchange American, LLC ("NYSE American"). PMI received $15.2 million in proceeds, net of underwriting discounts and commissions.

PMI used the net proceeds from the IPO to support its operations and expansion, research and development activities of a fully implantable system, including feasibility animal trials, and other design and development activities. The Company also used net proceeds to increase sales, marketing, and distribution capabilities, paid vendors and service providers, and addressed operating expenses. Further, net proceeds were used for repayment of obligations under Senior Secured Notes consisting of a series of related party notes and related party working capital notes issued between June of 2024 and August of 2025 with a total principal plus interest amount of approximately $8.2 million. For more information on the Senior Secured Notes and working capital related party loans, see Note 14 to the Consolidated Financial Statements. PMI also invested net proceeds in short- and intermediate-term, interest-bearing investment-grade instruments, certificates of deposit or direct, and/or guaranteed obligations of the United States government.

Securities Purchase Agreement

On December 24, 2025, PMI entered into a Securities Purchase Agreement with Institutional Investor pursuant to which the Company agreed to issue and sell senior secured notes due 2028 and warrants to purchase shares of PMI's common stock (the "Purchase Agreement"). An initial $15.0 million aggregate principal amount of Senior Secured notes was issued at the initial closing on December 26, 2025. PMI may issue up to an additional $35.0 million aggregate principal amount of notes in one or more subsequent closings, in each case subject to the terms and conditions set forth in the Purchase Agreement. The warrants issued at the initial closing are exercisable for up to 7,009,346 shares of PMI's common stock at an initial exercise price of $2.675 per share, subject to adjustment as provided in the warrants. Also, at closing, the placement agent was issued 700,934 warrants for shares of common stock at an exercise price of $2.675.

History and SynCardia TAH Development

Corporate

The commercial development of the SynCardia TAH was started by Symbion in 1985. In 1991, Symbion moved from Salt Lake City, Utah to Tucson, Arizona and the company became CardioWest, and later, SynCardia. SynCardia was incorporated in Delaware in August 2001 as SynCardia Systems, Inc., and has maintained its headquarters in Tucson, Arizona since then. In July 2011, SynCardia Systems, Inc. organized a wholly owned German subsidiary, SynCardia Systems Europe GmbH, (“GmbH”) to facilitate the sale and distribution of products throughout Europe. In May 2025, the Company initiated an orderly wind down of GmbH. The wind down process is expected to take up to two years due to administrative and regulatory requirements in Germany. In July 2016, the assets of SynCardia Systems, Inc. were acquired by a newly formed limited liability company called SynCardia Systems, LLC. In September 2021, Hunniwell Picard I (“Hunniwell”), through its majority held investment vehicle, PMI purchased 85% of the ownership interest in SynCardia Systems, LLC. In July 2023, PMI entered into an agreement, contingent upon the Company becoming publicly traded on a national securities exchange, to acquire a majority ownership interest in SMB, a company established in China in 2022 to support regulatory registration and distribution of the SynCardia TAH in China. As of the date of this filing, the Company has not completed the acquisition of the majority ownership interest in SMB and is working to extend the agreements. On January 2, 2024, SynCardia Systems Australia Pty Ltd. ("SynCardia Australia") was formed as a wholly owned Australian subsidiary to facilitate research and development in Australia. On September 2, 2025, PMI completed an initial public offering ("IPO") of 4,887,500 shares of common stock ("Common Stock"). The total IPO shares include an additional 637,500 shares issued pursuant to the underwriters' over-allotment options. The shares of common stock are listed on the New York Stock Exchange American, LLC ("NYSE American").

Products

The SynCardia TAH is a biventricular replacement device that consists of the SynCardia TAH implant, an external pneumatic driver that delivers precisely calibrated pulses of air to drive the implant and drivelines that connect the driver to the implant. The STAH received FDA premarket approval (“PMA”) in 2004 and Health Canada approval in 2005 for use as a BTT in patients with end stage biventricular heart failure. The SynCardia TAH is the only total artificial heart that is approved and commercially available in the United States and Canada for use as a BTT. As a total artificial heart, the SynCardia TAH replaces the functionality of both the left and right ventricles of the heart as well as all four heart valves in a similar manner as a human heart transplant. The SynCardia TAH fully supports the patient’s circulation. In combination with an external driver that delivers precisely calibrated pulses of air, the SynCardia TAH generates a cardiac output of up to 10.5 liters per minute by the 70cc implant, and up to 7.5 liters per minute by the 50cc implant, through each ventricle, lowering central venous pressure and promoting the recovery of other vital organs. In comparison, a normal human heart provides an average cardiac output of 5.6 liters per minute.

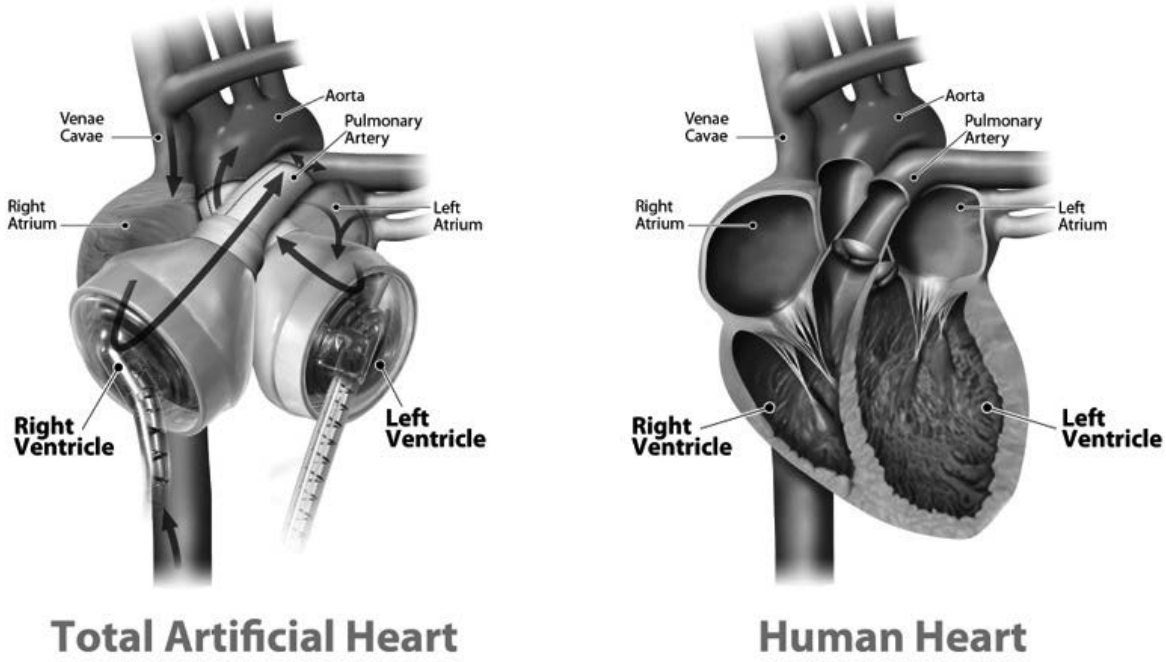
The SynCardia TAH implant is powered by external pneumatic drivers that deliver controlled air pulses to operate the artificial ventricles. The C2 driver received FDA approval in 2012 and is used in hospital settings, replacing the earlier “Big Blue” driver, which is no longer in service. The portable Freedom Driver received FDA approval in 2014 and allows certain patients to be discharged from the hospital and supported in outpatient environment.

SynCardia TAH Implant

The SynCardia TAH implant consists of two independent artificial ventricles which are powered by external pneumatic drivers (described below). Each artificial ventricle is made of a semi-rigid polyurethane housing and a rigid polyurethane base, with a four-layer flexible polyurethane diaphragm separating the blood chamber from the air chamber. The housing and diaphragms are manufactured using the Company's proprietary Segmented Polyurethane Solution ("SPUS") material.

When implanted, the left artificial ventricle is connected via a left atrial inflow connector to the left atrium and via an aortic outflow connector to the aorta. The right artificial ventricle is connected via a right atrial inflow connector to the right atrium and via a pulmonary artery outflow connector to the pulmonary artery. The base of each artificial ventricle includes a cannula that traverses the chest wall to couple that ventricle to an external pneumatic driver. Pneumatic pressure generated by the driver causes the diaphragms to move, allowing the ventricles to fill with blood and subsequently eject blood into the respective outflow grafts. Mechanical valves mounted in the inflow and outflow ports of each artificial ventricle control the unidirectional flow of blood through the SynCardia TAH implant. The valves are positioned within the artificial ventricles to facilitate continuous blood flow through the device and to reduce areas where blood stagnation could occur.

As a total artificial heart, the SynCardia TAH replaces the functionality of both the left and right ventricles of the heart as well as all four heart valves in a similar manner as a human heart transplant. The SynCardia TAH fully supports the patient’s circulation. In combination with an external driver that delivers precisely calibrated pulses of air, the SynCardia TAH generates a cardiac output of up to 10.5 liters per minute by the 70cc implant, and up to 7.5 liters per minute by the 50cc implant, through each ventricle, lowering central venous pressure and promoting the recovery of other vital organs. In comparison, a normal human heart provides an average cardiac output of 5.6 liters per minute. The figure immediately below illustrates the typical surgical attachment of the SynCardia TAH implant to the patient’s anatomy and the blood flow through the total artificial heart.



SynCardia TAH Positioning and Blood Flow

The implanted ventricles of the SynCardia TAH implant have three principal components: the shell, the diaphragm, and the valves. The shell is the outer housing of the SynCardia TAH implant and contains multiple layers of polymer intertwined with mesh. The diaphragm is a flexible component that is responsible for pumping blood using pressurized air from the pneumatic driver. The proprietary polymer that is used in the shell and diaphragm are made of SPUS. Fatigue resistance, strength, and biocompatibility make SPUS ideally suited for the blood contacting and flexing components of the SynCardia TAH and other medical devices. The Company uses its own formula, reactor, and manufacturing equipment to make SPUS, to ensure that SynCardia TAHs have the same consistent material properties and specifications and are subject to the same manufacturing process. SPUS is FDA approved and has been used in over 2,100 patients worldwide. SPUS must be manufactured within precise specifications to meet FDA and other regulatory requirements, and with significant sufficient production yields for the Company to succeed in manufacturing enough SynCardia TAHs at a commercially viable level. PMI believes that trade secrets protecting SPUS, and the biocompatibility and other specifications of SPUS, are likely to present a major barrier to any potential competitor using similar material.

50cc SynCardia TAH and 70cc SynCardia TAH

The SynCardia TAH is available in two sizes. The 50cc and 70cc SynCardia TAH implants operate on the same principle and are designed to provide mechanical circulatory support for patients with biventricular heart failure requiring cardiac replacement therapy. Both devices are currently approved for use as a BTT indication. The 70cc SynCardia TAH is designed primarily for implantation in adult patients. The device received CE mark approval in Europe in 1999 under the European Medical Device Directive ("MDD") and received FDA PMA approval in 2004. As of December 31, 2025, the 70cc SynCardia TAH has supported 1,951 patients globally since 1985, including 311 patients who were supported as part of early feasibility studies and compassionate use. The 50cc SynCardia TAH was developed to support smaller adult and pediatric patients and received CE mark approval in 2014 and FDA approval in 2020 just as the COVID-19 pandemic began. As of December 31, 2025, the 50cc SynCardia TAH has supported 122 patients globally since 2014. The 50cc and 70cc SynCardia TAH are currently not CE marked under the new European Medical Device Regulation ("MDR"). The prior CE mark under the MDD was cancelled in July 2022 following discussions with the Company's notified body ("BSI") during the recertification process. Since that time the device has remained available in certain jurisdictions under compassionate use frameworks.

Drivers

PMI currently has two approved external drivers for use with the SynCardia TAH implant: the C2 Driver and the Freedom Driver. The C2 Driver, which secured a CE Mark in Europe in 2011 and obtained FDA approval in 2012, is a mobile, external pneumatic driver intended for in-hospital use. The C2 Driver has replaced the original "Big Blue", which is no longer offered for sale. The C2 Driver includes a hospital cart/caddy, and drivelines connect the driver to the implant (see illustration below). Patients implanted with the SynCardia TAH are initially connected to a the C2 Driver during a period in which they are postoperatively stabilized. Once a patient becomes clinically stable and, in certain cases, ready to be discharged from the hospital, the patient is moved to the portable Freedom Driver.

Companion C2 Hospital Driver System

C2 Driver

C2 Driver
(Console & Driver)

C2 Caddy

SynCardia TAH with C2 Driver

The Freedom Driver received a CE Mark approval in 2010 and was approved by the FDA in 2014. The device is a portable (approximately 13-pound) version of the C2 Driver designed to allow certain patients supported by the SynCardia TAH to be discharged to their homes. Like the C2 Driver, the Freedom Driver connects to the implant by means of drivelines and may be carried using a handle, shoulder bag, or backpack (see illustration below). The Freedom Driver was first evaluated clinically in the Freedom Driver System Investigational Device Exemption ("IDE") Study, which assessed the safety and effectiveness of the portable driver system for supporting patients outside the hospital setting.

Freedom Driver System

Freedom Driver

Freedom Driver in Backpack

SynCardia TAH with Freedom Driver

Components

The SynCardia Total Artificial Heart incorporates the SynHall Valves, derived from the predecessor MedHall valve design originally developed by Medtronic, Inc. ("Medtronic"). The SynHall valves replace the four native heart valves and include tilting discs made of titanium and pyrolytic carbon. The SynHall Valves share substantially the same design, materials, and manufacturing processes as the original MedHall valves. SynHall valve components must be manufactured within precise specifications to support the production of SynCardia TAH systems. As of the date of this filing, the Company is not aware of any reported valve failures.

The Company previously operated under a non-exclusive license agreement with Medtronic relating to certain valve intellectual property. The agreement expired in July 2023. As of December 31, 2025, approximately $492,000 in royalty payments remained outstanding and Medtronic holds a first priority security interest in a related non-exclusive license until the balance is paid in full. This transfer remains ongoing. In December 2025, the Company initiated the transfer of certain SynHall Valve assembly steps from third party manufacturers to internal manufacturing operations, which remains ongoing.

Certain key components of the portable Freedom Driver and the hospital use C2 Driver that operate the SynCardia TAH are sourced from Bimba Ltd. ("Bimba"), part of Norgren Ltd, ("Norgen") through its distributor Heitek Automation LLC ("Heitek"). These include the piston cylinder assembly used in the Freedom Driver and the pneumatic manifold used in the driver systems. Bimba manufactures the piston cylinder assembly and the Freedom Driver pneumatic manifold, while Heitek Automation owns certain drawings and distributes these components to us. The Company currently procures these parts through Heitek Automation based on purchase orders and does not have long-term supply agreements covering the components or related drawings. As a result, PMI depends on Bimba and Heitek Automation for the continued supply of these components and related technical documentation. In June 2022, the Company entered into a purchase order arrangement with Heitek Automation under which credits from piston cylinder assembly purchases are applied toward the acquisition of the C2 Driver pneumatic manifold drawings. Upon reaching the agreed purchase threshold, the drawings will be transferred to the Company.

Reimbursement

In May 2008, the CMS approved implantation procedures using the SynCardia TAH was eligible for DRG 001, the highest reimbursement level under the DRG program. As of the date of this filing, implantation procedures using the SynCardia TAH are covered by CMS under National Coverage Determination ("NCD") 20.9.1. Reimbursement levels vary by facility and depend on several factors including patient mix and hospital specific adjustments.

For Medicare and Medicaid beneficiaries, hospital reimbursement for implantation of a total artificial heart generally falls under DRG 001, with payments ranging from approximately $187,000 to $482,000 depending on case specific factors and hospital adjustments. Hospitals typically obtain pre-authorization from private insurers prior to implantation procedures. Following implantation, hospitals submit claims for reimbursement based on the contracted case rate between the hospital and the applicable commercial insurer. Because hospital reimbursement is primarily determined by the procedure rather than the specific device used, hospitals evaluate mechanical circulatory support technologies based on clinical suitability, physician preference, and overall cost effectiveness within the applicable reimbursement framework. The Company does not bill insurers directly and therefore cannot determine the exact number of private insurers that reimburse for SynCardia TAH procedures or the reimbursement levels applicable in each case. Hospitals have reported obtaining reimbursement from a number of private insurers, including Aetna, Cigna, Anthem, United Healthcare, and Humana.

In addition to total artificial heart technologies, cardiologists use LVADs and other temporary mechanical circulatory support technologies, including ECMO and axial flow percutaneous left ventricular assist devices, to support patients with advanced heart failure. Like the SynCardia TAH, LVAD implantation procedures are reimbursed under DRG 001 and payments to hospitals may range from approximately $187,000 to $482,000. ECMO procedures are generally reimbursed under DRG 003 with average hospital payments of approximately $181,000. Temporary axial flow assist devices are reimbursed under DRG 215 or DRG 221 with average hospital payments of approximately $117,000 and $52,000 respectively. To the best of the Company's knowledge, the average selling price of competing devices is approximately $120,000 for the Abbott HeartMate 3 LVAD, between approximately $25,000 and $30,000 for the Abiomed Impella 2.5 and Impella 5.0 devices, respectively, and approximately $111,000 for the Getinge CardioHelp ECMO system.

Clinical Efficacy

A 2004 New England Journal of Medicine article published the results obtained from a study of 81 patients who received the SynCardia TAH compared to 35 control patients (“PMA FDA Study”). The control patients had not received a SynCardia TAH or mechanical circulatory support and were matched with the 81 patients who received the SynCardia TAH. The overall objective of this study was to generate data on the safety and efficacy of determine if the SynCardia TAH was safe and effective for in bridging of patients to cardiac transplantation, BTT. The primary efficacy endpoint of the study was treatment success. To be considered a success, a patient at 30 days post transplantation must have been: (1) alive; (2) New York Heart Association ("NYHA”) Class I or II; (3) ambulatory; (4) not ventilator dependent; and (5) not on dialysis. At 30 days post-transplant, 69.1% (56/81) of the core implant group met the criteria for treatment success. The primary safety endpoint included a clinical assessment of patients and an evaluation of adverse events (see table below for adverse event data). Secondary efficacy outcomes measures included the rate of survival to transplantation (79% for patients implanted with the SynCardia TAH as compared to 46% survival for the control group, $p<0.001$), and 1-year survival rate among the patients who received the artificial heart (70%, as compared with 31% among the controls, as well as, 1-year and 5-year survival rates after transplantation among patients who had received a total artificial heart as a bridge to transplantation (86% and 64%, respectively). In all instances, survival measured how long patients who received the SynCardia TAH, and control patients lived. The study was supported from 1991 to 2001 by CardioWest Technologies and thereafter by SynCardia Systems with respect to the costs of data collection. Dr. Copeland reported owning equity in SynCardia Systems, the manufacturer of the CardioWest Total Artificial Heart. Mr. Smith and Dr. Slepian reported owning equity in SynCardia Systems and being paid for part-time employment by the Company.

Patients included in this PMA FDA Study were selected according to the inclusion/exclusion criteria listed in the table below.

Inclusion Criteria	Exclusion Criteria
• **Eligible for transplantation according to institutional criteria** • **New York Heart Association class IV** • **Body surface area 1.7 to 2.5 m^2 OR distance ≥10 cm from anterior vertebral body to inner table of sternum at 10th thoracic vertebra on CT scan** • **Hemodynamic insufficiency defined as either:** ***Cardiac index ≤2.0 L/min/m^2 AND one of the following: systolic arterial pressure ≤90 mmHg OR central venous pressure ≥18 mmHg*** **OR** ***Two of the following: dopamine ≥10 µg/kg/min; dobutamine ≥10 µg/kg/min; epinephrine ≥2 µg/kg/min; other cardioactive drugs at maximal doses; intra-aortic balloon pump; or use of cardiopulmonary bypass***	• Use of any vascular assist device • Pulmonary vascular resistance ≥640 dyn·s·cm^{-5} • Dialysis within previous 7 days • Serum creatinine ≥5 mg/dL (440 µmol/L) • Cirrhosis with total bilirubin ≥5 mg/dL (29 µmol/L) • Cytotoxic antibody ≥10%

This publication also includes a list of adverse events observed over the course of the PMA FDA Study and the table that follows, which provides a list of adverse events.

Adverse Events, Including Those That Affected Outcomes, from the Time of Study Entry to 30 Days after Transplantation (FDA PMA Study)

Adverse Event[1]	All Patients Who Received an Implant (N=95)[2]			Patients Who Received an Implant per Protocol (N=81)[3]	
	All Events		Event Affecting Outcome	Event Delaying Transplantation	Event as Primary Cause of Death
	no. of events	*no. of patients (%)*	*no. of patients (%)*	*number of patients (%)*	
Bleeding (loss of blood during or after implantation, some requiring blood transfusions)	102	59(62)	15(16)	8(10)	1(1)
Device malfunction (e.g., perforation of implant diaphragm at day 124)	19	16(17)	1(1)	1(1)	1(1)
Fitting complication (challenging placement of implant in patients' chest, size / anatomical constrains)	5	5(5)	2(2)	2(2)	0
Reduced cardiac index (cardiac output of < 2.2 L/min/m2)	13	9(9)	2(2)	0	0
Reduced blood pressure (< than 90/60 mm Hg)	27	18(19)	8(8)	5(6)	2(2)
Hemolysis (rupture / destruction of red blood cells)	5	4(4)	0	0	0
Hepatic dysfunction (impaired liver function)	37	35(37)	13(14)	9(11)	0
Infection (airway, urinary & genital, digestive tract, blood, and driveline infections)	172	73(77)	18(19)	13(16)	1(1)
Neurologic event (occurrence that affects nervous system such as strokes, see discussion below)	35	26(27)	6(6)	5(6)	0
Operation (repeat surgery)	31	23(24)	2(2)	2(2)	0
Peripheral thromboembolism (condition that occurs when a blot clot breaks free and blocks a blood vessel in another organ, except for the brain)	18	13(14)	3(3)	2(2)	0
Renal dysfunction (impaired kidney function)	34	29(31)	16(17)	12(15)	0
Respiratory dysfunction (difficulty to breathe; patient on ventilator)	61	34(36)	15(16)	11(14)	0
Technical or procedural problems (e.g., valve obstruction by central venous catheter during ICU stay)	11	3(3)	2(2)	1(1)	1(1)
Other problem (other events not captured above, including sepsis)	10	9(9)	6(6)	3(4)	1(1)

(1) An adverse event ("AE") is any undesirable experience that occurs while a patient is using a medical product, while a serious adverse event ("SAE") is a subset of AEs that meet certain criteria. A SAE is an AE that results in death, is life-threatening, requires hospitalization, or causes disability or permanent damage. There were seven reported SAEs in this study.

(2) Category represents all patients who received an implant and includes 14 patients who were on a vascular assist device prior to receiving the implant. This group of patients was included in the safety analysis, but they were excluded from the efficacy analysis (being on a vascular assist device was an exclusion criteria).

(3) Category represents all patients who met all the inclusion / exclusion criteria and who were included in the efficacy analysis.

To the best of the Company's knowledge there have been no prospective “head-to-head” clinical trials comparing the SynCardia TAH clinical outcomes to other therapies. Therefore, all studies performed since the approvals of the SynCardia TAH in Europe and the United States have examined clinical outcomes (survival) in patients who have been implanted with a SynCardia TAH using retrospective analyses. Statistical analyses on survival vs. a comparator population, as performed in the prospective FDA PMA Study, have therefore not been performed.

The PMA FDA study results, which led to the FDA approval of the SynCardia TAH in 2004, were obtained in a highly controlled clinical study setting with carefully selected patients. Commencing with FDA approval, the SynCardia TAH was used in routine clinical practice in patients (“Real World Data”, “RWD”).

The following provides vignettes of recent studies examining the clinical outcomes of patients implanted with the SynCardia TAH. The vignettes contain essential published 1-year survival rates among patients who have received the SynCardia TAH in a RWD setting since 2004. Patients included in these studies have biventricular heart failure and need a heart transplant. One-year survival rates range from between 75% and 86.6%, depending on the experience of the center performing the procedures and on the INTERMACS patient profile, and confirm and expand upon the PMA FDA Study findings.

RWD clinical efficacy obtained with the SynCardia TAH

- A retrospective analysis examining outcomes after SynCardia TAH implantation between January 2014 and May 2019 was published in 2020 in the Journal of Heart and Lung Transplantation. Data from 217 patients at six high-volume centers (greater than 10 SynCardia TAH implants) in North America was analyzed. All patients were deemed candidates for heart transplantation and underwent SynCardia TAH implantation as a BTT strategy. At the end of the study period, 138 of 217 (63.5%) patients had successfully undergone heart transplant, and the overall survival rate in the entire cohort was 75% at the one-year mark[3]. Funding for this study was provided by SynCardia Systems, LLC, Tucson, Arizona.

- A retrospective analysis, published in 2022 in the Journal of Cardiac Surgery, studied adult patients listed for heart transplantation in the United Network for Organ Sharing (“UNOS”) system between 2004 and 2020 who received SynCardia TAH implants. The primary outcome was 1-year survival following heart transplantation following BTT with SynCardia TAH. Of the 433 patients on the waitlist who received a SynCardia TAH as BTT therapy, 375 (86.6%) underwent transplantation. Posttransplant survival for patients successfully bridged with a SynCardia TAH at 30 days was 90.9% and at 1 year was 80%[4]. The study was an institutional analysis. No external funding for this study was provided.

- An institutional database was used to identify 100 patients who underwent 101 SynCardia TAH implantations between 2012 and 2022 at Cedars-Sinai Medical Center. Patients were stratified and compared according to INTERMACS profile 1 vs 2 or greater: 61 patients (61%) were successfully bridged to transplantation; 30-day survival after transplantation was 96.7%; survival at 6 months, 1 year, and 5 years after transplantation was 95.1%, 86.6%, and 77.5%, respectively. These results were published in 2023 by The Annals of Thoracic Surgery[5]. Two of the authors, Jad Malas and Qiudong Chen, were supported by grants from the National Institutes of Health for advanced heart disease research (T32HL116273).

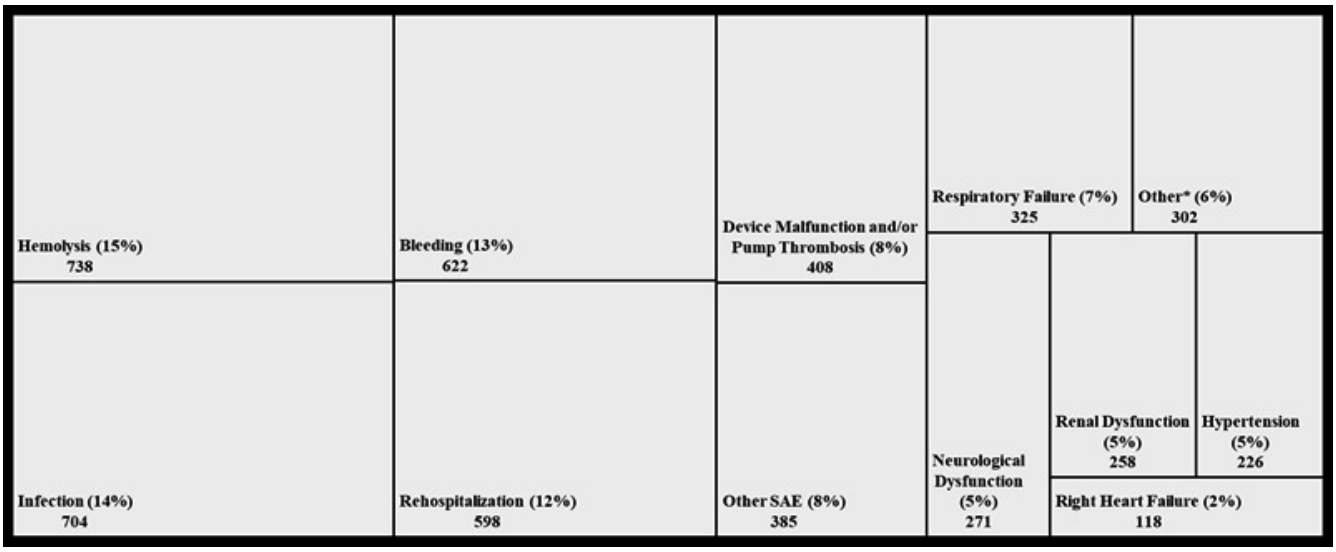
- A retrospective analysis examining outcomes in the United States after SynCardia TAH implantation between 2005 to 2018 was published in 2024 in the Journal of Thoracic and Cardiovascular Surgery. A total of 471 patients underwent SynCardia TAH implantation. Of 161 transplant centers, 11 centers had cumulative volume of 10 or more implants. The 6-month cumulative incidence of mortality on the total artificial heart was 24.6%. The 6-month cumulative incidence of transplant was 49.0%. The 1-year mortality post-transplantation was 20.0%. Cumulative center volume less than 10 implants were predictive of both mortality on the total artificial heart (hazard ratio, 2.2, 95% confidence interval, 1.5-3.1, $P < .001$) and post-transplant mortality after a total artificial heart bridge (hazard ratio, 1.5, 95% confidence interval, 1.0-2.2, $p = .039$)[6]. SynCardia Systems, LLC, Tucson, Arizona did not provide funding for this study.

RWD adverse event rates observed with the SynCardia TAH

INTERMACS is a North American registry in which data is collected for adults who were implanted with an FDA approved MCS system. The database was initiated in 2006 and became part of the Society of Thoracic Surgeons ("STS") national database in 2018. It is an interagency collaboration including the National Heart, Lung, and Blood Institute, the Food and Drug Administration, the Centers for Medicare & Medicaid Services, and others. INTERMACS provides SynCardia with detailed quarterly reports and raw data on patients implanted with a SynCardia TAH. This includes characteristics and outcomes for patients receiving a SynCardia TAH.

In 2024, SynCardia conducted a review of adverse events reported for SynCardia TAH patients in the INTERMACS registry during the period from 2006 to the end of first quarter 2024. The RWD dataset of 585 SynCardia TAH patients contains data on 4,914 recorded adverse events (patients may have experienced no adverse events, or multiple adverse events) over the course of the whole observation period which are depicted in the figure below.

Neurological events, comprising strokes, asymptomatic central nervous system ("CNS") injuries, and seizures, in this RWD population represent 5% of the total adverse events, highlighting a relatively low incidence in real world setting. This incidence also compares favorably to the neurological event rates seen in the PMA FDA study (27% for all patients who received an implant, and 5% for patients who received an implant per protocol; see Adverse Event table, above). Other adverse events, including the rates of bleeding, device malfunctions, and others also compare to event rates seen in the PMA FDA study. The figure below provides the percentages and total number of events. Patients may have experienced no adverse events or multiple adverse events.



* *Other: Neurological Dysfunction; Psychiatric Episode, Hepatic Dysfunction, Pericardial Drainage, Venous Thromboembolism, Arterial Non-CNS Thromboembolism, Wound Dehiscence, and Cardiac Arrythmia*

Pipeline

PMI is working on new products, upgrades to existing products, and regulatory approvals that would expand the indications and geographic availability of its approved products, including product registrations in the European Union and China. PMI works closely with regulatory authorities, including the FDA, to plan design changes and submission pathways in advance. The Company's regulatory affairs team conducts pre-submission meetings with the FDA and other international regulatory authorities to discuss clinical data strategy and product verification and validation. These interactions help align expectations prior to submission and may support a more efficient review process. Regulatory approval processes remain lengthy, time consuming, and inherently unpredictable.

The regulatory approval processes of the FDA and other regulatory authorities, including competent authorities in the European Union and the National Medical Products Administration ("NMPA") in China, are lengthy, time consuming, and inherently unpredictable. There is no guarantee that PMI will receive regulatory approval on its expected timeline or at all, and approvals may take longer than planned.

New Product Development

In 2023, PMI began the development of a fully implantable total artificial heart codenamed “Emperor”. The Emperor system will be powered by small mechanical drivers connected to the artificial ventricles and thus eliminate the need for external pneumatic drivers. The new fully implantable system will utilize the Company's FDA-approved artificial ventricles, which have been implanted in over 2,100 patients to date. Multiple prototype iterations of the Emperor have been built, and the pulsatile flow rate has been tested using the same techniques and equipment that the Company's on-market SynCardia TAH is tested with. These prototypes have been shown to achieve pulsatile flow with rates exceeding the minimum requirement of 3.5 liters per minute and meeting or exceeding the average flow rate of 5.6 liters per minute of cardiac output, as measured in liters per minute, that match PMI's on-market SynCardia TAH. ~2.5–3.0 liters per minute is generally considered the lowest viable cardiac output before perfusion becomes critically inadequate, potentially leading to shock. This higher minimum keeps the SynCardia TAH consistently above that range. These early prototypes have also shown high durability and low energy consumption. This technology has extensive intellectual property coverage, including the newly awarded U.S. patents No. 11,918,798 and No. 12,121,711 B2, No. 12,383,722 and, recently, the China National Intellectual Property Administration granted PMI patent application No. 202080094390.7 covering this technology. PMI began to perform the first-in-animal trials of this system in November 2025. PMI will continue animal trials in the first half of 2026. The regulatory approval processes of the FDA are lengthy, time-consuming and inherently unpredictable. There is no guarantee that the Company will receive regulatory approval on its expected timeline or at all, and approval may take longer than planned

In 2023, PMI began development of a next generation driver system codenamed “Unicorn”. The Unicorn driver system builds on the Company's extensive experience with its previous and current pneumatic driver systems. This new system is expected to introduce improvements including reductions in size, weight, noise, and power consumption, enabling improvements in battery life and patient quality of life. Future iterations of this design may be small and light enough to be implanted. The next steps for the Unicorn driver will be to develop the working prototype into a testable commercial product, and then complete regulatory testing. PMI expects to complete the regulatory testing in the second half of 2026. Submission to FDA will be a 180-day PMA supplement, which gives an approval date of approximately the middle of 2027. The regulatory approval processes of the FDA are lengthy, time-consuming and inherently unpredictable. There is no guarantee that PMI will receive regulatory approval on its expected timeline or at all, and approval may take longer than planned.

Product Upgrades

PMI continues to develop upgraded driver systems for both hospital and home use. The FDA is currently reviewing PMA supplements covering an upgraded portable driver system called Freedom+. The Company anticipates FDA approval by the end of 2026. It is anticipated that the upgraded Freedom+ Driver will be more durable and will substantially reduce false alarm rates. The Company is also working on next generation Freedom and C2 Drivers for which PMI expects to gain FDA approvals during the second quarter in each of 2026 and 2028, respectively. In addition to the Freedom+ Driver, the Company is in the process of further developing the Freedom Driver System to include improvements such as a quieter PCA, improved reliability, a smaller and lighter footprint, data export capabilities, and smaller, more efficient batteries. PMI is also developing an upgraded C2 hospital driver (“Companion 3 Driver”) to address obsolescence of components and to reduce its size and weight. The Company expects to submit supplemental PMAs covering each of these upgraded driver systems and anticipate releasing them in stages, starting with Freedom+ in 2026 and continuing throughout 2028. There is no guarantee that PMI will receive regulatory approval by, or on, its expected timeline or at all, and approval may take longer than planned.

Expanded Indications for Use of the SynCardia TAH

The 70cc SynCardia Total Artificial Heart received FDA approval for use as a BTT in 2004, and the 50cc SynCardia TAH received FDA approval for the same indication in 2020. In November 2024, the FDA approved revisions to the SynCardia TAH indications for use and product labeling removing the terms “temporary” and “-t” from the device name and indications. The Company has also engaged in discussions with the FDA regarding potential expansion of the indications for use for the SynCardia TAH. These discussions have focused on supporting (i) removal of the “imminent death” language currently included in the indications for use, (ii) addition of BTC, and (iii) expansion of the duration of support to include long-term use of two years or more. Following several pre-submission interactions with the FDA, the Company submitted a 180-day PMA supplement in January 2025 seeking approval to remove the “imminent death” language and to add bridge to candidacy to the indications for use. In March 2025, the FDA notified the Company that the submission had been converted to a Panel Track PMA supplement. The Company currently expects a decision from the FDA regarding this submission in the third quarter of 2026. The Company is also evaluating the data required to support expansion of the indications for use to include long-term support. The FDA has indicated that data from at least 50 patients supported for 24 months or longer may be required. As of the date of this filing, approximately 18 patients in the INTERMACS database and approximately 34 patients globally have been supported by the SynCardia TAH for 24 months or longer. The regulatory approval processes of the FDA are lengthy, time-consuming and inherently unpredictable. There is no guarantee that PMI will receive regulatory approval on its expected timeline or at all, and approval may take longer than planned.

International Product Approvals

The 50cc and 70cc SynCardia TAH are currently not CE marked under the new MDR. The prior CE mark under the MDD was cancelled in July 2022 following discussions with the Company's notified body ("BSI") during the recertification process. Since that time the device has remained available in certain jurisdictions under compassionate use frameworks, and PMI has been building up resources to address these deficiencies and all documentation to align with the requirements under MDR.

Since July 2023, SMB has received certain SynCardia TAH components from SynCardia required to start the registration process and submissions required for the certification (approval for commercial sale) of the 50cc and 70cc SynCardia TAH by the NMPA, formerly known as Chinese FDA ("CFDA") in China. The submissions will be based on data provided to obtain an FDA PMA for the SynCardia TAH, and NMPA-required non-clinical testing data. SBM expects to receive initial feedback on the status of the application during 2026, and that the NMPA could grant approval of the SynCardia TAH within 18 months from filing. However, there is no guarantee that the NMPA will grant approval on such a timeline, or at all. The NMPA may require SMB to conduct post-market studies at high volume centers in China. The regulatory approval process of the NMPA is lengthy, time consuming, and inherently unpredictable, and approvals may take longer than expected or may not be granted.

Industry Overview

Cardiovascular disease is the leading cause of death in the Unites States and globally. According to several studies published in 2024, 6.8 million people suffer from heart failure in the United States; globally there are 56.2 million people who suffer from the condition. One in four people is affected by heart failure in the United States, and heart disease accounted for 680,909 deaths in the United States in 2023. Worldwide, the death toll of heart failure is estimated at almost 18 million people. Although the overall prognosis for patients with heart failure has slightly improved in the past decades, the mortality rate for heart failure in the United States is around 10% at 30 days, 20–30% at one year, and 45–60% over five years. However, mortality rates vary by region and country and are highest in Africa and India, and lowest in China, South America, and the Middle East.

Heart transplantation ("HTx") is the treatment of choice for carefully selected patients with advanced or end-stage heart failure. Although estimates of the prevalence of advanced heart failure vary anywhere from 5% to 25%, at least 300,000 patients in the United States are living with this condition. However, the demand for donor hearts exceeds the available supply. In the United States, the country with the highest number of HTx globally, there are over 7,500 patients waiting on the heart transplant list and over 4,000 patients are added to the list each year. Last year, 4,539 HTx were performed in the United States; worldwide, the number of HTx was estimated at just under 8,200 in 2020.

The global market of heart implants is substantially larger outside the United States. PMI estimates approximately 15 million people with heart failure per year in the European Union, up to approximately 4.6 million in India, approximately 12 million in China, and approximately 3.75 million in the Middle East. While PMI's ability to price its products varies in each market, it has identified global expansion as a key driver of the Company's future success.

International Presence

The Company's primary commercial focus is currently North America. The Company also conducts certain research and development activities in Australia and is working toward obtaining regulatory approvals for the SynCardia TAH in additional jurisdictions, including MDR CE Mark in the European Union and approval from the NMPA in China. The Company may evaluate additional international markets in the future.

In July 2023, PMI entered into a Capital Increase Agreement ("Investment Agreement") with SMB and its stockholders, including CICH (Beijing) Investment Fund Management Co ("CICH"), Jinhu Zhu, and Binzhou Taige Shibei Venture Capital LLC. The Investment Agreement contemplated an investment by the Company of approximately $2.85 million in exchange for a 60% equity interest in SMB, with the remaining stockholders investing an additional $2.85 million for the remaining 40% equity interest. Completion of the investment was contingent upon the Company becoming publicly traded on a national securities exchange. As of the date of this filing, the Company has not completed the acquisition of the majority ownership interest in SMB.

