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 001-40133

ENVOY MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Delaware	**86-1369123**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

4875 White Bear Parkway, White Bear Lake, MN 55110
(Address of principal executive offices)

(877) 900-3277
(Registrant's telephone number, including area code)

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Class A Common Stock, par value $0.0001 per share	COCH	The Nasdaq Stock Market LLC
Redeemable Warrants, each exercisable for one share of Class A Common Stock at an exercise price of $11.50 per share	COCHW	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) 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 Section 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 Exchange Act). Yes ☐ No ☒

The aggregate market value of the registrant's Class A common stock, par value $0.0001 per share, held by non-affiliates of the registrant computed by reference to the last sales price of such stock, as of the last business day of the registrant's most recently completed fiscal quarter, which was December 31, 2025, was approximately $12.7 million. This calculation excludes shares of Class A common stock held by the registrant's officers and directors and each person known by the registrant to beneficially own more than 5% of the registrant's outstanding shares, as such persons may be deemed to be affiliates. This determination of affiliate status should not be deemed conclusive for any other purpose.

There were 76,881,110 shares of the registrant's Class A common stock, par value $0.0001 per share, outstanding as of March 20, 2026.

DOCUMENTS INCORPORATED IN PART BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2026 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

ENVOY MEDICAL, INC.

Annual Report on Form 10-K
For the Year Ended December 31, 2025

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CERTAIN TERMS

Unless otherwise stated in this Annual Report on Form 10-K (this "Report"), or the context otherwise requires, references to:

- "Acclaim CI" means the fully implanted Acclaim® cochlear implant;
- "Anzu" means Anzu Special Acquisition Corp I, a Delaware corporation, which was renamed "Envoy Medical, Inc." upon the closing of the Business Combination;
- "Board" means the board of directors of the Company;
- "Business Combination" means the merger and the other transactions contemplated by the Business Combination Agreement;
- "Business Combination Agreement" means the Business Combination Agreement, dated as of April 17, 2023, as amended by Amendment No. 1 to the Business Combination Agreement, dated May 12, 2023, and Amendment No. 2 to the Business Combination Agreement, dated August 31, 2023, by and among Anzu, Envoy Merger Sub, Inc., Merger Sub and Envoy Medical Corporation;
- "Bylaws" means the amended and restated bylaws of the Company;
- "Charter" means the second amended and restated certificate of incorporation of the Company;
- "Class A Common Stock" means the Company's Class A common stock, par value $0.0001 per share;
- "Closing" means the closing of the Merger;
- "Esteem FI-AMEI" means the Esteem® fully implanted active middle ear implant (FI-AMEI);
- "Exchange Act" means the Securities Exchange Act of 1934, as amended;
- "Forward Purchase Agreement" means the Forward Purchase Agreement, dated April 17, 2023, as amended by Amendment No. 1 to the Forward Purchase Agreement, entered into on May 5, 2023, Amendment No. 2 to the Forward Purchase Agreement, entered into on September 28, 2023, and, a confirmation amendment entered into on July 29, 2024, by and among Anzu, Envoy Medical Corporation, and the Meteora FPA Parties;
- "GAAP" means accounting principles generally accepted in the United States;
- "GAT Warrants" means warrants issued by Envoy Medical in 2024 in connection with debt financing transactions;
- "JOBS Act" means the Jumpstart Our Business Startups Act of 2012, as amended;
- "Meteora FPA Parties" means Meteora Special Opportunity Fund I, LP, Meteora Capital Partners, LP, Meteora Select Trading Opportunities Master, LP and Meteora Strategic Capital, LLC;
- "October 2025 Warrants" means warrants issued by the Company to investors in its offering completed October 7, 2025;
- "Placement Agent Warrants" means warrants issued to representatives of the placement agent in the Company's offerings completed in September and October 2025;
- "Sarbanes-Oxley Act" means the Sarbanes-Oxley Act of 2002, as amended;
- "SEC" means the Securities and Exchange Commission;
- "Securities Act" means the Securities Act of 1933, as amended;
- "Series A Preferred Stock" means the Company's Series A convertible preferred stock, par value $0.0001 per share;

- "September 2025 Warrants" means warrants issued by the Company to investors in its offering completed September 23, 2025;
- "Shortfall Warrants" means warrants issued to the Meteora FPA Parties for no additional consideration pursuant to the Forward Purchase Agreement;
- "Sponsor" means Anzu SPAC GP I LLC, a Delaware limited liability company and an affiliate of certain of Anzu's officers and directors; and
- "Warrants" means the GAT Warrants, Public Warrants, and Shortfall Warrants.