SynCardia and SMB, Inc previously entered into an Exclusive Distribution Agreement pursuant to which SMB was appointed the exclusive distributor of the SynCardia TAH system and related products in greater China, including mainland China, Hong Kong, Macao, and Taiwan. SynCardia and SMB also entered into a Regulatory Affairs Service Agreement under which SMB provides regulatory support services in connection with potential registration of the SynCardia TAH system with the NMPA in the People's Republic of China. For additional information regarding NMPA approvals see **International Product Approvals** in this filing.

On January 2, 2024, SynCardia Systems Australia Pty Ltd was formed as a wholly owned subsidiary to support research and development activities in Australia, including engineering development and collaboration with external technology partners related to the Emperor Total Artificial Heart program.

In May 2025, the Company initiated an orderly wind down of GmbH, which was established in 2011 to facilitate the sale and distribution of PMI products throughout Europe. The wind down process is expected to take up to two years due to administrative and regulatory requirements in Germany. For additional information regarding NMPA approvals see **Government Regulation, and International**.

Since July 2023, SMB has received certain SynCardia TAH components from SynCardia Systems, LLC required to start the registration process and submissions required for the certification (approval for commercial sale) of the SynCardia TAH by the National Medical Products Administration (NMPA, formerly known as Chinese FDA (CFDA)) in China. The submissions will be based on data provided to obtain US FDA PMA for the SynCardia TAH, and NMPA-required non-clinical testing data.

SMB expects to receive initial feedback on the status of the application during the last half of 2026 and PMI expects that the NMPA could grant approval of the SynCardia TAH within 12 months from filing. However, there is no guarantee that the NMPA will grant approval on such a timeline, or at all. The NMPA may require SMB. to conduct a post market study performed at high volume centers in China.

The medical device product registration process in China is broadly comparable to the approval process in the United States. Similar to the FDA's Center for Devices and Radiological Health, the NMPA's Center for Medical Device Evaluation ("CMDE") is responsible for the technical review and acceptance of registration applications covering imported (and domestic) medical device products, and SynCardia will need to meet all requirements as set forth by the CMDE/NMPA, including the following:

- National standards: While many of the Chinese standards are often identical, or at least similar, to FDA's standards, the NMPA does not accept IEC 60601-X test report forms for the testing of electromagnetic compatibility and electrical safety. It also insists on several national specifications.

- Non-clinical testing requirements: In addition to meeting non-clinical testing requirements that are comparable to those expected by the FDA, the NMPA requires additional "Type Testing" by an NMPA certified testing laboratory.

- Local quality management system requirements: The CMDE/NMPA have their own quality management system requirements. While these "GMP requirements" are similar to ISO 13485, CMDE/NMPA will review ISO 13485 certificate against the Chinese GMP requirements.

- Clinical testing requirements: Requirements for clinical investigation are still significantly different. While clinical evaluations can be based on the results of clinical investigations/studies and on non-clinical data obtained from a pivotal PMA study conducted outside of China, clinical investigations are required if no equivalent devices are approved for sale in China, and if safety and efficacy cannot be proven with other clinical and non-clinical data. In addition, the NMPA may also require results from additional clinical investigations conducted in China.

Strategy and Competitive Strengths

PMI faces competition from alternative, often more inexpensive, therapies, and other total artificial heart manufacturers. However, the Company believes that it has, and will maintain for some time, a strong position among total artificial heart manufacturers globally and enjoys certain competitive advantages compared to other total artificial heart manufacturers because of its track record, regulatory approvals, manufacturing processes, sales and marketing expertise, and long-term reputation for quality. The key differences that PMI has identified among the SynCardia, Carmat, and BiVACOR total artificial hearts are summarized in the following chart, which is based on publicly available data for Aeson and BiVACOR:

	SynCardia TAH	Carmat (Aeson)	BiVACOR
Status	Only US FDA and Health Canada approved artificial heart	Approved in the EU	Completed first 5 patients of 20 to be enrolled in Early Feasibility Study One patient in Australia
Approvals	US: 2004 (BTT) EU: 1999-2022 Rest of World: Canada 2005	US: None EU: 2020 under MDD (BTT) & 2025 under MDR (BTT) Rest of World: None	US: None EU: None Rest of World: None
Ventricle Blood Volume	50cc and 70cc Serves men, women and children	65cc May not fit women, children and smaller-built men	N/A, not a displacement pump
Total Implant Size (Volume)	250 and 400ml	750ml; may not fit women, children and smaller-built men	400ml
No. of Implants	More than 2,100 as of March 2026	108 as of March 2026	Six as of March, 2026
Implant Weight	200 and 240g	900g	Approx. 512g\

Development-stage advantages over other Total Artificial Hearts: PMI believes that it maintains a strong position among peers in the total artificial heart category. The SynCardia TAH is the only total artificial heart currently approved for commercial use in both the United States and Canada. Other companies are developing or commercializing total artificial heart technologies. For example, Carmat developed the Aeson total artificial heart, which received a CE Mark approval in the European Union in December 2020 under the MDD for BTT use and subsequently obtained a CE Mark certification under the European Union MDR in July 2025. As of the date of this filing, Carmat reported that more than 100 patients had been implanted with the Aeson device. In June 2025, Carmat entered insolvency proceedings in France, which resulted in a reduction or suspension of new implant procedures while the company focused on restructuring its operations and supporting existing patients. In December 2025, a French court approved the transfer of certain Carmat assets to a newly formed entity, CARMAT SAS. BiVACOR, is developing a total artificial heart based on a magnetically levitated rotary pump design intended to replace the function of both ventricles using a single continuous flow pump. BiVACOR initiated an FDA Early Feasibility Study in the United States in 2024, and a limited number of patients have been implanted with the device as part of early clinical evaluation. Total artificial heart technologies remain an evolving area of mechanical circulatory support and many competing programs are still in clinical development or early stages of commercialization. As a result, regulatory approvals, clinical outcomes, physician adoption, and long-term device performance may influence the competitive landscape over time.

Sales, Marketing, and clinical advantages over other Total Artificial Hearts: The SynCardia TAH is a sophisticated medical device that requires specialized surgical training and post implant patient management by experienced clinical teams. With over more than 30 years of clinical use and more than 2100 implants worldwide, the Company has developed a structured physician and clinical team training program to support use of the device. The Company currently employs two Clinical Support Specialists who provide training and clinical support to heart transplant and mechanical circulatory support centers that utilize the SynCardia TAH. These specialists support existing certified centers and assist in certifying new centers by training surgeons and their clinical teams. A center is considered certified after completion of the Company's four phase training curriculum including at least one proctored implant. Certification is valid for three years and the Company may provide additional training or retraining as needed, including in situations involving clinical staff turnover. To remain certified a center is expected to perform at least one SynCardia TAH implant during a 12-month period. As of the date of this filing, more than 30 centers had been certified to implant the SynCardia TAH with approximately 20 centers performing at least one implant during the preceding 36-month period. During this time 94 implants were performed across the United States Canada and international markets.

PMI's customers are major medical centers operating heart transplant MCS programs. The Company's marketing efforts focus on heart transplant surgeons, heart failure cardiologists, MCS Coordinators, and other clinical staff specializing in MCS and heart failure. In the United States, PMI employs its own sales staff to market and sell the Company's products. In Europe and other international markets, specialized distributors market and sell PMI's products. In July 2023, PMI entered an arrangement with SMB that will service, market, and sell its products in the Chinese market.

Integrated Manufacturing Processes. PMI technicians assemble SynCardia TAHs and make and service drivers in the Company's facility under an ISO 13485-certified quality management system, which is the standard required and recognized by the FDA, Health Canada, and competent authorities in Europe.

PMI is capable of performing the majority of manufacturing in-house in large part due to the considerable amount of proprietary manufacturing technology developed or acquired over the course of its operating history. All SynCardia TAHs and drivers are assembled, and selected components thereof manufactured, in PMI's rigorously monitored and maintained production environments. The manufacturing processes consist of fabricating precision components from a variety of materials and assembling these components, as well as components purchased from third parties, into specific configurations governed by design requirements. Both 70cc and 50cc SynCardia TAH implants are produced in a controlled environment suite while the drivers are made and serviced in a non-sterile environment. During the manufacturing process, the SynCardia TAH and driver assembly components thereof are rigorously tested to meet rigid operational and quality standards.

As a Class III medical device manufacturer, PMI's manufacturing facility, the facilities where sterilization is conducted, and the facilities of other critical suppliers are subject to periodic inspection by the FDA and other regulatory agencies. To date, all the International Organization for Standardization ("ISO") and Medical Device Single Audit Programs (“MDSAP”) audits that have been conducted at the Company's facilities have noted no deficiencies resulting in the suspension of manufacturing or quality system licenses. The Company successfully completed its most recent MDSAP audit in June 2025.

Intellectual Property

PMI's success depends in part on its ability to develop and maintain intellectual property rights relating to key aspects of the technology employed in the SynCardia TAH, maintain the Company's licenses to use intellectual property owned by third parties, preserve the confidentiality of PMI trade secrets, and operate without infringing the valid and enforceable patents and other proprietary rights of third parties. PMI relies upon certain patents, registered and common law trademarks, trade secrets, know-how, invention and patent assignment agreements, and continuing technological innovation to develop and maintain its competitive position. PMI is currently the holders of six awarded U.S. and international patents and the applicant for more than twelve pending U.S. and international patents. PMI intends to aggressively protect, defend, and extend the intellectual property rights protecting its technology.

For additional information relating to the risks associated with PMI's intellectual property position see “*Risk Factors—Risks Related to Our Intellectual Property*.”

Patents

The currently active (and, therefore, in-force) patents owned by PMI related to its technologies include:

Patent Number	Jurisdiction	Technology	Expiration Date
U.S. No. 7,811,318	United States	Pneumatic Driver	September 12, 2028
U.S. No. 8,070,455	United States	Scotch-Yoke	April 23, 2030
U.S. No. 8,021,422	United States	Pneumatic Driver	November 19, 2029

Additionally, PMI has applied for, or is preparing to apply for, a number of additional patents that protect the next generation TAH, product upgrades, and next generation drivers that stem from the International Patent Application No. PCT/US20/60785. Such patents and/or pending patent applications are targeting the United States, Europe, and China. The first two of such U.S. patents and one China patent have already been granted:

Patent Number	Jurisdiction	Technology	Expiration Date
U.S. No. 11,918,798	United States	Next Generation Total Artificial Heart	November 16, 2040
U.S. No. 12,121,711 B2	United States	Next Generation Total Artificial Heart	November 16, 2040
China Application No. 202080094390.7	China	Next Generation Total Artificial Heart (Counterpart to U.S. No. 11,918,798)	November 16, 2040
U.S. 12,383,722	United States	Next Generation Total Artificial Heart	November 16, 2040
European Application No. 20890347.6	Europe	Next Generation Total Artificial Heart (Counterpart to U.S. No. 11,918,798)	November 16, 2040

Furthermore, additional patent applications are in preparation and intended for protection of PMI's intellectual property in the United States, Canada, Europe (European Patent Convention and Eurasian Patent Convention), China (CNIPA), and India. Specifics of these additional patent applications are as follows:

Purpose[(1)]	Product Family	Patent Type	Expected Expiration Year
Usability-1	Driver	Utility	2044
Usability-2	Driver	Utility	2044
Usability-3	Driver	Utility	2044
Portability-1	Driver	Utility	2044
Usability-4	Driver	Utility	2044
Portability-2	Driver	Utility	2044
Reliability-1	Driver	Utility	2044
Reliability-2	Driver	Utility	2044
Portability-3	Driver	Utility	2044
Usability-5	Driver	Utility	2044
Usability-6	Driver	Utility	2044
Usability-7	Driver	Utility	2044

(1) Each of the “Purpose” designations pertains to the function of a component of the total artificial heart that is protected by the patent.

Trademarks

Registered Trademarks and Trademark Applications include:

Trademark	Jurisdiction	Class	Registration / Application Number
“FREEDOM” (Pending)	Europe	10	App. No. 00758776
“FREEDOM”	United States	10	Reg. No. 7,918,055
“FREEDOM” (Pending)	China	10	App. No. 85795403

Trade Secrets

The majority of the intellectual property related to the current versions of the SynCardia TAH is no longer protected by any patents or registered trademarks, and PMI relies primarily on a combination of non-patented proprietary technology, trade secrets, processes and procedures, technical knowledge and know-how accumulated or acquired since PMI's inception.

PMI considers the trade secrets relating to the manufacturing processes for its products to be particularly important. Because of the considerable amount of proprietary manufacturing technology, the Company has developed or acquired over the course of its operating history, it performs the majority of manufacturing activities related to its products at the Company's headquarters in Tucson, Arizona. Please refer to the section entitled "*Business — Manufacturing*" for a discussion of the highly technical manufacturing processes for the Company's SPUS and valves, which comprise a substantial competitive moat for PMI. The Company protects these trade secrets, in part, by entering into nondisclosure and confidentiality agreements with parties who have access to them, such as employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. Access to key trade secrets such as manufacturing processes and formulations is limited to a small number of highly trained employees. PMI also enters into invention or patent assignment agreements with employees and consultants that obligate them to assign any inventions developed in the course of their work.

Regulatory Approvals

The SynCardia TAH is the only total artificial heart approved for commercial use in the United States and Canada. Commercial approval in the United States requires the successful granting of PMA by the FDA. PMI remains the only company with an FDA-approved PMA for a total artificial heart. Obtaining an FDA approved PMA requires significant investment and clinical data.

Field Correction

The SynCardia TAH incorporates two cannulas that extend from the ventricles inside the patient's chest and connect to the drivelines outside of the patient's body. The cannulas are attached to the pneumatic driveline that interface to the SynCardia Freedom Driver. Users have reported tears in the cannula that occur over time from normal wear and tear as a result of stress on the cannula. Based on discussions with the FDA, PMI agreed to voluntarily initiate a customer notification under 21 CFR part 806. Pursuant to such notification, customers were informed of the potential failure mode and given instructions on what to do if the failure mode occurs. Failure investigation identified the root cause of breached cannula as wear caused by the repetitive stress placed on the cannula during use. Patients using a portable driver, like the Freedom driver, are more likely to place increased stress on the cannulas during day-to-day movement and motion. These stresses are concentrated where the effective stiffness of the cannula changes, specifically at the velour/cannula junction and driveline/cannula junction. This is attributable to the different material behaviors of the cannula when placed under flexural, rotational, or tensile stress; these increased stresses at the junctions can lead to a cannula tear. As of January 29, 2026, PMI had received 114 reports regarding cannula tears with zero reports of SAEs associated with these tears. PMI has developed a design change to address the cannula tears, which will be submitted to the FDA via a 180-day PMA Supplement when validation activities are completed. The Company expects to file this submission with the U.S. FDA in approximately the third quarter of 2026.

Government Regulation

The following is a summary of regulations governing PMI's business. The Company's products and operations are subject to extensive regulation by the FDA, and other federal authorities such as the Federal Trade Commission (FTC), state, and local authorities in the United States, as well as comparable authorities in foreign jurisdiction.

United States

The SynCardia Total Artificial Heart is regulated in the United States as a Class III medical device under the Federal Food, Drug and Cosmetic Act. Class III devices are subject to the highest level of regulatory control and generally require premarket approval ("PMA") by the FDA prior to commercial marketing. A PMA application must include extensive data demonstrating a reasonable assurance of the safety and effectiveness of the device for its intended use, including preclinical testing, clinical study results, manufacturing information, and labeling. The FDA may request additional information during the review process and may conduct inspections of clinical trial sites and manufacturing facilities. Even after approval, medical device manufacturers remain subject to ongoing regulatory requirements. These include compliance with the FDA Quality System Regulation QSR, medical device reporting MDR requirements for adverse events and product malfunctions, labeling and promotion restrictions, and periodic FDA inspections of manufacturing facilities. Failure to comply with these requirements may result in enforcement actions including warning letters, fines, product recalls, or withdrawal of product approval. The FDA also regulates changes to approved devices. Certain changes to manufacturing processes, design, labeling, or other aspects of an approved device may require submission and FDA approval of a PMA supplement prior to implementation. In addition, medical device manufacturers are subject to regulation of advertising and promotional activities by the Federal Trade Commission FTC, as well as various state consumer protection and licensing laws.

The below table displays a summary of the key PMA submissions, supplements, and their approval status for the SynCardia TAH. There are additional supplements not listed in the table below, and a complete list is detailed in P030011/S075.

Submission	Submission Description	Date of Approval
P03011	Original PMA Submission	October 15, 2004
S001	Post-market Surveillance Plan	October 26, 2005
S011	C2 Driver System PMA Supplement	May 16, 2012
S020	Freedom Driver PMA Supplement	June 26, 2014
S070	180-Day PMA Supplement to add 50cc SynCardia TAH	March 5, 2020
S084	Freedom Plus Software Update PMA	April 12, 2023
S092	PMA Supplement removing "Temporary" and "-t" from Trade Name	November 25, 2024
S093	PMA Supplement for CPC Driveline Connector Cover	November 19, 2025

PMI is subject to various federal and state healthcare laws, including, but not limited to, anti-kickback laws, laws prohibiting fraud in obtaining government approval or payment for goods or services, laws prohibiting use of bribes to win contracts, laws protecting the unauthorized use of patient information.

International

The Company's primary commercial market is currently the United States and Canada, where the SynCardia TAH is approved for commercial use. The Company is working toward obtaining regulatory approvals in additional jurisdictions, including CE Mark certification in the European Union under the MDR framework and approval from the National Medical Products Administration ("NMPA") in China, and may evaluate commercialization in these and other international markets following receipt of such approvals.

European Union

Medical devices in the European Union are regulated under the European Union MDR, which replaced the MDD. The MDR imposes more comprehensive regulatory requirements for medical devices, including enhanced clinical evidence, post-market surveillance, and oversight of notified bodies.

The SynCardia TAH 70cc implant first received CE Mark approval in Europe in 1999 under the MDD regulatory framework. The device subsequently received FDA premarket approval PMA in 2004 and Health Canada approval in 2005. In March 2021, the Company received a notification from its notified body, BSI Group BSI, regarding certain post-market surveillance documentation deficiencies related to the SynCardia TAH under the MDD framework. In December 2021, BSI suspended the CE Mark certificate pending completion of additional post-market surveillance activities. In June 2022, the Company requested cancellation of the MDD CE Mark in order to focus resources on pursuing CE Mark certification under the MDR regulatory framework. BSI cancelled the CE Mark certificate in July 2022. The Company notified its European distributors of the cancellation in accordance with applicable regulatory requirements. The Company is currently preparing to pursue CE Mark certification for the SynCardia TAH under the MDR framework. The Company's primary commercial market is currently the United States and Canada, where the SynCardia Total Artificial Heart is approved for commercial use.

SynCardia has implemented quality and regulatory compliance systems that supported its prior CE Mark certification under the MDD, FDA approvals, and other international regulatory clearances. These systems include post-market surveillance ("PMS") processes to monitor field performance and corrective and preventive action procedures designed to address identified product or process issues.

During the MDD recertification process, BSI identified certain deficiencies related to the incorporation of PMS data into the device's Clinical Evaluation Reports. As part of its ongoing efforts to pursue CE Mark certification under the European Union Medical Device Regulation MDR, the Company is implementing additional processes to address MDR post-market clinical follow-up ("PMCF") requirements and to strengthen its post-market surveillance framework.

Please refer to "*Risk Factors — Risks Related to Regulation of Our Industry*" for more information about the risks facing us regarding this issue.

China

Medical devices in China are regulated by the National Medical Products Administration ("NMPA"). The NMPA's Center for Medical Device Evaluation ("CMDE") is responsible for the technical review and evaluation of medical device registration applications. Medical devices must undergo regulatory review and approval before they may be marketed in China. The regulatory process may include submission of technical documentation, non-clinical testing, clinical evaluation or clinical trials, and review of manufacturing and quality management systems. In certain circumstances, additional testing or clinical studies conducted in China may be required as part of the approval process. The Company is working toward obtaining regulatory approval for the SynCardia TAH in China. Regulatory processes in China may be lengthy and subject to country specific requirements, and approvals may take longer than expected or may not be obtained.

Employees and Human Capital

As of December 31, 2025, PMI, through SynCardia, had 75 employees. In the United States, the Company employs its own sales staff to market and sell its products. In Europe and other international markets, specialized distributors market and sell the Company's products. PMI had employed more sales specialists in 2025, including a new Director of North American Sales. The Company also actively increased its presence in social media and interaction with its heart failure patients and their families through different outreach programs.

PMI employs and trains technicians to produce the Company's 70cc and 50cc SynCardia TAH and service the Companion 2 and Freedom Drivers. Depending on expected demand, the Company can scale up SynCardia TAH production in Tucson, AZ to approximately 450 units per year.

PMI considers its relationship with its employees to be good. The Company's human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing, and integrating existing and new employees, advisors, and consultants.

Facilities

PMI's manufacturing facilities are within its 34,443 square foot corporate office, located in Tucson, Arizona. The Company makes implants and drivers at the facility in Tucson, Arizona with components sourced from suppliers. The Company's lease for the Tucson facility expires in 2027. The facility includes a total of 7,882 square feet for manufacturing, 14,289 square feet of office space, and approximately 12,272 square feet of warehouse space.

INTERNET INFORMATION

Copies of PMI's annually reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act are available, free of charge, through PMI's investor relations website (*www.picardmedical.com*) as soon as reasonably practicable after the Company electronically files the material with, or furnishes it to, the Securities and Exchange Commission (the "SEC"). These reports and other information are also available, free of charge, at www.sec.gov.

PMI's corporate governance guidelines, outline of directorship qualifications, code of business conduct, and the charters of Picard's audit committee, compensation committee, nominations and governance committee, and public policy committee are all available on Picard's investor relations website (*www.Picardmedical.com*).

ITEM 1A. RISK FACTORS

The following risk factors and other information included in this Annual Report should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Please see the "Cautionary Statement Regarding Forward-Looking Statements" at the beginning of this Annual Report for a discussion of some of the forward-looking statements that are qualified by these risk factors. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Risks Related to Our Business and Industry

We have a history of significant losses. If we do not achieve and sustain profitability, our financial condition could suffer.

We have experienced significant net losses, and we expect to continue to incur losses for the foreseeable future while we expand our sales and marketing capabilities, increase manufacturing, pursue additional regulatory approvals for our products and continue our research and development activities. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' deficit and working capital for the foreseeable future. We do not anticipate being profitable in the near future. Even if we are successful in marketing existing products and launching additional products into the market, we expect to continue to incur substantial losses for the foreseeable future as we continue to sell and market, research, and develop and seek regulatory approvals for existing and future products.

If sales revenue is insufficient, if we are unable to develop and commercialize product candidates, or if product development is delayed, we may never become profitable. Even if we do become profitable, we may be unable to sustain or increase profitability on a quarterly or annual basis.

All of our revenue is generated from a limited number of products, and any decline in the sales of these products or failure to gain market acceptance of these products will negatively impact our business.

We have focused heavily on the development and commercialization of a limited number of products. We expect substantially all revenue to be derived from or related to sales of the SynCardia TAH for the immediate future. We expect that over time an increasing percentage of revenues will be derived from monthly rentals of our drivers, which is expected to result in longer, more consistent revenue streams. If we are unable to achieve and maintain significantly greater market acceptance of the TAH in general, and do not achieve sustained positive cash flow, we will be severely constrained in our ability to fund our operations. In addition, if we are unable to market our products as a result of a quality problem, shortage of components, failure to maintain or obtain regulatory approvals, unexpected or serious complications or other unforeseen negative effects, we would lose our only source of revenue, and our business will be adversely affected.

The manufacturing process of the SynCardia TAH requires highly specialized knowledge and operator skills, which could affect our ability to manufacture the SynCardia TAH on a timely basis. If we are unable to manufacture the SynCardia TAH on a timely basis consistent with our quality standards, our results of operations will be adversely impacted.

Manufacturing TAHs entails a variety of risks, including:

- the inability to meet product specifications and quality requirements consistently;
- a delay or inability to procure or expand sufficient manufacturing capacity to meet additional demand for our products;
- manufacturing and product quality issues related to the scale-up of manufacturing;
- the inability to produce a sufficient supply of products to meet product demands;
- the disruption of our manufacturing facility due to equipment failure, public health emergencies such as pandemics, natural disaster or failure to retain key personnel;
- an inability to ensure compliance with regulations and standards of the FDA including QSR and corresponding state and international regulatory authorities;
- concentration of manufacturing activity in a single location, which risks loss of manufacturing capacity and continuity of production in the event of a fire or other disruption; and
- the shell and diaphragm portions of the SynCardia TAH are constructed with a proprietary formulation of Segmented Polyurethane Solution (“SPUS”) with raw chemicals from qualified suppliers, and we may not obtain FDA approval for our efforts to source these raw chemicals from different suppliers.

Any of these events could lead to a reduction in product sales, product launch delays, or failure to obtain regulatory clearance or approval or impact our ability to successfully sell products and commercialize product candidates. Some of these events could be the basis for adverse actions by regulatory authorities, including injunctions, recalls, seizures, or total or partial suspension of production. The SynCardia TAH is currently manufactured by hand by highly trained technicians who cannot be quickly or easily replaced. The length of time required to obtain the skill necessary to build the SynCardia TAH is long, and each technician could face sickness, accidents, or life changes. The loss of any such personnel could result in production delays that could adversely affect our results of operations. To achieve revenue goals, we must successfully continue to increase production output to meet projected customer demand and product inventory requirements that are attendant to serving a global market. It is not certain that we will be able to increase output on anticipated timelines, or at all.

We rely on specialized suppliers and service providers for components of the SynCardia TAH and do not have second-source suppliers for the majority of components.

We rely on third party suppliers for materials and components necessary for the manufacture and assembly of our SynCardia TAH and components thereof. Several of our suppliers rely on proprietary processes and/or perform customized processes. While we aim to have secondary suppliers for our critical supplies, obtaining additional sources may not be feasible for all due to the nature of materials used and/or processes applied. We have entered into quality agreements with most of our critical suppliers. Issuers arising from production stoppages, adverse business conditions, and failure to meet agreed production and quality standards may have an adverse effect on our performance.

We have second-source suppliers for some, but not all, of our components. In particular, we do not have second-source suppliers for many of our driver components or for the SynHall Valves, a component of the SynCardia TAH. Even if we engage a second-source supplier for our valve discs, we would need to obtain regulatory approvals in order to sell SynCardia TAHs with valve discs manufactured by a backup supplier. Additionally, we have not sourced a backup supplier for the housings that are used in the SynHall Valves. Our reliance on third party suppliers also subjects us to other risks that could harm our business, including:

- suppliers may give the needs of other customers higher priority than us or discontinue or modify components based on demand from other customers;
- some components must be manufactured to extremely tight tolerances and specifications with the result that our suppliers, especially new suppliers, may make errors in manufacturing or conduct unauthorized rework that could negatively affect the efficacy or safety of the products or cause components not to be delivered on time or at all or to be delivered outside of our specifications;
- the inability to obtain adequate supply in a timely manner or on commercially reasonable terms;
- the availability of second-source suppliers may be extremely limited or their implementation as a supplier may take lengthy amount of time due to the tight tolerances and specifications in which we typically operate;
- switching components or changes to components, specifications or designs may require product redesign and submission to the FDA of a post-market approval supplement, which can lead to production interruptions;
- suppliers manufacture products for a range of customers, and fluctuations in demand for the products these suppliers manufacture for others may affect their ability to deliver products to use in a timely manner; and
- suppliers may encounter financial hardships unrelated to our demand, which could inhibit their ability to fulfill orders and meet requirements.

In the event that any of our suppliers decreases or discontinues production of any components, or in the event we encounter quality issues or other problems with components provided by suppliers, we may not be able to quickly establish additional or alternative suppliers in part because of the FDA approval process. Furthermore, we have experienced production delays associated with selecting and engaging alternative suppliers for certain components. Any interruption or delay in obtaining products from third party suppliers, or an inability to obtain products from qualified alternate sources at acceptable prices in a timely manner, could impair our ability to meet customer demand and cause customers to switch to competing products.

Additionally, we may experience problems or delays in our own manufacturing and assembly processes, which may be harmful to our financial status or reputation and, therefore, make it more difficult or expensive for us to continue with or enter into relationships with specialized suppliers. Our business plan is predicated on maintaining strong relationships and favorable supply arrangements with a series of external parties to manufacture components of the SynCardia TAH and related drivers. If we are unsuccessful in this regard or are unable to secure or maintain agreements with these manufacturers on favorable terms or at all, then our ability to commercialize our technology and expand our operations will be dramatically impaired.

The future demand for our current products and future products is unproven. Our current products and future products may not be accepted by hospitals, surgeons or patients, and may not become commercially successful.

Physicians and hospitals may not perceive the benefits of our products and may be reluctant or unwilling to adopt using the SynCardia TAH as a treatment option, particularly as an alternative to existing treatment options. For example, LVADs are currently the Mechanical Circulatory Support ("MCS") devices most commonly used by physicians to bridge the time between when a transplant is needed for a heart failure patient and when a donor heart becomes available. While we believe that the SynCardia TAH is a complementary treatment alternative to LVADs or other ventricular assist devices ("VADs") to treat patients with heart failure may be reluctant to adopt broad use of the SynCardia TAH.

Physicians and hospitals may be slow to change their practices because of perceived risks arising from the use of new products or due to specific operational characteristics related to the use of the SynCardia TAH and its related drivers. For example, physicians and hospitals have reported that the noise level generated by the Freedom Portable Driver has impacted their willingness to use the Freedom Portable Driver in the hospital setting. In addition, unlike LVADs, implanting the SynCardia TAH involves the removal of the patient's native heart. While we believe that replacement of the native heart with the SynCardia TAH provides many benefits over LVADs, the concept of removing a patient's native heart may cause a negative emotional reaction from certain physicians, patients and their families, and make them reluctant to use our products.

In order to establish markets for our products and build those markets through appropriate and compliant physician education and awareness programs, publication in peer-reviewed medical journals of results from studies using the SynCardia TAH were important for adoption by physicians and in reimbursement decisions of third-party payors. The process of publication in leading medical journals is lengthy and subject to a peer review process. Peer reviewers may not consider the results of studies of the SynCardia TAH and any future products sufficiently novel or worthy of publication. Failure to have our studies published in peer reviewed journals may adversely affect adoption of our products.

Once our products have been proven either safe and with probable benefit (through an approved Humanitarian Device Exemption) or safe and effective (through an approved Premarket Approval process), educating physicians and hospitals on the safety and benefits of our products requires significant commitment by our marketing team and sales organization. We cannot predict when, if ever, the SynCardia TAH will become widely accepted by physicians and hospitals. If we are unable to adequately educate physicians and hospitals about the advantages of the SynCardia TAH, achieve significantly greater market acceptance of our products, gain momentum in our sales activities, or fail to significantly grow our market share, we will not be able to grow revenue, and our business and financial condition will be adversely affected.

Once SynCardia TAH has been proven either safe and with probable benefit (through an approved HDE) or safe and effective (through an approved PMA), If SynCardia is unable to educate physicians on the safe and effective use of the SynCardia TAH and the procedure to implement the SynCardia TAH, we may be unable to achieve our expected growth.

It is critical to the success of our commercialization efforts that we educate physicians on proper implantation and aftercare techniques for the SynCardia TAH and provide them with adequate support during clinical procedures. There is a learning process for physicians to become proficient in the use of the SynCardia TAH, and it typically takes several procedures for a physician to become comfortable implanting the SynCardia TAH. If a physician experiences difficulties during a procedure involving the SynCardia TAH, that physician may be less likely to continue to use our products or to recommend them to other physicians. It is important for our growth that physicians advocate for the benefits of our products in the broader marketplace. If physicians are not properly trained, they may misuse or ineffectively use our products, which may also result in unsatisfactory patient outcomes, patient injuries, negative publicity, or lawsuits against us, any of which could have an adverse effect on our business.

If we fail to develop and retain a direct sales force and effective network of international distributors, we may be unable to achieve expected growth targets and our business could suffer.

We employ two sales specialists and three clinical support specialists who together cover the United States and Canadian markets. We also utilize a network of independent distributors and agents for sales outside of the United States. We work, or plan to work, with distributors in Europe, India, China, Saudi Arabia, and Serbia. As we launch new products, increase our current sales efforts and expand into new geographies and increase our efforts in each geography, we will need to retain, grow, and develop our community of direct sales personnel, distributors, and agents. There is significant competition for sales personnel experience in relevant medical device sales. In addition, the training process for new personnel is lengthy because it requires significant education to achieve an acceptable level of clinical competency with SynCardia TAH. Upon completion of training, sales representatives typically require lead time in the field to develop or expand their network of accounts and achieve the productivity levels they are expected to reach in any individual territory. If we are unable to attract, motivate, develop, and retain a sufficient number of qualified sales and clinical support personnel, and if they do not achieve the expected productivity levels, our revenue will not grow at the rate that we expect, and financial performance will suffer.

The establishment of a distribution network is expensive and time consuming. Even if we engage and maintain suitable relationships with an adequate number of distributors, they may not generate revenue as quickly as expected, commit the necessary resources to effectively market and sell the products, or ultimately succeed in selling the products. Moreover, if our sales force and distributors are unable to recruit new medical centers to become SynCardia Certified Centers, we may be unable to achieve expected growth, and our business could suffer. In addition, we cannot assure investors that we will succeed in entering into and maintaining productive arrangements with an adequate number of distributors that are sufficiently committed to selling the SynCardia TAH in international markets.

Reliance on distributors and third parties to market and sell our products could negatively impact our business.

We may not be able to find suitable distributors for our products on satisfactory terms or our agreements with distributors may prematurely terminate. Our future distributor relationships or contracts may preclude us or limit us from entering into arrangements with other distributors. We also may not be able to negotiate new or renew existing distribution agreements on acceptable terms, or at all.

We operate in a market segment that is subject to rapid technological change. If our competitors are able to develop and market technologies or products that are safer, more effective, less costly, easier to use or otherwise more attractive than our products, our business will be adversely impacted.

The medical device industry is highly competitive and subject to technological change. Our success depends, in part, upon our ability to maintain a competitive position in the development of technologies and products for use in the treatment of advanced heart failure. We face significant competition in the United States and internationally, and we expect the intensity of competition to increase over time. For example, our products are likely to compete against future products offered by larger public companies such as Abbott. In addition to these potential competitors, we may also face competition from smaller companies with active MCS device development programs. Other competitors may emerge in the future. Many of the companies developing or marketing competing products enjoy several advantages relative to us, including:

- greater financial and human resources for product development, sales and marketing;
- greater name recognition;
- long-established relationships with physicians and hospitals;
- the ability to offer rebates or bundle multiple product offerings to offer greater discounts or incentives;
- more established distribution channels, as well as sales and marketing capabilities; and
- greater experience in resources for conducting research and development, clinical studies, manufacturing, preparing regulatory submissions, obtaining regulatory clearance or approval, and marketing approved products.

The SynCardia TAH is currently the only total artificial heart that is commercially available in the United States and Canada for use as a bridge to transplantation. The SynCardia TAH is also used under compassionate use/special dispensation regimes in several countries outside of North America. Although we believe that the SynCardia TAH is a complementary treatment alternative to LVADs on the continuum of care, we cannot assure investors that hospitals, physicians and investors will not view our products as competitive with LVADs that are marketed and sold by much larger and more established companies. Our competitors may develop and patent processes or products earlier than we do, obtain regulatory clearance or approvals for competing products more rapidly than us or develop more effective, more convenient or less expensive products or technologies that render our technology or products obsolete or less competitive. In addition, our ability to increase gross margins is dependent in part upon product development, including increasing service intervals for drivers. We also face competition in recruiting and retaining qualified sales, scientific and management personnel, establishing clinical trial sites and enrolling patients in clinical studies. If our competitors are more successful than we are in these matters, our business may be harmed.

SynCardia has significant customer concentrations, and economic difficulties or changes in the purchasing policies or patterns of our key customers could have a significant impact on our business and operating results. We have no long-term exclusive agreements with our customers and, as a result, generally operate on an invoice and purchase order basis to meet our customers' needs.

A small number of customers or key surgeons account for a substantial portion of our revenues. There are also a limited number of hospitals and surgical centers with heart transplant centers and MCS programs. Sales of products to our customers are not based on long-term, committed-volume purchase contracts, and we may not continue to receive significant revenues from any customer. Because of this significant customer concentration, our revenue could fluctuate significantly due to changes in economic conditions, the use of competitive products, or the loss of, reduction of business with, or less favorable terms with our significant customers. A reduction or delay in orders from significant customers, or a delay or default in payment by any significant customer, could materially harm our business and results of operations.

Our future success depends on our ability to develop, receive regulatory approval (including long term indication) for, and introduce new products or product enhancements that will be accepted by the market in a timely manner.

It is important to our business that we continue to build a pipeline of product offerings for the treatment of heart failure in order to remain competitive. As such, our success will depend in part on our ability to develop and introduce new products. However, we may not be able to successfully maintain our regulatory approvals for existing products, or develop, obtain, and maintain regulatory clearance or approval for product enhancements, or long-term indication for our products, or new products, or these products may not be accepted by physicians or the payors who financially support many of the procedures performed with our products.

The success of any new product offering or enhancement to an existing product will depend on several factors, including our ability to:

- identify and anticipate physician and patient needs properly;
- develop and introduce new products or product enhancements in a timely manner;
- avoid infringing the intellectual property rights of third parties;
- demonstrate the safety and efficacy of new products with data from preclinical studies and clinical studies;
- obtain the necessary regulatory approvals for new products or product enhancements;
- comply fully with FDA and applicable foreign government agencies' regulations on marketing of new devices or modified products;
- provide adequate training to potential users of our products; and
- receive coverage and adequate reimbursement for procedures performed with our products.

If we do not develop new products or product enhancements in time to meet market demand, if there is insufficient demand for these products or enhancements, or if our competitors introduce new products with enhanced functionalities that are superior to our products, our results of operations will suffer.

If we are unable to successfully complete the pre-clinical studies or clinical trials necessary to support premarket approval applications or PMA supplements, our ability to obtain approvals for new products will be limited.

In some cases, where we develop new products, we may be able to engage in limited use of such products via emergency or compassionate use provisions prior to completion of clinical trials and receipt of regulatory approval. However, before broadly using medical devices in the United States, we must apply for and obtain approval for either a HDE or PMA from the FDA. Before submitting an HDE or PMA application, we must successfully complete pre-clinical studies and clinical trials to demonstrate that the product is safe and either provides probable benefit (for an HDE) or is effective (for a PMA). Product development, including pre-clinical studies and clinical trials, is a long, expensive, and uncertain process and is subject to delays, and failure may occur at any stage. Furthermore, the data obtained from the trial may be inadequate to support approval of a PMA application. The commencement or completion of any clinical trials may be delayed or halted, or be inadequate to support approval of a PMA application, for numerous reasons, including, but not limited to, the following:

- the FDA, institutional review boards or other regulatory authorities do not approve a clinical study protocol, require a modification to a previously approved protocol, or place a clinical study on temporary hold;
- sites do not apply to participate in a clinical study, or apply at a lower rate than expected;
- there are difficulties or delays in the process of qualifying sites to participate in a clinical study;
- patients do not enroll in, or enroll at a lower rate than expected, or do not complete a clinical study;
- patients or investigators do not comply with study protocols;
- patients do not return for post-treatment follow-up at the expected rate;
- patients experience serious or unexpected adverse side effects, whether because of the product or because of serious co-morbidities that may exist at the time of treatment, causing a clinical study to be put on hold;
- sites participating in an ongoing clinical study withdraw, requiring us to engage new sites;
- difficulties or delays associated with establishing additional clinical sites;
- third-party clinical investigators decline to participate in clinical studies, do not perform the clinical studies on the anticipated schedule, or are inconsistent with the investigator agreement, clinical study protocol, good clinical practices, and other FDA and institutional review board requirements;
- third-party organizations do not perform data collection and analysis in a timely or accurate manner;
- regulatory inspections of clinical studies or manufacturing facilities require us to undertake corrective action or suspend or terminate our clinical studies;
- changes in federal, state, or foreign governmental statutes, regulations or policies;
- interim results are inconclusive or unfavorable as to immediate and long-term safety or efficacy; or
- not meeting the statistical endpoints.

The results of clinical studies do not necessarily predict future clinical trial results, and predecessor clinical trial results may not be repeated in subsequent clinical trials. Additionally, the FDA may disagree with our interpretation of the data from our pre-clinical studies and clinical trials, or may find the clinical trial design, conduct or results inadequate to prove safety or efficacy, and may require us to pursue additional pre-clinical studies or clinical trials, which could further delay the approval of our products. If we are unable to demonstrate the safety and efficacy of our products in our clinical trials, we will be unable to obtain regulatory approval to market our products. The data collected from INTERMACS database, or our clinical trials may not be sufficient to support FDA approval of product upgrades or indication expansions. Moreover, if the results of any post-market clinical studies are not favorable, our existing clearances or approvals may be impacted.

The risks described above also apply to foreign clinical trials and regulatory approvals. If we cannot timely conduct foreign trials in our major target markets (to the extent required in order to market our device in such locations) and receive timely approval in those jurisdictions to market our device for a variety of indications, our business will suffer.

Premarket approvals for our therapeutic medical devices could be denied or significantly delayed.

Under the Federal Food, Drug, and Cosmetic Act ("FDCA") and FDA regulations, unless exempt, a new medical device may only be commercially distributed after it has received the requisite clearance or approval. We expect that all our products will require approval of PMAs in order to be marketed. The PMA process in the U.S. and other jurisdictions can vary substantially, based on the type, complexity and novelty of the product involved and is typically costly, lengthy, and uncertain, and usually requires substantial clinical studies. The PMA process, including the gathering of clinical and pre-clinical data and the submission to and review by the FDA, involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing, and labeling. Preclinical testing and clinical trials must comply with the regulations of the FDA and other government authorities in the U.S. and similar agencies in other countries. A PMA is not guaranteed and may take considerable time, and the FDA may ultimately respond to a PMA submission with a "not approvable" determination and require additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay approval. Such delays or refusals, regardless of the cause, could have a material adverse effect on our business, financial condition, and results of operations. The FDA may also change its approval policies, adopt additional regulations, or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products.

The FDA can delay, limit, or deny PMA approval of a device for many reasons, including, but not necessarily limited to:

- Similarly, regulators may determine that our financial relationships with our principal investigators resulted in a perceived or actual conflict of interest that may have affected the interpretation of a study, the integrity of the data generated at the applicable clinical trial site or the utility of the clinical trial itself. Even if we are granted regulatory approval, they may include significant limitations on the indicated uses for the product, which may limit the market for the product.
- As a condition of approving a PMA application, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up 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 safety and effectiveness data for the device. Failure to conduct a post-approval study in compliance with applicable regulations or to timely complete required post-approval studies or comply with other post-approval requirements could result in withdrawal of approval of a PMA, which would harm our business.

We are subject to extensive post-marketing regulation by the FDA and comparable authorities in other jurisdictions, which could impact the sales and marketing of our products and could cause us to incur significant costs to maintain compliance. In addition, we may become subject to additional regulation in other jurisdictions as we increase our efforts to market and sell our products outside of the U.S.

We will market and sell our products, if approved, subject to extensive regulation by the FDA and numerous other federal, state, and governmental authorities in other jurisdictions. These regulations are broad and relate to, among other things, the conduct of pre-clinical and clinical studies, product design, development, manufacturing, labeling, testing, product storage and shipping, premarket clearance and approval, conformity assessment procedures, premarket clearance and approval of modifications introduced in marketed products, post-market surveillance and monitoring, reporting of adverse events and incidents, pricing and reimbursement, interactions with healthcare professionals, interactions with patients, information security, advertising and promotion and product sales and distribution. The ability to market our products for new indications will require additional FDA approval, such as a new PMA or PMA supplemental application for modifications made to our products. This approval process is costly and uncertain, and it could take one to three years, or longer, from the time the application is submitted to the FDA. We may make modifications in the future that we believe do not or will not require additional approvals. If the FDA disagrees and requires new PMAs or PMA supplemental applications for the modifications, we may be required to recall and to stop marketing the modified versions of our products.

In addition, before our products can be marketed in the EU, our products must obtain a CE Certificate from a notified body. New intended uses of CE marked medical devices falling outside the scope of the current CE Certificate require a completely new conformity assessment before the device can be CE marked and marketed in the EU for the new intended use. The process required to gather necessary information and draw up documentation in order to obtain CE Certification of a medical device in the EU can be expensive and lengthy and its outcome can be uncertain. We may make modifications to our products in the future that we believe do not or will not require notifications to our notified body or new conformity assessments to permit the maintenance of our current CE Certificate. If the competent authorities of the EU member states or our notified body disagree and require the conduct of a new conformity assessment, the modification of the existing CE Certificate or the issuance of a new CE Certificate, we may be required to recall or suspend the marketing of the modified versions of our products.

In the U.S. and other jurisdictions, we also are subject to numerous post-marketing regulatory requirements, which include regulations under the QSR related to the manufacturing of our products, labeling regulations, MDR regulations and recordkeeping requirements. In addition, these regulatory requirements may in the future change in a way that adversely affects us. If we fail to comply with present or future regulatory requirements that are applicable to us, we may be subject to enforcement action by the FDA or comparable regulatory authorities in other jurisdictions and notified bodies, which may include sanctions.

The occurrence of any of these events could have a material adverse effect on our business, prospects, financial condition and results of operations and cause our stock price to decline.

If third-party payors do not continue to provide adequate coverage and reimbursement for the use of our products, it is unlikely that our products will be widely used, and our revenues will be negatively impacted.

Our success in marketing our products depend in large part on whether U.S. and international government health administrative authorities, private health insurers and other organizations will adequately cover and reimburse customers for the cost of the products. The SynCardia 70cc and 50cc TAH are currently reimbursed by Medicare as part of a DRG payment pursuant to CMS' revised National Coverage Determinations, which are routinely followed by private insurers in the United States. We generally understand from our interactions with hospitals that they are reimbursed and this, together with the fact that we have been regularly repaid for our SynCardia TAH implants since 2008, supports our conclusion that private reimbursement in the United States is provided to substantially all hospitals that have implanted the SynCardia TAHs. In the United States, the commercial success of our existing products and any future products will depend, in part, on the extent to which governmental payors at the federal and state levels, including Medicare and Medicaid, private health insurers and other third-party payors provide coverage for and establish adequate reimbursement levels for procedures utilizing our products. The existence of coverage and adequate reimbursement for our products and related procedures by government and private payors is critical to market acceptance of our existing and future products. Neither hospitals nor surgeons are likely to use our products if they do not receive adequate reimbursement for the procedures utilizing our products.

Some private payors in the United States may base their reimbursement policies on the coverage decisions determined by the Centers for Medicare and Medicaid Services, or CMS, which administers the Medicare program. Others may adopt different coverage or reimbursement policies for procedures performed using the SynCardia TAH, while some governmental programs, such as Medicaid, have reimbursement policies that vary from state to state, some of which may not pay for the SynCardia TAH in an amount that supports its selling price, if at all. A Medicare national or local coverage decision denying coverage for the SynCardia TAH or any other products could result in private and other third-party payors also denying coverage. For example, in 1986, CMS issued a non-coverage policy regarding the use of artificial hearts under the Medicare program. Most private payors followed this determination and denied coverage for products similar to ours. As a result, hospitals in the United States generally were unable to obtain reimbursement through Medicare or most private insurers for the use of our products until 2008 when CMS issued a Coverage Decision Memorandum stating that CMS reimbursements of the SynCardia TAH would only be provided to hospitals enrolled in approved studies with evidence development. Following the issuance of this Coverage Decision Memorandum, private payors began to provide reimbursement coverage for the SynCardia TAH, including for hospitals not enrolled in such studies.

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. We cannot assure investors that the SynCardia TAH will be considered cost-effective by international third-party payors, that reimbursement will be available or, if available, that the third-party payors' reimbursement policies will not adversely affect our ability to sell the SynCardia TAH profitably. If sufficient coverage and reimbursement are not available for our current or future products, in either the United States or internationally, the demand for our products and our revenues will be adversely affected.

Our manufacturing operations, research and development activities, and corporate headquarters are currently based at a single location, which may subject us to a variety of risks.

We currently conduct all manufacturing, development, and management activities at a single location in Tucson, Arizona. We have taken precautions to safeguard our facilities, including insurance, secure access and health and safety protocols. However, vandalism, terrorism, or a natural or other disaster such as a flood or fire could cause substantial delays in operations, damage or destroy our equipment or inventory, and cause us to incur additional expenses. The insurance coverage maintained by us may not be adequate to cover losses in any particular case.

Product liability claims could damage our reputation or adversely affect our business.

The design, manufacture and marketing of human medical devices, particularly implantable life-sustaining medical devices, carries an inherent risk of product liability claims and other damage claims. In addition to the exposure we may have for defective products, physicians may misuse our products or use improper techniques, regardless of how well trained, potentially leading to injury and an increased risk of product liability. A product liability or other damages claim, product recall or product misuse could require us to spend significant time and money on litigation, regardless of the ultimate outcome, or to pay significant damages and could seriously harm our business. We maintain limited product liability insurance. We cannot be certain that insurance will be sufficient to cover all claims that may be made against us. Our insurance policies generally must be renewed on an annual basis. We may not be able to maintain or increase insurance on acceptable terms or at reasonable costs. A successful claim brought against us in excess, or outside of, our insurance coverage could seriously harm our financial condition or results of operations. Generally, our clinical trials will be conducted in (and our commercial sales will be made to sites in respect of) patients with serious life-threatening diseases for whom conventional treatments have been unsuccessful or for whom no conventional treatment exists. During the course of treatment, these patients could suffer adverse medical effects or die for reasons that may or may not be related to our medical devices. Any of these events could result in a claim of liability.

Product deficiencies could result in field actions, recalls, substantial costs and write-downs; these could also lead to the delay or termination of planned studies or future clinical trials, if any, and harm our reputation and our business and financial results.

Our products are subject to various regulatory guidelines and involve complex technologies. The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture that could affect patient safety. Manufacturers may, under their own initiative, conduct a product notification or recall to inform physicians of changes to instructions for use or if a deficiency in a device is found or suspected.

Identified quality problems, such as failure of critical components including batteries or controllers, or the failure of third parties to supply us with sufficient conforming quantities of these products or components, could impact the availability of our products in the marketplace or lead to adverse clinical events that could cause us to amend, repeat or terminate clinical trials. In addition, product improvements, product redundancies or failure to sell a product before its expiration date could result in scrapping or expensive rework of products, and our business, financial condition or results of operations could suffer. Product complaints, quality issues and necessary corrective and preventative actions could result in communications to customers or patients, field actions, the scrapping, rework, recall or replacement of products, substantial costs and write-offs, and harm to our business reputation and financial results. Further, these activities could adversely affect our relationships with our customers or affect our reputation, which could materially adversely affect our earnings, results, and financial viability.

On February 17, 2023, we issued an urgent field safety notice (the "Notice") to health care providers of patients implanted with the SynCardia TAH to alert the providers of the potential for a hole or tear that may occur in the pneumatic cannula of the SynCardia TAH and what actions should be taken in the event of occurrence, as part of the FDA Class 2 recall under Part 806. The Notice stated that although we have received 93 complaints regarding cannula tears as of October 24, 2022, there have been zero reported Serious Adverse Events associated with a cannula hole or tear. To date, there have been 11 additional complaints regarding cannula tears, and there continue to have been zero reported Serious Adverse Events associated with a cannula hole or tear as of March 20, 2025. Corrective action to address this issue is currently undergoing process validation and is expected to be completed by the first half of 2026.

A future field action or recall announcement could harm our reputation with customers, negatively affect sales, and subject SynCardia to FDA enforcement actions. Moreover, depending on the corrective action taken to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new approvals or clearances for the device before we could market or distribute the corrected device. Seeking such approvals or clearances may delay our ability to replace the recalled devices in a timely manner. If we do not adequately address problems associated with our devices, we could face additional regulatory enforcement action, including FDA warning letters, product seizures, injunctions, administrative penalties, or civil or criminal fines.

Any identified quality issue can therefore both harm our business reputation and result in substantial costs and write-offs, which in either case could materially harm our business and financial results.

Any claims related to improper handling, storage or disposal of hazardous chemicals and biomaterials could be time-consuming and costly to address.

Our operations require the use of hazardous materials, including chemicals and biomaterials. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. We could be subject to both criminal liability and civil damages in the event of an improper or unauthorized release of, or exposure of individuals to, hazardous materials. In addition, claimants may sue us for injury or contamination that results from the use or the use by third parties of these materials, and our liability may exceed our total assets. Compliance with environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development or production efforts or harm our operating results.

Our international operations subject us to certain operating risks, which could adversely impact our results of operations and financial condition.

Since our inception, we have sold products in United States, France, Germany, Canada, Italy, Turkey, United Kingdom, Slovakia, Australia, Slovenia, Sweden, Austria, Macedonia/Yugoslavia, Spain, Kuwait, Croatia, Lithuania, Poland, Saudi Arabia, Serbia, Finland, Greece, Israel, Lebanon, and the Russian Federation. The sale and shipment of products across international borders, as well as the purchase of components from international sources, subjects us to U.S. and foreign governmental trade, import and export, and customs regulations and laws. Compliance with these regulations and laws is costly and exposes us to penalties for non-compliance. Other laws and regulations that can significantly impact us include various anti-bribery laws, including the U.S. Foreign Corrupt Practices Act and anti-boycott laws, as well as export controls laws. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, restrictions on certain business activities and exclusion or debarment from government contracting. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of shipping and sales activities.

In addition, several of the countries in which we sell our products are, to some degree, subject to political, economic, or social instability, and certain of such countries are or may in the future become the subject of U.S. or international sanctions.

Our international operations expose us and our distributors to risks inherent in operating in foreign jurisdictions. These risks include:

- difficulties in enforcing or defending intellectual property rights;
- pricing pressure that we may experience internationally;
- a shortage of high-quality salespeople and distributors;
- third-party reimbursement policies that may require some of the patients who receive our products to directly absorb medical costs or that may necessitate a reduction of the selling prices of such products;
- disadvantage to competition with established business and customer relationships;
- the imposition of additional U.S. and foreign governmental controls or regulations;
- economic or political instability;
- changes in duties and tariffs, license obligations and other non-tariff barriers to trade;
- the imposition of restrictions on the activities of foreign agents, representatives, and distributors;
- potentially adverse tax consequences, including in respect of transfer pricing, value added and other tax systems, double taxation, and/or taxation on repatriation of earnings, which could result in significant fines, penalties and additional taxes being imposed on us;
- laws and business practices favoring local companies;
- difficulties in maintaining consistency with our internal guidelines;
- the imposition of costly and lengthy new export licensing requirements;
- the imposition of U.S. or international sanctions against a country, company, person, or entity with whom we do business that would restrict or prohibit continued business with the sanctioned country, company, person, or entity;
- negative publicity or public sentiment towards a country, company, person, or entity with whom we do business that would result in continued business with the sanctioned country, company, person, or entity to bring unfavorable publicity to us; and
- the imposition of new trade restrictions.

If any of these events or circumstances were to occur, our sales in foreign countries may be harmed and our results of operations would suffer.

Changes in U.S. and international trade policies, particularly with respect to China, may adversely impact our business and operating results.

The U.S. government has recently made statements and taken certain actions that may lead to potential changes to U.S. and international trade policies, including imposing several rounds of tariffs and export control and sanctions restrictions affecting certain products manufactured in China. Both China and the United States have each imposed tariffs indicating the potential for further trade barriers, including the U.S. Commerce Department adding numerous Chinese entities to its Unverified List, which requires U.S. exporters to go through more procedures before exporting goods to such entities. It is unknown whether and to what extent new tariffs, export controls, or other new laws or regulations will be adopted, or the effect that any such actions would have on us or our industry.

If any new tariffs, export controls, sanctions, legislation, and/or regulations are implemented, or if existing trade agreements are renegotiated or, in particular, if either the U.S. or Chinese government takes retaliatory trade actions due to the recent trade tensions, such changes could have an adverse effect on our business, financial condition and results of operations.

We are subject to credit risk from our accounts receivable related to our product sales, which include sales within foreign countries that have recently experienced economic turmoil.

Our accounts receivable in the United States are due from both third-party hospitals and private hospitals. In contrast, our accounts receivable outside of the United States are primarily due from third-party distributors, and to a lesser extent, public government-owned and private hospitals, which present a greater risk of uncollectible accounts. In addition, changes in foreign currency exchange rates between foreign currencies and the U.S. dollar could materially impact our results of operations and distort period-to-period comparisons. Fluctuations in foreign currency exchange rates also impact the reporting of our receivables and payables in non-U.S. currencies. As a result of such foreign currency fluctuations, it could be more difficult to detect underlying trends in our business and the results of operations. Although we do not currently hedge our foreign currency exchange rate risks, we may engage in exchange rate hedging activities in the future in an effort to mitigate the impact of exchange rate fluctuations. If the hedging activities are not effective, changes in currency exchange rates may have a more significant impact on our results of operations.

Changes in U.S. and foreign tax laws could have a material adverse effect on our business, cash flow, results of operations or financial conditions.

The tax regimes to which we are subject or operate under, including income and non-income tax laws, are constantly under review and may be subject to significant change. Changes in tax laws, regulations, or rulings, or changes in interpretations of existing laws and regulations, could materially affect our financial position and results of operations. For example, the 2017 Tax Cuts and Jobs Act, or ("Tax Act"), made broad and complex changes to the U.S. tax code, including changes to U.S. federal tax rates, additional limitations on the deductibility of interest, both positive and adverse changes to the utilization of future net operating loss ("NOL") carryforwards, allowance for the expensing of certain capital expenditures. In addition, for tax years beginning in 2022 and later, the Tax Act eliminates the currently available option to deduct research and development expenditures and requires taxpayers to amortize them generally over five years (or, in certain cases, fifteen years). The 2020 Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, modified certain provisions of the Tax Act. In addition, on August 16, 2022, the Inflation Reduction Act of 2022 (the "IR Act"), among other provisions, imposes a 15% minimum tax on the adjusted financial statement income of certain large corporations and a 1% excise tax on corporate stock repurchases by U.S. publicly traded corporations and certain U.S. subsidiaries of non-U.S. publicly traded corporations. The exact impact of the Tax Act, the CARES Act, the IR Act, and the OBBBA, for future years is difficult to quantify, but these changes could materially affect our effective tax rate in future periods, in addition to any changes made by new tax legislation.

Our ability to use net operating loss carryforwards and certain other tax attributes may be subject to limitations.

Under current law, unused federal NOLs generated for tax years beginning before January 1, 2018, may be carried forward 20 years, and unused federal NOLs generated for taxable years beginning after December 31, 2017, may be carried forward indefinitely. The deductibility of post-2017 NOL carryforwards generally is limited to 80% of taxable income. In addition, under Sections 382 and 383 of the Code, federal NOL carryforwards and other tax attributes may become subject to an annual limitation in the event a company undergoes an "ownership change", generally defined as a greater than 50 percentage point change (by value) in our equity ownership by certain stockholders over a rolling three-year period. Our ability to utilize NOL carryforwards and certain other tax attributes to offset future taxable income or tax liabilities may be subject to limitations as a result of previous or future ownership changes. Similar rules may apply under state tax laws. If any of the above-described limitations were applicable, it could result in increased future income tax liability to us and our future cash flows could be adversely affected.

Our ability to maintain our competitive position depends on our ability to attract and retain highly qualified personnel.

Our future success depends on our ability to attract and retain our executive officers and other key employees. We may not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among companies in the medical device business and related industries, particularly in the Tucson, Arizona area, where we are headquartered. We may be required to spend significant time and expend significant financial resources in our employee recruitment and retention efforts. Many of the other medical device companies with whom we compete for qualified personnel have greater financial and other resources and different risk profiles than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than what we have to offer. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will impede significantly our ability to implement our business strategy and achieve our business objectives.

If we acquire other companies or businesses, we will be subject to risks that could hurt our business.

We may in the future acquire complementary businesses, products, or technologies. Any such acquisition may not produce the revenues, earnings, or business synergies that we anticipate, and any acquired business, product or technology might not perform as we expect. Our management could spend a significant amount of time, effort, and money on identifying, pursuing, and completing acquisitions. If we complete an acquisition, we may encounter significant difficulties and incur substantial expenses in integrating the operations and personnel of the acquired company into our operations. In particular, we may lose the services of key employees of the acquired company, and we may make changes in management that impair the acquired company's relationships with employees, vendors, and customers. Additionally, we may acquire development-stage companies that are not yet profitable and require continued investment, which could decrease our future earnings or increase our futures losses.

Any of these outcomes could prevent us from realizing the anticipated benefits of an acquisition. To pay for an acquisition, we might use stock or cash. Alternatively, we might borrow money from a bank or other lender. If we use stock, our stockholders would experience dilution of their ownership interests. If we use cash or debt financing, our financial liquidity would be reduced. Any acquisition could result in us recording significant amounts of goodwill or other intangible assets, some of which could result in significant quarterly amortization expenses. Moreover, if we determine during annual reviews or otherwise that an intangible asset has been impaired, we may need to write off some or all of its carrying value, resulting in large charges to expense. Amortization charges and write-downs or write-offs of intangibles would decrease our future earnings or increase our future losses.

Failure to protect our information technology infrastructure against cyber-based attacks, network security breaches, service interruptions, or data corruption could significantly disrupt our operations and adversely affect our business and operating results.

We rely on information technology and telephone networks and systems, including the Internet, to process and transmit sensitive electronic information and to manage or support a variety of business processes and activities, including sales, billing, customer service, procurement and supply chain, manufacturing, and distribution. We use enterprise information technology systems to record, process, and summarize financial information and results of operations for internal reporting purposes and to comply with regulatory financial reporting, legal, and tax requirements. Our information technology systems, some of which are managed by third parties, may be susceptible to damage, disruptions or shutdowns due to computer viruses, attacks by computer hackers, failures during the process of upgrading or replacing software, databases, or components thereof, power outages, hardware failures, telecommunication failures, user errors or catastrophic events. Despite the precautionary measures we have taken to prevent breakdowns in our information technology and telephone systems, if our systems suffer severe damage, disruption or shutdown and we are unable to effectively resolve the issues in a timely manner, our business and operating results, and our reputation, may suffer. Such security incidents may increase the risk of regulatory scrutiny, enforcement and civil litigation, and associated costs, fines, and judgements, including increased costs associated with investigating and remediation of our systems. Such costs may not be adequately covered by existing insurance.

Failure to protect the product and patient from cybersecurity risks associated with using the device could endanger patient safety and our ability to market the product.

Under the Protecting and Transforming Cyber Health Care Act of 2022 (the "PATCH Act"), all new medical device submissions will have to demonstrate that the medical device under review is safe and reliable in the face of cybersecurity threats. There are similar regulations for cybersecurity in the EU and elsewhere, one such example being MDCG 2019-16: Guidance on Cybersecurity for Medical Devices. We anticipate that our new products, including expanded indications of our current products and upgrades to our products, will be subject to review in accordance with the PATCH Act. Our quality and regulatory affairs routinely monitor the FDA and ISO standard organizations for new rules and guidance. The current C2 and Freedom Driver product designs do not rely on the internet, Bluetooth, or other connectivity application to communicate or operate the C2 or Freedom Drivers. The current C2 and Freedom Driver configurations' cybersecurity risks are managed using the software bill of materials to identify the software and connectivity tools used on the on-market design. The post-market surveillance monitors for issues in the field. The Freedom Driver has been reviewed by the FDA for a recent software update, with no concerns related to the current state of cybersecurity with the SynCardia TAH. Moving to future designs with more connectivity tools, like Bluetooth interacting with applications on patient cell phones, would require the manufacturer to demonstrate the risk controls put into place to prevent unauthorized access or control. Security features and design plans will be discussed with both the FDA and the EU Notified Bodies to ensure a robust and compliant cybersecurity plan is in place, with periodic safety updates and surveillance reporting, before the product is brought to market.

The demand for total artificial hearts depends on a variety of factors. In particular, medical advances, that would either provide a better alternative or replace the use of a SynCardia TAH, which would ultimately result in the demand for SynCardia TAHs to decrease and would adversely affect our business, prospects, financial condition, and operating results.

We believe that the present and projected demand for SynCardia TAHs depends on a variety of factors. These factors include, but are not limited to, (i) a rising trend in heart related disorders and failures, (ii) a market need for both a short-term and long-term alternative to heart transplants, (iii) industry competition within the total artificial heart space, and (iv) medical advances that could provide permanent solutions to the heart related problems currently addressed by total artificial hearts. Any development in the aforementioned factors could positively or adversely affect the demand for total artificial hearts and subsequently our business and operations. In particular, a variety of medical advances (e.g., new medications or new surgical techniques) could result in an alternative, more cost effective or less invasive, manner to address heart failure and heart disorders currently addressed by a total artificial heart. In the event that demand for total artificial hearts decreases, and consequently no market exists for SynCardia TAHs, our business, prospects, financial condition, and operating results would be severely and adversely affected.

Risks Related to Regulation of Our Industry

Our business is subject to extensive government regulations that could make it more expensive and time-consuming to introduce new or improved products.

Our products must comply with regulatory requirements imposed by the FDA, the U.S. Department of Health and Human Services, and other government agencies in the United States, and similar agencies in foreign jurisdictions. These requirements involve lengthy and detailed laboratory and clinical testing procedures, sampling activities, an extensive agency review process, and other costly and time-consuming procedures. It often takes several years to satisfy these requirements, depending on the complexity and novelty of the product. We are also subject to numerous additional licensing and regulatory requirements relating to safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. Some of the most important requirements include:

- FDA Regulations;
- EU CE mark requirements;
- Health Canada requirements;
- Regulations under the Drug Administration Law of China;
- Medical Device Quality Management System requirements; and
- Occupational Safety and Health Administration requirements.

Government regulations may impede our ability to conduct clinical studies and to manufacture existing and future products. Government regulations also could delay the marketing of new products for a considerable period of time and impose costly procedures on our activities. The FDA and other regulatory agencies may not approve any future products on a timely basis, if at all. Any delay in obtaining, or failure to obtain, such approvals could negatively impact the marketing of any future products and reduce our product revenues. Regulatory bodies may review our products once they are on the market and determine that they do not satisfy applicable regulatory requirements. Failure to comply with applicable requirements in the future may lead to EEA regulatory bodies ordering the suspension or withdrawal of our products from the EEA market, or as discussed below, notified bodies withdrawing certificates of conformity for devices and/or the underlying quality systems.

Even after receiving pre-market approval, our products remain subject to strict regulatory controls on manufacturing, marketing, and use. We may be forced to modify or recall a product after release in response to regulatory action or unanticipated difficulties encountered in general use. To satisfy U.S. FDA requirements, our facilities and associated quality systems are required to comply with FDA regulations, including but not limited to, 21 CFR 820 and we are subject to periodic inspections by the FDA or an FDA-accredited third party. To satisfy EU CE mark requirements our facilities and associated quality systems are required to comply with ISO 13485:2016, and we are subject to periodic audits by a third-party notified body. Our certificate of compliance with ISO 13485:2016 is subject to a three-year renewal period. Failure to maintain an adequate quality system could lead to interruption of the supply of our products until our quality system is deemed compliant. Any such action could have a material effect on the reputation of our products and on our business and financial position. Further, regulations may change, and any additional regulation could limit or restrict our ability to use any of our technologies, which could harm our business. We could also be subject to new international, federal, state or local regulations that could affect our research and development programs and harm our business in unforeseen ways.

The off-label use or misuse of our products may harm our image in the marketplace, result in injuries that lead to product liability suits, which could be damaging to our reputation and costly to our business, and/or result in costly investigations and regulatory agency sanctions or even civil or criminal penalties if we are deemed to have engaged in such promotion.

Medical devices may only be marketed for the indications for which they are approved. The products we currently market in the United States have been approved by the FDA for specific indications. For example, the SynCardia 70cc TAH is approved only for patients with a specific cardiac condition, and then only as a bridge to transplantation rather than for destination therapy. Our clinical support staff and marketing and sales force have been trained not to promote the products for uses outside of the approved indications for use, known as “off-label uses.” We cannot, however, prevent a physician from using the products in a manner determined by the physician, in the exercise of medical judgment, to be appropriate. There may be increased risk of injury to patients if physicians attempt to use our products off-label. Furthermore, the use of our products for indications other than those approved by the FDA may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients. If the FDA or other federal, state, or foreign enforcement authorities determine that we have promoted an off-label or other improper use, they could subject us to significant regulatory or enforcement actions, and this could significantly harm our reputation, business, and results of operations, and potentially subject us to civil and/or criminal penalties.

We are required to comply with medical device reporting, or MDR, requirements and must report certain malfunctions, deaths, and serious injuries associated with our products, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA MDR regulations (21 CFR 803), medical device manufacturers are required to submit information to the FDA when they receive a report or become aware that a device has or may have caused or contributed to a death or serious injury or has or may have a malfunction that would likely cause or contribute to death or serious injury if the malfunction were to recur. All manufacturers placing medical devices on the market in the EEA are legally bound to report any serious or potentially serious incidents involving devices they produce or sell (MEDDEV 2.12-1) to the regulatory agency in whose jurisdiction the incident occurred.

Malfunction of our products could result in future voluntary corrective actions, such as recalls, including corrections, or customer notifications, or agency action, such as inspection or enforcement actions. If malfunctions do occur, we may be unable to correct the malfunctions adequately or prevent further malfunctions, in which case we may need to cease manufacture and distribution of the affected products, initiate voluntary recalls, and redesign the products. Regulatory authorities may also take action against us, such as ordering recalls, imposing fines, or seizing the affected products. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, will distract management from operating our business, and may harm our reputation and financial results.

Our employees, independent contractors, principal investigators, consultants, commercial partners, and suppliers may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud, misconduct, or other improper activities. Misconduct by employees and independent contractors could include failure to comply with FDA regulations, failure to provide accurate information to the FDA, failure to comply with manufacturing standards we have established, failure to comply with federal and state healthcare fraud and abuse laws, failure to report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of business activities, including, but not limited to, research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee and independent contractor misconduct could also involve the improper use of individually identifiable patient information, including, without limitation, 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 employee and independent contractor misconduct, and any precautions we take to detect and prevent improper activities 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 be in compliance with such laws. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate.

We are subject to various federal, state, and foreign healthcare laws and regulations, and a finding of failure to comply with such laws and regulations could have a material adverse effect on our business.

Our operations are, and will continue to be, directly and indirectly affected by various federal, state, and foreign healthcare laws, including, but not limited to, those described below.

We are subject to the federal Anti-Kickback Statute (42 U.S. Code § 1320a-7b), which prohibits any person or entity from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, in cash or in kind, in return for or to induce the referring, ordering, leasing, purchasing or arranging for or recommending the referring, ordering, purchasing or leasing of any good, facility, item or service, for which payment may be made, in whole or in part, under federal healthcare programs, such as the Medicare and Medicaid programs.

We are also subject to the federal "Sunshine" (42 U.S. Code § 1320a-7h) law, which imposes a duty to track and report annually to CMS information related to certain payments and other "transfers of value" provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals and to report annually to CMS ownership and investment interests held by physicians, as defined above, and their immediate family members in the Company. We are also subject to similar foreign "sunshine" laws or codes of conduct, which vary country by country.

In addition, we are subject to the federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, persons, or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim to, or the knowing use of false records or statements to obtain payment from, or approval by, the federal government. Suits filed under the False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government and such individuals, commonly known as "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the False Claims Act (31 U.S. Code § 3729–3733), it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim.

We are also subject to the federal Health Insurance Portability and Accountability Act of 1996, or "HIPAA", statute, which, among other things, created federal criminal laws that prohibit knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any healthcare benefit program and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of or payment for health care benefits, items or services. Additionally, HIPAA imposes certain requirements relating to the privacy, security, and transmission of individually identifiable health information without appropriate authorization on entities subject to the law, such as health plans, clearinghouses, and healthcare providers and their business associates. Internationally, substantially every jurisdiction in which we operate has established its own data security and privacy legal framework with which we must comply, including the General Data Protection Regulation ("GDPR") and its national implementation in the member states of the European Union.

Many states have also adopted laws similar to each of the above federal laws, such as anti-kickback and false claims laws, which may be broader in scope and apply to items or services reimbursed by any third-party payor, including commercial insurers, as well as laws that restrict our marketing activities with health care professionals and entities, and require us to track and report payments and other transfers of value, including consulting fees, provided to healthcare professionals and entities. We are also subject to foreign fraud and abuse laws, which vary by country. We can provide no assurance that we are, or will remain in, compliance with the diverse requirements in all jurisdictions in which we do business. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us now or in the future, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, individual imprisonment, contractual damages, reputational harm, exclusion from governmental health care programs, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

The SynCardia TAH is currently approved in the U.S. for bridge to transplant indications. We plan to seek approval for long-term indications of 2 years, or more, in the future. If we do not receive that approval within the next year, we may need to undertake additional clinical trials, which could cost significant funds and adversely affect our business.

The SynCardia TAH is currently approved in the U.S. for bridge to transplant indications. We plan to seek approval for a long-term indication of 2 years, or more, which involves additional time and resources of management and our employees. If we do not receive that approval within the next year, we may need to undertake additional clinical trials to continue pursuing long-term indication, which could cost significant funds and adversely affect our business.

In Europe, we voluntarily withdrew our CE certificate under CE MDD in 2022 and terminated our relationship with our CE notified body to migrate from CE MDD to CE MDR, and failure to reinstate our CE certificate under CE MDR or could have a material adverse effect on our business.

The European Union Medical Device Directive ("CE MDD") and the European Union Medical Device Regulation ("CE MDR") are different regulatory frameworks that govern medical devices in the European Union. The CE MDR was adopted by the EU in 2017 and has a phased implementation process, with the first deadline for compliance occurring on May 26, 2021, and full implementation expected in 2027 for Class III devices. The CE MDR replaces the CE MDD and other directives that were previously in place. The CE MDR is a more comprehensive and stringent regulatory framework than the CE MDD. For example, the CE MDR places a greater emphasis on clinical evaluation, requiring more extensive clinical data and evidence to demonstrate the safety and efficacy of a medical device. The CE MDR also requires more stringent oversight and auditing of notified bodies, which are non-governmental organizations responsible for assessing the conformity of medical devices to the applicable regulatory regime.

While we are in the process of transitioning to the CE MDR, there can be no assurance that we will be able to comply with all of the new requirements in a timely manner or in a manner that will not be an undue burden on our management. Specifically, due to our change of control in 2021 and the installation of new management, our managers have identified significant issues with our regulatory compliance regime and are actively working to solve these issues. We cannot guarantee that we will be able to obtain CE MDR certification or that our regulatory compliance regime will meet the standards in the jurisdictions in which we operate, including the EU.

We and our predecessors have had clearance under CE MDD since 1998. In June 2022, we voluntarily withdrew our CE MDD certificate so that we could address post market surveillance reporting requirements, expected as part of compliance with CE MDR. We are in the advanced phase of working with a notified body, TUV SUD, to file a CE mark for our 70cc SynCardia TAH under MDR, and we expect to file our submission for clearance under CE MDR in 2027. Relevant EU authorities and authorized representatives will be notified as needed, and in accordance with applicable EU regulations.

Any delay or failure to obtain CE MDR certification, or mistakes made by management in the process of obtaining CE MDR certification, could have a material adverse effect on our business, financial condition, and results of operations. Investors are encouraged to inquire with our officers for more detailed information about our transition to CE MDR certification and our regulatory compliance regime.

Prior weaknesses in our CE MDD regulatory regime and compliance with developing European Union medical device regulations, including the CE MDD, may limit our ability to market or sell products in European markets or to introduce new products into European markets.

Prior weaknesses in our compliance with our post-market surveillance reporting obligations under CE MDD may limit our ability to market or sell products in European markets or to introduce new products into European markets. If we are unable to maintain compliance, we could lose potential market share in Europe resulting in adverse effects to our business and results of operations.

Risks Related to Our Intellectual Property

Many aspects of the SynCardia TAH are no longer protected by patents, and we may be unable to, in the long term, protect our products from competition through other means.

Our success depends in part on our ability to develop and protect intellectual property rights relating to key aspects of the technology employed in the SynCardia TAH, maintain our licenses to use intellectual property owned by third parties, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and other proprietary rights of third parties. Although the original inventions underlying the total artificial heart were previously protected by patents, such patents have now expired. Therefore, many aspects of the SynCardia TAH are no longer protected by any patents, and we rely primarily on a combination of non-patented proprietary technology, trade secrets, processes and procedures, technical knowledge and know-how accumulated or acquired since our inception. To the extent that aspects of the SynCardia TAH and/or any new products are protected by patents, if we attempt to enforce those patents against a competitor, we may not be successful in doing so. For example, the competitor may be found not to infringe our patents. Or, for example, although patents in the United States and other jurisdictions are presumed to be valid, our patents may be held to be unenforceable and/or invalid. To the extent that aspects of the SynCardia TAH and/or any new products are protected by trade secrets and/or know-how, if those trade secrets and/or know-how are misappropriated or become publicly known their value may be diminished or lost. Indeed, any of our intellectual property rights could be challenged, invalidated, circumvented, or misappropriated. We generally seek to protect this information by confidentiality, non-disclosure, and assignment of invention agreements with our employees, consultants, scientific advisors and third parties. These agreements may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may be disclosed to or otherwise become known or be independently developed by competitors. The intellectual property owned by us affords only limited protection and may not provide any commercial benefit. In addition, the laws of some of the countries in which our products are or may be sold may not protect our products and intellectual property to the same extent as U.S. laws, if at all. We may be unable to protect our rights in trade secrets and unpatented proprietary technology in these countries.

The medical device industry is characterized by extensive patents and other intellectual property litigation, and we could become subject to litigation that could be costly, result in the diversion of management's attention, require us to pay significant damages or royalty payments, or prevent us from marketing and selling our existing or future products.

Our success depends in part on not infringing the patents or violating the other proprietary rights of others. Significant litigation regarding patent rights occurs in the medical device industry, including among companies focused on artificial transplants. It is possible that U.S. and foreign patents and pending patent applications controlled by third parties may be alleged to cover the SynCardia TAH and related technologies, including our drivers. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit, or otherwise interfere with our ability to make, use, and sell our products.

We may receive, in the future, communications from patent holders alleging infringement of patents or other intellectual property rights, or misappropriation of trade secrets, or offering licenses to such intellectual property. At any given time, we may be involved as either a plaintiff or a defendant in patent infringement actions, the outcomes of which may not be known for prolonged periods of time.

For example, in July 2013, we and Medtronic entered into a License Agreement for non-patented intellectual property relating to the design and production of Med-Hall Valves, including as used in the SynCardia TAH. Although the License Agreement expired by its terms in July 2023, as of December 31, 2025, we owed Medtronic approximately $492,000 in outstanding royalty payments. Pursuant to the License Agreement, and as security for our obligations thereunder, we granted Medtronic a security interest of first priority in a non-exclusive license to use, sell, import, or distribute SynCardia TAHs that incorporate the Med-Hall Valves as a component part and to use certain other documentation, among other terms. So long as our balance under the License Agreement remains outstanding, Medtronic could foreclose on such security interest, and we could potentially face litigation in connection with Medtronic's recovery of the amounts owed under the License Agreement, which could materially harm our reputation, business, financial condition and results of operation. See the section entitled "*Business—Our Components*" for additional information regarding the License Agreement and the various components composing the SynCardia TAH.