Additionally, references in this Report to the "Company," the "registrant," "Envoy Medical," "we," "us" and "our" in this Report refer to Envoy Medical, Inc. (formerly known as Anzu Special Acquisition Corp I), and references to our "management" or our "management team" refer to our officers and directors, other than certain historical information which refers to Legacy Envoy prior to the consummation of the Business Combination.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Report contains certain "forward-looking statements" within the meaning of the United States Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act and Section 21E of the Exchange Act. All statements other than statements of historical fact contained in this Report, including statements as to future results of operations and financial position, revenue and other metrics, products, business strategy and plans, objectives of management for future operations of the Company, market size and growth, competitive position and technological and market trends, are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "will," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. All forward-looking statements are subject to risks, uncertainties, and other factors which could cause actual results to differ materially from those expressed or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to:

- Unpredictability in the medical device industry, the regulatory process to approve medical devices, and the clinical development process of the Company's products;
- Potential need to make design changes to products to meet desired safety and efficacy endpoints;
- Changes in federal or state reimbursement policies that would adversely affect sales of the Company's products;
- Introduction of other scientific advancements, including gene therapy or pharmaceuticals, that may impact the need for hearing devices such as cochlear implants or fully implanted active middle ear implants;
- Competition in the medical device industry, and the failure to introduce new products and services in a timely manner or at competitive prices to compete successfully against competitors;
- Disruptions in relationships with the Company's suppliers, or disruptions in the Company's own production capabilities for some of the key components and materials of its products;
- Changes in the need for capital and the availability of financing and capital to fund these needs;
- Changes in interest rates or rates of inflation;
- Legal, regulatory and other proceedings could be costly and time-consuming to defend;
- Changes in applicable laws or regulations, or the application thereof on the Company;
- A loss of any of the Company's key intellectual property rights or failure to adequately protect intellectual property rights;
- The Company's ability to maintain the listing of its securities on Nasdaq following the Business Combination;
- The effects of catastrophic events, including war, terrorism and other international conflicts; and
- Other risks and uncertainties indicated in this Report, including those set forth under the section entitled "*Risk Factors*."

Should one or more of these risks or uncertainties materialize, or should any of the underlying assumptions prove incorrect, actual results may vary in material respects from those expressed or implied by these forward-looking statements. Nothing in this Report should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. You should not place undue reliance on these forward-looking statements. The Company does not give any assurance that it will achieve its expected results and does not undertake any duty to update these forward-looking statements, except as required by law.

Summary Risk Factors

Our Company is subject to numerous risks described in *Item 1A. Risk Factors* and elsewhere in this Report. You should carefully consider these risks before making an investment. Some of these risks relating to our business objectives, our organization and structure and our securities include:

- We are an early-stage company with a history of losses. We have not been profitable historically and may not be able to achieve profitability in the future.
- We have generated limited revenue from product sales and may never be profitable.
- If the Acclaim CI contains design or manufacturing defects, our business and financial results could be harmed.
- We may need to raise substantial additional funding, which may not be available on acceptable terms, or at all. Failure to obtain funding on acceptable terms and on a timely basis may require us to curtail, delay or discontinue our product development efforts or other operations.
- Raising additional capital would cause dilution to our existing stockholders and may adversely affect the rights of existing stockholders.
- Failure of a key information technology system, process or site could have an adverse effect on our business.
- We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and the value of our stock.
- Our financial statements contain an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern, which could prevent us from obtaining new financing on reasonable terms or at all.
- Clinical failure can occur at any stage of clinical development. Our clinical experience to date does not necessarily predict future results and may not have revealed certain potential limitations of the technology or potential complications from the Acclaim CI and may require further clinical validation. Any product version we advance through clinical trials may not have favorable results in later clinical trials or receive regulatory approval.
- The successful commercialization of the Acclaim CI, if it receives FDA approval, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates could limit our ability to market those products and decrease our ability to generate revenue.
- We operate in a very competitive business environment, and if we are unable to compete successfully against our existing or potential competitors, our business, financial condition and results of operations may be adversely affected.
- We expect to derive most of our revenues from sales of the Acclaim CI. Our inability to successfully commercialize this product, or any subsequent decline in demand for this product, could severely harm our ability to generate revenues.
- If healthcare professionals do not recommend the Acclaim CI to their patients, the Acclaim CI may not achieve market acceptance and we may not become profitable.
- We will be dependent upon contract manufacturing organizations and material suppliers, making us vulnerable to supply shortages and problems, increased costs and quality or compliance issues, any of which could harm our business.