The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technologies involved and the uncertainty of litigation (including the possibility of a finding or non-finding of patent infringement, validity, and/or enforceability) significantly increase the risks related to any patent litigation. Any potential intellectual property litigation also could force us to do one or more of the following:

- stop selling, making, or using products that use the disputed intellectual property;
- obtain a license from the intellectual property owner to continue selling, making, licensing, or using products, which license may require substantial royalty payments and may not be available on reasonable terms, or at all;
- incur significant legal expenses;
- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing;
- pay the attorney fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing; or
- redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive and/or infeasible.

If any of the foregoing occurs, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products, all of which could have a material adverse effect on our business, results of operations and financial condition. Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. Further, as the number of participants in the artificial heart industry grows, the possibility of intellectual property infringement claims against us increases.

In addition, we may indemnify our customers and international distributors with respect to infringement by our products of the proprietary rights of third parties. Third parties may assert infringement claims against our customers or distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or distributors, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers or distributors or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products.

If we cease our commercial ties or contractual arrangements with either Bimba or Heitek Automation, we will be required to source crucial components for the C2 and Freedom Driver from an alternative supplier, which could have a negative impact on our business and operations if one is not found.

If Bimba, a part of Norgren and the sole source supplier of components for our drivers, ceases business operations or terminates commercial ties with its distributor Heitek Automation, or with us, or if Heitek Automation ceases business operations or terminates commercial ties with us, we might not be able to procure components to produce the C2 and Freedom Drivers.

Bimba owns the drawing of and manufactures the Piston Cylinder Assembly (the "PCA") used in the assembly of the Freedom Driver. Bimba also manufactures the pneumatic manifold used in the Freedom Driver while Heitek Automation owns the drawings. Heitek Automation distributes the PCA and the pneumatic manifold, and we purchase both components from Heitek Automation. Bimba and Heitek are thus material for our continued success, and, if Bimba and/or Heitek Automation cease business operations or terminate commercial ties with us, we will have to source the component from alternative suppliers or develop it internally.

We currently do not have an agreement with either Bimba or Heitek Automation covering the supply of PCA or access to the drawings of PCA. We have an ongoing commercial relationship with Bimba and Heitek wherein we place orders through Heitek, the distributor for Bimba manufactured parts and assemblies, including the PCA for the Freedom Driver and the Pneumatic Manifold Assembly for the C2 Driver. There are no commercial agreements with Bimba and Heitek beyond the purchase orders that we place, and we depend on Bimba and Heitek for certain technical drawings. Additionally, on June 7, 2022, Heitek Automation and we entered into a purchase order, which covers the terms for purchasing the pneumatic manifold drawings for the C2 Driver. Under such purchase order, Heitek Automation credits $500 for every PCA that we purchase from Heitek Automation towards the cost of the C2 manifold drawings. When we have purchased a total of 400 PCA units totaling $200,000 worth of credits, Heitek Automation will transfer to us the C2 pneumatic manifold drawings. We can then use these drawings to make new C2 pneumatic manifold assemblies. In addition, we have started the development of the C3 Driver, which will not need this pneumatic manifold and is expected to be approved by the end of 2026. The regulatory approval processes of the FDA are lengthy, time-consuming and inherently unpredictable. There is no guarantee that we will receive regulatory approval on our expected timeline or at all, and approval may take longer than planned.

We may be subject to claims that we or our employees have inadvertently or intentionally used or disclosed trade secrets or other proprietary information of former employers of our employees.

We employ individuals who were previously employed at other medical device companies, including competitors or potential competitors. To the extent that the employees are involved in research areas that are similar to those in which they were involved with their former employers, we may be subject to claims that such employees have inadvertently or intentionally used or disclosed the alleged trade secrets or other proprietary information of the former employers. Litigation may be necessary to defend against such claims.

Risks Related to Ownership of Our Securities

Our share price may be volatile, and purchasers of our securities could incur substantial losses.

Our share price may be volatile. The securities markets in general, and the market for biotechnology and medical device companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. You may not be able to resell your shares at an attractive price due to a number of factors, including, but not limited to, the following:

- our ability to successfully commercialize, and realize revenues from sales of, the SynCardia TAH;
- the success of competitive products or technologies;
- results of clinical studies of the SynCardia TAH or other current or future products or those of our competitors;
- regulatory or legal developments in the U.S. and other countries, especially changes in laws or regulations applicable to our products;
- introductions and announcements of new products by us, our commercialization partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our products, clinical studies, manufacturing processes or sales and marketing terms;
- variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional products or planned products;
- developments concerning our collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;
- developments concerning our ability to bring our manufacturing processes to scale in a cost-effective manner;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain and maintain patent protection for our products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of health care payment systems;
- market conditions in the medical device and biotechnology sectors;
- actual or anticipated changes in earnings estimates or changes in securities analyst recommendations regarding common stock, other comparable companies or our industry generally;
- trading volume of common stock;
- our election to account for the Senior Secured note at fair value, as well as the classification of associated warrants as liabilities;
- guidance or projections, if any, that we provide to the public, any changes in this guidance or projections or our failure to meet this guidance or projections;
- sales of common stock by us or our stockholders;
- general economic and political conditions such as recessions, interest rates, fuel prices, trade wars, pandemics (such as COVID-19), currency fluctuations and acts of war or terrorism;
- the effects of natural disasters, terrorist attacks and the spread and/or abatement of infectious diseases, such as COVID-19, including with respect to potential operational disruptions, labor disruptions, increased costs, and impacts to demand related thereto; and
- the other risks described in this "*Risk Factors*" section.

These broad market and industry factors may harm the market price of common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could adversely affect our business, financial condition, results of operations and growth prospects.

Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements included in this Registration Statement for the fiscal year ended December 31, 2025.

The report from our independent registered public accounting firm for the years ended December 31, 2025, and 2024, includes an explanatory paragraph stating that we have significant working capital deficiency, and have incurred operating losses since inception. These conditions raise substantial doubt about our ability to continue as a going concern. We believe that our existing cash and cash equivalents as of December 31, 2025, and our anticipated expenditures and commitments for the next twelve months, will not enable us to fund our operating expenses and capital expenditure requirements for the twelve months from the date our financial statements were issued. Our recurring losses from operations since inception and required additional funding to finance our operations raise substantial doubt about our ability to continue as a going concern. These conditions could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise. There is no assurance that sufficient financing will be available when needed, or at all, to allow us to continue as a going concern. The perception that we may not be able to continue as a going concern may also make it more difficult to operate our business due to concerns about our ability to meet our contractual obligations.

If we are unable to secure additional capital, we may be required to curtail our clinical and research and development initiatives and take additional measures to reduce costs in order to conserve our cash in amounts sufficient to sustain operations and meet our obligations. These measures could cause significant delays in our clinical and regulatory efforts, which is critical to the realization of our business plan. The consolidated financial statements do not include any adjustments that may be necessary should we be unable to continue as a going concern. It is not possible for us to predict at this time the potential success of our business. The revenue and income potential of our proposed business and operations are currently unknown. If we cannot continue as a viable entity, you may lose some or all of your investment.

We are a "controlled company" within the meaning of the applicable rules of NYSE and, as a result, qualify for exemptions from certain corporate governance requirements. We rely on these exemptions while we search for candidates to serve as independent directors, and accordingly, our stockholders will not have the same protections afforded to stockholders of companies that are subject to such requirements.

Hunniwell Picard I, LLC controls a majority of the voting power of the outstanding common stock, and we are a "controlled company" within the meaning of applicable rules of NYSE American. Under these rules, a company of which more than 50% of the voting power for the election of directors is held by an individual, group or another company is a "controlled company" and may elect not to comply with certain corporate governance requirements, including the requirements:

- that a majority of the board consists of independent directors;
- for an annual performance evaluation of the nominating and corporate governance and compensation committees;
- that the controlled company has a nominating and corporate governance committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities; and
- that the controlled company has a compensation committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibility.

We rely on these exemptions while we search for candidates to serve as independent directors on the Board. As a result, our stockholders may not have the same protections afforded to stockholders of companies that are subject to all of the NYSE American corporate governance requirements.

We do not intend to pay cash dividends for the foreseeable future. As a result, your ability to achieve a return on your investment will depend on appreciation in the market price of our common stock.

We currently intend to retain our future earnings, if any, to finance the further development and expansion of our business and do not intend to pay cash dividends in the foreseeable future. Any future determination to pay dividends will be at the discretion of the Board and will depend on our financial condition, results of operations, capital requirements, restrictions contained in future agreements and financing instruments, business prospects and such other factors as the Board deems relevant. Accordingly, investors must for the foreseeable future rely on the market price of our common stock as the only way to realize any future gains on their investments, which may never occur.

Future issuances of common stock, or the perception that future issuances may occur, may cause the market price of common stock to decline, regardless of our operating performance.

Significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities, warrants or other equity securities in one or more transactions at prices and in a manner as determined from time to time. If we sell common stock, convertible securities, warrants, or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to existing stockholders, and new investors could gain rights, preferences, and privileges senior to the holders of common stock. Any issuance of additional securities in connection with investments or acquisitions may result in additional dilution. Our stockholders may be subject to significant dilution upon the occurrence of certain events. These conversions and any issuance of additional securities may result in additional dilution to our stockholders and increase the volatility of the trading price of our common stock.

The exercise of outstanding warrants and stock options, and the sale of common stock upon exercise thereof, may adversely affect the trading price of our securities.

As of the date of this report, we had (a) 7,009,346 shares of common stock issuable upon the exercise of warrants issued to an institutional investor in connection with our December 2025 Securities Purchase Agreement, with an exercise price of $2.675 per share and a term of five years; (b) 700,934 shares of common stock issuable upon the exercise of warrants issued to the placement agent in connection with our December 2025 Securities Purchase Agreement, with an exercise price of $2.675 per share and a term of five years; and (c) 7,643,147 shares of common stock issuable upon the exercise of outstanding stock options under our 2021 Equity Incentive Plan, as amended, with a weighted average exercise price of approximately $0.49 per share. In addition, we may issue up to an additional $35.0 million aggregate principal amount of senior secured notes in one or more subsequent closings under the Securities Purchase Agreement, together with corresponding additional warrants to purchase shares of our common stock. There can be no assurance that we will not issue additional warrants or other dilutive securities in subsequent closings or otherwise. For the life of the warrants and options, the holders have the opportunity to profit from a rise in the market price of our common stock without assuming the risk of ownership. The issuance of shares upon the exercise of outstanding securities will also dilute the ownership interests of our existing stockholders.

The availability of these shares for public resale, as well as any actual resales of these shares, could adversely affect the trading price of our common stock. We cannot predict the size of future issuances of our common stock pursuant to the exercise of outstanding options or warrants or conversion of other securities, or the effect, if any, that future issuances and sales of shares of our common stock may have on the market price of our common stock. Sales or distributions of substantial amounts of our common stock (including shares issued in connection with an acquisition), or the perception that such sales could occur, may cause the market price of our common stock to decline.

In addition, the common stock issuable upon exercise of outstanding warrants and stock options may represent overhang that may also adversely affect the market price of our common stock. Overhang occurs when there is a greater supply of a company's stock in the market than there is demand for that stock. When this happens the price of our stock will decrease, and any additional shares which stockholders attempt to sell in the market will only further decrease the share price. If the share volume of our common stock cannot absorb shares sold by holders of our outstanding warrants and stock options, then the value of our common stock will likely decrease.

The warrants issued in connection with our December 2025 Securities Purchase Agreement contain cashless exercise provisions that permit the holders thereof to exercise the warrants without paying cash to us in the event that there is no effective registration statement registering, or the prospectus contained therein is not available for, the resale of the warrant shares. In a cashless exercise, the holder receives a net number of warrant shares based on a formula that accounts for the difference between the then-current market price and the exercise price, which means that such warrants can be exercised without paying us any cash and instead with the holder netting the value of the exercise price against the value of the shares issuable upon exercise thereof. Under the terms of the warrants, warrant shares issued in a cashless exercise are acknowledged to take on the registered characteristics of the warrants being exercised in accordance with Section 3(a)(9) of the Securities Act. Accordingly, any shares of common stock issuable upon the cashless exercise of such warrants will likely be able to tack the holding period of the warrants for purposes of determining the applicable holding period under Rule 144 of the Securities Act, which may allow such shares to be resold into the public market sooner than would otherwise be the case.

Furthermore, the warrants contain anti-dilution adjustment provisions that could result in a reduction of the exercise price and a corresponding increase in the number of warrant shares issuable upon exercise thereof in the event we issue additional shares of common stock or common stock equivalents at a price below the applicable price set forth in the warrants. Any such adjustment could increase the total number of shares of common stock issuable upon exercise of the warrants, further exacerbating the dilutive impact on existing stockholders. In addition, the warrants provide that the Company may force the holders to exercise all or a portion of the warrants if the closing sale price of the common stock exceeds 200% of the exercise price on each of twenty consecutive trading days, subject to applicable conditions. Such forced exercises, if effected during periods in which no effective registration statement is available, would be conducted on a cashless basis, which could result in a significant number of shares being issued into the public market without any corresponding cash proceeds to the Company.

The influx of any of these shares into the public market could potentially have a negative effect on the trading price of our common stock.

We continue to incur increased costs and become subject to additional regulations and requirements as a result of becoming a public company, and our management will continue to be required to devote substantial time to compliance matters, which could lower our profits or make it more difficult to run our business. Compliance failures could adversely affect our business, results of operations, and financial condition.

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934 (the "Exchange Act"), the listing standards of the NYSE American, and other applicable securities rules and regulations. The requirements of these rules and regulations continue to increase our legal, accounting and financial compliance costs, make some activities more difficult, time-consuming and costly, and place significant strain on our personnel, systems and resources. As a result of the complexity involved in complying with the rules and regulations applicable to public companies, our management's attention may be diverted from other business concerns, which could harm our business, results of operations and financial condition. Although we have already hired additional employees to assist us in complying with these requirements, we may need to hire more employees in the future or engage outside consultants, which will increase our operating expenses. If we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions, and other regulatory action and potentially civil litigation.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs, and making some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We invest substantial resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from business operations to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

These laws and regulations could make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

As a result of disclosure of information in filings required of a public company, our business and financial condition will become more visible, which may result in an increased risk of threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business and results of operations could be harmed, and even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and harm our business, results of operations, and financial condition.

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

We are an emerging growth company ("EGC") as defined in Section 2(a) of the Securities Act, as modified by the JOBS Act. As an EGC we take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not EGCs, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in 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. Further, Section 102(b)(1) of the JOBS Act exempts EGCs from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a registration statement under the Securities Act 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 EGC, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparability of our financial statements with another public company which is neither an emerging growth company nor an EGC which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

Additionally, we are a smaller reporting company ("SRC") as defined in Item 10(f)(1) of Regulation S-K, which would allow us to take advantage of certain exemptions from disclosure requirements including exemption from compliance with the auditor attestation requirements of Section 404 and reduced disclosure obligations regarding executive compensation. We will remain a smaller reporting company until the last day of the fiscal year in which (i) the market value of the shares of our common stock held by non-affiliates exceeds $250 million as of the prior June 30, and (ii) our annual revenue exceeded $100 million during such completed fiscal year or the market value of the shares of common stock held by non-affiliates exceeds $700 million as of the prior June 30. 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. If some investors find our common stock less attractive as a result of EGC and SRC status, there may be a less active trading market for our common stock and our stock price may decline and/or become more volatile.

We could be subject to securities class action or derivative litigation.

In the past, securities class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Securities litigation brought against us following volatility in the price of common stock, regardless of the merit or ultimate results of such litigation, could result in substantial costs, which would hurt our financial condition and results of operations and divert management's attention and resources from our business. Additionally, securities class action lawsuits and derivative lawsuits are often brought against public companies that have entered into merger agreements. Even if the lawsuits are without merit, defending against these claims can result in substantial costs and divert management time and resources. An adverse judgment could result in monetary damages, which could have a negative impact on our liquidity and financial condition. Additionally, if a plaintiff is successful in obtaining an injunction, which may adversely affect our businesses, financial condition and results of operation.

Litigation Related to Trading of Our Securities

From time to time, we are subject to claims, investigations and other legal proceedings that could adversely affect our business, financial condition and results of operations. In February 2026, a lawsuit was filed against us alleging violations of the federal securities laws. Defending this matter, and any related or future securities litigation or regulatory proceedings, could result in substantial legal fees and other costs, significant diversion of management's attention and company resources, increased directors' and officers' liability insurance premiums or retentions, and potential indemnification obligations. For additional information, see "Item 3. Legal Proceedings."

Litigation or regulatory proceedings may result in unfavorable judgments or settlements requiring monetary damages, fines or other relief; the posting of bonds, letters of credit or similar instruments; and reputational harm, sanctions or other disciplinary actions. The outcome of such matters is inherently uncertain and could have a material adverse effect on our business, financial condition and results of operations.

If we are unable to implement and maintain effective internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of common stock may decrease.

We are in the process of improving our internal controls over financial reporting, which is time-consuming, costly and complicated. We have concluded that our internal control over financial reporting was not effective as of December 31, 2025, due to material weaknesses. We have begun remediation efforts, but we may not complete them on our expected timetable. Until remediated, these weaknesses increase the risk of errors in our financial statements, delayed SEC filings, or restatements, and we may be unable to assert, and our independent registered public accounting firm may be unable to attest that our internal control over financial reporting is effective under Section 404. Failure to remediate could result in stockholder litigation, regulatory inquiries or enforcement actions, and listing-exchange sanctions, and could increase our financing and insurance costs, any of which could negatively affect the trading price and liquidity of our common stock. We cannot provide assurances that, if remedied, there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future.

An active trading market may not develop or be sustained.

The market for our securities may be highly volatile or may decline regardless of our operating performance. An active public market for our securities may not develop or be sustained. We cannot predict the extent to which investor interest in us will lead to the development of an active trading market in common stock or how liquid that market might become. If an active market does not develop or is not sustained, or if we fail to satisfy the continued listing standards of the NYSE American for any reason and our securities are delisted, it may be difficult for you to sell your securities at the time you wish to sell them, at a price that is attractive to you, or at all. An inactive trading market may also impair our ability to both raise capital by selling shares of capital stock, attract and motivate employees through equity incentive awards and acquire other companies, products or technologies by using shares of capital stock as consideration.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our common stock share price and trading volume could decline.

The trading market for our common stock will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on us. If no securities or industry analysts commence coverage of us, the trading price for our common stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our share price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our share price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our share price and trading volume to decline.

Our Charter designates specific courts as the exclusive forum for substantially all stockholder litigation matters, which could limit the ability of our stockholders to obtain a favorable forum for disputes with us or our directors, officers or employees.

Our Charter requires, to the fullest extent permitted by law, that derivative actions brought in our name, actions against current or former directors, officers or other employees for breach of fiduciary duty, any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law ("DGCL"), the Charter or the Bylaws, or any action asserting a claim governed by the internal affairs doctrine of the State of Delaware, confer jurisdiction to the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware), unless we consent in writing to the selection of an alternative forum. This provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. The Charter also provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended. 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. This provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us and our directors, officers or other employees and may have the effect of discouraging lawsuits against our directors, officers and other employees. Furthermore, stockholders may be subject to increased costs to bring these claims, and the exclusive forum provision could have the effect of discouraging claims or limiting investors' ability to bring claims in a judicial forum that they find favorable.

In addition, the enforceability of similar exclusive forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with one or more actions or proceedings described above, a court could rule that this provision in the Proposed Charter is inapplicable or unenforceable. In March 2020, the Delaware Supreme Court issued a decision in Salzburg et al. v. Sciabacucchi which found that an exclusive forum provision providing for claims under the Securities Act to be brought in federal court is facially valid under Delaware law. We intend to enforce this provision, but we do not know whether courts in other jurisdictions will agree with this decision or enforce it. If a court were to find the exclusive forum provision contained in the 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 our business, prospects, financial condition and operating results.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Risk Management and Strategy

PMI's cybersecurity risk management process is designed to identify and assess internal and external cybersecurity threats and vulnerabilities to and within the Company's business and operations and to analyze and prioritize risks from cybersecurity threats to inform strategies and action plans aimed at mitigating and managing these risks.

PMI's cybersecurity program utilizes a variety of technical and process controls that are designed to identify, protect against, detect, respond to, and recover from cybersecurity threats, including:

- dedicated cybersecurity professionals who are responsible for analyzing cybersecurity threats, defining cybersecurity policy and requirements, implementing protections, and monitoring and responding to cybersecurity incidents;
- periodic cybersecurity awareness training for relevant employees and contractors on PMI policies and emerging cybersecurity threats, including phishing awareness training;
- internal and third party cybersecurity testing, including penetration testing of PMI's information systems and hardware;
- cybersecurity risk assessments for PMI's systems and applications;
- cybersecurity monitoring and response processes intended to identify, assess, escalate, investigate, contain, and remediate incidents; and
- disaster recovery plans.

In addition, risks from cybersecurity threats are integrated into the Company's enterprise risk management ("ERM") program. The ERM program establishes a risk management framework that seeks to identify and assess risks that could materially impact PMI's business and operations.

As part of PMI's cybersecurity program, the Company regularly engages with assessors and third-party advisers to perform various services, including (i) assessments of process design and operating effectiveness; (ii) security testing and attestation; (iii) periodic assessment of enterprise cybersecurity maturity; (iv) industry benchmarking; and (v) thought leadership related to continuous improvement of processes, training, technology, and data.

PMI's cybersecurity program also aims to identify and assess cybersecurity risks associated with its use of third-party service providers with access to the Company's systems and data, as well as such third-party service providers' adherence to certain cybersecurity standards and processes. As appropriate, PMI requires such third-party service providers to agree to be subject to cybersecurity evaluations by the Company.

A discussion of how PMI's business, results of operations, and financial condition could be materially adversely affected by risks from cybersecurity threats is contained in Item 1A. Risk Factors under "*Picard depends on sophisticated information systems and maintains protected personal data, and a significant cybersecurity incident or other disruption affecting these information systems or protected personal data could have a material adverse effect on Picard's business, financial condition and results of operations."*

Governance

The Board has risk oversight responsibility for PMI, which it administers directly and with assistance from its committees. Throughout the year, the Board and its committees engage with management to discuss a wide range of enterprise risks.

The audit committee assists the Board in fulfilling its oversight responsibilities with respect to ERM, including risks from cybersecurity threats, and the steps management has taken to monitor and mitigate those risks. The audit committee receives reports semiannually from the Chief Finance Officer on the Company's cybersecurity strategy and program. In addition, the audit committee conducts an annual review of the ERM process, including the program structure, risk assessment, and risk mitigation.

ITEM 2. PROPERTIES

As of December 31, 2025, the Company does not own any real property. The Company’s offices and primary operating facility are located at 1992 E. Silverlake Road, Tucson, Arizona, which the Company leases.

The facility consists of approximately 34,034 square feet and serves as the Company’s corporate headquarters and primary operating location, supporting manufacturing operations, research and development activities, quality and regulatory functions, and administrative offices. The Company believes that this facility is suitable and adequate for its current operations and expected near-term growth. The lease for the facility expires on January 31, 2027.

The Company’s manufacturing and quality operations conducted at this facility are subject to regulatory oversight applicable to medical device manufacturers, including compliance with the FDA’s Quality System Regulation and other applicable federal, state, and local regulatory requirements. Operations at this facility are also subject to standard environmental and safety regulations. The Company is not aware of any material environmental issues affecting the use of this facility.

The Company does not own or lease any properties outside of the United States, and the facility described above represents the primary location from which the Company conducts its operations.

ITEM 3. LEGAL PROCEEDINGS

PMI is subject from time to time to various claims, lawsuits, and other legal and administrative proceedings (including those described below). Some of these claims, lawsuits and other proceedings may involve highly complex issues that are subject to substantial uncertainties and could result in damages, fines and penalties, non-monetary sanctions, or other relief. The Company intends to recognize provisions for claims or pending litigation when it determines that an unfavorable outcome is probable, and the amount of loss can be reasonably estimated. Due to the inherent uncertain nature of litigation, the ultimate outcome or actual cost of settlement may materially vary from estimates. For additional information, see “Risk Factors – Litigation Related to Trading of Our Securities.”

On February 2, 2026, a putative securities class action captioned *Louie v. Picard Medical, Inc., et al.*, Case No. 5:26-CV-01024, was filed in the United States District Court for the Northern District of California, San Jose Division. The complaint names PMI as a defendant, along with certain of its current and former officers and directors and other third parties, and purports to assert claims under Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder. The putative class period alleged is from September 2, 2025, through October 31, 2025. The complaint generally alleges, among other things, that defendants made materially false or misleading statements or omissions in connection with the Company’s initial public offering and subsequent public disclosures, and that the Company’s securities were affected by social-media-based promotion activity. The complaint seeks unspecified compensatory damages, attorneys’ fees and costs, and other relief.

PMI believes the claims against the Company and its officers and directors are without merit and intends to defend this matter vigorously. Given the early stage of the proceedings, the outcome is inherently uncertain, PMI cannot reasonably estimate a possible loss or range of loss. The Company will continue to evaluate developments in this litigation each reporting period and record an accrual for loss contingencies when, and to the extent, required by applicable accounting standards.

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

On September 2, 2025, PMI closed an IPO and its common stock began trading on NYSE American under the symbol "PMI." Prior to that time, there was no public market for our common stock.

Stockholder Information

There were 26 stockholders of record of PMI common stock as of March 23, 2026.

Dividends

PMI has not and does not anticipate declaring or paying any cash dividends to holders of its common stock in the foreseeable future. The Company currently intends to retain all available funds and any future earnings to finance the growth of our business. If PMI decides to pay dividends in the future, the declaration and payment of such dividends will be at the sole discretion of its Board and may be discontinued at any time.

Use of Proceeds

On August 12, 2025, PMI's Registration Statement on Form S-1 (File No. 333-286295) was declared effective by the SEC for the Company's IPO pursuant to which PMI registered and sold an aggregate of 4,887,500 shares of our common stock (including 637,500 shares sold to WestPark Capital, Inc., as representative of the underwriters, pursuant to the underwriters' over-allotment option) at a price of $4.00 per share. The offering commenced on August 29, 2025, and closed on September 2,2025, and did not terminate before all of the securities registered in the registration statement were sold. Transaction costs related to the issuances described above amounted to $4.35 million. The resulting net proceeds were approximately $15.2 million.

PMI used the net proceeds from the IPO to support operations and expansion. Proceeds were designated for research and development activities of the Company's fully implantable system, including feasibility animal trials, and other design and development activities. PMI also grew its sales, marketing, and distribution capabilities, paid vendors and service providers, and addressed operating expenses. Further, PMI utilized proceeds for repayment of obligations under Senior Secured Notes consisting of a series of related party notes and related party working capital loans issued between June of 2024 and August of 2025 with a total principal plus interest amount of approximately $8.2 million. For more information on the Senior Secured Notes, see Note 14 to the Consolidated Financial Statements. PMI also invested net proceeds in short- and intermediate-term, interest-bearing investment-grade instruments, certificates of deposit, and/or direct or guaranteed obligations of the U.S. government.

Unregistered sales of equity securities.

None.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with the financial statements and accompanying notes and the information contained in other sections of this Annual Report, particularly under the headings "*Risk Factors*" *and* "*Business.*" *It contains forward-looking statements that involve risks and uncertainties, and is based on the beliefs of our management, as well as assumptions made by, and information currently available to, our management. Our actual results could differ materially from those anticipated by our management in these forward-looking statements as a result of various factors, including those discussed below and in this filing, particularly under the heading* "*Risk Factors.*"

Overview

We are a holding company that is the sole owner of SynCardia. The business of our company is carried out by SynCardia, and thus most of the information set forth in this Annual Report relates to the business of SynCardia.

Our long-term mission is to build a portfolio of medical technology companies active in the cardiovascular space. We intend to achieve this goal by acquiring, developing, or by in-licensing of promising technologies or assets with a focus on approved devices, or devices close to being approved. We manufacture and sell an FDA approved implantable Total Artificial Heart designed to temporarily replace the full function of a human heart in patients suffering from advanced heart failure. Our product development roadmap is focused on developing, manufacturing, and commercializing successive generations of the SynCardia TAH to further improve clinical outcomes, usability, and patient quality of life.

The SynCardia TAH is the only total artificial heart that is approved and commercially available in the United States as a bridge to heart transplant, and it is also available in a number of other countries around the world under special exemptions or compassionate use. The system is comprised of an implant which is surgically placed inside the human body, and which is powered by an external driver. The SynCardia TAH replaces the functionality of both the left and right ventricles of the heart as well as all four heart valves. Almost all other commercially available devices that claim to be an "artificial heart" are VADs which do not replace the heart. To date, over 2,100 SynCardia TAHs have been implanted in 27 countries globally, including the US, France, Germany, Australia, United Kingdom, Canada, Italy, Turkey, Kuwait, and Saudi Arabia.

Components of Our Results of Operations

Revenues

We generate revenue from the sale of our total artificial heart for patients, rental of Freedom drivers, and from training and certification services, which are required before the first time a transplant center may deploy a SynCardia TAH. Revenue includes sales and services to appropriate patient aftercare ("**Centers**") located in the United States as well as Centers domiciled in foreign countries.

Cost of Revenues

Cost of revenues includes product costs, labor, overhead, inbound freight, and other product-related costs including excess inventory and obsolescence charges.

Research and Development Costs

Included in research and development costs are wages, stock-based compensation and benefits of employees performing research and development, and other operational costs related to our research and development activities, including facility-related expenses, allocation of corporate costs, and external costs of outside contractors. While research and development supply expense are isolated by product, personnel are not. Research and Development personnel do not work on current product production, therefore labor expense is not isolated by product.

Selling, General and Administrative

Selling, general and administrative expenses consist primarily of personnel-related expenses for executives, human resources, finance, and other general and administrative employees, including salary and stock-based compensation, professional services costs and allocation of facility and overhead costs.

We anticipate that our general and administrative expenses will increase in the future in connection with one-time costs of becoming a public company as well as ongoing costs of operating as a public company, including expanding headcount and increased fees for directors and outside advisors. We expect to incur significant costs to comply with corporate governance, internal controls, and similar requirements applicable to public companies. Additionally, we expect to incur increased costs associated with establishing sales, marketing, and revenue growth.

Other Income (Expenses), net

Other income (expenses), net, primarily consists of financing charges, interest expense, derivative loss, change in fair value of senior secured note, warrants, and various immaterial income and expense items.

Provision for Income Taxes

We are subject to U.S. federal and state income taxes and foreign taxes based on enacted rates, as adjusted for allowable credits, deductions, uncertain tax positions, changes in deferred tax assets and liabilities and changes in tax laws.

Provision for income taxes primarily relates to state income taxes.

Results of Operations

Comparison of Year Ended December 31, 2025 and 2024

The following table summarizes our results of operations (in thousands, except percentages):

	Year ended December 31		Change	
	2025	2024	$	%
Revenues, net:				
Products	$ 4,746	$ 4,254	$ 492	12%
Rentals	194	137	57	42%
Total revenues	4,940	4,391	549	13%
Cost of revenues:				
Products	3,432	2,494	938	38%
Rentals	1,712	2,009	(297)	(15)%
Total cost of revenues	5,144	4,503	641	14%
Gross loss	(204)	(112)	(92)	82%
Operating expenses:				
Research and development costs	3,049	3,380	(331)	(10)%
Selling, general and administrative expenses	10,004	10,220	(216)	(2)%
Total operating expenses	13,053	13,600	(547)	(4)%
Operating loss	(13,257)	(13,712)	455	(3)%
Other expense:				
Derivative loss	(7,040)	(4,291)	(2,749)	64%
Interest expense	(5,393)	(3,067)	(2,326)	76%
Change in fair value of senior secured note payable and warrant liabilities	1,017	-	1,017	100%
Financing charges	(2,294)	-	(2,294)	100%
Total other expense, net	(13,710)	(7,358)	(6,352)	86%
Loss before income tax provision	(26,967)	(21,070)	(5,897)	28%
Provision (benefit) for income taxes	35	(15)	50	(333)%
Net loss	$ (27,002)	$ (21,055)	$ (5,947)	28%

Revenues

Total revenues increased by $0.5 million or 13% for the year ended December 31, 2025, as compared to the year ended December 31, 2024. The increase is due to an increase in USA sales of $1.0 million, offset by a decrease in the rest of the world sales of $0.1 million, and by a decrease in Europe sales of $0.4 million.

Cost of Revenues

Total cost of revenues increased by $0.6 million, or 14%, for the year ended December 31, 2025, as compared to the year ended December 31, 2024. The increase in cost of revenues for the year ended December 31, 2025, was mainly due to product cost increase of $937,000, offset with decrease of driver service cost of $280,000.

The cost of products pertains to the various components of the SynCardia TAH system. These may include, but are not limited to, the following: (i) TAH Kit 70cc, (ii) TAH Kit 50cc, (iii) C2 driver and handpump ("C2 driver"), (iv) Companion Cart Hospital ("Cart"), and (v) Companion Caddy ("Caddy"). Product revenue is earned upon the sale of a TAH Kit 70cc or a TAH Kit 50cc to the hospital. The C2 driver, Cart, and Caddy are equipment used within the hospital to operate and calibrate the TAH and do not represent a distinct performance obligation, as the customer cannot benefit from the TAH Kit without the C2 driver, Cart, or Caddy. This equipment is not rented but is provided free of charge to the hospital. The C2 driver, caddy and cart remain in the hospital and are used for multiple patients before maintenance is required. The C2 driver maintenance costs, as well as labor costs of the C2 driver technicians, are included in the Cost of revenues: Products and are expensed as incurred.

The rental costs are mainly related to machine maintenance to maintain reliability and is incurred on a time schedule that is dependent on the amount of time the driver is actually used. The driver may be used for multiple patients before maintenance service is required. Rental revenue is earned over the period of usage when a patient is discharged from a hospital with a Freedom Driver. Rental Revenue is recognized when it becomes likely that we will receive payment. The timing differences between usage and payment receipt generally do not correlate to the cost of service maintenance, resulting in negative gross margins. Our total cost of revenue as a percentage of total sales for the year ended December 31, 2025, and 2024 was 104% and 103%, respectively.

Research and Development Expenses

Research and development expenses decreased by $0.3 million, or 10%, for the year ended December 31, 2025, as compared to the year ended December 31, 2024. The decrease was primarily attributable to reduced activity and phase scheduling in the new product research. We do not track expenses by product candidate. While research and development supply expense are isolated by product, personnel are not. Research and Development personnel do not work on current product production, therefore labor expense is not isolated by product.

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased by $0.2 million, or 2%, for the year ended December 31, 2025, as compared to the year ended December 31, 2024. The decrease was primarily attributable to a reduction of $0.2 million in salaries.

Total Other Expenses

Total other expenses increased by $6.4 million, or 86%, for the year ended December 31, 2025, as compared to the year ended December 31, 2024. The increase was attributed to interest expense and derivative (non-cash) accounting for the issued convertible note, warrants issued, financing costs associated issuance of the senior secured note.

Liquidity and Capital Resources

Funding Requirements and Going Concern

We have incurred operating losses since inception, including net losses of $27.0 million and $21.1 million for the years ended December 31, 2025 and 2024, respectively. While we already have FDA-approved products that are generating commercial revenue, the business needs to scale up in order to offset a large, fixed overhead cost from our site in Tucson, AZ. Moreover, we are also investing heavily in the development of updates and next generation devices and therefore expect to continue to incur significant expenses and operating losses for the foreseeable future. Furthermore, we expect to incur additional expenses with transitioning to, and operating as, a public company.

Until such a time as we can sufficiently grow product and rental revenue, we expect to finance our cash needs through a combination of equity and debt financing, or other capital sources, including with related parties. To the extent that we raise additional capital through the future sale of equity or debt, the ownership interest of our stockholders will be diluted. The terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. If we are unable to raise sufficient funds through equity or debt financing, we may be required to delay, limit, curtail or terminate our product development or future growth efforts. Additionally, we may never become profitable, or if we do, may not be able to sustain profitability on a recurring basis.

We have considered that our long-term operations anticipate continuing net losses and the need for potential debt or equity financing. However, there can be no assurances that additional funding or other sources of capital will be available on terms acceptable to us, or at all. If additional capital is not secured when required, we may need to delay or curtail our operations until such funding is received. If we cannot expand our operations or otherwise capitalize on our business opportunities because we lack sufficient capital, our business, financial condition and results of operations could be materially adversely affected. As a result of these conditions, we have concluded that there is substantial doubt over our ability to continue as a going concern as conditions and events, considered in the aggregate, indicate it is probable we will be unable to meet our obligations as they become due within one year after the date that the consolidated financial statements included in this filing are issued. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and settlement of liabilities and commitments in the normal course of business. The financial information and consolidated financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to increase sales and raise additional funds and financing including through 2026 based on our current business plan, and expectations and assumptions considering current macroeconomic conditions. Our future capital requirements and the adequacy of available funds will depend on many factors, including those set forth herein, in the section of our Annual Report, entitled “Risk Factors."

Sources of Liquidity

To date, we have funded our operations primarily with the proceeds from the Initial Public Offering ("IPO"), consummated on September 2, 2025, Series A-1 Preferred Stock, loans from related parties, debt financing, warrants and convertible notes issued to related parties and other investors. See also Part II. Item 5–Use of Proceeds, above.

Cash Flows

The following table shows a summary of our cash flows (in thousands):

	Year Ended December 31,	
	2025	**2024**
Net cash used in operating activities	$ (15,673)	$ (11,874)
Net cash used in investing activities	$ -	$ -
Net cash provided by financing activities	$ 27,078	$ 11,741

Net cash used in operating activities

Net cash used in operating activities of $15.7 million for the year ended December 31, 2025, was primarily attributable to Picard’s net loss of $27.0 million after offsetting non-cash expenses related to depreciation and amortization, stock-based compensation, derivative loss, change in fair value of senior secured note and warrant liabilities, financing charges from issuance of senior secured note, inventory provision, and amortization of discount on debt issued and amortization of right of use assets totaling approximately $14.5 million and a decrease in accounts payable of $3.2 million.

Net cash used in operating activities of $11.9 million for the year ended December 31, 2024, was primarily attributable to Picard’s net loss of $21.1 million after offsetting accounts payable totaling approximately $2.2 million and non-cash expenses related to depreciation and amortization, stock-based compensation, and derivative liabilities totaling approximately $7.8 million.

Net cash used in investing activities

There was no net cash used in investing activities for the years ended December 31, 2025 and 2024.

Net cash provided by financing activities

Net cash provided by financing activities was $27.1 million for the year ended December 31, 2025, which primarily consisted of net proceeds of $2.0 million from the issuance of convertible notes, $17.4 million from the issuance and subscriptions of common stock in connection with our IPO, $12.0 million net proceeds from senior secured note and warrants, and offset by $4.3 million net payments of related party loans.

Net cash provided by financing activities was $11.7 million for the year ended December 31, 2024, which primarily consisted of net proceeds of $3.7 million from the issuance of convertible notes and $8.1 million net of related party loans.

Contractual obligations and Commitments

In February 2015, we entered into an operating lease agreement for office space located in Tucson, Arizona with a lease term of approximately five years. Rent payments commenced in February 2015. The lease terminated on December 31, 2021, and was subsequently renewed from February 1, 2022, until January 31, 2027. The first 5.5 months of the renewed term were rent-free and rent payments escalate annually by 2.5%.

Off-Balance Sheet Arrangements

As of December 31, 2025 and 2024, we had no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Critical Accounting Policies and Estimates

Management's discussion and analysis of financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires our management to make judgments, assumptions and estimates that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. We evaluate these judgments, assumptions and estimates for changes that would affect the reported amounts. These estimates are based on management's historical industry experience and on various other judgments and assumptions that are believed to be reasonable under the circumstances. Actual results may differ from these judgments, assumptions and estimates. A discussion of recent accounting pronouncements and our significant accounting policies can be found in Note 2 "Summary of Significant Accounting Policies" to our consolidated financial statements included in this annual report. None of those policies are deemed to be critical accounting policies nor critical accounting estimates.

Emerging Growth Company and Smaller Reporting Company Status

Section 107 of the JOBS Act provides that an emerging growthy company can take advantage of the extended transition period provided in Section 13(a) of the Exchange Act for complying with new or revised accounting standards applicable to public companies. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of this extended transition period. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates for such new or revised standards. We may elect to comply with public company effective dates at any time, and such election would be irrevocable pursuant to Section 107(b) of the JOBS Act.

We are also a "smaller reporting company" as defined in Regulation S-K under the Securities Act and may elect to take advantage of certain of the scaled disclosures available to smaller reporting companies. We may be a smaller reporting company even after we are no longer an "emerging growth company."

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a "smaller reporting company" as defined by Rule 12b-2 of the Exchange Act, and pursuant to Item 305 of Regulation S-K, we are not required to disclose information under this section.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

December 31, 2025 and 2024

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
Picard Medical, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Picard Medical, Inc and its subsidiaries (collectively, the "Company") as of December 31, 2025, and 2024, and the related consolidated statements of operations and comprehensive loss, changes in temporary equity and stockholders' equity (deficit), and cash flows for the years then ended, 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, 2025 and 2024, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Matter

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 that raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to 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 the Company's 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/ MaloneBailey, LLP
www.malonebailey.com
We have served as the Company's auditor since 2022.
Houston, Texas
March 27, 2026

PICARD MEDICAL, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share data)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 7,451	$ 96
Restricted cash	4,000	-
Accounts receivable	623	513
Inventories, net	7,303	8,115
Due from related parties	134	112
Prepaid expenses and other current assets	1,215	955
Total current assets	20,726	9,791
Property and equipment, net	183	227
Finance lease right-of-use assets, net	152	177
Operating lease right-of-use assets, net	363	700
Intangible assets, net	509	596
Goodwill	615	615
Total assets	$ 22,548	$ 12,106
Liabilities, Temporary Equity and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 2,079	$ 5,293
Current portion of finance lease liability	77	63
Current portion of operating lease liability	386	371
Loans from related parties	1,000	5,148
Convertible notes payable, net	-	14,828
Senior secured note	5,448	-
Derivative liability	-	6,759
Warrant liabilities	7,842	-
Accrued interest	6	761
Other accrued liabilities	1,857	2,102
Total current liabilities	18,695	35,325
Finance lease liability, net of current portion	30	96
Operating lease liability, net of current portion	34	421
Total liabilities	18,759	35,842
Commitments and contingencies (Note 7)		
Temporary equity:		
Preferred stock, $0.0001 par value; 30,000,000 shares authorized; 0 and 18,406,857 Series A-1 issued and outstanding as of December 31, 2025 and 2024, respectively; liquidation value $0 and $25,405 as of December 31, 2025 and 2024, respectively	-	20,265
Stockholders' deficit:		
Common stock, $0.0001 par value; 150,000,000 shares authorized; 73,701,176 and 9,286,235 shares issued as of December 31, 2025 and 2024, respectively, of which 73,701,176 and 7,943,585 are outstanding as of December 31, 2025 and 2024, respectively	7	1
Additional paid-in capital	80,397	5,561
Accumulated other comprehensive income	228	278
Accumulated deficit	(76,843)	(49,841)
Stockholders' equity (deficit)	3,789	(44,001)
Total liabilities, temporary equity and stockholders' equity (deficit)	$ 22,548	$ 12,106

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

PICARD MEDICAL, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)

	Year ended December 31, 2025	2024
Revenues, net:		
Products	$ 4,746	$ 4,254
Rentals	194	137
Total revenues	4,940	4,391
Cost of revenues:		
Products	3,432	2,494
Rentals	1,712	2,009
Total cost of revenues	5,144	4,503
Gross loss	(204)	(112)
Operating expenses:		
Research and development	3,049	3,380
Selling, general and administrative	10,004	10,220
Total operating expenses	13,053	13,600
Operating loss	(13,257)	(13,712)
Other income and (expense):		
Derivative loss	(7,040)	(4,291)
Interest expense	(5,393)	(3,067)
Change in fair values of senior secured note and warrant liabilities	1,017	-
Financing charges	(2,294)	-
Other expense, net	(13,710)	(7,358)
Loss before income taxes	(26,967)	(21,070)
Provision (benefit) for income taxes	35	(15)
Net loss	(27,002)	(21,055)
Undeclared Series A-1 preferred dividends	-	(2,682)
Net loss attributable to common stockholders	$ (27,002)	$ (23,737)
Net loss per share—basic and diluted	$ (0.75)	$ (2.99)
Weighted average common shares outstanding—basic and diluted	36,233,084	7,943,585
Comprehensive Loss:		
Net loss	$ (27,002)	$ (21,055)
Foreign currency translation adjustments, net of tax	(50)	(15)
Comprehensive loss	$ (27,052)	$ (21,070)

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

PICARD MEDICAL, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN TEMPORARY EQUITY AND STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands, except share data)

	Series A-1 Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balances as of December 31, 2024	18,406,857	$ 20,265	9,286,235	$ 1	$ 5,561	$ (49,841)	$ 278	$ (44,001)
Common Stock issuance - IPO, net of offering costs	—	—	4,887,500	—	15,209	—	—	15,209
Common Stock issued for cash	—	—	1,616,312	—	2,235	—	—	2,235
Common Stock cancellation	—	—	(1,342,650)	—	—	—	—	—
Common Stock issued for conversion of Convertible Notes	—	—	19,634,860	2	36,489	—	—	36,491
Preferred Stock Conversion to Common Stock	(18,406,857)	(20,265)	39,618,919	4	20,261	—	—	20,265
Stock-based compensation	—	—	—	—	754	—	—	754
Write off of related party note receivable	—	—	—	—	(112)	—	—	(112)
Net loss	—	—	—	—	—	(27,002)	—	(27,002)
Translation adjustment	—	—	—	—	—	—	(50)	(50)
Balances as of December 31, 2025	—	$ —	73,701,176	$ 7	$ 80,397	$ (76,843)	$ 228	$ 3,789

	Series A-1 Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balances as of December 31, 2023	18,406,857	$ 20,265	7,943,585	$ 1	$ 4,675	$ (28,786)	$ 293	$ (23,817)
Stock-based compensation	—	—	—	—	886	—	—	886
Net loss	—	—	—	—	—	(21,055)	—	(21,055)
Translation adjustment	—	—	—	—	—	—	(15)	(15)
Stock-based compensation - Unicorn	—	—	1,342,650	—	—	—	—	—
Balances as of December 31, 2024	18,406,857	$ 20,265	9,286,235	$ 1	$ 5,561	$ (49,841)	$ 278	$ (44,001)

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

PICARD MEDICAL, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year ended December 31, 2025	2024
Cash flows from operating activities:		
Net loss	$ (27,002)	$ (21,055)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	163	226
Amortization of right of use asset	349	318
Amortization of discount on debt issued	4,525	2,389
Derivative loss	7,040	4,291
Change in fair values of senior secured note and warrant liabilities	(1,017)	-
Financing charges from issuance of senior secured note	2,294	-
Provision for excess and obsolete inventory	423	108
Stock-based compensation	754	886
Changes in operating assets and liabilities:		
Accounts receivable	(120)	116
Inventories	390	(1,330)
Prepaid expenses and other assets	(250)	(72)
Accounts payable	(3,211)	2,210
Accrued expenses and other liabilities	361	350
Operating lease obligation	(372)	(311)
Net cash used in operating activities	(15,673)	(11,874)
Cash flows from investing activities:	-	-
Cash flows from financing activities:		
Proceeds from loans from related parties	3,909	9,419
Payments to loans from related parties	(8,190)	(1,322)
Proceeds from notes payable	13,500	-
Financing costs paid	(1,488)	-
Proceeds from issuance of convertible notes	2,000	3,700
Repayment of convertible notes	(25)	-
Proceeds from issuance of Common Stock	15,209	-
Proceeds from subscription of Common Stock	2,235	-
Repayment of finance lease obligations	(72)	(56)
Net cash provided by financing activities	27,078	11,741
Effect of exchange rate changes on cash and cash equivalents	(50)	(15)
Net increase (decrease) in cash, cash equivalents and restricted cash	11,355	(148)
Cash, cash equivalents and restricted cash at beginning of the period	96	244
Cash, cash equivalents and restricted cash at end of the period	$ 11,451	$ 96
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 259	$ 1
Cash paid for income taxes	$ 4	$ -
Non-cash investing and financing activities:		
Right of use assets acquired under finance leases	$ 19	$ 203
Write-off of related party receivable	$ 112	$ -
Preferred stock conversion to common stock	$ 20,265	$ -
Right of use assets acquired under operating leases	$ -	$ 43
Reclassification of plant, property and equipment from right of use assets acquired under operating leases	$ 32	$ -
Interest added to principal on convertible notes	$ -	$ 56
Derivative liability recognized on issuance of convertible notes	$ 4,447	$ 2,468
Conversion of convertible note and accrued interest to common stock	$ 18,245	$ -
Derecognition of derivative liability upon conversion of convertible notes	$ 18,246	$ -
Cash, cash equivalents and restricted cash at end of the period		
Cash and cash equivalents	$ 7,451	$ 96
Restricted cash	4,000	-
Cash, cash equivalents and restricted cash at end of the period	$ 11,451	$ 96

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

1. DESCRIPTION OF BUSINESS, BASIS OF PRESENTATION AND MANAGEMENT'S PLAN

Description of Business

Picard Systems, Inc. was originally incorporated in the state of Delaware on April 8, 2021, for the purpose of investing in and acquiring medical device companies, including SynCardia Systems, LLC ("SynCardia") and its fully consolidated subsidiaries SynCardia Systems Europe, GmbH ("SynCardia GmbH") and SynCardia Systems Australia Pty Ltd.. On September 27, 2021, Picard Systems, Inc. acquired all of the authorized and outstanding membership units of SynCardia and it changed its name to Picard Medical, Inc. ("PMI", or collectively, the "Company").

The Company is engaged in the business of designing, manufacturing, production, supply, marketing and sale of medical device products, including the SynCardia total artificial heart for patients ("SynCardia TAH"). The SynCardia TAH is an implantable system designed to assume the full function of a failed human heart in patients suffering from advanced heart failure. SynCardia has one operating subsidiary, SynCardia GmbH, which was formed to facilitate the sale and distribution of SynCardia's products throughout Europe.

Basis of Presentation and Consolidation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The consolidated financial statements include the financial statements of PMI and its subsidiaries. All intercompany transactions and account balances between PMI and its subsidiaries have been eliminated in consolidation.

On July 3, 2025, the Company completed a 1 for 2.2 forward stock split of the Company's common stock and on July 11, 2025, the Company completed a 1.0221 for 1 reverse stock split of the Company's common stock, resulting in an overall forward stock split of 1 for 2.1524. All share and per share amounts in the financial statements have been retrospectively adjusted for all periods presented to reflect the stock split. The Company's authorized common stock was increased from 45,000,000 to 150,000,000 as a result of the stock split.

Going Concern, Liquidity and Management's Plans

The Company has evaluated whether there are any conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern for at least twelve months from the date of this report, and the near term thereafter. The Company has incurred operating losses and negative cash flows from operations for the year ended December 31, 2025, and SynCardia has a history of operating losses dating back to its inception. The Company expects that operating losses and negative cash flows from operations will continue into the foreseeable future, and the Company will need to raise additional debt and/or equity financing to fund operations until it generates positive cash flows from operations.

To date, the Company's available liquidity and operations have been financed primarily through the issuance of common stock, preferred stock and debt. During the year ended December 31, 2025, the Company raised $9.7 million, net of repayments from the issuance of debt and warrants, and $17.4 million of net proceeds from the issuance of common stock. In order to proceed with the Company's business plan, the Company will need to raise additional funds through the issuance of additional debt, equity, or other commercial arrangements, which may not be available to the Company when needed or on terms that the Company deems to be favorable. To the extent the Company raises additional capital through the sale of equity, the ownership interest of its current 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 the Company's ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures, or declaring dividends. If the Company is unable to obtain sufficient financial resources, its business, financial condition, and results of operations may be materially and adversely affected. The Company may be required to delay, limit, reduce or terminate parts of its strategic business plan or future commercialization efforts. There can be no assurance the Company will be able to obtain financing on acceptable terms. Therefore, based on the Company's current financial condition and expected future cash flows, there is substantial doubt about the Company's ability to continue as a going concern for at least twelve months from the date of this report. The financial statements do not include any adjustments to the carrying amounts and classification of assets, liabilities and reported expenses that may be necessary if the Company is unable to continue as a going concern.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and disclosure of contingent assets and liabilities in the financial statements and accompanying notes. These estimates are based on information available through the date of the issuance of the financial statements and actual results and outcomes could differ from these estimates and assumptions. Areas requiring significant estimates and assumptions by the Company include, but are not limited to:

- Provisions for income taxes and related valuation allowances and tax uncertainties;
- Recoverability of long-lived assets and their related estimated useful lives;
- Accruals for estimated liabilities;
- Valuation of inventories;
- Valuation of leased assets;
- Valuation of stock-based compensation;
- Valuation of embedded derivative liability;
- Valuation of common and preferred stock;
- Valuation of senior secured note; and
- Valuation of warrants

Foreign Currency Translation

The functional currency of SynCardia GmbH is the Euro. The functional currency of SynCardia Australia is the Australian dollar. Assets and liabilities are translated into U.S. dollars, the reporting currency, at the exchange rate on the balance sheet date. Revenues and expenses are translated into U.S. dollars at the average rates of exchange prevailing during each reporting period. Foreign currency translation adjustments resulting from this process are reported as an element of other comprehensive income (loss), net of income taxes, on the consolidated statements of operations and comprehensive loss. Transactions executed in different currencies are translated at spot rates and resulting foreign exchange transaction gains and losses are charged to income.

Cash and Cash Equivalents

The Company considers all highly liquid debt investments with a remaining maturity of 90 days or less when purchased to be cash and cash equivalents. The Company places its cash in commercial banks. Accounts in the United States are secured by the Federal Deposit Insurance Corporation (“FDIC”) up to $250,000. From time to time, the Company’s total deposits at commercial banks exceed the balances insured. The Company has not experienced any losses in these accounts and believes it is not exposed to any significant credit risk in this area.

Restricted Cash

Restricted cash represents cash set aside by the Company to comply with the minimum liquidity requirement in our senior secured note.

Financial Instruments and Concentrations of Credit and Business Risk

Financial instruments that potentially subject the Company to a concentration of credit risk principally consist of cash, cash equivalents, restricted cash, and accounts receivable.

Fair Value of Financial Instruments

Fair value accounting is applied for all financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). Financial instruments include cash and cash equivalents, accounts receivable, notes receivable, accounts payable, notes payable, derivative liabilities and accrued liabilities.

The Company has elected the fair value option for its Senior Secured Note in accordance with ASC 825, "Financial Instruments". Under this election, the note is recognized at fair value at issuance and subsequently remeasured at fair value at each reporting date with changes in fair value recognized in earnings.

Fair Value Measurements

Assets and liabilities recorded at fair value on a recurring basis in the consolidated balance sheets are categorized based upon the level of judgment associated with inputs used to measure their fair values. The accounting guidance also establishes a three-level valuation hierarchy that prioritizes the inputs to valuation techniques used to measure fair value based upon whether such inputs are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions made by the reporting entity.

The three-level hierarchy for the inputs to valuation techniques is briefly summarized as follows:

Level 1 — Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2 — Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and

Level 3 — Unobservable inputs that are significant to the measurement of the fair value of the assets or liabilities that are supported by little or no market data.

Embedded Derivatives

The Company reviews the terms of debt and equity financing transactions to identify whether there are any embedded derivatives that require separation from the related host financial instrument. Any such derivatives are presented at fair value in the consolidated balance sheets, with changes in fair value recorded in other income and (expense) in the consolidated statements of operations and comprehensive loss. The Company separates an embedded provision in a debt or equity contract in which (i) the economic characteristics and risks of the embedded provision are not clearly and closely related to the economic characteristics and risks of the host instrument, (ii) the host instrument itself is not carried at fair value in the consolidated balance sheets, and (iii) the embedded provision would meet the definition of a derivative financial instrument. The Company has identified embedded derivatives that require bifurcation from its host instrument, namely the Convertible Notes (see also Notes 3 and 8).

Accounts Receivable and Allowance for Credit Losses

The Company's accounts receivable represent amounts considered to be collectible that are owed by its customers. Credit is extended based on evaluation of customers' financial condition and, generally, collateral is not required. An allowance for credit losses is maintained for estimated losses resulting from the inability of customers to pay. All accounts receivable are reviewed on an account-by-account basis to assess collectability. After exhausting all collection efforts on past due accounts, an account is written off against the allowance for credit losses. Any collections on accounts previously written off are recorded as income in the period of collection. The Company has not recorded an allowance against its receivables based on management's estimate that the balances recorded in all periods presented are fully collectible.

Inventories, net

Inventory is stated at the lower of cost, determined using the first in, first out basis, or net realizable value. Inventory consists primarily of raw material components used in the manufacturing of SynCardia TAHs and related equipment as well as work-in-process inventory related primarily to SynCardia TAHs. Finished goods consist primarily of SynCardia TAHs and related equipment located at medical centers trained and certified in the implantation of the SynCardia TAH and appropriate patient aftercare ("Centers"). Work-in-process and finished goods include the cost of all direct material, labor and overhead costs. Inventory write-downs are recorded based on excess and obsolete exposures, determined primarily by future demand forecasts. These write-downs are measured as the difference between the cost of the inventory and net realizable value based upon assumptions about future demand and charged to the provision for inventory, which is a component of cost of sales. In addition, a liability is recorded for firm, noncancelable, and unconditional purchase commitments with contract manufacturers and suppliers for quantities that exceed forecasts of future demand. As of December 31, 2025 and 2024, the Company had no unconditional and noncancelable purchase commitments.

Property and Equipment

Property and equipment are recorded at cost, net of accumulated depreciation. Improvements, renewals, and extraordinary repairs that materially extend the useful life of the asset are capitalized; other repairs and maintenance charges are expensed as incurred.

Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets. Depreciation begins at the time the asset is placed in service. Upon sale or retirement of assets, the cost and related accumulated depreciation are removed from the consolidated balance sheets, and the resulting gain or loss is reflected in operating expenses in the period realized.

The useful lives of the property and equipment are as follows:

	Years
TAH-Driver equipment	3-5
Laboratory equipment	2-10
Office and computer equipment	5
Leasehold improvements	Shorter of remaining lease term or estimated useful life

Intangible Assets, net

Intangible assets comprise developed technology and trade name. Intangible assets are carried at cost less accumulated amortization. Amortization is computed using the straight-line method over useful lives of twelve years for developed technology and five years for trade name.

Goodwill

Goodwill is subject to an annual impairment test, or earlier if indicators of potential impairment exist. The annual impairment test is performed as of December 31 of each year. The Company has the option to perform a qualitative assessment by examining relevant events and circumstances which could have a negative impact on goodwill, including macroeconomic conditions, industry and market conditions, cost factors, overall financial performance and other relevant events specific to the Company. If, after assessing the totality of events or circumstances described above, the Company determines that it is more likely than not that a reporting unit's fair value is less than its carrying value, the Company will perform a quantitative impairment test. Upon performing the quantitative impairment test, if the fair value of the reporting unit is less than its carrying amount, goodwill is impaired and the excess of the reporting unit's carrying value over the fair value is recognized as an impairment loss; however, the loss recognized would not exceed the total amount of goodwill allocated to that reporting unit. For the purpose of completing its impairment test, the Company performs either a qualitative or a quantitative analysis on a reporting unit basis. All of the goodwill is expected to be deductible for income tax purposes.

Quantitative impairment tests consider both the income approach and the market approach to estimate a reporting unit's fair value. The income and market valuation approaches consider a number of factors that include, but are not limited to, prospective financial information, growth rates, residual values, discount rates and comparable multiples from publicly traded companies in the Company's industry and require it to make certain assumptions and estimates regarding industry economic factors and the future profitability of the business. As of December 31, 2025 and 2024, the Company has assessed no impairment of goodwill.

Impairment of Long-Lived Assets

The Company evaluates long-lived assets, primarily property and equipment, right-of-use lease assets, developed technology, and trade names, for impairment on an annual basis, or whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. When the Company determines that it is probable that undiscounted future cash flows will not be sufficient to recover an asset's carrying amount, the asset is written down to its fair value. Assets to be disposed of by sale, if any, are reported at the lower of the carrying amount or fair value less cost to sell. As of December 31, 2025 and 2024, the Company has assessed no impairment of its long-lived assets.

Revenue Recognition

The Company generates revenue from the sale of its SynCardia TAH, rental of Freedom drivers, and from training and certification services, which are required before the first time a transplant center may purchase a SynCardia TAH. Revenue includes sales and services to Centers located in the United States as well as Centers domiciled in foreign countries.

The Company recognizes revenue when it transfers control of promised goods or services to its customers, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition, the Company performs the following five steps:

(i) identification of the promised goods or services in the contract;

(ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract;

(iii) measurement of the transaction price, including the constraint on variable consideration;

(iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and

(v) recognition of revenue when (or as) the Company satisfies each performance obligation. A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account.

Product Revenues

The Company recognizes revenue when performance obligations identified under the terms of contracts with its customers are satisfied, which generally occurs, for SynCardia TAH kits, upon the transfer of control in accordance with the contractual terms and conditions of the sale. The majority of the Company's revenue associated with SynCardia TAH kits are recognized at a point in time when the SynCardia TAH kit is shipped to the customer. The Company only offers assurance-type standard warranties that do not represent separate performance obligations. The Company records amounts billed to customers for reimbursement of shipping and handling costs within revenue. Shipping and handling costs associated with outbound freight after control over a SynCardia TAH kit has transferred to a customer are accounted for as fulfillment costs and are included in cost of revenues. Sales taxes and other usage-based taxes are excluded from revenue. The Company gives certain discounts to product distributors based on a contracted amount on the sale of its products. Discounts applied to invoices are not associated with future purchases and solely relate to the product invoiced. As a result, the invoice and transaction price are recorded net of any discounts. The amount of consideration to which the entity will be entitled in exchange for transferring the promised goods or services to a customer is estimated using the expected value method. Product revenue is billed at the point of sale upon shipment and typically collected within 30 days.

Rental Revenues

Rental revenues primarily consist of rental fees charged to customers who rent the Company's driver. Rental revenue is earned over the period of usage which begins when a patient is discharged from a hospital and is recognized when it becomes likely that we will receive payment. Rental revenue is billed at month end and typically collected within 30 days.

Professional Services Revenues

Professional services revenues primarily consist of training and certification services. The Company's professional services revenue is recognized when the services are performed. Professional services revenue is billed upon completion of services and typically collected within 30 days.

Contracts with Multiple Performance Obligations

From time to time, the Company has contracts with customers that contain multiple performance obligations. For these contracts, the Company accounts for individual performance obligations separately if they are distinct. The Company accounts for individual goods and services separately if they are distinct performance obligations, which often requires significant judgment based upon knowledge of the products and/or services, the solution provided and the structure of the sales contract. The transaction price is allocated to the separate performance obligations on a relative standalone selling price basis for those performance obligations with stable observable prices. The Company determines the standalone selling prices based on its overall pricing objectives, taking into consideration market conditions and other factors, including the value of the contracts, pricing when certain services are sold on a standalone basis, the products sold, customer demographics, geographic locations, and the volume of services purchased. As of December 31, 2025 and 2024, there were no unsatisfied performance obligations associated with its customer contracts.

Returns

The Company does not offer rights of return for its products and services in the normal course of business.

Contract Balances

The Company's contract liabilities, if any, consist of advance payments for systems as well as deferred revenue on service obligations (see Note 5). As of December 31, 2025 and 2024, there was no amount of deferred revenue recorded on the Company's consolidated balance sheet, respectively.

Practical Expedients

The Company applies a practical expedient to expense costs as incurred for costs to obtain a contract when the amortization period would have been one year or less. These costs are recorded within selling, general and administrative expenses in the consolidated statements of operations and comprehensive loss.

Payment Terms

Payment terms vary by customer but typically provide for the customer to pay within 30 days. Therefore, customer payment terms are for 12 months or less and do not include significant financing components. The Company performs credit evaluations of customers and evaluates the need for allowances for potential credit losses based on historical experience, as well as current and expected general economic conditions.

Cost of revenues

Cost of revenues includes product costs, labor, overhead, inbound freight, and other product-related costs including maintenance costs, excess inventory, and obsolescence charges.

Shipping and Handling Fees and Costs

The Company includes shipping and handling fees billed to customers as part of net sales and shipping and handling costs associated with the outbound freight are included in cost of sales.

Research and Development Costs

Included in research and development costs are wages, stock-based compensation and benefits of employees performing research and development, and other operational costs related to the Company's research and development activities, including facility-related expenses, allocation of corporate costs, and external costs of outside contractors.

Comprehensive Income (Loss)

Comprehensive income (loss) consists of net income (loss), and foreign currency translation adjustments, net of tax, which are recorded within other comprehensive income (loss).

Income Taxes

The Company calculates its provision for income tax on the basis of the tax laws enacted at the balance sheet date. The Company uses an asset and liability approach for financial accounting and reporting for income taxes that allows recognition and measurement of deferred tax assets based upon the likelihood of realization of tax benefits in future years. Management makes an assessment of the likelihood that the resulting deferred tax assets will be realized. Under the asset and liability approach, deferred taxes are provided for the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. A valuation allowance is provided for deferred tax assets if it is more likely than not these items will either expire before the Company is able to realize their benefits, or that future deductibility is uncertain. The Company records unrecognized tax benefits, where appropriate, for all uncertain income tax positions. The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense. Due to the Company's historical operating performance and net losses, the net deferred tax assets have been fully offset by a valuation allowance.

Net Loss Per Share

Basic net loss per share is computed by dividing net loss available to common stockholders by the weighted average number of common shares outstanding during the period, without consideration of potential common shares.

Diluted net loss per share is calculated by dividing net loss available to common stockholders by the weighted average number of common shares outstanding plus common share equivalents from conversion of dilutive stock options using the treasury method, except when antidilutive. In the event of a net loss, the effects of all potentially dilutive shares are excluded from the diluted net loss per share calculation as their inclusion would be antidilutive.

Stock-Based Compensation

The Company measures the fair value of all stock-based awards, including stock options, on the grant date and records the fair value of these awards to compensation expense over the service period. The Company has elected to account for forfeitures as they occur. The fair value of stock option awards is estimated using the Black-Scholes valuation model, which considers several variables and assumptions in estimating the fair value of stock-based awards. These assumptions include:

- per share fair value of the underlying common stock;
- risk-free interest rate;
- expected term;
- expected stock price volatility over the expected term; and
- expected annual dividend yield.

The Company calculates the expected term using the simplified method, or the arithmetic average of the original contractual term and the average vesting term, for "plain vanilla" stock option awards. The risk-free interest rate is based on the yield available on U.S. Treasury zero-coupon issues similar in duration to the expected term of the stock-based award. The Company's common stock is not publicly traded; therefore, it uses the weighted average of the historic volatilities of the stock price of similar publicly traded peer companies, with extra weighting attached to those companies most similar in terms of size, financial leverage and business activity. The Company utilizes a dividend yield of zero, as it has no history or plan of declaring dividends on its common stock.

Leases

The Company records operating leases as right-of-use assets and operating lease liabilities in its consolidated balance sheets for all operating leases with terms exceeding one year. Right-of-use assets represent the right to use an underlying asset for the lease term, including extension options considered reasonably certain to be exercised, and operating lease liabilities represent obligations to make lease payments. Right-of-use assets and operating lease liabilities are recognized based on the present value of lease payments over the lease term. To the extent that lease agreements do not provide an implicit rate, the Company uses its incremental borrowing rate based on information available at the lease commencement date to determine the present value of lease payments. The expense for operating lease payments is recognized on a straight-line basis over the lease term and is included in operating expenses in the Company's consolidated statement of operations. The Company has elected to not separate lease and non-lease components of its operating leases.

Segment Information

Operating segments are defined as components of an enterprise for which separate financial information is evaluated regularly by the chief operating decision maker ("CODM") who is the Company's Chief Executive Officer, Chief Financial Officer, and Chief Operating Officer, in deciding how to allocate resources and assess the Company's financial and operational performance. The CODM evaluates the Company's financial information and resources and assesses the performance of these resources on a consolidated and aggregated basis. Accordingly, the Company has determined that it operates in one operating and reportable segment.

The Company internally reports the following segment financial information, on a consolidated basis, to its CODM: revenue by product and rentals, cost of revenues by product and rentals, and gross profit (loss). Gross profit (loss) is the measure of segment profitability used by the CODM to assess performance and allocate resources and is presented on the consolidated statements of operations and comprehensive loss. The CODM also reviews the disaggregation of revenue by geography that is presented in Note 5. There are no segment operating expenses that require disclosure other than the expense categories presented on the consolidated statements of operations and comprehensive loss. The measure of segment assets is reported on the consolidated balance sheets as total assets.

Reclassification

Certain prior year amounts have been reclassified for consistency with the current year presentation. These reclassifications had no effect on the reported results of operations.

Recent Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, Income taxes (Topic 740), Improvement to income tax disclosures, which enhances the disclosures required for income taxes in the Company's annual financial statements. This standard is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company adopted this standard for the year ended December 31, 2025, and there was no material impact on the Company's financial statements.

In November 2024, the FASB issued ASU 2024-03, Disaggregation of Income Statement Expenses (DISE), which applies to all public business entities. This standard is effective for annual reporting periods beginning after December 15, 2026, with early adoption permitted. The Company expects to adopt this standard for the period beginning after December 15, 2026, with no material impact on the Company's financial statements.

The Company has reviewed all newly issued accounting pronouncements and concluded that they either are not applicable to the Company's operations, or no material effect is expected on its consolidated financial statements as a result of future adoption.

3. FAIR VALUE OF FINANCIAL INSTRUMENTS

The following fair value measurement table presents information about the Company's financial liabilities that are measured at fair value on a recurring basis and the fair value hierarchy of the valuation (in thousands):

	December 31, 2025			
Category Class	**Total**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Senior Secured Note (unpaid principal of $15,000)	$ 5,448	$ -	$ -	$ 5,448
Warrant Liabilities	7,842	-	-	7,842
Total	$ 13,290	$ -	$ -	$ 13,290

	December 31, 2024			
Category Class	**Total**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Derivative Liability	$ 6,759	$ -	$ -	$ 6,759
Total	$ 6,759	$ -	$ -	$ 6,759

The December 31, 2024, derivative liabilities relate to the embedded redemption features in connection with the convertible promissory notes. The fair value of the embedded redemption features at issuance of the convertible promissory notes and each reporting period was estimated based on significant inputs not observable in the market, which represent Level 3 measurements within the fair value hierarchy. The Company used a scenario-based model ("SBM") and a discounted cash flow method to incorporate estimates and assumptions concerning its prospects and market indications into a model to estimate the value of the derivative liability. An SBM considers a range of various potential scenario outcomes assumed to occur with associated probabilities. Cash flow outcomes are then discounted to present value to estimate fair value. The most significant estimates and assumptions used as inputs in the SBM valuation technique impacting the fair value of the embedded redemption features are the timing and probability of a successful financing or IPO, maturity, qualified financing or change of control scenario outcomes. The calculated payments due to the holders of the convertible promissory notes were calculated with and without the embedded redemption feature and discounted to present value. The discounted cash flows were calculated using a discount rate at the issuance dates and at the reporting date, based on an assessment of the Company's credit position and market yields of companies with similar credit risk at the date of each valuation.

The significant unobservable inputs that are included in the valuation of derivative liabilities at issuance and as of December 31, 2025 and 2024, are as follows:

	Input Range	
	December 31, 2025	**December 31, 2024**
Significant Unobservable Inputs:		
Discount rate	18.7% - 25.0%	18.7% - 25.0%
Expected term (in years)	0.1 - 0.6	0.3 - 0.9
Probability scenarios:		
Successful financing/IPO	27.6% - 98%	27.6% - 63.9%
Maturity	0%-20%	16% - 65.5%
Qualified Financing	0% - 3.4%	0% - 3.4%
Change of Control	0% - 3.4%	0% - 3.4%

The following table provides a rollforward of the aggregate fair values of the derivative liability (in thousands):

	Embedded Derivative
Balance as of December 31, 2023	$ -
Initial fair value of derivative liabilities at issuance	2,468
Change in fair value	4,291
Balance as of December 31, 2024	$ 6,759
Initial fair value of derivative liabilities at issuance	4,447
Change in fair value	7,040
Derecognition of derivative liability	(18,246)
Balance as of December 31, 2025	$ -

The fair value of the Senior Secured Note at issuance and as of December 31, 2025, has been determined using a discounted cash flow model. The fair value of the warrant liabilities at issuance and as of December 31, 2025, was measured using a Monte Carlo simulation model.

The significant unobservable inputs that are included in the valuation model of the Senior Secured Note and warrants at issuance and at December 31, 2025, are as follows:

	Input Range December 31, 2025	
	Senior Secured Note	Warrants
Significant Unobservable Inputs:		
Discount rate	25% - 25.1%	-
Tern to expiration (in years)	2.99-3.0	4.99-5.0
Calibration discount	61.5%	-
No exercise window (in years)	-	0.19-0.21
Volatility	-	82.4%-82.5%
Risk-fee rate	-	3.65%

The following table provides a rollforward of the aggregate fair values of the senior secured note and warrant liabilities (in thousands):

	Senior Secured Note	Warrant Liabilities
Balance as of December 31, 2024	$ -	$ -
Initial fair value at issuance	5,437	8,870
Change in fair value	11	(1,028)
Balance as of December 31, 2025	$ 5,448	$ 7,842

The Company has certain non-financial assets, primarily intangible assets and goodwill, which are measured at fair value on a nonrecurring basis and are adjusted to fair value only to the extent that an impairment charge is recognized. The Company estimates the fair value of these assets using primarily unobservable inputs; therefore, these are considered Level 3 fair value measurements.

4. CERTAIN BALANCE SHEET COMPONENTS

(a) Inventories, Net

Inventories, net of provisions for potentially excess, obsolete or impaired goods, consists of the following (in thousands):

	December 31, 2025	December 31, 2024
Raw materials	$ 6,125	$ 6,319
Work in process	2,533	2,764
Finished goods	1,478	1,443
	$ 10,136	$ 10,526
Allowance for excess and obsolete inventory	(2,833)	(2,411)
Inventories, net	$ 7,303	$ 8,115

(b) Property and Equipment, Net

Property and equipment, net consists of the following (in thousands):

	December 31, 2025	December 31, 2024
Equipment	$ 675	$ 643
Furniture and fixtures	6	6
Leasehold improvements	101	101
Total cost	$ 782	$ 750
Less: accumulated depreciation	(599)	(523)
Property and equipment, net	$ 183	$ 227

Depreciation expense was $76,000, of which $27,000 was included in cost of goods sold, and $138,000, of which $28,000 was included in cost of goods sold, for the years ended December 31, 2025, and 2024, respectively. For the years ended December 31, 2025 and 2024, the Company disposed of no equipment and $74,000 of equipment, respectively.

(c) Intangible Assets, Net

Intangible assets consist of the following (in thousands):

	December 31, 2025		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Value
Developed Technology	$ 760	$ (269)	$ 491
Trade Name	120	(102)	18
Total	$ 880	$ (371)	$ 509

	December 31, 2024		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Value
Developed Technology	$ 760	$ (206)	$ 554
Trade Name	120	(78)	42
Total	$ 880	$ (284)	$ 596

Amortization expense was $87,000 for both years ended December 31, 2025 and 2024.

As of December 31, 2025, developed technology and trade name had remaining lives of 7.75 and 0.75 years, respectively. The estimated future amortization expense for the next five years and thereafter is as follows (in thousands):

	December 31, 2025
2026	$ 87
2027	87
2028	82
2029	64
2030	63
Thereafter	126
Total	$ 509

(d) Other Accrued Liabilities

Other accrued liabilities consist of the following (in thousands):

	December 31, 2025	December 31, 2024
Accrued compensation	$ 574	$ 941
Accrued clinical and manufacturing expenses	190	617
Accrued professional and consulting services	594	51
Other liabilities, current portion	499	493
Total other accrued liabilities, current portion	1,857	2,102
Other liabilities, noncurrent portion	-	-
Total current and noncurrent other accrued liabilities	$ 1,857	$ 2,102

Accrued compensation includes sales commissions, payroll, employee PTO, and employee NEO bonuses. Accrued clinical and manufacturing expenses represent royalties payable under a ten-year worldwide licensing agreement related to intellectual property covering the design and production of valves used in the SynCardia TAH and service costs on drivers returned, mostly from customers outside the U.S. The sums due to the vendor are secured by the license agreement, which has expired. Accrued professional and consulting services represent payables related to legal, accounting, and valuation services provided in preparation of the Company's potential acquisition or its initial public offering. At the end of 2023, the Company's management made the decision to terminate its sales and distribution agreement with State of the Art Medical Products, Inc. (SOTA). In connection with the termination of the agreement, the Company agreed to pay a termination penalty of $505,085, payable at $21,045 per month over a period of 24 months and a refund of $415,000 for returned inventory payable on May 1, 2025. Any payments not received on the due dates are subject to a monthly interest of 1%. As of December 31, 2025, $500,000 plus $94,915 in interest on the termination penalty was paid. As of December 31, 2025, outstanding balances related to the termination penalty and the refund for returned inventory amounted to $0 and $415,000, respectively. As of December 31, 2024, outstanding balances related to the termination penalty and the refund for returned inventory amounted to $505,085 and $415,000, respectively.

5. REVENUE

Disaggregation of Revenue

The Company believes that the nature, amount, timing and uncertainty of its revenue and cash flows and how they are affected by economic factors are most appropriately depicted by (i) geographic region, based on the shipping location of the customer, and (ii) type of product or service provided.

Total revenue based on the disaggregation criteria described above is as follows (in thousands, except percentages):

	Year Ended December 31,			
	2025		2024	
	Revenue	% of revenue	Revenue	% of revenue
Revenue by geographic area				
United States	$ 4,360	88%	$ 3,266	74%
Europe	580	12%	991	23%
Rest of the world	-	-%	134	3%
Total	$ 4,940	100%	$ 4,391	100%
Revenue by type				
Products	$ 4,746	96%	$ 4,254	97%
Rentals	194	4%	137	3%
Total	$ 4,940	100%	$ 4,391	100%

Revenue from products includes related services, which represented less than 10% of product revenue for both periods. In the year ended December 31, 2025, sales included $658,000 or 13% of total revenue to Serbia. In the year ended December 31, 2024, sales included $135,000 or 3%, $494,000 or 11% and $193,000 or 4% of total revenue to Canada, Serbia and Germany, respectively. Customer concentrations are disclosed in Note 6.

Contract assets. There were no contract assets, representing unbilled receivables where revenue has been recognized in advance of customer billings, as of December 31, 2025 and 2024.

Remaining Performance Obligations. Remaining Performance Obligations ("RPO") comprise deferred revenue plus unbilled contract revenue. As of December 31, 2025 and 2024, there was no RPO.

6. CONCENTRATIONS

Customers accounting for more than 10% of revenue in any of the periods presented are summarized as follows (in thousands, except percentages):

	Year Ended December 31,			
	2025		2024	
Customer A	$ 2,122	43%	$ 1,796	41%
Customer B	$ 658	13%	$ 494	11%
Customer I	$ 546	11%	$ 8	-%

As of December 31, 2025, Customer A, B, F, and H accounted for 29%, 14%, 29%, and 29%, of the accounts receivable, respectively. As of December 31, 2024, Customer A, B, E, and F accounted for 0%, 0%, 48%, and 34% of the accounts receivable balance, respectively.