- Our business plan relies on certain assumptions about the market for our product; however, the size and expected growth of our addressable market has not been established with precision and may be smaller than we estimate, and even if the addressable market is as large as we estimate, we may not be able to capture market share.
- We depend on third parties to manage our pre-clinical studies and clinical trials, perform related data collection and analysis, and to enroll patients for our clinical trials, and, as a result, we may face costs and delays that are beyond our control.
- We are highly dependent on key members of our executive management team. Our inability to retain these individuals could impede our business plan and growth strategies, which could have a negative impact on our business and the value of your investment.
- The market price of our Class A Common Stock and Public Warrants has been and may continue to be extremely volatile, which could cause purchasers of our securities to incur substantial losses.
- While we will pay dividends on shares of Series A Preferred Stock pursuant to the Certificate of Designation, we do not intend to pay dividends on shares of Class A Common Stock for the foreseeable future.
- We have been and in the future may become a defendant in one or more stockholder derivative, class-action and other litigation, and any such lawsuits may adversely affect our business, financial condition, results of operations and cash flows.

PART I

ITEM 1. Business

Unless otherwise noted or the context otherwise requires, all references in this section to "Envoy Medical," "we," "us" or "our" refer to Envoy Medical, Inc. following the Business Combination, other than certain historical information which refers to the business of Legacy Envoy prior to the consummation of the Business Combination.

Overview

We are a hearing health company focused on providing innovative medical technologies across the hearing loss spectrum. Our technologies are designed to shift the paradigm within the hearing industry and bring both providers and patients the hearing devices they desire. We are dedicated to pushing beyond the status quo to provide patients with improved access, usability, independence, and quality of life. We believe leveraging the ear's natural anatomy, rather than external or sub-dermal artificial microphone, is the ideal way for people to hear.

To leverage the natural ear's benefits, an implanted sensor was created to pick up incoming sound energy from the ossicular chain (i.e., the three tiny hearing bones that connect the eardrum to the cochlea). The sensor absorbs the mechanical energy from ossicular chain and turns it into a signal that can be processed, improved, and increased for a patient's particular hearing needs.

Our first product, the Esteem FI-AMEI, received FDA approval in 2010. The Esteem FI-AMEI remains the only FDA approved fully implanted active hearing implant on the market. The Esteem FI-AMEI failed to gain commercial traction, primarily because the Centers for Medicaid and Medicare Services ("*CMS*") classified it as a hearing aid and therefore not eligible for coverage. We believe hearing aid classification is improper for the Esteem FI-AMEI and we continue to work towards having the Esteem FI-AMEI properly classified as a Fully Implanted Active Middle Ear Implant.

Despite the commercial challenges of the Esteem FI-AMEI, roughly 1,000 devices were implanted globally. Some devices were implanted in the early 2000s during clinical trials, providing us with over two decades of experience with its implantable sensor technology. Throughout our experience, our sensor technology proved a viable alternative to external or implanted microphones.

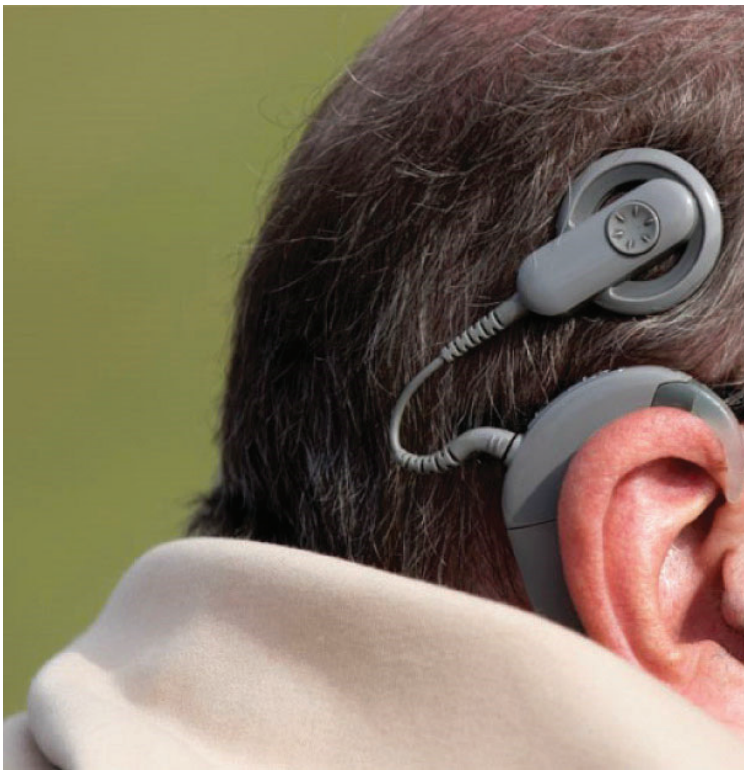
In late 2015, we made the decision to shift our focus from the Esteem FI-AMEI to a new product that would leverage our sensor technology and incorporate it into a cochlear implant. As a result, we have developed the investigational Acclaim CI. We now believe we have the possibility to disrupt the cochlear implant market currently dominated by three main incumbents.