Concentrations of revenues derived from foreign countries are disclosed in Note 5.

Long-lived assets by geographic areas are as follows (in thousands):

	December 31, 2025	December 31, 2024
United States	$ 174	$ 213
Foreign, principally in Europe	9	14
Property and equipment, net	$ 183	$ 227

7. COMMITMENTS AND CONTINGENCIES

(a) Leases

The Company has one master lease for office and manufacturing facilities which is considered an operating lease. The Company obtained the right of use of real estate located in Tucson, Arizona, in February 2015 under a lease which was subsequently renewed until January 31, 2027. The lease currently requires monthly payments of approximately $34,000 per month with 2.5% annual escalation. Two other operating leases expired prior to December 31, 2025.

Right-of-use assets acquired under finance and operating leases consist of the following (in thousands):

	December 31, 2025	December 31, 2024
Finance leases:		
Office equipment	$ 152	$ 177
Finance lease right-of-use assets, net	$ 152	$ 177
Operating Leases:		
Facilities	$ 363	$ 653
Office equipment	-	47
Operating lease right-of-use assets, net	$ 363	$ 700

As of December 31, 2025, the Company had three finance leases for office equipment with a weighted-average discount rate of 7.4% and a weighted-average remaining lease term of 1.30 years. As of December 31, 2024, the Company had three finance leases for office equipment with a weighted-average discount rate of 6.80% and a weighted-average remaining lease term of 2.26 years.

As of December 31, 2025 and 2024, the weighted average discount rate for operating leases was 12.0%, and the weighted average remaining term of these leases was 1.00 and 1.95 years, respectively.

The following table summarizes the Company's undiscounted cash payment obligations for its operating and finance lease liabilities with initial terms of more than twelve months (in thousands):

	December 31, 2025	
	Operating Leases	Finance Lease
2026	$ 412	$ 88
2027	34	32
Undiscounted total	446	120
Less: imputed interest	(26)	(13)
Present value of future minimum payments	420	107
Current portion of lease liability	(386)	(77)
Lease liability, net of current portion	$ 34	$ 30

Certain operating lease agreements for facilities include non-lease costs, such as common area maintenance, which are recorded as variable lease costs. Cash paid for amounts included in the measurement of operating lease liabilities totaled $443,000 and $418,000 in the years ended December 31, 2025, and 2024, respectively. Operating lease expenses are summarized as follows (in thousands):

	Year Ended December 31, 2025	2024
Operating lease cost	$ 359	$ 384
Short-term lease cost	53	11
Variable lease cost	15	29
Total operating lease cost	$ 427	$ 424

Cash paid under finance leases totaled $72,000 and $56,000 in the years ended December 31, 2025, and 2024, respectively.

(b) China Corporation

On July 2, 2023, the Company granted SynCardia Medical (Beijing), Inc. ("SMB") exclusive distribution rights of its products in mainland China, Hong Kong, Macau and Taiwan. Contingent on the Company becoming publicly traded on a stock exchange, it would be committed to contribute approximately $2.85 million in exchange for a 60% ownership interest and control of the board of directors of SMB. Should this occur, non-controlling owners would also invest approximately $2.85 million to obtain a 40% ownership interest in SMB and the Company would begin to consolidate its results in its consolidated financial statements. For the year ended December 31, 2024, the Company sent inventory to SMB primarily for the purpose of regulatory registration inspection and testing. The Company recorded the value of these inventories amounting to approximately $540,000 to general and administrative expense.

As of December 31, 2025, the Company had not consummated the contemplated investment, and SMB continued to operate solely as an independent distributor. The agreement remains in effect; however, the Company is monitoring international and market conditions and intends to work on extending the agreement with SMB. Accordingly, no amounts related to this arrangement have been recognized in the Company's consolidated financial statements for the year ended December 31, 2025.

(c) Indemnifications

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend indemnified parties for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third-party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions, during the years ended December 31, 2025 and 2024. The Company currently has directors' and officers' insurance.

(d) Litigation

From time to time the Company may be involved in claims arising in connection with its business. Based on information currently available, the Company believes that the amount, or range, of reasonably possible losses in connection with any pending actions against it in excess of established reserves, in the aggregate, are not material to its consolidated financial condition or cash flows. However, losses may be material to the Company's operating results for any particular future period, depending on the level of income or loss for such period.

8. DEBT

2025 Senior Secured Note

On December 24, 2025, the Company entered into a Securities Purchase Agreement with an Institutional Investor pursuant to which PMI agreed to issue and sell senior secured notes and warrants to purchase shares of our common stock. An initial $15.0 million aggregate principal amount of Senior Secured Note was issued at the initial closing on December 26, 2025, with a maturity date of December 26, 2028. PMI received proceeds of $13.5 million, net of an original issue discount of $1.5 million (or 10%) and also incurred debt issuance costs of $1.5 million. The terms of the Senior Secured Note provides, among other things, for the following:

- Monthly partial redemption payments starting on February 1, 2026, of $1,764,706 or $882,353 if the Company completes a qualified equity financing as defined in the agreement. The Company has the option to settle the partial redemption payments in cash or in common stock (if certain equity conditions are met) at a price equal to 93% of the lowest daily volume-weighted average price ("VWAP") during the five VWAP trading days prior to the conversion date. The noteholder, at its sole discretion and retroactively, may elect to increase the amount to be settled in shares up to $3.5 million in the aggregate.
- Requires the Company to maintain a minimum liquidity amount of $4,000,000.
- Maintain a first priority lien on all tangible and intangible assets of the Company, until the outstanding total principal is satisfied.
- A default interest rate of 15% which accrues upon an event of default.
- In connection with a fundamental change, as defined in the Securities Purchase Agreement, repurchase price is 105% of outstanding principal plus accrued interest.

The Company also issued 7,009,346 common stock warrants to the noteholder and 700,934 common stock warrants to the placement agent. The warrants have an exercise price of $2.675 per share and a term of 5 years. Due to certain ratchet provisions in the warrant agreements, the above-mentioned warrants are classified as liabilities under ASC 815-40. Part of the proceeds of the note was allocated to the fair value of the warrants at issuance amounting to $8.1 million. The fair value of the warrants issued to the placement agent of $0.8 million are recorded as debt issuance costs.

Upon issuance, the Company elected to account for the Senior Secured Note under the fair value option. The primary reason for electing the fair value option is for simplification and cost-benefit considerations of accounting for the Senior Secured Note at fair value in its entirety versus bifurcation of the embedded features. Under the fair value election, debt issuance costs are expensed as incurred and the debt liability is subsequently valued at fair market value during each reporting period until settlement. The fair value of the Senior Secured Note at issuance and as of December 31, 2025, amounted to $5.4 million, each. The change in fair value for the year ended December 31, 2025, was $0.012 million and was charged to earnings. Debt issuance costs of $2.3 million were expensed during the year ended December 31, 2025, and reported in financing charges in the consolidated statements of operations and comprehensive loss.

Convertible Notes

During the period May through September of 2023, the Company issued unsecured convertible notes (the "2023 Convertible Notes") for a total of $4.2 million, $0.3 million of which is from a limited partner in Hunniwell, which accrue simple interest at 6% per annum commencing on the issuance date of each 2023 Convertible Note. Issuance costs were not significant, and interest accrued totaled none and $0.375 million as of December 31, 2025 and 2024, respectively. The maturity date of each 2023 Convertible Note is two years after the issuance date. Each 2023 Convertible Note shall be automatically converted into a number of shares of PMI's common stock equaling the outstanding balance of the note, being the principal plus accrued interest, divided by 3.2714, on the maturity date or, if sooner, on the day before the Company becomes publicly traded on a stock exchange. The Company is in the process of modifying this loan's conversion price to a conversion price equal to 50% of the lowest price per share paid by purchasers of our securities in the event we consummate an IPO, or an equity, debt or other financing, which would be dilutive to current and future investors in our common stock. The Company determined that the 2023 Convertible Notes did not contain any embedded derivatives requiring bifurcation.

In April, May, and July 2025, the Company amended $4.1 million of the $4.2 million 2023 Convertible Notes to extend the maturity date until August 25, 2025, and change the automatic conversion rate to a conversion price equal to 50% (23% post-split) of the lowest price per share paid by purchasers of our securities in the event we consummate an IPO (the "Amended Conversion"). On September 9, 2025, $0.025 million of the 2023 Convertible Notes plus interest was paid in cash.

The Company determined that the Amended Conversion features on the 2023 Convertible Notes met the definition of embedded derivatives that were required to be bifurcated and accounted for as derivative liabilities. The Company recorded the fair value of the derivative liabilities at issuance of $3.1 million as a debt discount to the 2023 Convertible Notes and is amortized to interest expense over the term of the notes. Amortization expense for the year ended December 31, 2025, amounted to $3.1 million. The debt discount was fully amortized as of September 2, 2025. The Company evaluated the amendment of the $4.1 million 2023 Convertible Notes under the guidance in ASC 470-50, Debt Modifications and Extinguishments, and determined that the amendment was substantive. The original debt and amended debt have the same principal, interest rate and no consideration was received by the debtor in exchange for the amended note, meaning the net carrying amount of the original debt is equal to the reacquisition amount of the amended debt, therefore no gain or loss on the extinguishment accounting was recognized. As such, the embedded conversion feature is accounted for at fair value at the amendment date and changes in the fair value of the Amended Conversion option are charged to earnings. On September 2, 2025, $4.1 million of the 2023 Convertible Notes plus $0.5 million of related interest were converted to a total 5,029,463 shares of common stock, and the balance of the derivative liability was reclassed to Additional Paid In Capital.

Between April 2024 and May 2025, the Company delivered a Convertible Note Purchase Agreement ("2024 Convertible Note Agreement") to prospective investors seeking to raise an aggregate amount of up to $15.0 million ("2024 Convertible Note").The unsecured 2024 Convertible Notes accrue simple interest at 6% per annum commencing on the issuance date of each 2024 Convertible Note. The maturity date of each 2024 Convertible Note is six months after the issuance date, or if sooner, on the date in which the Company consummates an IPO. Each 2024 Convertible Note, together with unpaid accrued interest, shall be automatically converted into the securities issued in the IPO at a conversion price equal to 50% (23% post-split) of the lowest price per share paid by the other purchasers of equity securities in the IPO ("conversion price"). Alternatively, in the event the Company consummates an equity, debt, or other financing prior to an IPO, then all principal, together with all unpaid accrued interest under the 2024 Convertible Notes, shall automatically convert, in the event of an equity financing, into the securities issued at a conversion price equal to 50% (23% post-split) of the lowest price per share paid by the other purchasers of equity securities prior to such financing, or, in the event of a debt financing prior to an IPO, the terms of these 2024 Convertible Notes shall be amended and restated to match the terms of such debt financing at the lender's option. The Company has raised total principal of approximately $5.7 million as of December 31, 2025. The Company determined that the conversion features on the 2024 Convertible Notes met the definition of embedded derivatives that were required to be bifurcated and accounted for as derivative liabilities. The Company recorded the fair value of the derivative liabilities at issuance of $1.8 million as a debt discount to the 2024 Convertible Notes and is amortized to interest expense over the term of the notes. Amortization expense for the year ended December 31, 2025, was $1.4 million. In July 2024, $2.7 million of the $5.7 million 2024 convertible notes were modified to reduce the conversion percentage from 80% to 50% (37% to 23% post-split). The Company evaluated the modification of the $2.7 million 2024 Convertible Notes under the guidance in ASC 470-50, Debt Modifications and Extinguishments, and determined that the modification was not substantive. Since the embedded conversion feature is accounted for at fair value both before and after modification, changes in the fair value of the conversion option are charged to earnings. On September 2, 2025, $5.7 million of the 2024 Convertible Notes plus $0.3 million of related interest were converted to 6,496,363 shares of common stock, the balance of the derivative liability was reclassed to Additional Paid In Capital and the remaining unamortized debt discount was fully amortized to interest expense.

On November 12, 2024, Richard Fang, former Chief Executive Officer and current director, has donated the $7.0 million aggregated convertible note, dated July 2, 2024, and the related accrued interest, to the not for profits organizations, Nexus Science Foundation Inc. ("Nexus"), and Another Dimension Foundation ("Another Dimension"). Under this donation, Nexus and Another Dimension will each receive 50% of the converted value in registered shares. On September 2, 2025, $3.5 million of the Nexus note plus $0.2 million of related interest, and $3.5 million of the Another Dimension note plus $0.2 million of related interest were converted to 4,054,517 and 4,054,517 shares of common stock, respectively. The balance of the derivative liability was reclassed to Additional Paid In Capital and the remaining unamortized debt discount was fully amortized to interest expense.

The following table summarizes the balances of the convertible notes and senior secured note (in thousands):

	December 31, 2025	December 31, 2024
2023 Convertible Notes	$ -	$ 4,160
2024 Convertible Notes	-	10,746
2025 Senior Secured Note	5,448	-
Less: unamortized debt discount	-	(78)
Subtotal	5,448	14,828
Less: Current portion	(5,448)	(14,828)
Debt, net of current portion	$ -	$ -
Accrued cumulative interest:	$ -	$ 725

9. TEMPORARY EQUITY AND STOCKHOLDER'S EQUITY (DEFICIT)

(a) Redeemable Convertible Preferred Stock

In September 2021, the Company amended the Articles of Incorporation to allow for the issuance of 30,000,000 shares of Series A-1 Preferred Stock (the "Preferred Stock"). Upon certain change in control events that are outside of the Company's control, including sale of substantially all of the Company's assets or the occurrence of a Deemed Liquidation Event, the holders of the Preferred Stock may cause redemption of the Preferred Stock. Accordingly, these shares are considered contingently redeemable and are classified as temporary equity on the accompanying consolidated balance sheets. The Series A-1 Preferred Stock may be converted at the option of the holder at any time and without the payment of additional consideration by the holder into a number of fully paid and non-assessable shares of common stock based on the terms within the Articles of Incorporation.

In September 2021, 10,000,000 shares of Series A-1 Preferred Stock were sold for cash proceeds of $1.00 per share, and 2,065,000 shares of Series A-1 Preferred Stock were issued as conversion shares to holders of the then outstanding convertible notes at a price of $1.00 per share. In December 2022, 5,550,000 shares of Series A-1 Preferred Stock were issued for payment in kind of notes payable at a price of $1.00 per share. In December 2022, 791,857 shares of Series A-1 Preferred Stock were issued for a total consideration of $2.7 million. No gain or loss is recognized on the settlement of the $5.6 million notes as the conversion of the notes and the proceeds received of $2.7 million were considered capital contributions to reach the $20.0 million capital raise provided for in the acquisition agreement with Sindex.

Following are the rights and privileges related to the Series A-1 redeemable convertible preferred stock:

- Dividend Provision: The holders of the preferred stock in preference to the holders of common stock are entitled to receive, if and when declared by the board of directors, dividends at the rate of 12% of the original issue price, defined as $1.00, per annum. Such dividends are cumulative and compound annually. No dividends have been declared to date. In addition, the holders of the preferred stock are entitled to receive a dividend equal to any dividend paid on common stock, when and if declared by the board, on the basis of the number of common shares into which the preferred stock may be convertible. As of December 31, 2025 and 2024, undeclared dividends with respect to the outstanding Series A-1 Preferred Stock totaled approximately none and $7.0 million, respectively. In the event of liquidation, dissolution or winding up of the Company, the holders of the Series A-1 Preferred Stock will be entitled to the original issue price plus accrued dividends before any funds are available to common stockholders.

- Conversion Rights: All holders of the Company's preferred stock have a right to convert the outstanding balances of preferred shares at any time following the date of issuance into a number of fully paid common shares, as specified in the Articles of Incorporation. The conversion rate is the original issue price for the relevant shares divided by the conversion price of the relevant shares, subject to anti-dilution adjustments. In the event of a sale of shares in a public offering resulting in gross proceeds of $25.0 million to the Company, such conversion into common stock would be mandatory. The 18,406,857 shares of Series A-1 Preferred Stock outstanding as in July 2025, were converted, by the holders, into 39,618,919 shares of common stock. As of December 31, 2025, there were no outstanding Preferred Stockholders.

- Liquidation Preferences: In the event of any liquidation, dissolution, winding-up or sale or merger of the Company, whether voluntarily or involuntarily, each holder of Preferred Stock is entitled to receive, in preference to the holders of common stock, a per-share amount equal to the original issue price, plus all declared but unpaid dividends. As of December 31, 2025, there was no redemption preference on liquidation.

- Voting Rights: Each holder of outstanding shares of Preferred Stock is entitled to the number of votes equal to the number of whole shares of Common Stock into which the shares of Preferred Stock held by such holder are convertible as of the record date for determining stockholders entitled to vote on such matter. Holders of Preferred Stock vote together with the holders of Common Stock on an as-converted-to-Common-Stock-basis and not as a separate class.

Preferred Conversion: In July 2025, Hunniwell exercised the option to convert all of its Series A-1 Preferred Stock to 39,619,919 shares of common stock. At the time of conversion, no dividends were declared or paid.

(b) Common Stock

As of December 31, 2025, the Company was authorized to issue 150,000,000 shares of common stock, $0.0001 par value per share. The voting, dividend and liquidation rights of the common stock are subject to and qualified by the rights, powers and preferences of the holders of the Series A-1 Preferred Stock. The Company shall not declare or pay a dividend on any share of Preferred Stock without also declaring or paying a dividend on any share of common stock that is equal to the dividend declared and/or paid on the share of Preferred Stock divided by the number of shares of common stock into which such share of Preferred Stock is then convertible.

The holders of common stock are entitled to one vote per share at all meetings of stockholders, provided that they may not vote to amend the Certificate of Incorporation relating to the terms of any outstanding series of Preferred Stock if the holders of that series are entitled to vote thereon. The number of authorized shares of common stock may only be changed by the affirmative vote of the holders of a majority of shares outstanding. There are no sinking fund provisions applicable to the common stock.

The Company had shares of common stock reserved for issuance as follows:

	December 31, 2025	December 31, 2024
Conversion of Convertible Notes	-	1,386,344
Options issued and outstanding	7,556,434	7,210,742
Issued Warrants	7,710,280	-
Available for future grants of equity awards	10,443,566	1,183,618
Total	25,710,280	9,780,704

(c) US Unicorn Agreement

On August 19, 2024, the Company entered into an agreement with the US Unicorn Foundation, Inc. (“Unicorn”) to provide advisory services in relation to the Company’s planned IPO listing (“Listing”). More specifically, Unicorn would make its best effort to raise, $5.0 million in capital for the pre-IPO financing round, and connect the Company with underwriters that could support the Listing, as well as other Listing related services in exchange for 2% of Company equity due on signing of the Unicorn agreement, followed by an additional 3% of Company equity if a follow-on financing is completed within 12 months of the Listing. The agreement allowed for a return of the 2% equity if Unicorn is unsuccessful. On August 25, 2024, the Company issued 1,342,650 shares at a fair value of $0.80 per share to Unicorn in satisfaction of the 2% of Company equity due on signing of the Unicorn agreement. On July 21, 2025, the Company sent a notice of termination to Unicorn to terminate Unicorn Agreements. On August 22, 2025, the 1,342,650 shares were returned and were then cancelled by the Company.

(d) Common Stock Issuance

In March 2025, the Company entered into subscription agreements with certain investors for the sale of 352,852 shares of the Company’s common stock at a price of $1.42 per share for total consideration of $0.5 million.

In April 2025, the Company entered into subscription agreements with certain investors for the sale of 695,277 shares of the Company’s common stock at a price of $1.42 per share for total consideration of $1.0 million.

In July 2025, Hunniwell exercised the option to convert all of its Series A-1 Preferred Stock to 39,618,919 shares of common stock. At the time of conversion, no dividends were declared or paid.

In July 2025, the Company received $0.75 million from three investors for the purchase of 568,184 shares of common stock at a price of $1.32 per share.

(e) ***Completion of Initial Public Offering***

On September 2, 2025, the Company completed its IPO of 4,250,000 shares of common stock at a price of $4.00 per share for gross proceeds to the Company of $17 million. In connection with the IPO, the 2023 Convertible Notes, 2024 Convertible Notes, and Another Dimension and Nexus notes were automatically converted into 19,634,860 shares of common stock. The offering cost of the IPO included approximately $4.2 million in underwriter commissions, legal expenses, and other related offering costs resulting in net proceeds to the Company of $12.9 million.

On September 9, 2025, the Company completed the closing of the underwriter overallotment for 637,500 shares of common stock at a price of $4.00 per share for gross proceeds to the Company of $2.6 million. The offering costs of this closing were $0.2 million in underwriter commissions and expenses, for net proceeds to the Company of $2.4 million.

10. SHARE BASED COMPENSATION

On September 26, 2021, the Company's board of directors approved the adoption of the 2021 Equity Incentive Plan (the "2021 Plan"), under which the Company is authorized to issue incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock awards, restricted stock units, other stock awards, and performance awards that may be settled in cash, stock, or other property.

The aggregate number of shares of common stock authorized for issuance under the 2021 Plan is 8,394,360 shares, which may be increased through an amendment to the 2021 Plan adopted by the board of directors. The number of shares authorized is subject to standard adjustments in the event of a stock split, stock dividend or other extraordinary dividend, or other similar change in the Company's common stock or capital structure. Awards that expire or are cancelled generally become available for issuance again under the 2021 Plan. Awards have a maximum term of ten years from the grant date and generally vest over four years, but may vest over varying periods, as specified by the Company's board of directors for each grant. On October 10, 2025, the Company's stockholders approved an amendment to the Company's 2021 Equity Incentive Plan (the "Amended Incentive Plan") to (i) increase the aggregate number of shares of Common Stock available under the 2021 Equity Incentive Plan to a total of 18,000,000 shares, (ii) include warrant as a type of awards issuable under the Amended Incentive Plan, and (iii) to ratify the 2021 Equity Incentive Plan.

A summary of stock option transactions is as follows:

	Shares Available For Grant	Number of Options Outstanding	Weighted Average Exercise Price
Balance at December 31, 2024	1,183,618	7,210,742	$ 0.49
Approved pool increase	9,605,640	-	-
Granted	(837,036)	837,036	2.14
Forfeited	107,323	(107,323)	0.23
Cancelled	384,021	(384,021)	0.83
Balance at December 31, 2025	10,443,566	7,556,434	$ 0.44

As of December 31, 2025, there were 7,556,434 options outstanding, with a weighted average exercise price of $0.44, a weighted average remaining term of 7.08 years, and an aggregate intrinsic value of $8.6 million. Of these, 5,204,064 were vested, with a weighted average exercise price of $0.43, a weighted average remaining term of 6.61 years and an aggregate intrinsic value of $6.8 million.

On May 30, 2025, the Company granted 833,588 stock options with a post stock split exercise price of $2.11 and a term of 10 years. The options vest over a period of 4 years. The Company measures the fair value of all stock-based awards on the grant date and records the fair value of these awards to compensation expense over the vesting period. The fair market value of the May 30, 2025, stock-based awards was determined using the Black-Scholes option pricing model which used the following assumptions:

Stock Price	$ 1.42
Expected dividend yield	-%
Expected stock price volatility	189%
Risk-free interest rate	4.69%
Expected term (years)	6.08

On September 29, 2025, the Company granted 3,448 stock options with an exercise price of $8.70 and a term of 10 years. The options vest over a period of 4 years. The Company measures the fair value of all stock-based awards on the grant date and records the fair value of these awards to compensation expense over the vesting period. The fair market value of the September 29, 2025, stock-based awards was determined using the Black-Scholes option pricing model which used the following assumptions:

Stock Price	$ 8.70
Expected dividend yield	-%
Expected stock price volatility	146%
Risk-free interest rate	3.77%
Expected term (years)	6.08

Total stock-based compensation recognized for options was as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Cost of revenue	$ 58	$ 12
Research and development	61	13
Selling, general and administrative	635	861
Total stock-based compensation	$ 754	$ 886

As of December 31, 2025, the unrecognized stock-based compensation cost related to outstanding stock options that are expected to vest was $1.6 million, which the Company expects to recognize over an estimated weighted average period of 2.52 years.

11. INCOME TAXES

Income (or loss) from continuing operations before income tax expense (or benefit) disaggregated between domestic and foreign are as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Domestic	$ (27,002)	$ (20,570)
Foreign	35	(500)
(Loss) Income before (benefit) provision for income taxes	$ (26,967)	$ (21,070)

Income tax expense (or benefit) from continuing operations disaggregated by federal (national), state, and foreign consists of (in thousands):

	Year Ended December 31,	
	2025	2024
Current:		
Federal	$ -	$ -
State	35	(15)
Foreign	-	-
Total Current	35	(15)
Deferred:		
Federal	-	-
State	-	-
Total Deferred	-	-
Total provision/(benefit)	$ 35	$ (15)

Reconciliation of the provision/(benefit) for income taxes calculated at the statutory rate to our provision/(benefit) for income taxes is as follows (in thousands, except percentages):

	Year Ended December 31,			
	2025		2024	
U.S. Federal statutory income tax (benefit)	$ (5,663)	21.0%	$ (4,421)	21.0%
State and local income taxes, net of federal benefit[1]	(491)	1.8%	(387)	1.8%
Foreign Tax Effects:				
Foreign Rate Differential	1	0.0%	(9)	0.0%
Foreign Non-Deductible Items	(40)	0.1%	-	0.0%
Foreign NOL deferred adjustment	245	-0.9%	-	0.0%
Change in valuation allowance	3,947	-14.6%	2,835	-13.5%
Nontaxable / nondeductible items (permanent items)				
Incentive Stock based compensation	32	-0.1%	161	-0.8%
Changes in fair values - derivative & warrant liabilities	1,265	-4.7%	901	-4.3%
Non-deductible Convertible Note interest and debt discount amortization	938	-3.5%	644	-3.1%
Non-deductible issuance costs	126	-0.5%	306	-1.5%
Other	2	0.0%	41	-0.2%
Tax Credits	(130)	0.5%	(178)	0.8%
Effects of deferred tax adjustments, net of federal benefits	(186)	0.7%	81	-0.4%
Effects of change in state tax rate, net of federal benefits	46	-0.2%	94	-0.4%
Other	(57)	0.2%	(83)	0.4%
			-	
Income Tax Provision/(Benefit) and Effective Income Tax Rate	$ 35	-0.1%	$ (15)	0.1%

[1] For the year ended December 31, 2025, the net state income tax benefit includes deferred tax effects from temporary differences primarily in Arizona and California, offset by current state income tax expense in California, New Jersey, and Texas. These jurisdictions collectively represent more than 50% of the net state and local income tax effect.

Deferred income taxes reflect the net tax effects of (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, and (b) operating losses and tax credit carryforwards.

Significant components of the Company's deferred tax assets and liabilities are as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Deferred Tax Assets:		
Net operating loss carry-forwards	$ 10,217	$ 7,440
Tax Credits Carryforwards	673	$ 543
Capitalized research	1,696	1,319
Stock based Compensation	403	55
Accruals and reserves	297	502
Inventory allowance	710	687
Debt Issuance Costs	493	-
Right-of-use Lease liability	132	242
Other	3	3
Gross deferred income tax assets	14,624	10,791
Less: Valuation allowance	(14,429)	(10,483)
Net Deferred Income Tax Assets, net of valuation allowance	195	308
Deferred Tax Liabilities:		
Right-of-use asset	(129)	(223)
Depreciation and amortization	(66)	(85)
Total Deferred Tax Liability	(195)	(308)
Net Deferred Income Tax Assets, net of valuation allowance	$ -	$ -

As of December 31, 2025, the Company had federal and state net operating loss carryforwards of approximately $40.6 million and $37.7 million, respectively. Federal net operating loss ("NOL") carryforwards generated after tax year 2017 are subject to an 80% limitation on taxable income, do not expire and will carryforward indefinitely. State net operating loss carryforwards in the amount of $0.1 million begin expiring in 2032.

In addition, as of December 31, 2025, the Company also had federal research and development tax credit carryforwards of $0.7 million, which may be available to reduce future tax liabilities and expire beginning in 2042.

Utilization of the U.S. federal and state net operating loss carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Section 382 and Section 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income and tax liabilities.

Realization of deferred tax assets is dependent upon future earnings, if any, the timing, and amount of which are uncertain. Due to the lack of earnings history, the net deferred tax assets have been fully offset by a valuation allowance. Management believes, based on a variety of factors, it is more likely than not that the deferred income tax assets will not be fully realized. The valuation allowance increased by approximately $3.9 million and $2.8 million during the years ended December 31, 2025, and 2024, respectively.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was enacted in the United States. The OBBBA includes significant provisions, such as the permanent extension of certain expiring provisions of the Tax Cuts and Jobs Act ("TCJA"), modifications to the international tax framework and the restoration of favorable tax treatment for certain business provisions including the immediate expensing of United States research and development expenditures. The legislation has multiple effective dates, with certain provisions effective in the current fiscal period and others in the fiscal year ended January 31, 2027.

Among its many provisions, the Act substantially amended the treatment of research or experimental (R&E) expenditures under the Internal Revenue Code. Under prior law (post-TCJA), domestic R&E expenditures incurred in tax years beginning after December 31, 2021, were required to be capitalized and amortized over five years (domestic) or fifteen years (foreign). The OBBBA introduced new Section 174A, which permits taxpayers to immediately deduct domestic R&E expenditures for tax years beginning after December 31, 2024, or elect to capitalize and amortize over not less than 60 months; it also incorporates transition rules for previously capitalized domestic R&E expenditures (incurred or paid from January 1, 2022 through December 31, 2024) and allows eligible small businesses to apply the new treatment retroactively to those years. For foreign R&E expenditures, the 15-year amortization requirement remains unchanged.

In addition, all taxpayers are permitted to make an election to accelerate the deductions for unamortized R&E expenditures that were capitalized after December 31, 2021, and before January 1, 2025, over a one-or-two year period beginning with the taxpayer's first tax year beginning after December 31, 2024.

The Company elected to continue to capitalize and amortize Sec 174 costs for 2025 and continue to amortize all pre-2025 unamortized costs.

Uncertain Tax Positions

It is the Company's policy to include penalties and interest expense related to income taxes as a component of interest and other income, net, as necessary. As of December 31, 2025 and 2024, there were no accrued interest and penalties related to uncertain tax positions.

There are no uncertain tax positions as of December 31, 2025.

The Company is subject to examination by U.S. federal and state tax authorities for all years since the Company's inception in 2021.

Income Tax Payments

The following is a summary of income taxes paid by jurisdiction, net of refunds, pursuant to the disclosure requirements of ASU No. 2023-09 (in thousands):

	Year Ended December 31,	
	2025	2024
United States - Federal	$ -	$ -
United States - California	3	-
United States - New Jersey	-	-
United States - Texas	-	-
United States - other states	1	-
Germany	-	-
Australia	-	-
Total Cash paid for income taxes, net of refunds	$ 4	$ -

12. NET LOSS PER SHARE

Basic and diluted net loss per share are shown in the consolidated statements of operations and comprehensive loss.

No adjustment has been made to the net loss for charges related to the Convertible Notes or Series A-1 Convertible Preferred Stock as the effect would be anti-dilutive due to the Company's net loss. The following outstanding stock options, warrants, and shares issuable upon conversion of the Convertible Notes and the Series A-1 Convertible Preferred Stock were not considered in the computation of diluted net loss per share attributable to holders of common stock as they had antidilutive effects:

	Year Ended December 31,	
	2025	2024
Common shares issuable upon exercise of issued warrants	7,710,280	-
Common shares issuable upon exercise of common stock options	7,556,434	7,210,742
Common shares issuable upon conversion of Convertible Notes	-	1,386,344
Shares issuable upon conversion of Series A-1 Preferred Stock	-	39,618,919
Total common shares excluded from denominator for diluted earnings per share computation	15,266,714	48,216,005

13. RETIREMENT PLANS

The Company maintains a 401(k) Plan for the benefit of eligible employees in the United States. The 401(k) Plan includes a cash or deferred arrangement pursuant to Section 401(k) of the Internal Revenue Code sponsored by the Company to provide eligible employees an opportunity to defer compensation and have such deferred amounts contributed to the 401(k) Plan on a pre-tax basis, subject to certain limitations. The Company, at the discretion of the Board of Directors, may make contributions of cash to match deferrals of compensation by participants in the 401(k) Plan. To date, the Company has made no matching contributions to the 401(k) Plan.

14. RELATED PARTY TRANSACTIONS

Versa Capital Management, LLC ("Versa") shares common ownership with Sindex SSI Financing, LLC ("Sindex"), which owned 100% of the outstanding membership interest of SynCardia prior to the acquisition by PMI. To enable Versa to pay transaction costs on behalf of SynCardia in conjunction with PMI's acquisition, on September 27, 2021, PMI advanced $100,000 to Versa under an unsecured promissory note (the "Versa Note") which accrues interest at 8% per annum, compounding annually, repayable within 18 months. The balance receivable under the Versa Note, including accrued interest, is included within the caption "Due from related parties" within current assets and was $0 and $112,000 as of December 31, 2025 and 2024, respectively. On December 31, 2025, the Company determined this note to be uncollectible and wrote off the $137,000 of principal and accrued interest.

On January 11, 2024, the Company borrowed $1.0 million from Fang Family Fund, LLC, an entity affiliated with one of its executive directors. This loan was consolidated in a convertible note on July 2, 2024 (“FFF Convertible Note”) as described below.

On February 6, 2024, the Company borrowed $450,000 from Fang Family Fund, LLC, an entity affiliated with one of its executive directors, under an interest-free loan which was repaid on February 8, 2024.

On February 21, 2024, the Company borrowed $450,000 from Fang Family Fund, LLC, an entity affiliated with one of its executive directors. This loan was consolidated in a convertible note on July 2, 2024 (“FFF Convertible Note”) as described below.

On March 11, 2024, the Company borrowed $500,000 from Fang Family Fund II, LLC, an entity affiliated with one of its executive directors, under an interest-free loan which was repaid on May 17, 2024.

On March 28, 2024, the Company borrowed $500,000 from Fang Family Fund II, LLC, an entity affiliated with one of its executive directors. This loan was consolidated in a convertible note on July 2, 2024 (“FFF Convertible Note”) as described below.

On April 10, 2024, the Company borrowed $500,000 from Fang Family Fund II, LLC, an entity affiliated with one of its executive directors. This loan was consolidated in a convertible note on July 2, 2024 (“FFF Convertible Note”) as described below.

On April 17, 2024, the Company borrowed $200,000 from Fang Family Fund II, LLC, an entity affiliated with one of its executive directors, under an interest-free loan which was repaid on May 17, 2024.

On June 5, 2024, the Company borrowed $500,000 from Fang Family Fund II, LLC, an entity affiliated with one of its executive directors. This loan was consolidated in a convertible note on July 2, 2024 (“FFF Convertible Note”) as described below.

On June 25, 2024, the Company borrowed $350,000 from Fang Family Fund II, LLC, an entity affiliated with one of its executive directors, under an interest-free loan, repayable after six months or, if sooner, on a date within two months of the loan execution date on which $1,000,000 in external funding is received. On November 18, 2024, $172,450 of this loan has been repaid. On May 6, 2025, $90,000 of this loan has been repaid. On September 3, 2025, the $87,500 remaining balance on this loan was repaid.

Effective July 2, 2024, all loans outstanding as of June 20, 2024, from Richard Fang, Fang Family Fund, LLC and Fang Family Fund II, LLC, were consolidated into one loan with a total principal amount of approximately $7.0 million. This loan accrues simple interest at the rate of 6% per annum, and is repayable after six months, unless amended. However, in the event of an initial public offering, while the loan remains outstanding, all principal, together with all unpaid accrued interest, would be automatically converted into common stock of the Company at a 77% discount to the lowest price per share paid by the other purchasers of the equity securities in the initial public offering. The Company evaluated the modification of the notes under ASC 470-50, Debt Modifications and Extinguishments, and determined that the notes were extinguished due to the addition of a substantive conversion option. There was no gain or loss from the debt extinguishment. The Company determined that the conversion feature on the convertible note met the definition of an embedded derivative that was required to be bifurcated recorded the fair value of the derivative liability at issuance of approximately $2.0 million as a debt discount to this convertible note and is amortized to interest expense over the term of the notes. Amortization expense for the year ended December 31, 2025 and 2024, amounted to $22,000 and $1,970,000, respectively. On November 12, 2024, Richard Fang, former Chief Executive Officer and current director, has donated the $7.0 million aggregated convertible note, dated July 2, 2024, and the related accrued interest, to the unrelated not-for-profit organizations, Nexus Science Foundation Inc. (“Nexus”), and Another Dimension Foundation (“Another Dimension”). Under this donation, Nexus and Another Dimension will each receive 50% of the converted value in registered shares. On September 2, 2025, the Nexus note and the Another Dimension note were converted, see also *8. Convertible Notes.*

On July 9, 2024, the Company borrowed $580,000 from Fang Family Fund II, LLC, an entity affiliated with one of its executive directors, under a loan which bears interest at the LIBOR rate, compounding monthly, repayable after six months or, if sooner, on the date in which $5 million in external funding is received. The Company has amended this loan to reflect the change to SOFR from LIBOR. This loan plus accrued interest of $31,918 was repaid on September 4, 2025.

On August 7, 2024, the Company borrowed $110,000 from Fang Family Fund II, LLC, an entity affiliated with one of its executive directors, under an interest-free loan, repayable after six months or, if sooner, on the date on which the Company goes public through a successful IPO or receives $5 million in external funding. This loan was repaid on September 4, 2025.

On August 20, 2024, the Company borrowed $250,000 from Hunniwell, an entity affiliated with one of its executive directors, under an interest-free loan, repayable upon the Company receiving the same amount of funds or greater within a 30-day period after receiving the subject loan from an external investor that is not a related party or as determined by the Board of Directors. On July 1, 2025, the Company amended this loan to the same terms as the Senior Secured Notes and issued a $93,633 loan to Hunniwell for travel expense reimbursements and a $187,190 loan to Daniel Teo, for severance from prior employment, under the same terms as the Senior Secured Notes. Under the Senior Secured Notes, the Company unconditionally grants, assigns, and pledges to the Holder a continuing security interest in all of the Company's right, title, and interest in all currently existing and hereafter acquired or arising Collateral to secure prompt repayment of any, and all sums due under the Senior Secured Notes. On July 1, 2025, the Company extended the maturity date of the Senior Secured Notes to October 15, 2025. On September 9, 2025, the $250,000 related party working capital loan plus $15,781 interest, the $93,633 Hunniwell travel expense reimbursement loan plus $5,237 interest, and the $187,190 severance loan plus $2,042 interest have been paid.

On August 21, 2024, the Company borrowed $350,000 from Fang Family Fund II, LLC, an entity affiliated with one of its executive directors, under an interest-free loan, repayable after six months or, if sooner, on a date within in which $5,000,000 in external funding is received or the Company successfully completes an Initial Public Offering ("IPO"). This loan was repaid on September 4, 2025.

On September 17, 2024, the Company borrowed $450,000 from Fang Family Fund II, LLC, an entity affiliated with one of its executive directors, under an interest-free loan, repayable after sixty (60) days. If, after the Company does not make payment during the sixty (60) day period, the Fang Family Fund II, LLC will be entitled to all proceeds from sales until the loan is paid. This loan was repaid on September 4, 2025.

On October 1, 2024, the Company borrowed $400,000 from Fang Family Fund II, LLC, an entity affiliated with one of its executive directors, under an interest-free loan, repayable after sixty (60) days. If, after the Company does not receive the same amount from an external investor (not related party) during the sixty (60) day period, the Fang Family Fund II, LLC will be entitled to all proceeds from sales until the loan is paid. This loan was repaid on September 4, 2025.

On October 16, 2024, we borrowed $700,000 from Fang Family Fund II, LLC, an entity affiliated with one of our executive directors, under a loan agreement which bears 6% interest per annum. The principal and accrued interest of this Note will be due and payable by us in cash at any time before or after twelve (12) months from the date of the transfer of funds (the "Maturity Date") at our written election or upon written demand by the Holder. Notwithstanding the foregoing sentence, we may, with the written consent of Holder, elect to extend the Maturity Date. Under this note, the Company unconditionally grants, assigns, and pledges to the Holder a continuing security interest in all of the Company's right, title, and interest in all currently existing and hereafter acquired or arising Collateral to secure prompt repayment of any and all sums due under this note. On July 1, 2025, the Company modified the maturity date of the Note to October 15, 2025. This loan was repaid on September 3, 2025.

On October 28, 2024, we borrowed $450,000 from Fang Family Fund II, LLC, an entity affiliated with one of our executive directors, under a loan agreement which bears 6% interest per annum. The principal and accrued interest of this Note will be due and payable by us in cash at any time before or after twelve (12) months from the date of the transfer of funds (the "Maturity Date") at our written election or upon written demand by the Holder. Notwithstanding the foregoing sentence, we may, with the written consent of Holder, elect to extend the Maturity Date. Under this note, the Company unconditionally grants, assigns, and pledges to the Holder a continuing security interest in all of the Company's right, title, and interest in all currently existing and hereafter acquired or arising Collateral to secure prompt repayment of any and all sums due under this note. On July 1, 2025, the Company modified the maturity date of the Note to October 15, 2025. This loan was repaid on September 3, 2025.

On November 13, 2024, we borrowed $480,000 from Fang Family Fund II, LLC, an entity affiliated with one of our executive directors, under a loan agreement which bears 6% interest per annum. The principal and accrued interest of this Note will be due and payable by us in cash at any time before or after twelve (12) months from the date of the transfer of funds (the "Maturity Date") at our written election or upon written demand by the Holder. Notwithstanding the foregoing sentence, we may, with the written consent of Holder, elect to extend the Maturity Date. Under this note, the Company unconditionally grants, assigns, and pledges to the Holder a continuing security interest in all of the Company's right, title, and interest in all currently existing and hereafter acquired or arising Collateral to secure prompt repayment of any and all sums due under this note. On July 1, 2025, the Company modified the maturity date of the Note to October 15, 2025. This loan was repaid on September 3, 2025.

On November 25, 2024, we borrowed $400,000 from Fang Family Fund II, LLC, an entity affiliated with one of our executive directors, under a loan agreement which bears 6% interest per annum. The principal and accrued interest of this Note will be due and payable by us in cash at any time before or after twelve (12) months from the date of the transfer of funds (the "Maturity Date") at our written election or upon written demand by the Holder. Notwithstanding the foregoing sentence, we may, with the written consent of Holder, elect to extend the Maturity Date. Under this note, the Company unconditionally grants, assigns, and pledges to the Holder a continuing security interest in all of the Company's right, title, and interest in all currently existing and hereafter acquired or arising Collateral to secure prompt repayment of any and all sums due under this note. On July 1, 2025, the Company modified the maturity date of the Note to October 15, 2025. This loan was repaid on September 3, 2025.

On December 9, 2024, we borrowed $450,000 from Fang Family Fund II, LLC, an entity affiliated with one of our executive directors, under a loan agreement which bears 6% interest per annum. The principal and accrued interest of this Note will be due and payable by us in cash at any time before or after twelve (12) months from the date of the transfer of funds (the "Maturity Date") at our written election or upon written demand by the Holder. Notwithstanding the foregoing sentence, we may, with the written consent of Holder, elect to extend the Maturity Date. Under this note, the Company unconditionally grants, assigns, and pledges to the Holder a continuing security interest in all of the Company's right, title, and interest in all currently existing and hereafter acquired or arising Collateral to secure prompt repayment of any and all sums due under this note. On July 1, 2025, the Company modified the maturity date of the Note to October 15, 2025. This loan was repaid on September 3, 2025.

On December 26, 2024, we borrowed $350,000 from Fang Family Fund I, LLC, an entity affiliated with one of our executive directors, under a loan agreement which bears 6% interest per annum. The principal and accrued interest of this Note will be due and payable by the Company in cash on the Maturity Date, which is defined as 365 days from the receipt of a deposit from a Holder at any time on or after December 26, 2025 (the "Maturity Date") at the Company's written election or upon written demand by the Holder. Notwithstanding the foregoing sentence, the Company may, with the written consent of Holder, elect to extend the Maturity Date. Under this note, the Company unconditionally grants, assigns, and pledges to the Holder a continuing security interest in all of the Company's right, title, and interest in all currently existing and hereafter acquired or arising Collateral to secure prompt repayment of any and all sums due under this note. On July 1, 2025, the Company modified the maturity date of the Note to October 15, 2025. This loan was repaid on September 3, 2025.

On January 9, 2025, we borrowed $301,000 from Fang Family Fund II LLC, an entity affiliated with one of our executive directors, under a loan agreement which bears 6% interest per annum. The principal and accrued interest of this Note will be due and payable by the Company in cash on the Maturity Date, which is defined as 365 days from the receipt of a deposit from a Holder at any time on or after January 9, 2026 (the "Maturity Date") at the Company's written election or upon written demand by the Holder. Notwithstanding the foregoing sentence, the Company may, with the written consent of Holder, elect to extend the Maturity Date. Under this note, the Company unconditionally grants, assigns, and pledges to the Holder a continuing security interest in all of the Company's right, title, and interest in all currently existing and hereafter acquired or arising Collateral to secure prompt repayment of any and all sums due under this note. On July 1, 2025, the Company modified the maturity date of the Note to October 15, 2025. This loan was repaid on September 3, 2025.

On January 22, 2025, we borrowed $376,000 from Fang Family Fund II LLC, an entity affiliated with one of our executive directors, under a loan agreement which bears 6% interest per annum. The principal and accrued interest of this Note will be due and payable by the Company in cash on the Maturity Date, which is defined as 365 days from the receipt of a deposit from a Holder at any time on or after January 22, 2026 (the "Maturity Date") at the Company's written election or upon written demand by the Holder. Notwithstanding the foregoing sentence, the Company may, with the written consent of Holder, elect to extend the Maturity Date. Under this note, the Company unconditionally grants, assigns, and pledges to the Holder a continuing security interest in all of the Company's right, title, and interest in all currently existing and hereafter acquired or arising Collateral to secure prompt repayment of any and all sums due under this note. On July 1, 2025, the Company modified the maturity date of the Note to October 15, 2025. This loan was repaid on September 3, 2025.

On March 4, 2025, we borrowed $325,000 from Fang Family Fund I LLC, an entity affiliated with one of our executive directors, under a loan agreement which bears 6% interest per annum. The principal and accrued interest of this Note will be due and payable by the Company in cash on the Maturity Date, which is defined as 365 days from the receipt of a deposit from a Holder at any time on or after March 4, 2026 (the "Maturity Date") at the Company's written election or upon written demand by the Holder. Notwithstanding the foregoing sentence, the Company may, with the written consent of Holder, elect to extend the Maturity Date. Under this note, the Company unconditionally grants, assigns, and pledges to the Holder a continuing security interest in all of the Company's right, title, and interest in all currently existing and hereafter acquired or arising Collateral to secure prompt repayment of any and all sums due under this note. On July 1, 2025, the Company modified the maturity date of the Note to October 15, 2025. This loan was repaid on September 3, 2025.

On March 21, 2025, we borrowed $350,000 from Fang Family Fund I LLC, an entity affiliated with one of our executive directors, under a loan agreement which bears 6% interest per annum. The principal and accrued interest of this Note will be due and payable by the Company in cash on the Maturity Date, which is defined as 365 days from the receipt of a deposit from a Holder at any time on or after March 21, 2026 (the "Maturity Date") at the Company's written election or upon written demand by the Holder. Notwithstanding the foregoing sentence, the Company may, with the written consent of Holder, elect to extend the Maturity Date. Under this note, the Company unconditionally grants, assigns, and pledges to the Holder a continuing security interest in all of the Company's right, title and interest in all currently existing and hereafter acquired or arising Collateral to secure prompt repayment of any and all sums due under this note. On July 1, 2025, the Company modified the maturity date of the Note to October 15, 2025. This loan was repaid on September 3, 2025.

On April 30, 2025, we borrowed $90,000 from Fang Family Fund I LLC, an entity affiliated with one of our executive directors, under a loan agreement which bears 6% interest per annum. The principal and accrued interest of this Note will be due and payable by the Company in cash on the Maturity Date, which is defined as 365 days from the receipt of a deposit from a Holder at any time on or after April 30, 2026 (the "Maturity Date") at the Company's written election or upon written demand by the Holder. Notwithstanding the foregoing sentence, the Company may, with the written consent of Holder, elect to extend the Maturity Date. Under this note, the Company unconditionally grants, assigns, and pledges to the Holder a continuing security interest in all of the Company's right, title, and interest in all currently existing and hereafter acquired or arising Collateral to secure prompt repayment of any and all sums due under this note. On July 1, 2025, the Company modified the maturity date of the Note to October 15, 2025. This loan was repaid on September 3, 2025.

On June 24, 2025 the Company borrowed $310,000 from Fang Family Fund I, LLC, an entity affiliated with one of its executive directors, under a loan agreement which bears 6% interest per annum. The principal and accrued interest of this Note will be due and payable by the Company in cash at any time before or after twelve (12) months from the date of the transfer of funds (the "Maturity Date") at the Company's written election or upon written demand by the Holder. Notwithstanding the foregoing sentence, the Company may, with the written consent of Holder, elect to extend the Maturity Date. Under these notes, the Company unconditionally grants, assigns, and pledges to the Holder a continuing security interest in all of the Company's right, title, and interest in all currently existing and hereafter acquired or arising Collateral to secure prompt repayment of any and all sums due under this note. On July 1, 2025, the Company modified the maturity date of the Note to October 15, 2025. This loan was repaid on September 3, 2025.

On July 8, 2025, the Company borrowed $425,000 from Fang Family Fund I, LLC, an entity affiliated with one of its executive directors, under a loan agreement which bears 6% interest per annum. The principal and accrued interest of this Note will be due and payable by the Company in cash on October 15, 2025 (the “Maturity Date”) at the Company’s written election or upon written demand by the Holder. Notwithstanding the foregoing sentence, the Company may, with the written consent of Holder, elect to extend the Maturity Date. Under these notes, the Company unconditionally grants, assigns, and pledges to the Holder a continuing security interest in all of the Company’s right, title, and interest in all currently existing and hereafter acquired or arising Collateral to secure prompt repayment of any and all sums due under this note. On September 4, 2025, the $425,000 loan plus $4,533 interest was paid.

On August 18, 2025, the Company borrowed $450,000 from Fang Family Fund I, LLC, an entity affiliated with one of its executive directors, under a loan agreement which bears 6% interest per annum. The principal and accrued interest of this Note will be due and payable by the Company in cash on October 15, 2025 (the “Maturity Date”) at the Company’s written election or upon written demand by the Holder. Notwithstanding the foregoing sentence, the Company may, with the written consent of Holder, elect to extend the Maturity Date. Under these notes, the company unconditionally grants, assigns, and pledges to the Holder a continuing security interest in all of the company’s right, title, and interest in all currently existing and hereafter acquired or arising Collateral to secure prompt repayment of any and all sums due under this note. On September 4, 2025, the $450,000 loan plus $1,200 interest was paid.

On November 26, 2025, the Company borrowed $1.0 million from Fang Family Fund I, LLC, an entity affiliated with one of its executive directors, under a loan agreement ("Note") which bears 6% interest per annum. The principal and accrued interest of this Note will be due and payable by the Company in cash on November 27, 2026 (the “Maturity Date”) at the Company’s written election or upon written demand by the Holder. Notwithstanding the foregoing sentence, the Company may, with the written consent of Holder, elect to extend the Maturity Date. Upon the consummation by the Company or any subsidiary of equity or equity-linked financing (including, without limitation, a private investment in public equity, an underwritten public offering pursuant to a registration statement on Form S-1 (or other applicable form), an at-the-market offering, or the issuance of convertible or exchangeable securities) for aggregate gross proceeds to the Company of not less than $10.0 million, the Company shall, on the date of the closing of the Qualified Financing automatically prepay this Note in an amount equal to the then-outstanding principal, together with all accrued and unpaid interest and other amounts due hereunder, without premium or penalty. As of December 31, 2025, this loan remains outstanding. The term Collateral in the above loans refers to all assets of the Company, including without limitation all of the Company’s right, title, and interest in assets, whether now owned or hereafter acquired or arising and wherever located.

As of December 31, 2025, the Company determined that it overpaid interest on the above Fang Family loans of $134,712 and recognized this amount as a receivable reported in “Due from related parties” in the consolidated balance sheet as of December 31, 2025.

15. SUBSEQUENT EVENTS

In connection with the issuance of the consolidated financial statements for the year ended December 31, 2025, the Company has evaluated subsequent events through the date the consolidated financial statements were issued.

Related Party Transactions

On January 6, 2026, the Company repaid $1.0 million plus $7,025 interest on the November 26, 2025 related party note, offset by $134,712 related party note receivable.

On various dates in February and March, 2026, a total of 129,735 of non-qualified vested stock options were exercised.

On February 28, 2026, the Company borrowed $0.7 million from Fang Family Fund I, LLC, an entity affiliated with one of its executive directors, under a loan agreement ("Note") which bears 6% interest per annum. The principal and accrued interest of this Note will be due and payable by the Company in cash on November 27, 2026 (the “Maturity Date”) at the Company’s written election or upon written demand by the Holder.

Stock option awards

In February 2026, the Company granted to certain employees a total of 216,448 common stock options with exercise prices ranging from $1.08 to $1.69 and a term of 10 years.

Senior Secured Note

In connection with the Senior Secured Note issued in December 2025 (see Note 8), the Company:

- Made principal payments in February and March 2026, totaling $3.4 million in cash.
- In February and March 2026, issued a total of 1,380,359 shares of common stock to settle $2.1 million of note principal as a result of the noteholder's election to accelerate repayment in shares.
- On March 9, 2026, paid the minimum liquidity requirement of $4.0 million to the noteholder in satisfaction of the equivalent principal amount.

Common share authorization

On March 10, 2026, the stockholders of the Company approved an amendment to the Company's Second Amended and Restated Certificate of Incorporation to increase the number of authorized shares of common stock from the previously authorized amount of 150,000,000 shares to 300,000,000 shares. The Second Amended and Restated Certificate of Incorporation was filed with the Secretary of State of the State of Delaware and became effective on March 24, 2026.

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

As required by Rule 13a-15(b) and Rule 15d-15(b) under the Exchange Act, our management, including our Chief Executive Officer and Chief Financial Officer, evaluated, as of December 31, 2025, the effectiveness of our disclosure controls and procedures as defined in Exchange Act Rule 13a-15(e) and Rule 15d-15(e). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective as of December 31, 2025. Management concluded that a material weakness existed related to:

- Lack of segregation of duties due to limited accounting personnel.
- Lack of a formal review process that includes multiple levels review over financial disclosure and reporting processes.

The Company is taking steps to enhance its internal control environment and expects to remediate all weaknesses listed above as additional resources become available. We have adopted a specific remediation plan, including:

- Retaining additional accounting personnel with public company financial reporting, technical accounting, SEC compliance, and strategic financial advisory experience to achieve adequate segregation of duties;
- Implementing multiple level reviews over financial disclosure and reporting processes

Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives of ensuring that information we are required to disclose in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to enable timely decisions regarding required disclosures, and is recorded, processed, summarized, and reported within the time periods specified in the rules and forms promulgated by the SEC. Our management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and there is no assurance that our disclosure controls and procedures will operate effectively under all circumstances.

Other than material weakness and remediation efforts described above, there have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that occurred during the quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management Report on Internal Control Over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

ITEM 9B. OTHER INFORMATION.

Entry into a Material Definitive Agreement.

On February 28, 2026, the Company entered into a Related Party Unsecured Promissory Note (the "Note") with Fang Family Fund, LLC – Series I (the "Holder"). The Holder is a "related person" within the meaning of Item 404(a) of Regulation S-K by virtue of being an affiliate of Richard Fang, a current member of the Board of Directors of the Company (the "Board"). Pursuant to the Related Party Transactions Policy of the Company (the "Policy"), the Audit Committee and other disinterested members of the Board approved the Note in accordance with the guidelines set forth in the Policy.

The Note provides for principal of up to an aggregate of $0.7 million (the "Maximum Principal Amount"), and the Company received $0.7 million in proceeds from the Holder. Amounts outstanding under the Note bear interest at a fixed rate of 6.00% per annum, compounded annually. Interest is payable in kind on each quarterly anniversary of the Note's date, although the Company may, at its option, pay interest in cash on any interest payment date. The outstanding principal and any accrued and unpaid interest are payable in cash on February 28, 2027 (the "Maturity Date"). The Company may, with the Holder's written consent, extend the Maturity Date. The Company may prepay the Note at any time, in whole or in part, without premium or penalty.

The Note requires mandatory prepayment upon the consummation by the Company or any subsidiary of a Qualified Financing, defined as an equity or equity-linked financing for aggregate gross proceeds to the Company of at least $5 million. Upon a Qualified Financing, the Company must prepay the then-outstanding principal together with all accrued and unpaid interest and other amounts due under the Note on the closing date of such financing or, if the Company retains proceeds sufficient to fund at least $2.0 million of post-closing working capital after payment of reasonable transaction fees and expenses, no later than the first Business Day following the Company's receipt of the remaining proceeds. Mandatory prepayment is subject to any applicable intercreditor arrangements and is not intended to contravene any then-existing senior secured debt facility; the Company will use commercially reasonable efforts to obtain any required consents.

The Note is unsecured and ranks pari passu in right of payment with all other unsubordinated, unsecured indebtedness of the Company. Events of default under the Note include failure to pay when due (subject to a 30-day cure period for nonpayment), dissolution or cessation of operations, and certain bankruptcy or insolvency events. The Note also includes customary information, inspection, confidentiality, and other provisions.

The Company intends to use the net proceeds from the Note for short-term liquidity needs and other business expenses, including those that may be incurred in pursuing additional equity financing.

The Note contains representations and warranties, affirmative and negative covenants, and events of default that the Company considers customary for an agreement of this type and on terms fair to, or no less favorable to, terms the Company than could have obtained in a comparable transaction with an unaffiliated party. The foregoing summary of the Note does not purport to be complete and is qualified in its entirety by reference to the full text of the Note, a copy of which is filed as Exhibit 10.59 to this Annual Report and incorporated herein by reference.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

MANAGEMENT

Executive Officers and Directors

The following table sets forth certain information regarding our executive officers, and directors as of the date of this Annual Report:

Name	Age	Position(s)
Patrick NJ Schnegelsberg	62	Chief Executive Officer and Director
Bernard Skaggs	63	Chief Financial Officer
Matt Schuster	45	Chief Operating Officer
Richard Fang	60	Director
Sam Van	48	Director
George Ye	50	Director

Executive Officers

Patrick NJ Schnegelsberg, Chief Executive Officer and Director

Patrick NJ Schnegelsberg serves as our Chief Executive Officer. Patrick has over 25 years of executive leadership experience and a proven track record in the medical device sector. Patrick served as CEO of Syntach AB from December 2022 to July 2023, and as COO and CEO with the Occlutech Group and its subsidiaries from July 2012 to March 2021. He has also held C-level positions with European and U.S. med- and biotech start-ups, including a U.S.-listed biotech company. Before working in the medical device industry, Patrick held director-level positions with buy- and sell-side firms on Wall Street. Patrick conducted extensive research in molecular biology at MIT and graduated from Harvard Medical School and Clark University. He currently serves as independent Chairman on the advisory board of Acorai AB and is a former board member of Scandinavian Real Heart. Patrick is qualified to serve on our board due to his background as an executive of other medical device and biotech companies.

Bernard Skaggs, Chief Financial Officer

Bernard Skaggs was appointed as our Chief Financial Officer in November 2023. Bernard has over 30 years of experience in finance and accounting. Prior to his role as Chief Financial Officer, Bernard served as our Controller from February 2023 to November 2023. Prior to his time at SynCardia, Bernard was Controller at Golden Vertex Corporation from June 2022 to February 2023, Plant Controller at Asarco LLC from May 2020 to June 2022, Controller Consultant at Experis from December 2019 to May 2020, Plant Controller at Embraer Aero Seating Technologies, a subsidiary of Embraer, from December 2017 to September 2019, and Accounting Manager at Cancer Prevention Pharmaceuticals from April 2015 to December 2017. Bernard started his career with Deloitte and has held a range of positions in the United States and Japan and is a U.S. Army Veteran. Bernard received his undergraduate degree from the University of Arizona, a master's degree in Accountancy from the University of Phoenix, and an MBA from the Thunderbird School of Global Management.

Matt Schuster, Chief Operating Officer

Matt Schuster was appointed as our Chief Operating Officer in November 2023. Prior to this role, Matt was the Director of Research and Development for SynCardia from May 2023 to November 2023. From January 2021 through May 2023, Matt held various roles with Roche, including as an Engineering Contractor, Staff Mechanical Engineer, and Systems Development Lead. Prior to his roles at Roche, Matt was the Director of Manufacturing and Facilities at SynCardia from April 2018 to January 2021. He has played a key role in development projects for SynCardia, including the smaller sized 50cc total artificial heart and next generation pneumatic driver. Matt received his bachelor's degree in Mechanical Engineering from Northern Arizona University.

Directors

Patrick NJ Schnegelsberg also serves as a Director of the Company. See "Executive Officers" above for additional information.

Richard Fang, Director

Richard Fang, Ph.D. is a founder and managing partner of Hunniwell Lake Ventures LLC ("HLV"), an investment group investing in the medical device space. HLV was formed in 2019. HLV, through us, recently acquired SynCardia Systems, which is now part of the HLV family of companies. In addition to HLV, Richard founded Reach Surgical, a minimally invasive surgical instruments company in California in 2005. Over a 15-year period, he drove the growth of Reach Surgical into an industry-leading brand with presence on six continents. During that time, he oversaw the development, manufacturing, marketing, and sales of three product lines including dozens of SKUs. His tenure with Reach Surgical culminated in the recent sale of the company to a private equity buyer. Richard has over 20 years of professional hands-on experience in the medical device industry, including Johnson & Johnson in the United States. He has an MBA from the University of Cincinnati, as well as a Ph.D. in Physics from Purdue University in Indianapolis. As a sci-fi fan, he believes in the ironman heart and has a vision that the SynCardia TAH will be a preferred alternative to heart transplant. We believe Richard is qualified to serve on our board due to his background in the medical device industry.

Sam Van, Director

Sam has been the founder and CEO of SRO Partners since May 2024. He served as the Head of Advisory Services and Senior Vice President for Freedom U.S. Markets, a dividing of Freedom Holding Corp (Nasdaq: FRHC] from September 2022 to May 2024, and as president and a director of Deltec Investment Adviser Limited from May 2017 to September 2022. Earlier in his career, Sam held senior roles at the New York Stock Exchange, including Director of International Listings, where he originated over 60 listings, and as a Senior Examiner in NYSE Regulation. He has also served as a director and as audit committee chair and a member of the nominating committee of Reed's Inc. since October 2024, as a director of Relm Insurance Limited (Bermuda) since January 2019 and as a director for Phoenix Motor, Inc. from June 2022 to May 2024. Sam began his career as an examiner with FINRA. He holds an MBA from Cornell University's Johnson School of Business and a BS in Finance from St. John's University. Sam is qualified to serve on our board due to his extensive regulatory, financial, and capital markets experience, and his leadership roles across both public and private companies.

George Ye, Director

George previously served in various roles at Edwards Lifesciences (NYSE: EW), including Senior Vice President and General Manager, Greater China Region from April 2019 to October 2024, Vice President and General Manager, Japan Surgical, from October 2016 to April 2019, and Senior Director, Japan and Asia Pacific Strategy from April 2015 to September 2016. Prior, George held various roles at Abbott Laboratories and Johnson & Johnson. George received his Bachelor of Science in Chemical Engineering and his MBA from Northwestern University. George is qualified to serve on our board based on his healthcare, medical technology and life sciences experience.

Family Relationships

There are no family relationships among any of our executive officers or directors.

Controlled Company Exemptions

Hunniwell controls a majority of the voting power of the outstanding common stock. As a result of Hunniwell's voting control, Hunniwell will effectively be able to determine the outcome of all matters requiring shareholder approval, including the election and removal of directors. Hunniwell is governed by three managers, Dr. Richard Fang, Daniel Teo and Chris Hsieh. Dr. Richard Fang serves as a director. As a result, they are effectively able to determine the outcome of all matters requiring shareholder approval, including the election and removal of directors, and combined with their membership on the Board, effectively control mergers and acquisitions, payment of dividends and other matters of corporate or management policy. This concentration of ownership may delay or deter possible changes in control and limit the liquidity of the trading market for common stock, which may reduce the value of an investment in such shares.

Additionally, we are a "controlled company" within the meaning of applicable NYSE rules. Under these rules, a company of which more than 50% of the voting power for the election of directors is held by an individual, group or another company is a "controlled company" and may elect not to comply with certain corporate governance requirements, including the requirements:

- that a majority of the board consists of independent directors;
- for an annual performance evaluation of the nominating and corporate governance and compensation committees;
- that the controlled company has a nominating and corporate governance committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities; and
- that the controlled company has a compensation committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibility.

Accordingly, you may not have the same protections afforded to stockholders of companies that are subject to all of the corporate governance requirements of NYSE. See the section entitled "*Risk Factors – Risks Related to Ownership of Our Securities – We are a* "*controlled company*" *within the meaning of the applicable rules of NYSE and, as a result, qualify for exemptions from certain corporate governance requirements.*"

Involvement in Certain Legal Proceedings

None of our directors or executive officers has been involved in any legal proceedings described in Item 401(f) of Regulation S-K during the past ten years.

Committees of Our Board of Directors

The Board has an audit committee, a compensation committee, and a nominating and corporate governance committee. In addition, from time to time, special committees may be established under the direction of the Board when necessary to address specific issues. Copies of each board committee's charter are posted on our website. Our website and the information contained on, or that can be accessed through such website, are not deemed to be incorporated by reference in, and are not considered part of, this Annual Report. The composition and responsibilities of each of the committees of the Board are described below. Members serve on these committees until their resignation or until otherwise determined by the Board.

The NYSE American permits a phase-in period of up to one year for an issuer registering securities in an initial public offering to meet the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee independence requirements. Under the initial public offering phase-in period, only one member of each committee is required to satisfy the heightened independence requirements at the time our registration statement becomes effective, a majority of the members of each committee must satisfy the heightened independence requirements within 90 days following the effectiveness of our registration statement, and all members of each committee must satisfy the heightened independence requirements within one year from the effectiveness of our registration statement.

Audit Committee

Sam Van and George Ye serve as members of our audit committee, with Sam Van serving as the chair of the Audit Committee. The board has determined that each member of the audit committee satisfies the independence requirements under the NYSE American Listing Rules and Rule 10A-3(b)(1) of the Exchange Act. Sam Van, the chair of the audit committee is an "audit committee financial expert" within the meaning of SEC regulations. Each member of the audit committee is able to read and understand fundamental financial statements in accordance with applicable listing standards. In arriving at these determinations, we examine each audit committee member's scope of experience and the nature of his or her employment. The primary purpose of the audit committee is to discharge the responsibilities of the Board with respect to corporate accounting and financial reporting processes, systems of internal control, and financial statement audits, and to oversee our independent registered public accounting firm. Specific responsibilities of the audit committee include:

- helping the Board oversee the corporate accounting and financial reporting processes;
- managing and/or assessing the selection, engagement, qualifications, independence, and performance of a qualified firm to serve as the independent registered public accounting firm to audit our consolidated financial statements;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and the independent accountants, our interim and year-end operating results;

- developing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- reviewing related party transactions;
- reviewing our policies on risk assessment and risk management;
- reviewing, with the independent registered public accounting firm, our internal quality control procedures, any material issues with such procedures and any steps taken to deal with such issues; and
- pre-approving audit and permissible non-audit services to be performed by the independent registered public accounting firm.

Our audit committee operates under a written charter, that satisfies the applicable NYSE American Listing Rules.

Compensation Committee

Sam Van and George Ye serve as members of our compensation committee, with George Ye serving as chair of the Compensation committee. The primary purpose of our compensation committee is to discharge the responsibilities of the Board in overseeing our compensation policies, plans, and programs and to review and determine the compensation to be paid to our executive officers, directors, and other senior management, as appropriate. Specific responsibilities of the compensation committee include:

- reviewing and recommending to the Board the compensation of executive officers;
- reviewing and recommending to the Board the compensation of directors;
- administering our equity incentive plans and other benefit programs;
- reviewing, adopting, amending, and terminating incentive compensation and equity plans, severance agreements, profit sharing plans, bonus plans, change-of-control protections, and any other compensatory arrangements for our executive officers and other senior management; and
- reviewing and establishing general policies relating to compensation and benefits of our employees, including our overall compensation philosophy.

Our compensation committee operates under a written charter that satisfies the applicable NYSE American Listing Rules.

Nominating and Corporate Governance Committee

Sam Van and George Ye serve as members of our nominating and governance committee, with George Ye serving as the chair of the nominating and corporate governance. The board determines that each member of the nominating and corporate governance committee satisfies the independence requirements under the NYSE American Listing Rules.

Specific responsibilities of our nominating and corporate governance committee include:

- identifying and evaluating candidates, including the nomination of incumbent directors for reelection and nominees recommended by stockholders, to serve on the Board;
- considering and making recommendations to the Board regarding the composition and chairpersonship of the Board and committees of the Board;
- reviewing developments in corporate governance practices;
- developing and making recommendations to the Board regarding corporate governance guidelines and matters; and
- overseeing periodic evaluations of the Board performance, including committees of the Board

Our nominating and corporate governance committee operates under a written charter that satisfies the applicable NYSE American Listing Rules.

Picard has a code of ethics that applies to its principal executive officer, principal financial officer, and principal accounting officer and controller. Among other matters, our code of business conduct and ethics is designed to deter wrongdoing and to promote:

- honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships;
- full, fair, accurate, timely and understandable disclosure in our SEC reports and other public communications;
- compliance with laws, rules and regulations;
- prompt internal reporting of violations of the code to appropriate persons identified in the code; and
- accountability for adherence to the code of business conduct and ethics.

That code is part of Picard's code of business conduct which is available free of charge through Picard's investor relations website (*www.Picardinvestor.com*). Picard intends to include on its website any amendment to, or waiver from, a provision of its code of ethics that applies to Picard's principal executive officer, principal financial officer, and principal accounting officer and controller that relates to any element of the code of ethics definition enumerated in Item 406(b) of Regulation S-K.

Picard has an insider trading policy governing the purchase, sale, and other dispositions of Picard securities by its directors, officers and employees, as well as Picard itself, that Picard believes is reasonably designed to promote compliance with insider trading laws, rules and regulations, and NYSE American listing standards.

ITEM 11. EXECUTIVE COMPENSATION

As an emerging growth company, we have opted to comply with the executive compensation disclosure rules applicable to smaller reporting companies, as such term is defined in the rules promulgated under the Securities Act. This section describes the material components of the executive compensation program for our named executive officers ("NEOs") for the fiscal year ended December 31, 2025 ("fiscal year 2025").

For fiscal year 2025, our NEOs were:

- Patrick NJ Schnegelsberg, Chief Executive Officer;
- Matt Schuster, Chief Operating Officer; and
- Bernard Skaggs, Chief Financial Officer.

Executive Compensation Program

The objective of our compensation program is to provide a total compensation package to each NEO that will enable us to attract, motivate, and retain outstanding individuals, align the interests of our executive team with those of our stockholders, encourage individual and collective contributions to the successful execution of our short and long-term business strategies, and reward NEOs for favorable performance.

Summary Compensation Table

The following table shows information concerning the annual compensation for services provided to us by our NEOs during fiscal years ended December 31, 2025 and 2024. Additional information on our NEOs annual compensation for fiscal year 2025 is provided in the narrative sections following the Summary Compensation Table:

Name and Position	Year	Salary ($)	Annual Cash Bonus Awards ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
Patrick NJ Schnegelsberg,	2025	400,000	-	-	-	-	-	400,000
Chief Executive Officer	2024	400,000	-	-	1,248,946	-	-	1,648,946
				-		-	-	
Bernard Skaggs,	2025	200,000	-	-	-	-	-	200,000
Chief Financial Officer	2024	200,000	-	-	272,617	-	-	472,617
				-		-	-	
Matt Schuster,	2025	220,000	-	-	-	-	-	220,000
Chief Operating Officer	2024	220,000	-	-	309,442	-	-	529,442

Narrative Disclosure to the Summary Compensation Table

Base Salaries

Base salary is paid to attract and retain qualified talent and is set at a level that is commensurate with the executive's duties and authorities, contributions, prior experience, and sustained performance, as well as considering market competitive levels. For fiscal year 2025, the NEOs had the following base salary rates: Mr. Schnegelsberg - $400,000, Mr. Schuster - $220,000, and Mr. Skaggs - $200,000.

Annual Cash Bonuses

Annual cash bonuses can be earned if the NEOs achieve certain annual financial and operating performance metrics. In fiscal year 2026, and the following NEOs were eligible for bonus compensation for the 2025 performance year: Mr. Schnegelsberg - $200,000 or 50% of base salary, Mr. Schuster - $33,000 or 15% of base salary, and Mr. Skaggs - $40,000 or 20% of base salary.

Employee Benefits

In addition to any individual benefits set forth in each NEOs employment arrangements (described below), the NEOs are generally eligible to participate in certain executive and employee health and welfare, retirement and other employee benefit programs maintained and administered by Voya Financial Service, a third-party professional employer organization ("Voya"), on the same basis as other employees, subject to applicable law. Each NEO meeting the eligibility requirements is eligible to participate in the Company's 401(k) plan, under which participants may elect to contribute a portion of their eligible compensation as pre-tax or Roth deferrals in accordance with the limitations imposed under the Code. At this time, we do not make any employer contributions on behalf of employees to the Company's 401(k) plan.

Equity Incentive Awards

We adopted the 2021 Equity Incentive Plan, a broad-based incentive plan in which our employees, including our NEOs, may receive options to purchase shares of our common stock. The 2021 Equity Incentive Plan included an initial share reserve of 5,565,159 shares of our common stock available for issuance via future grants made under the plan. On July 1, 2024, an increase of an additional 2,829,200 share reserve under the plan was approved. On October 10, 2025, the Company's stockholders approved an amendment to the Company's 2021 Equity Incentive Plan (the "Amended Incentive Plan") to (i) increase the aggregate number of shares of Common Stock available under the 2021 Equity Incentive Plan to a total of 18,000,000 shares, (ii) include warrant as a type of awards issuable under the Amended Incentive Plan, and (iii) to ratify the 2021 Equity Incentive Plan. The awards described below have been adjusted to reflect the Stock Split. On June 28, 2024, we granted the following stock option awards (intended to be incentive stock options under Code Section 422) to the NEOs: 2,378,124 options to Patrick Schnegelsberg, with a vesting commencement date of July 5, 2023, 102,239 options and 408,956 options to Bernard Skaggs, with a vesting commencement date of February 21, 2023 and November 27, 2023, respectively, and 102,239 options, 408,956 options and 68,608 options to Matt Schuster, with a vesting commencement date of May 29, 2023, November 27, 2023, and May 29, 2023, respectively (the "2024 Options"). One quarter of the options cliff vest upon the first anniversary of the vesting commencement date, and the remaining options vest ratably in equal monthly installments over the 36 months following the first anniversary of the vesting commencement date, generally subject to the continued service of the NEO through each applicable vesting date. As of December 31, 2025, Patrick Schnegelsberg was vested in 1,436,783 options, Bernard Skaggs was vested in 285,416 options, and Matt Schuster was vested in 323,335 options. The grant date fair value of the options is in the table above.

If in connection with a Change of Control (as defined under the 2021 Equity Incentive Plan), and the acquiring entity fails to assume, replace, fully accelerate, cash out, or substitute the 2022 Options, then provided the NEO has remained in continued service through such Change of Control, we will accelerate the vesting of all then-unvested 2022 Options.

For purposes of this section, "Change of Control" means the transaction(s) which results in (i) a change in more than 50% of the combined voting power of our then outstanding shares, (ii) a merger, consolidation, or similar transaction which results in our stockholders owning less than 50% of (x) our voting shares thereafter or (y) the surviving parent entity's voting power, or (iii) sale, lease, exclusive license or other disposition of all or substantially all of our consolidated assets and our subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of our consolidated assets and our subsidiaries to a person or entity, more than 50% of the combined voting power of the voting securities of which are owned by our stockholders in substantially the same proportions as their ownership of our outstanding voting securities immediately prior to such sale, lease, license or other disposition.

Outstanding Equity Awards at 2025 Fiscal Year-End

The following table shows information regarding equity awards held by the NEOs as of December 31, 2025. The awards described below have been adjusted to reflect the Stock Split that was affected in connection with our IPO:

	Option Awards[(1)]			
Name	**Number of securities underlying unexercised options (#) exercisable**	**Number of securities underlying unexercised options (#) unexercisable**	**Option exercise price ($)**	**Option expiration date**
Patrick Schnegelsberg	1,436,783	941,341	$0.71	7/2/2033
Bernard Skaggs	285,416	225,779	$0.71	2/18/2033, 11/24/2033
Matt Schuster	323,335	256,468	$0.71	5/26/2033, 11/24/2033

(1) All awards reflected in this table were granted under the 2021 Equity Incentive Plan.

Potential Payments Upon Termination or Change in Control

None of our NEOs are eligible to receive any payment or benefit in connection with a termination for any reason. Except as described above under "*Equity Incentive Awards*," none of our NEOs are eligible to receive any payment or benefit in connection with a change in control.

Pension Benefits

We do not provide any of our officers with pension benefits.

Nonqualified Deferred Compensation

We do not provide any of our officers with any nonqualified deferred compensation plans.

Clawback Policy

In connection with our IPO, the Board adopted a clawback policy (the "Clawback Policy") in compliance with Section 10D of the Exchange Act and Section 303A.14 of the NYSE Listed Company Manual (The "Clawback Listing Standards"). The Clawback Policy provides that promptly following an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws (including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period), the Compensation Committee will determine the amount of the excess of incentive-based compensation received by Section 16 officers during the three completed fiscal years immediately preceding the required restatement date over the amount of incentive-based compensation that otherwise would have been received had it been determined based on the restated amounts. The Company will provide each such officer with a written notice of such amount and a demand for repayment or return. If such repayment or return is not made within a reasonable time, the Clawback Policy provides that the Company will recover the erroneously awarded compensation in a reasonable and prompt manner using any lawful method, subject to limited exceptions as permitted by the Clawback Listing Standards.

Director Compensation Program

Directors who are officers of the Company do not receive compensation for their service as directors.

We provide the following compensation for non-management directors:

- Each non-management director receives an annual director's fee payable in cash equal to $35,000 and an annual grant of $15,000 stock options;
- The chair of the audit committee receives an additional annual fee payable in cash equal to $15,000;
- The chair of the compensation committee receives an additional annual fee payable in cash equal to $10,000.

We also reimburse directors for all expenses incurred in attending Board and committee meetings.

The following table provides information regarding the compensation of our non-management directors for the year ended December 31, 2025:

Name	Fees Earned Or Paid in Cash	Stock Option Awards[(1)]	Total
Richard Fang	$ -	$ -	$ -
Sam Van	$ 16,667	$ 14,028	$ 30,695
George Ye	$ 15,000	$ 14,028	$ 29,028

(1) Reflects grant date fair value of $8.137 per share.

Compensation Committee Interlocks and Insider Participation

None of the members or intended members of the compensation committee is currently, or has been at any time, one of our executive officers or employees. None of our executive officers currently serves, or has served during the last calendar year, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

(a) *Equity Compensation Plan Information*.