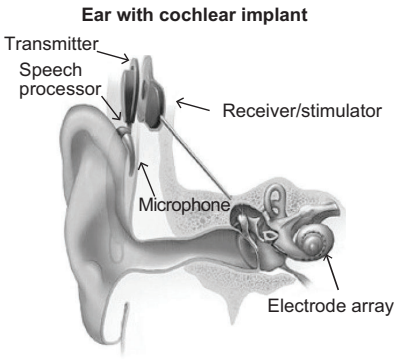
Our Product

Cochlear Implants — Fully Implanted vs. Partially Implanted

The cochlea converts vibrations from the ossicular chain into nerve signals that are transmitted through the auditory nerve for processing by the brain. Cochlear implants use electronic signals to directly stimulate the auditory nerve via the cochlea.

Partially implanted cochlear implants have two main components: a large external component that sits on or behind the patient's ear and a surgically implanted internal component. The external component contains a microphone, sound processer, and batteries. A magnetic coil on the external component lines up with an internal magnetic coil in the internal component. The signal from the external component is transferred to the internal coil where it is delivered to the electrode array, which is implanted in the cochlea, to electrically stimulate the cochlea.

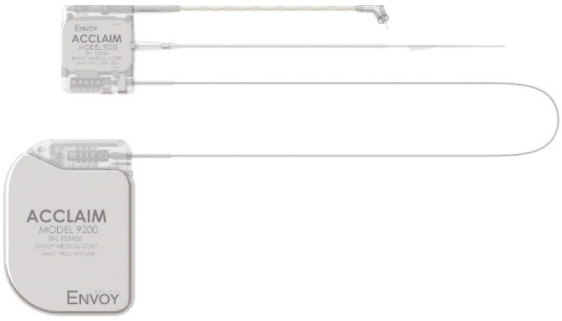




Source: NIH/NIDCD

The Acclaim CI is fully implanted and does not have the need for any external component to be worn on the ear. Unlike partially implanted devices, the Acclaim CI uses the ear to capture sound via a piezoelectric sensor that is implanted in the middle ear. The sound processor and power source are also implanted.

CAUTION: Investigational Device — Limited by Federal Law to Investigational Use.



Acclaim CI — A Breakthrough Device

The Acclaim CI received the Breakthrough Device Designation from the U.S. Food and Drug Administration ("FDA") in 2019. However, the process of medical device development is inherently uncertain and there is no guarantee that this designation will accelerate the timeline for approval or make it more likely that the Acclaim CI will be approved.

Hearing loss is currently an irreversible and debilitating human condition. Significant hearing loss is correlated with increased anxiety, depression, social isolation, falls, and other costly health issues. An article published in the journal Acta Otorhinolaryngol Italica in June 2016 suggests that untreated or undertreated moderate to profound hearing loss correlates with earlier loss of cognitive function and poorer cardiovascular health.[1] While some solutions for hearing loss already exist (e.g., hearing aids, traditional cochlear implants) these have inherent limitations in being fully or partially external, which limit patients in initial time to adoption, hours of use during the day (inherent compliance restrictions), lifestyle, and quality of life.

We believe that the Acclaim CI will be able to offer hearing benefit over the patient's baseline condition and may also offer other important advantages over alternative hearing loss treatments, such as:

- **Increased daily usage.** We believe that the fully implanted nature of the Acclaim CI will facilitate an increase in daily usage over other types of cochlear implants because the device can be used 24-hours a day.
- **Hearing at night.** Unlike other types of available cochlear implants, the Acclaim CI can be used at night. This capability will support audibility of alarms, sirens, telephones, and other people for an added sense of security while they sleep.
- **Hearing in and around water.** Patients using the Acclaim CI will not need to worry about removing their device when showering, at the beach, or swimming laps. They will also not need to worry about damaging the device if caught in the rain.
- **Hearing in active situations.** A patient using the Acclaim CI will not need to worry about the external processor falling off during exercise or other physical activities. The patient will not need to preemptively remove the device prior to engaging in these types of activities, thus retaining audibility of the surrounding environment.
- **Lowered battery maintenance.** Other cochlear implants require near-daily battery replacement or battery charging. In addition to the logistical hassle of worrying about keeping the batteries charged, this can be challenging for patients who have issues with dexterity or neuropathy, as the batteries and components are small and can be hard to handle. The Acclaim CI is designed with a battery contained within the implanted system components intended to be charged wirelessly through the skin. The Acclaim CI battery is expected to last for several days between charges and will not require the patient to use or handle small components like current cochlear implant systems do.
- **No need for backup or secondary processors.** Many patients who have partially implanted cochlear implants with external hardware desire or need a backup processor. The backup processor provides the patient with a sense of security because they know if their primary processor is lost or damaged, they will be left without hearing for a period of time while they wait for a replacement. In addition, lost or damaged components can be expensive to replace, with the cost of replacement often not covered by insurance. The Acclaim CI processor is implanted and therefore not susceptible to issues associated with moisture, germs, dirt, or other external causes of loss or physical damage due to having an externally worn processor.
- **Flexibility with equipment or accessories.** The externally worn components of currently available cochlear implants can make wearing equipment or accessories difficult for existing cochlear implant patients. For example, wearing helmets, hats, headphones, stethoscopes, or other accessories can interfere with the placement of the external components and cause "coil offs" or prevent the patient from using the device altogether.

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1 Source: Fortunato S, et al.; A Review of New Insights on the Association Between Hearing Loss and Cognitive Decline in Ageing; ACTA OTORHINOLARYNGOLOGICA ITALICA (Jun 2016), finding that increasing evidence has linked age related hearing loss to more rapid progression of cognitive decline and incidental dementia and that many aspects of daily living of elderly people have been associated to hearing abilities, showing that hearing loss affects the quality of life, social relationships, motor skills, psychological aspects and function and morphology in specific brain areas.

- **Earlier adoption of cochlear implant technology from reduced stigma.** For many potential users of hearing instruments like hearing aids and cochlear implants, the perception of stigma associated with those technologies can prevent or delay the adoption of the technology. We believe that the Acclaim CI, with no externally worn components, may help reduce or perhaps even eliminate such stigma. We believe we can increase penetration rates for adult cochlear implants in the U.S.

- **Potential to significantly reduce overall costs while improving net healthcare outcomes.** We believe a fully implanted cochlear implant could reduce cochlear implant costs over time by eliminating costly external components that are frequently replaced at the expense of the patient, the insurer, Medicare, or other third-party payor. There is also reason to believe that increasing compliance and use of cochlear implants, reducing time to adoption for candidates, and increasing safety and security by providing the ability for true all-day hearing may improve the net healthcare outcome for society over time.

The Acclaim CI is implanted by a surgeon through a procedure that we believe will average around two and a half to three hours under general anesthesia. We expect that patients will experience mild to moderate discomfort after the procedure and benefit from several days of rest after surgery. A four-week waiting period is required before the Acclaim CI can be activated to allow the middle ear to heal and fluid from surgery to dissipate. It is expected that the Acclaim CI battery pack will be replaced every 8-12 years via a less invasive surgical procedure that only replaces the Acclaim CI battery pack in the pectoral region (i.e., the whole system does not need to be replaced, just the Acclaim CI battery pack).

All of the competitive advantages referred to above require that the Acclaim CI obtain FDA approval in its current form and substantially on our planned timeline. If FDA approval is materially delayed for any reason, it is possible that competitors will offer products with similar features before we are able to market the Acclaim CI.

Market Overview

Overview of Hearing Loss

According to the National Center for Health Statistics, hearing loss impacts about 15% of the adult population in the United States.[2] Among older adults, nearly 25% of people aged 65 to 74 have disabling hearing loss, and 50% of those aged 75 and older have disabling hearing loss, according to the National Institute on Deafness and Other Communications Disorders.[3] Organizations such as the Centers for Disease Control and Prevention ("CDC") and the World Health Organization ("WHO") have recognized significant hearing loss as one of the most common disabilities impacting people around the world.[4] The WHO estimates economic impact of untreated or undertreated hearing loss is approximately $750 billion each year.[5]

In common parlance, the terms "hearing loss," "hard of hearing," or "deafness" are often used to describe a variety of types, levels, and causes of hearing loss that are treated differently clinically. The hearing loss market can be classified based on causes and severity of hearing loss.

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2 Source: *National Health Interview Survey*; Center For Disease Control And Prevention: National Center For Health Statistics (2022), finding that as of 2022 15.5% of US adults reported some level of difficulty hearing.

3 Source: *Quick Statistics About Hearing;* National Institute Of Health; National Institute On Deafness And Other Communications Disorders (*https://www.nidcd.nih.gov/health/statistics/quick-statistics-hearing*), summarizing statistics on hearing loss, including that 25% of people aged 65 to 74 have disabling hearing loss, and 50% of those aged 75 and older have disabling hearing loss.