The following table presents information as of December 31, 2025, about our compensation plans under which Picard common shares have been authorized for issuance:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders [(1)]	7,556,434	$ 0.44	10,443,566
Equity compensation plans not approved by security holders	—	—	—
Total [(1)]	7,556,434	$ 0.44	10,443,566

(1) On September 26, 2021, the Company's board of directors approved the adoption of the 2021 Equity Incentive Plan (the "2021 Plan"), under which the Company is authorized to issue incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock awards, restricted stock units, other stock awards and performance awards that may be settled in cash, stock, or other property.

The following table sets forth information known to us regarding the beneficial ownership of our common stock as of March 26, 2026, by (i) any person who is known by us to be the beneficial owner of more than 5% of the outstanding shares of common stock, (ii) our directors, (iii) our executive officers, and (iv) all of our directors and executive officers as a group. The address for each beneficial owner is c/o Picard Medical, Inc., 1992 E Silverlake Rd, Tucson, AZ 85713, unless otherwise provided.

Shares of Common Stock Beneficially Owned

Name of Beneficial Owner	Number of Shares	Percentage[1]
Directors and Named Executive Officers		
Patrick NJ Schnegelsberg	-	0.00%
Bernard Skaggs	-	0.00%
Matt Schuster	-	0.00%
Richard Fang[2]	-	0.00%
George Ye	-	0.00%
Sam Van	-	0.00%
5% Stockholders		
Hunniwell[3]	39,618,919	52.70%
Sindex SSI Lending, LLC[4]	7,943,585	10.57%
Hudson Bay Capital Management LP[5]	7,009,346	9.32%
Another Dimension[6]	4,054,517	5.39%
Ju Wang[7]	5,280,309	7.03%
All directors, director nominees and current executive officers as a group (7 persons)	**-**	**0.00%**

(1) Based on 75,178,535 shares as of March 23, 2026.

(2) Richard Fang is a partner of Hunniwell Picard GP, LLC, which manages Hunniwell Picard I, LLC. By virtue of the "rule of three" described in footnote (4) below, Mr. Fang is not deemed to be the beneficial owner of the shares held by Hunniwell Picard I, LLC, even though he holds a pecuniary interest therein.

(3) Hunniwell Picard I, LLC is a manager-managed venture capital fund managed by Hunniwell Picard GP, LLC where dispositive decisions require the unanimous vote of all three partners, namely Yuncai (“Richard”) Fang, Sinyew (“Daniel”) Teo & Chris Hsieh. Under the so-called “rule of three” because voting and dispositive decisions are made by a unanimous vote of all three partners, none of the partners is deemed to be a beneficial owner of shares, even those in which any director holds a pecuniary interest.

(4) Sindex SSI Lending, LLC is a subsidiary of Versa Capital Fund III, L.P. Versa FGP-III, L.P. is the general partner of Versa Capital Fund III, L.P. Versa UGP-III, LLC is the general partner of Versa FGP-III, L.P. Versa Capital Group, LLC is the sole member of Versa UGP-III, LLC. Gregory L. Segall has sole voting and dispositive power over the shares owned by Sindex SSI Lending, LLC. The address of Sindex SSI Lending, LLC is c/o Versa Capital Management, Two Commerce Square, 2001 Market Street, Suite 3110, Philadelphia, PA 1910.

(5) Hudson Bay Capital Management LP is an investment adviser in accordance with § 240.13d-1(b)(1)(ii)(E) and serves as the investment manager to HT Investments MA LLC, in whose name the securities are held. Mr. Sander Gerber serves as the managing member of Hudson Bay Capital GP LLC, which is the general partner of Hudson Bay Capital Management LP. The address of Hudson Bay Capital Management LP's principal business office is 290 Harbor Dr., Stamford, CT 06902.

(6) Another Dimension Foundation - Jun Liu, Ph.D. has sole voting and dispositive power over the shares owned by Another Dimension. The address of Another Dimension is 2800 Glades Circle, Suite 159 Weston, FL 33327-2279.

(7) Represents shares held (i) held directly by Ju Wang in his own name and (ii) by Nexus Science Foundation, Inc. Ju Wang has sole voting and dispositive power over the shares owned by Nexus. The address of Nexus is 14738 SW 23rd Steet Miami, FL 33185-5922.

Change in Control

The Company is not aware of any arrangements which may at a subsequent date result in a change of control of the Company, except that shares of common stock may be issued pursuant to the Purchase Agreement dated December 24, 2025. Such issuances could result in dilution of the shares held by Hunniwell Picard I, the Company's current controlling stockholder, and may result in a change of control of the Company.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The following is a summary of transactions for the years ended December 31, 2025 and 2024, to which we have been a participant in which the amount involved exceeded or will exceed the lesser of $120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Executive and Director Compensation" elsewhere in this Annual Report.

Versa Capital Management, LLC (“Versa”) shares common ownership with Sindex SSI Financing, LLC (“Sindex”), which owned 100% of the outstanding membership interest of SynCardia prior to the acquisition by PMI. To enable Versa to pay transaction costs on behalf of SynCardia in conjunction with PMI’s acquisition, on September 27, 2021, PMI advanced $100,000 to Versa under an unsecured promissory note (the “Versa Note”) which accrues interest at 8% per annum, compounding annually, repayable within 18 months. The balance receivable under the Versa Note, including accrued interest, is included within the caption "Due from related parties" within current assets and was $0 and $112,000 as of December 31, 2025 and 2024, respectively. On December 31, 2025, the Company determined this note to be uncollectible and wrote-off the $137,000 of principal and accrued interest.

On January 11, 2024, the Company borrowed $1.0 million from Fang Family Fund, LLC, an entity affiliated with one of its executive directors. This loan was consolidated in a convertible note on July 2, 2024 (“FFF Convertible Note”) as described below.

On February 6, 2024, the Company borrowed $450,000 from Fang Family Fund, LLC, an entity affiliated with one of its executive directors, under an interest-free loan which was repaid on February 8, 2024.

On February 21, 2024, the Company borrowed $450,000 from Fang Family Fund, LLC, an entity affiliated with one of its executive directors. This loan was consolidated in a convertible note on July 2, 2024 (“FFF Convertible Note”) as described below.

On March 11, 2024, the Company borrowed $500,000 from Fang Family Fund II, LLC, an entity affiliated with one of its executive directors, under an interest-free loan which was repaid on May 17, 2024.

On March 28, 2024, the Company borrowed $500,000 from Fang Family Fund II, LLC, an entity affiliated with one of its executive directors. This loan was consolidated in a convertible note on July 2, 2024 (“FFF Convertible Note”) as described below.

On April 10, 2024, the Company borrowed $500,000 from Fang Family Fund II, LLC, an entity affiliated with one of its executive directors. This loan was consolidated in a convertible note on July 2, 2024 (“FFF Convertible Note”) as described below.

On April 17, 2024, the Company borrowed $200,000 from Fang Family Fund II, LLC, an entity affiliated with one of its executive directors, under an interest-free loan which was repaid on May 17, 2024.

On June 5, 2024, the Company borrowed $500,000 from Fang Family Fund II, LLC, an entity affiliated with one of its executive directors. This loan was consolidated in a convertible note on July 2, 2024 (“FFF Convertible Note”) as described below.

On June 25, 2024, the Company borrowed $350,000 from Fang Family Fund II, LLC, an entity affiliated with one of its executive directors, under an interest-free loan, repayable after six months or, if sooner, on a date within two months of the loan execution date on which $1,000,000 in external funding is received. On November 18, 2024, $172,450 of this loan has been repaid. On May 6, 2025, $90,000 of this loan has been repaid. On September 3, 2025, the $87,500 remaining balance on this loan was repaid.

FFF Convertible Note: Effective July 2, 2024, all loans outstanding as of June 20, 2024, from Richard Fang, Fang Family Fund, LLC and Fang Family Fund II, LLC, were consolidated into one loan with a total principal amount of approximately $7.0 million. This loan accrues simple interest at the rate of 6% per annum, and is repayable after six months, unless amended. However, in the event of an initial public offering, while the loan remains outstanding, all principal, together with all unpaid accrued interest, would be automatically converted into common stock of the Company at a 77% discount to the lowest price per share paid by the other purchasers of the equity securities in the initial public offering. The Company evaluated the modification of the notes under ASC 470-50, Debt Modifications and Extinguishments, and determined that the notes were extinguished due to the addition of a substantive conversion option. There was no gain or loss from the debt extinguishment. The Company determined that the conversion feature on the convertible note met the definition of an embedded derivative that was required to be bifurcated recorded the fair value of the derivative liability at issuance of approximately $2.0 million as a debt discount to this convertible note and is amortized to interest expense over the term of the notes. Amortization expense for the year ended December 31, 2025 and 2024, amounted to $22,000 and $1,970,000, respectively. On November 12, 2024, Richard Fang, former Chief Executive Officer and current director, has donated the $7.0 million aggregated convertible note, dated July 2, 2024, and the related accrued interest, to the unrelated not-for-profit organizations, Nexus Science Foundation Inc. (“Nexus”), and Another Dimension Foundation (“Another Dimension”). Under this donation, Nexus and Another Dimension will each receive 50% of the converted value in registered shares. At the IPO, Nexus and Another Dimension each received 4,054,517 common shares.

On July 9, 2024, the Company borrowed $580,000 from Fang Family Fund II, LLC, an entity affiliated with one of its executive directors, under a loan which bears interest at the LIBOR rate, compounding monthly, repayable after six months or, if sooner, on the date in which $5 million in external funding is received. The Company has amended this loan to reflect the change to SOFR from LIBOR. This loan plus accrued interest of $31,918 was repaid on September 4, 2025.

On August 7, 2024, the Company borrowed $110,000 from Fang Family Fund II, LLC, an entity affiliated with one of its executive directors, under an interest-free loan, repayable after six months or, if sooner, on the date on which the Company goes public through a successful IPO or receives $5 million in external funding. This loan was repaid on September 4, 2025.

On August 20, 2024, the Company borrowed $250,000 from Hunniwell, an entity affiliated with one of its executive directors, under an interest-free loan, repayable upon the Company receiving the same amount of funds or greater within a 30-day period after receiving the subject loan from an external investor that is not a related party or as determined by the Board of Directors. On July 1, 2025, the Company amended this loan to the same terms as the Senior Secured Notes and issued a $93,633 loan to Hunniwell for travel expense reimbursements and a $187,190 loan to Daniel Teo, for severance from prior employment, under the same terms as the Senior Secured Notes. Under the Senior Secured Notes, the Company unconditionally grants, assigns, and pledges to the Holder a continuing security interest in all of the Company’s right, title, and interest in all currently existing and hereafter acquired or arising Collateral to secure prompt repayment of any, and all sums due under the Senior Secured Notes. On July 1, 2025, the Company extended the maturity date of the Senior Secured Notes to October 15, 2025. On September 9, 2025, the $250,000 related party working capital loan plus $15,781 interest, the $93,633 Hunniwell travel expense reimbursement loan plus $5,237 interest, and the $187,190 severance loan plus $2,042 interest have been paid.

On August 21, 2024, the Company borrowed $350,000 from Fang Family Fund II, LLC, an entity affiliated with one of its executive directors, under an interest-free loan, repayable after six months or, if sooner, on a date within in which $5,000,000 in external funding is received or the Company successfully completes an Initial Public Offering (“IPO”). This loan was repaid on September 4, 2025.

On September 17, 2024, the Company borrowed $450,000 from Fang Family Fund II, LLC, an entity affiliated with one of its executive directors, under an interest-free loan, repayable after sixty (60) days. If, after the Company does not make payment during the sixty (60) day period, the Fang Family Fund II, LLC will be entitled to all proceeds from sales until the loan is paid. This loan was repaid on September 4, 2025.

On October 1, 2024, the Company borrowed $400,000 from Fang Family Fund II, LLC, an entity affiliated with one of our executive directors, under an interest-free loan, repayable after sixty (60) days. If, after the Company does not receive the same amount from an external investor (not related party) during the sixty (60) day period, the Fang Family Fund II, LLC will be entitled to all proceeds from sales until the loan is paid. This loan was repaid on September 4, 2025.

On October 16, 2024, we borrowed $700,000 from Fang Family Fund II, LLC, an entity affiliated with one of our executive directors, under a loan agreement which bears 6% interest per annum. The principal and accrued interest of this Note will be due and payable by us in cash at any time before or after twelve (12) months from the date of the transfer of funds (the "Maturity Date") at our written election or upon written demand by the Holder. Notwithstanding the foregoing sentence, we may, with the written consent of Holder, elect to extend the Maturity Date. Under this note, the Company unconditionally grants, assigns, and pledges to the Holder a continuing security interest in all of the Company's right, title, and interest in all currently existing and hereafter acquired or arising Collateral to secure prompt repayment of any and all sums due under this note. On July 1, 2025, the Company modified the maturity date of the Note to October 15, 2025. On September 3, 2025, this loan was paid off.

On October 28, 2024, we borrowed $450,000 from Fang Family Fund II, LLC, an entity affiliated with one of our executive directors, under a loan agreement which bears 6% interest per annum. The principal and accrued interest of this Note will be due and payable by us in cash at any time before or after twelve (12) months from the date of the transfer of funds (the "Maturity Date") at our written election or upon written demand by the Holder. Notwithstanding the foregoing sentence, we may, with the written consent of Holder, elect to extend the Maturity Date. Under this note, the Company unconditionally grants, assigns, and pledges to the Holder a continuing security interest in all of the Company's right, title, and interest in all currently existing and hereafter acquired or arising Collateral to secure prompt repayment of any and all sums due under this note. On July 1, 2025, the Company modified the maturity date of the Note to October 15, 2025. On September 3, 2025, this loan was paid off.

On November 13, 2024, we borrowed $480,000 from Fang Family Fund II, LLC, an entity affiliated with one of our executive directors, under a loan agreement which bears 6% interest per annum. The principal and accrued interest of this Note will be due and payable by us in cash at any time before or after twelve (12) months from the date of the transfer of funds (the "Maturity Date") at our written election or upon written demand by the Holder. Notwithstanding the foregoing sentence, we may, with the written consent of Holder, elect to extend the Maturity Date. Under this note, the Company unconditionally grants, assigns, and pledges to the Holder a continuing security interest in all of the Company's right, title, and interest in all currently existing and hereafter acquired or arising Collateral to secure prompt repayment of any and all sums due under this note. On July 1, 2025, the Company modified the maturity date of the Note to October 15, 2025. On September 3, 2025, this loan was paid off.

On November 25, 2024, we borrowed $400,000 from Fang Family Fund II, LLC, an entity affiliated with one of our executive directors, under a loan agreement which bears 6% interest per annum. The principal and accrued interest of this Note will be due and payable by us in cash at any time before or after twelve (12) months from the date of the transfer of funds (the "Maturity Date") at our written election or upon written demand by the Holder. Notwithstanding the foregoing sentence, we may, with the written consent of Holder, elect to extend the Maturity Date. Under this note, the Company unconditionally grants, assigns, and pledges to the Holder a continuing security interest in all of the Company's right, title, and interest in all currently existing and hereafter acquired or arising Collateral to secure prompt repayment of any and all sums due under this note. On July 1, 2025, the Company modified the maturity date of the Note to October 15, 2025. On September 3, 2025, this loan was paid off.

On December 9, 2024, we borrowed $450,000 from Fang Family Fund II, LLC, an entity affiliated with one of our executive directors, under a loan agreement which bears 6% interest per annum. The principal and accrued interest of this Note will be due and payable by us in cash at any time before or after twelve (12) months from the date of the transfer of funds (the "Maturity Date") at our written election or upon written demand by the Holder. Notwithstanding the foregoing sentence, we may, with the written consent of Holder, elect to extend the Maturity Date. Under this note, the Company unconditionally grants, assigns, and pledges to the Holder a continuing security interest in all of the Company's right, title, and interest in all currently existing and hereafter acquired or arising Collateral to secure prompt repayment of any and all sums due under this note. On July 1, 2025, the Company modified the maturity date of the Note to October 15, 2025. On September 3, 2025, this loan was paid off.

On December 26, 2024, we borrowed $350,000 from Fang Family Fund I, LLC, an entity affiliated with one of our executive directors, under a loan agreement which bears 6% interest per annum. The principal and accrued interest of this Note will be due and payable by the Company in cash on the Maturity Date, which is defined as 365 days from the receipt of a deposit from a Holder at any time on or after December 26, 2025 (the "Maturity Date") at the Company's written election or upon written demand by the Holder. Notwithstanding the foregoing sentence, the Company may, with the written consent of Holder, elect to extend the Maturity Date. Under this note, the Company unconditionally grants, assigns, and pledges to the Holder a continuing security interest in all of the Company's right, title, and interest in all currently existing and hereafter acquired or arising Collateral to secure prompt repayment of any and all sums due under this note. On July 1, 2025, the Company modified the maturity date of the Note to October 15, 2025. On September 3, 2025, this loan was paid off.

On January 9, 2025, we borrowed $301,000 from Fang Family Fund II LLC, an entity affiliated with one of our executive directors, under a loan agreement which bears 6% interest per annum. The principal and accrued interest of this Note will be due and payable by the Company in cash on the Maturity Date, which is defined as 365 days from the receipt of a deposit from a Holder at any time on or after January 9, 2026 (the "Maturity Date") at the Company's written election or upon written demand by the Holder. Notwithstanding the foregoing sentence, the Company may, with the written consent of Holder, elect to extend the Maturity Date. Under this note, the Company unconditionally grants, assigns, and pledges to the Holder a continuing security interest in all of the Company's right, title, and interest in all currently existing and hereafter acquired or arising Collateral to secure prompt repayment of any and all sums due under this note. On July 1, 2025, the Company modified the maturity date of the Note to October 15, 2025. On September 3, 2025, this loan was paid off.

On January 22, 2025, we borrowed $376,000 from Fang Family Fund II LLC, an entity affiliated with one of our executive directors, under a loan agreement which bears 6% interest per annum. The principal and accrued interest of this Note will be due and payable by the Company in cash on the Maturity Date, which is defined as 365 days from the receipt of a deposit from a Holder at any time on or after January 22, 2026 (the "Maturity Date") at the Company's written election or upon written demand by the Holder. Notwithstanding the foregoing sentence, the Company may, with the written consent of Holder, elect to extend the Maturity Date. Under this note, the Company unconditionally grants, assigns, and pledges to the Holder a continuing security interest in all of the Company's right, title, and interest in all currently existing and hereafter acquired or arising Collateral to secure prompt repayment of any and all sums due under this note. On July 1, 2025, the Company modified the maturity date of the Note to October 15, 2025. On September 3, 2025, this loan was paid off.

On March 4, 2025, we borrowed $325,000 from Fang Family Fund I LLC, an entity affiliated with one of our executive directors, under a loan agreement which bears 6% interest per annum. The principal and accrued interest of this Note will be due and payable by the Company in cash on the Maturity Date, which is defined as 365 days from the receipt of a deposit from a Holder at any time on or after March 4, 2026 (the "Maturity Date") at the Company's written election or upon written demand by the Holder. Notwithstanding the foregoing sentence, the Company may, with the written consent of Holder, elect to extend the Maturity Date. Under this note, the Company unconditionally grants, assigns, and pledges to the Holder a continuing security interest in all of the Company's right, title, and interest in all currently existing and hereafter acquired or arising Collateral to secure prompt repayment of any and all sums due under this note. On July 1, 2025, the Company modified the maturity date of the Note to October 15, 2025. On September 3, 2025, this loan was paid off.

On March 21, 2025, we borrowed $350,000 from Fang Family Fund I LLC, an entity affiliated with one of our executive directors, under a loan agreement which bears 6% interest per annum. The principal and accrued interest of this Note will be due and payable by the Company in cash on the Maturity Date, which is defined as 365 days from the receipt of a deposit from a Holder at any time on or after March 21, 2026 (the "Maturity Date") at the Company's written election or upon written demand by the Holder. Notwithstanding the foregoing sentence, the Company may, with the written consent of Holder, elect to extend the Maturity Date. Under this note, the Company unconditionally grants, assigns, and pledges to the Holder a continuing security interest in all of the Company's right, title and interest in all currently existing and hereafter acquired or arising Collateral to secure prompt repayment of any and all sums due under this note. On July 1, 2025, the Company modified the maturity date of the Note to October 15, 2025. On September 3, 2025, this loan was paid off.

On April 30, 2025, we borrowed $90,000 from Fang Family Fund I LLC, an entity affiliated with one of our executive directors, under a loan agreement which bears 6% interest per annum. The principal and accrued interest of this Note will be due and payable by the Company in cash on the Maturity Date, which is defined as 365 days from the receipt of a deposit from a Holder at any time on or after April 30, 2026 (the "Maturity Date") at the Company's written election or upon written demand by the Holder. Notwithstanding the foregoing sentence, the Company may, with the written consent of Holder, elect to extend the Maturity Date. Under this note, the Company unconditionally grants, assigns, and pledges to the Holder a continuing security interest in all of the Company's right, title, and interest in all currently existing and hereafter acquired or arising Collateral to secure prompt repayment of any and all sums due under this note. On July 1, 2025, the Company modified the maturity date of the Note to October 15, 2025. On September 3, 2025, this loan was paid off.

On June 24, 2025, the Company borrowed $310,000 from Fang Family Fund I, LLC, an entity affiliated with one of its executive directors, under a loan agreement which bears 6% interest per annum. The principal and accrued interest of this Note will be due and payable by the Company in cash at any time before or after twelve (12) months from the date of the transfer of funds (the "Maturity Date") at the Company's written election or upon written demand by the Holder. Notwithstanding the foregoing sentence, the Company may, with the written consent of Holder, elect to extend the Maturity Date. Under these notes, the Company unconditionally grants, assigns, and pledges to the Holder a continuing security interest in all of the Company's right, title, and interest in all currently existing and hereafter acquired or arising Collateral to secure prompt repayment of any and all sums due under this note. On July 1, 2025, the Company modified the maturity date of the Note to October 15, 2025. On September 3, 2025, this loan was paid off.

On July 8, 2025, the Company borrowed $425,000 from Fang Family Fund I, LLC, an entity affiliated with one of its executive directors, under a loan agreement which bears 6% interest per annum. The principal and accrued interest of this Note will be due and payable by the Company in cash on October 15, 2025 (the "Maturity Date") at the Company's written election or upon written demand by the Holder. Notwithstanding the foregoing sentence, the Company may, with the written consent of Holder, elect to extend the Maturity Date. Under these notes, the Company unconditionally grants, assigns, and pledges to the Holder a continuing security interest in all of the Company's right, title, and interest in all currently existing and hereafter acquired or arising Collateral to secure prompt repayment of any and all sums due under this note. On September 4, 2025, the $425,000 loan plus $4,533 interest has been paid.

On August 18, 2025, the Company borrowed $450,000 from Fang Family Fund I, LLC, an entity affiliated with one of its executive directors, under a loan agreement which bears 6% interest per annum. The principal and accrued interest of this Note will be due and payable by the Company in cash on October 15, 2025 (the "Maturity Date") at the Company's written election or upon written demand by the Holder. Notwithstanding the foregoing sentence, the Company may, with the written consent of Holder, elect to extend the Maturity Date. Under these notes, the company unconditionally grants, assigns, and pledges to the Holder a continuing security interest in all of the company's right, title, and interest in all currently existing and hereafter acquired or arising Collateral to secure prompt repayment of any and all sums due under this note. On September 4, 2025, the $450,000 loan plus $1,200 interest has been paid.

On November 26, 2025, the Company borrowed $1,000,000 from Fang Family Fund I, LLC, an entity affiliated with one of its executive directors, under a loan agreement which bears 6% interest per annum. The principal and accrued interest of this Note will be due and payable by the Company in cash on November 27, 2026 (the "Maturity Date") at the Company's written election or upon written demand by the Holder. Notwithstanding the foregoing sentence, the Company may, with the written consent of Holder, elect to extend the Maturity Date. On January 5, 2026, the $1,000,000 loan plus $6,575 interest, less the amount of the $134,712 Related Party Receivable has been paid.

As of December 31, 2025, the Company determined that it overpaid interest on the above Fang Family loans of $134,712 and recognized this amount as a receivable reported in "Due from related parties" in the consolidated balance sheet as of December 31, 2025.

The term Collateral in the above loans refers to all assets of the Company, including without limitation all of the Company's right, title, and interest in assets, whether now owned or hereafter acquired or arising and wherever located.

Indemnification Agreements

We have entered into indemnification agreements with each of our directors and executive officers in addition to the indemnification provided for in our bylaws. These agreements, among other things, require us to indemnify each director and executive officer to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys' fees, judgments, fines and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person's services as a director or executive officer.

Related Party Transaction Policy

We have a written related party transaction policy that sets forth the following policies and procedures for the review and approval or ratification of related person transactions. A "Related Party Transaction" is a transaction, arrangement, or relationship in which we or any of our subsidiaries was, is or will be a participant, the amount of which involved exceeds the lesser of $120,000 per year or 1% of the average of our total assets for the last two completed fiscal years, and in which any Related Party had, has or will have a direct or indirect material interest. A "Related Party" means:

- any person who is, or at any time during the applicable period was, one of our officers or one of our directors;
- any person who is known by us to be the beneficial owner of more than five percent (5%) of our voting stock; and
- any immediate family member of any of the foregoing persons, which means any child, stepchild, parent, stepparent, spouse, sibling, mother-in-law, father-in-law, daughter-in-law, brother-in-law or sister-in-law of a director, executive officer or a beneficial owner of more than five percent (5%) of our voting stock, and any person (other than a tenant or employee) sharing the household of such director, executive officer or beneficial owner of more than five percent (5%) of our voting stock.

We have policies and procedures designed to minimize potential conflicts of interest arising from any dealings we may have with our affiliates and to provide appropriate procedures for the disclosure of any real or potential conflicts of interest that may exist from time to time. Specifically, pursuant to our charter, the audit committee has the responsibility to review related party transactions.

Director Independence

See "Item 10. Directors, Executive Officers and Corporate Governance" above for a discussion regarding the independence of the members of our Board.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Audit and Non-Audit Fees. The following table presents fees for audit services rendered by MaloneBailey for the audit of the Company's annual financial statements and fees billed for other services rendered by MaloneBailey:

	Year Ended December 31,	
	2025	**2024**
Audit Fees [(1)]	$ 621,000	$ 511,000
Audit-Related Fees	-	-
Tax Fees [(2)]	-	29,435
All Other Fees	-	-
Total	$ 621,000	$ 540,435

(1) Includes fees for audits of our annual financial statements, reviews of the related quarterly financial statements, and services that are normally provided by the independent accountants in connection with statutory and regulatory filings or engagements, including comfort letters and consents issued in connection with SEC filings and reviews of documents filed with the SEC. Also includes fees incurred for the audit of internal controls over financial reporting as required by Section 404 of the Sarbanes-Oxley Act of 2002.

(2) Tax fees relate to professional services rendered for tax compliance, tax return review and preparation and related tax advice.

Pursuant to the charter of the audit committee, the audit committee is responsible for the oversight of our accounting, reporting and financial practices. The audit committee has the responsibility to select, appoint, engage, oversee, retain, evaluate and terminate our external auditors; pre-approve all audit and non-audit services to be provided, consistent with all applicable laws, to us by our external auditors; and establish the fees and other compensation to be paid to our external auditors.

The audit committee has adopted a policy to pre-approve all audit and permitted non-audit services provided by our principal independent accountants. All audit and non-audit services for 2025 were pre-approved by the audit committee.

PART IV

ITEM 15. EXHIBIT AND FINANCIAL STATEMENT SCHEDULES

(a) Documents filed as part of this Form 10-K.

(1) *Financial Statements:* See Item 8, "Financial Statements and Supplementary Data," for a list of financial statements.

(2) *Financial Statement Schedules:*

All financial statements schedules are omitted because they are not applicable or the amounts are immaterial and not required, or the required information is presented in the financial statements and notes thereto.

(3) *Exhibits Required by Item 601 of Regulation S-K:* The information called for by this paragraph is set forth in Item 15(b) below.

(b) Exhibits filed.

Picard Medical, Inc.
Index to Exhibits

Exhibit No.	Exhibit Title
3.1**	Second Amended and Restated Certificate of Incorporation, dated as of August 28, 2025 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-42801), filed with the SEC on September 3, 2025).
3.2**	Amended and Restated Bylaws, dated as of August 28, 2025 (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-42801), filed with the SEC on September 3, 2025).
3.3*	Certificate of Amendment to the Second Amended and Restated Certificate of Incorporation, dated as of March 10, 2026, filed with the Delaware Secretary of State on March 24, 2026.
4.1**	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on July 17, 2025).
4.2**	Form of Warrant, dated December 26, 2025 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K (File No. 001-42801), filed with the SEC on December 30, 2025).
4.3**	Form of Senior Secured Note due 2028, dated December 26, 2025 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K (File No. 001-42801), filed with the SEC on December 30, 2025).
4.4*	Description of Registered Securities
10.1**	Form of Indemnification Agreement dated as of August 28, 2025 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-42801), filed with the SEC on September 3, 2025).
10.2**	Employment Offer Letter, dated November 1, 2021 by and between the Company and Frank Tinker (incorporated by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.3**	Aggregated Convertible Note, dated July 2, 2024 by and between the Company and Richard Fang, Fang Family Fund, LLC and Fang Family Fund II, LLC (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.4**	Membership Interest Purchase Agreement, dated September 27, 2021 by and between the Company and Sindex SSI Financing LLC, an affiliate of Versa Capital Management, LLC (incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.5**	Series A-1 Preferred Stock Purchase Agreement, dated December 28, 2022 by and between the Company and Hunniwell Picard I (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.6**	Convertible Note, dated September 25, 2023 by and between the Company and Zhu Jin (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.7**	Amended and Restated Short-Term Loan Agreement, dated March 27, 2024 by and between the Company and the Fang Family Fund II, LLC (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).

10.8**	Convertible Note, dated April 9, 2024, by and between the Company and Dr. Chang You Zhou (incorporated by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.9**	Short-Term Loan Agreement, dated April 8, 2024 by and between the Company and the Fang Family Fund II, LLC (incorporated by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.10**	Short-Term Loan Agreement, dated April 17, 2024 by and between the Company and the Fang Family Fund II, LLC (incorporated by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.11**	Convertible Note, dated April 27, 2024 by and between the Company and Nanyan Zheng (incorporated by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.12**	Convertible Note, dated June 5, 2024 by and between the Company and Xiaohong Shang (incorporated by reference to Exhibit 10.12 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.13**	Short-Term Loan Agreement, dated June 11, 2024 by and between the Company and the Fang Family Fund II, LLC (incorporated by reference to Exhibit 10.13 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.14**	Short-Term Loan Agreement, dated June 25, 2024 by and between the Company and the Fang Family Fund II, LLC (incorporated by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.15**	Convertible Note, dated July 9, 2024 by and between the Company and the Fang Family Fund II, LLC (incorporated by reference to Exhibit 10.15 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.16**	Convertible Note, dated August 7, 2024 by and between the Company and the Fang Family Fund II, LLC (incorporated by reference to Exhibit 10.16 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.17**	Convertible Note, dated August 21, 2024 by and between the Company and the Fang Family Fund II, LLC (incorporated by reference to Exhibit 10.17 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.18**	Convertible Note, dated September 17, 2024 by and between the Company and the Fang Family Fund II, LLC (incorporated by reference to Exhibit 10.18 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.19**	Convertible Note, dated October 1, 2024 by and between the Company and the Fang Family Fund II, LLC (incorporated by reference to Exhibit 10.19 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.20**	Convertible Note, dated October 15, 2024, by and between the Company and the Fang Family Fund II, LLC (incorporated by reference to Exhibit 10.20 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.21**	Convertible Note, dated October 28, 2024 by and between the Company and the Fang Family Fund II, LLC (incorporated by reference to Exhibit 10.21 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.22**	Convertible Note, dated November 13, 2024 by and between the Company and the Fang Family Fund II, LLC (incorporated by reference to Exhibit 10.22 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.23**	Convertible Note, dated November 25, 2024 by and between the Company and the Fang Family Fund II, LLC (incorporated by reference to Exhibit 10.23 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.24**	Convertible Note, dated December 9, 2024, by and between the Company and the Fang Family Fund II, LLC (incorporated by reference to Exhibit 10.24 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.25†	Picard Medical, Inc.'s 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-42801), filed with the SEC on October 14, 2025).
10.26**	Lease Agreement dated November 28, 2016, as amended, by and between SynCardia Systems, Inc. and Cherrylake Partners, LLC (incorporated by reference to Exhibit 10.26 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.27**	Intellectual Property and License Transfer Agreement, dated July 2, 2023, by and between SynCardia Systems, LLC and SynCardia Medical (Beijing), Inc. (incorporated by reference to Exhibit 10.27 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).

10.28**	Capital Increase Agreement, dated July 2, 2023, by and between the Company and Binzhou Taige Shibei Venture Capital LLC (incorporated by reference to Exhibit 10.28 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.29**	Exclusive Distributor Agreement, dated July 2, 2023 by and between SynCardia Systems, LLC and SynCardia Medical (Beijing), Inc. (incorporated by reference to Exhibit 10.29 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.30**	Regulatory Affairs Service Agreement, dated July 2, 2023, by and between SynCardia Systems, LLC and SynCardia Medical (Beijing), Inc. (incorporated by reference to Exhibit 10.30 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.31**	Sales Distribution and Representation Agreement, dated May 1, 2020, by and between SynCardia Systems, LLC and State of the Art Medical Products, Inc., as amended by amendment No. 1, dated April 28, 2021, as further amended by amendment No. 2, dated April 28, 2021 and further amended by amendment No. 3 dated August 18, 2021 (incorporated by reference to Exhibit 10.31 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.32**	Exclusive Distribution Agreement, dated July 1, 2020, by and between SynCardia Systems, LLC and Arabian Trade House (incorporated by reference to Exhibit 10.32 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.33**	Exclusive Distributor Agreement, dated September 1, 2018, by and between SynCardia Systems, LLC and Medica d.o.o (incorporated by reference to Exhibit 10.32 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.34**	Exclusive Distributor Agreement, dated September 1, 2020 by and between SynCardia Systems, LLC and Merce V. Electromedicina (incorporated by reference to Exhibit 10.34 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.35**	Exclusive Distributor Agreement, dated July 1, 2018, by and between SynCardia Systems, LLC and MyDevice s.r.o (incorporated by reference to Exhibit 10.35 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.36**	Exclusive Distributor Agreement, dated August 15, 2020, by and between SynCardia Systems, LLC and NEUCOMED GmbH (incorporated by reference to Exhibit 10.36 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.37**	Exclusive Distributor Agreement, dated July 1, 2018, by and between SynCardia Systems, LLC and Sanomed (incorporated by reference to Exhibit 10.37 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.38**	Exclusive Distributor Agreement, dated November 15, 2022, by and between SynCardia Systems, LLC and Sylvain Thuadet Consulting (incorporated by reference to Exhibit 10.38 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.39**	Exclusive Distribution Agreement, dated November 14, 2017, by and between SynCardia Systems, LLC and VEGA SPA (incorporated by reference to Exhibit 10.39 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.40**	Quality Agreement, dated February 21, 2019, by and between Sterigenics U.S., LLC and SynCardia Systems, LLC (incorporated by reference to Exhibit 10.40 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.41**	Quality Agreement, dated October 7, 2019, by and between SynCardia Systems, LLC and CryoLife, Inc. (incorporated by reference to Exhibit 10.41 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.42**	Quality Agreement, dated June 2, 2023, by and between SynCardia Systems, LLC and Heitek Automation (incorporated by reference to Exhibit 10.42 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.43**	Quality Agreement, dated November 7, 2018, by and between SynCardia Systems, LLC and New Era Manufacturing (incorporated by reference to Exhibit 10.43 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.44**	Quality Agreement, dated March 15, 2019, by and between SynCardia Systems, LLC and Carclo Technical Plastics (incorporated by reference to Exhibit 10.44 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.45**	Quality Agreement, dated July 17, 2019, by and between SynCardia Systems, LLC and Greatbatch, Ltd. (incorporated by reference to Exhibit 10.45 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.46**	Quality Agreement, dated March 4, 2019, by and between SynCardia Systems, LLC and Nelson Laboratories, LLC (incorporated by reference to Exhibit 10.46 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).

10.47**	Quality Agreement, dated February 8, 2019, by and between SynCardia Systems, LLC and Tecomet Precision Technologies (incorporated by reference to Exhibit 10.47 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.48**	Quality Agreement, dated February 28, 2019, by and between SynCardia Systems, LLC and Celera Motion (incorporated by reference to Exhibit 10.48 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.49**	Quality Agreement, dated February 21, 2019, by and between SynCardia Systems, LLC and Murrietta Circuits (incorporated by reference to Exhibit 10.49 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.50**	Security Agreement, dated July 27, 2023, by and between SynCardia Systems, Inc. and Medtronic, Inc. (incorporated by reference to Exhibit 10.50 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.51**	Non-Exclusive License Agreement, dated July 27, 2023, by and between SynCardia Systems, Inc. and Medtronic, Inc. (incorporated by reference to Exhibit 10.51 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.52**	Form of 2023 Convertible Note Purchase Agreement (incorporated by reference to Exhibit 10.52 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.53**	Form of 2024 Convertible Note Purchase Agreement (incorporated by reference to Exhibit 10.53 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.54**	Advisory Services Agreement, dated August 19, 2024, by and between the Company and US Unicorn Foundation Inc. (incorporated by reference to Exhibit 10.54 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
10.55	Promissory Note, dated November 26, 2025, among Picard Medical, Inc. and Fang Family Fund, LLC – Series I (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-42801), filed with the SEC on November 26, 2025).
10.56**	Securities Purchase Agreement, dated December 24, 2025, by and between Picard Medical, Inc. and an institutional investor (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-42801), filed with the SEC on November 26, 2025).
10.57**	Security Agreement, dated December 24, 2025, by and between Picard Medical, Inc. and an institutional investor (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File No. 001-42801), filed with the SEC on December 30, 2025).
10.58**	Intellectual Property Security Agreement, dated December 24, 2025, among SynCardia Systems, LLC and an institutional investor (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K (File No. 001-42801), filed with the SEC on December 30, 2025).
10.59*	Promissory Note dated February 28, 2026, by and among Fang Family Fund, LLC-Series I and the Company.
14.1**	Code of Ethics (incorporated by reference to Exhibit 14.1 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
19.1*	Insider Trading Policy
21.1**	List of Subsidiaries (incorporated by reference to Exhibit 21.1 to the Company's Registration Statement on Form S-1, as amended (File No. 333-286295), filed with the SEC on August 6, 2025).
23.1*	Consent of MaloneBailey LLP, Independent Registered Public Accounting Firm
31.1*	Certification of the Chief Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a).
31.2*	Certification of the Chief Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a).
32.1+	Certification of the Chief Executive Officer required by Rule 13a-14(b) or Rule 15d-14(b) and 18 U.S.C. 1350.
32.2+	Certification of the Chief Financial Officer required by Rule 13a-14(b) or Rule 15d-14(b) and 18 U.S.C. 1350.
97.1	Clawback Policy
101.INS*	Inline XBRL Instance Document (The instance document does not appear in the interactive data file because its XBRL tags are embedded within the inline XBRL document)
101.SCH*	Inline XBRL Taxonomy Extension Schema
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

*	Filed herewith.
+	Furnished herewith.
†	Management contract, compensatory plan or other arrangement
**	Previously Filed.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, Picard has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

PICARD MEDICAL, INC.

By /s/Patrick NJ Schnegelsberg
Patrick NJ Schnegelsberg
Chief Executive Officer

Date: March 27, 2026

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report has been signed below by the following persons on behalf of the Company on March 27, 2026 in the capacities indicated below.

/s/Patrick NJ Schnegelsberg
Patrick NJ Schnegelsberg
Principal Executive Officer and Director

/s/George Ye
George Ye
Director

/s/Bernard Skaggs
Bernard Skaggs
Principal Financial Officer and Principal Accounting Officer

/s/ Richard Fang
Richard Fang
Director

/s/Sam Van
Sam Van
Director

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