4 Source: *Preventing Noise-Induced Hearing Loss*; Center For Disease Control And Prevention (2022); and *Deafness and Hearing Loss*, World Health Organization (2023), each providing an overview of the prevalence of hearing loss.

5 Source: *Global Costs of Unaddressed Hearing Loss and Cost-Effectiveness of Intervention*; World Health Organization (2017), providing an overview of the global costs of hearing loss, including components of cost and the monetary values attributable to such elements as costs typically incurred by health-care systems and patients, respectively, and reaching the conclusion that the cost of untreated or undertreated hearing loss is approximately $750 billion each year.

There are three main types of hearing loss: sensorineural, conductive, and mixed. Sensorineural hearing loss is due to problems of the inner ear and is often caused by damage to "hearing hair cells" in the cochlea. Common causes include normal aging, excessive noise exposure, viral infections, and exposure to drugs that are toxic to the hearing system. According to data published in the Journal of the American Medical Association, sensorineural hearing loss is the most common form of hearing loss, representing approximately 90% of all hearing loss.[6]

Conductive hearing loss is due to mechanical or structural problems with a part of the hearing system, generally a result of congenital issues with or damage to the ear canal, ear drum, or ossicular chain. Common causes include malformation of a particular part of the hearing system, middle ear infection, perforation of the eardrum, wax buildup, or dislocation of the ossicles. Conductive hearing loss represents approximately 10% of all hearing loss, according to data published in the Journal of the American Medical Association.[7] Finally, mixed hearing loss has some combination of both sensorineural and conductive components.

In addition to the three main types of hearing loss, there are generally five levels of hearing loss severity: normal, mild, moderate, severe, and profound. Normal hearing is often defined as 0-20 decibels ("dB") of hearing loss and even with a slight loss most people do not notice any impact. Mild hearing loss is often defined as 20-40 dB of hearing loss with some people reporting difficulty hearing soft spoken people. Most people with mild hearing loss do not address their hearing loss.

As hearing loss progresses, the impact on the individual becomes more noticeable. Moderate hearing loss is often defined as 40-70 dB of hearing loss and begins to show up with people reporting the ability to "hear but not understand" speech. More words are missed in conversations, and it is harder to hear in certain environments.

Moderate to profound hearing loss is often defined as 70-90 dB of hearing loss. People with severe hearing loss are unable to hear most speech and miss large portions of conversations without assistance. People with severe hearing loss may find that even with hearing aids they are not getting enough benefit to hear and understand most of the words in a conversation.

Profound hearing loss is often defined as 90 dB or more of hearing loss. People with profound hearing loss cannot hear speech or loud sounds such as sirens or horns. Most people who are considered clinically "deaf" would have severe to profound hearing loss.

Overview of Hearing Devices

There are several different types of hearing devices to address hearing loss. It is common for hearing loss to progress (i.e. continue to get worse) over the course of an individual's life, so it is possible that a patient may have one or more hearing devices during the course of their lives.

Personal Sound Amplification Devices ("PSAPs") are small electronic devices used to make sounds louder but with little sophistication. They are limited in ability and are only suitable for normal to mild hearing loss.

Hearing aids are the most common form of hearing device. These are small sound-amplifying devices that come in a variety of shapes and sizes. They are always external and pick up sound through a microphone and amplify the sound through a speaker in the ear canal. There are over-the-counter hearing aids (no prescription required) designed to treat mild to moderate hearing loss and prescription hearing aids designed to treat more significant hearing loss. Hearing aids can be used for all types of hearing loss and are typically the first device a person with hearing loss will try.

Active middle ear implants are implanted fully or partially in the middle ear (i.e., where the three ossicles or hearing bones are located). They are typically designed to treat moderate to severe sensorineural hearing loss, but some also can address a certain level of mixed hearing loss. Middle ear implants use mechanical energy to directly drive

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6 Source: Yueh B, et al.; *Screening and Management of Adult Hearing Loss in Primary Care: Scientific Review*; Journal Of The American Medical Association (2003), providing an epidemiology of types of hearing loss and identifying sensorineural hearing loss as the cause of 90% of hearing loss.

7 Source: Yueh B, et al.; *Screening and Management of Adult Hearing Loss in Primary Care: Scientific Review*; Journal Of The American Medical Association (2003), providing an epidemiology of hearing loss, including the allocation of hearing loss between sensorineural hearing loss and other types.

the cochlea with mechanical energy. Middle ear implants are not common due to the lack of reimbursement coverage throughout the world. The Esteem FI-AMEI is the only fully implanted active middle ear device currently with FDA approval and commercially available in the United States.

Cochlear implants are electrical hearing devices. They deliver electrical stimulation to the cochlea via an electrode array. The electrical stimulation is picked up by the hearing nerve and patients are able to perceive sound. Traditionally, all cochlear implants were partially implanted with an external component. We believe the Acclaim CI will be the first-of-a-kind cochlear implant with no external component worn on the ear or required for daily hearing and that leverages the ear to pick up sound (i.e., versus a microphone).

Auditory osseointegrated implants (i.e. bone conduction implants) are used for conductive or certain types of mixed hearing loss. They are not used for sensorineural hearing loss. They address a patient's conductive hearing loss by transferring sound information through the patient's skull via vibration.

Acclaim CI's Market Opportunity

The Acclaim CI is designed to address sensorineural hearing loss that is not adequately addressed by hearing aids. As part of the clinical trial, the Acclaim CI will only be intended for adults with severe-to-profound sensorineural hearing loss who have been deemed adequate candidates by a qualified physician.

We believe there is a significant population of adults in the United States who are cochlear implant candidates but choose not to get traditional, partially-implanted cochlear implants because of the external component required for daily hearing. We believe this is one of the main reasons why industry sources, such as a 2018 paper published in the journal Trends in Hearing, and our own market research estimate 5-8% penetration rate for cochlear implants in the adult population.[8]

Based on published literature and industry sources (prior to candidacy expansion for cochlear implant candidates), including the American Journal of Public Health, we believe there are approximately 6.6 million Americans age 12 or older with severe to profound hearing loss in at least one ear.[9] Incorporating estimates for clinical indications (including limited benefit from hearing aids), we believe there are approximately 2.8 million adults in the United States who could qualify for a cochlear implant. Based on an assumed selling price in the United States for a traditional cochlear implant of $30,000 (a $5,000 premium over the average sale price of current partially-implanted devices), we believe the adult cochlear implant market in the United States alone represents a potential market opportunity of over $80 billion.

Based on the published literature and industry sources previously referenced, we believe there will be roughly 25,000 – 30,000 adults implanted with a cochlear implant in the United States every year by 2026. Based on an assumed selling price of $30,000, that is an annual market opportunity that exceeds $750 million for just the United States adult population.

In addition, many estimates from published literature and industry sources were made prior to changing candidacy within the cochlear implant market. Two major shifts in clinical candidacy have likely increased the market sizes: (a) the CMS has expanded coverage from 40% word recognition scores to 60% word recognition scores and (b) there is more acceptance of treating single sided deafness with a cochlear implant.

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8 Sources: Holder JT, et al., *Current Profile of Adults Presenting for Preoperative Cochlear Implant Evaluation*; Trends In Hearing (2018), providing an analysis of implantation rates of cochlear implants among adults receiving preoperative screening, including a determination that "the market penetration for cochlear implantation was just 7.7% in the adult population of individuals with severe-to-profound sensory hearing loss." We have also commissioned market research by S2N Health, which analyzed available literature and estimates from other market participants to reach the 5 – 8% penetration rate, based in part on an expansion of candidacy criteria since the publication of the Holder article. As an example of the effect of changing candidacy criteria, Nassiri AM, et al., determined penetration rates to be 12.1% based on the prior more restrictive criteria and 2.1% based on the current, broader criteria. *Current Estimates of Cochlear Implant Utilization in the United States*, Otol Neurotol (June 2022).

9 Source: Goman, AM and Frank RL, *Prevalence of Hearing Loss by Severity in the United States*, American Journal of Public Health (Oct 2016), estimating that 6.6 million (2.5%) of Americans aged 12 years or older have severe to profound hearing loss in at least one ear, with three quarters of these individuals being older than 60 years. We do not plan to market the Acclaim CI to patients under age 18.

While these numbers represent the entire adult cochlear implant market in the United States, we believe that if we are able to establish distribution channels and strategic relationships with clinics and healthcare professionals, the Acclaim CI will be in a unique position to capture existing market share quickly and to also capture a healthy portion of the unserved market — those who are not pursuing a cochlear implant because of the external components. Moreover, it is reasonable to believe that Acclaim CI will demand a higher average selling price than existing partially implanted cochlear implants.

We also believe there are substantial total market and annual market opportunities outside the United States. Currently, our analysis estimates that approximately 50% of the hearing device market is international. Given the greater number of hearing loss patients outside the United States, we also believe the international market is currently significantly underserved and offers significant opportunity for expansion if we are able to obtain the necessary regulatory approvals and expand our international distribution capabilities. However, we will be unable to expand into international markets if we are unable to obtain these regulatory approvals.

Market Competition

There are currently three major cochlear implant manufacturers — Cochlear Ltd., Advanced Bionics ("Sonova"), and Med-El. Oticon Medical ("Demant") was set to become the fourth global cochlear implant player, but Cochlear Ltd purchased the cochlear implant business portion of Oticon Medical from Demant. There are a few other minor regional players, such as Nurotron in China, which appears to be focused on developing countries.

Cochlear Ltd. (ASX: COH) is the leading cochlear implant device manufacturer with approximately 65% of global market share and a market capitalization of approximately $12 billion USD as of December 31, 2025.

In comparison to Envoy Medical, the three current primary providers of cochlear implants have a greater penetration into the hearing loss treatment market, which has allowed them to develop relationships with audiologists, otolaryngologists (ENT physicians), hearing loss centers, and the other physicians on whom providers rely for referrals. The current providers also have existing relationships with patients who have used their devices. In addition, current providers also have substantially greater financial and operational resources, which may give them an advantage in capitalizing on new technology and responding to other changes to the marketplace.

If we are able to obtain regulatory approval of the Acclaim CI, we believe physicians and patients will be receptive to its competitive advantage as a fully implanted cochlear implant. However, based on our lack of history in the market, we will need to make material investments in patient advertising, provider education and training, distribution capabilities, and physician strategic relationships to capitalize on such advantages and gain market share. We will be unable to begin investing in these areas until we obtain FDA approval.

Market Trends

The first documented cochlear implant was completed in 1961. The initial devices were crude single electrode cochlear implants with the intended purpose of giving some basic environmental and situational awareness to adults with profound hearing loss. A few years later, multi-channel devices were introduced. Over time, multi-channel devices evolved more quickly and allowed for more robust processing and mapping strategies. By the 1980s, cochlear implants were an accepted standard of care for adults with profound hearing loss with the multi-channel devices becoming the preferred design by most healthcare professionals.

The next two to three decades focused on the evolution of multi-channel electrodes and creating new sound processing and electrode mapping techniques to focus on speech understanding. As a result, most cochlear implant patients can understand speech quite well with the appropriate follow-up and speech therapy. Candidacy was expanded to include children and people with different levels or types of hearing loss.

Over the last few years, the trends of the cochlear implant industry have mirrored that of the hearing aid industry, with less emphasis on hardware design and more placed on appearance and usability. The physical form and function have not changed significantly, although new sound processing strategies have been implemented to improve patient outcomes. While product reliability has gradually improved, clinical efficacy seems to have plateaued.

To increase market share, manufacturers have focused on making cochlear implants more visibly appealing (e.g., slightly smaller external components, color "kits" for the external components), user friendly (e.g., connectivity), environmentally robust (e.g., water resistance), and more reliable (e.g., fewer recalls).

We believe that the trend over the next decade will be a continuation of the focus on usability, connectivity, lifestyle, and miniaturization. As cochlear implants become more accepted as a therapy for individuals with moderate to profound sensorineural hearing loss, manufacturers will pay attention to ways of making patients interested in their device over a similarly performing competing device.

Another major trend within the industry is the loosening of the clinical candidacy requirements. In addition to people with "better" hearing levels being considered for cochlear implants (e.g., people with moderate hearing in the lower frequencies) there has also been a movement to implant people with "single sided deafness" ("*SSD*"). Both Med El (in 2019) and Cochlear (in 2021) achieved FDA approval for treatment of those with SSD and asymmetric hearing loss. As a result, more patients are eligible for cochlear implants than ever before.

Finally, industry participants have made material investments to inform more adult candidates about cochlear implants to increase usage. Currently, industry sources, including a 2018 paper published in the journal Trends in Hearing,[10] and our own market research estimate that less than 10% of adults who meet the indications for cochlear implant candidacy are implanted, leaving more than 90% of the current adult market as untapped potential for new technologies. However, we will require FDA approval for the Acclaim CI and significant investment in our training and distribution network before we can access such market.

Reimbursement Strategy

Cochlear implants enjoy a fully developed reimbursement pathway. Cochlear implants have been deemed a coverable benefit by CMS and enjoy an existing National Coverage Determination ("*NCD*"). In the United States, many private and public payors cover at least one cochlear implant per adult. There is existing coding, coverage, and payment for cochlear implants.

Unlike the Esteem FI-AMEI, which was classified as a hearing aid by CMS and therefore statutorily excluded from being a coverable benefit under Medicare and Medicaid, the Acclaim CI is expected to be eligible for Medicare and Medicaid coverage as a cochlear implant.

As mentioned above, the Acclaim CI received Breakthrough Device Designation. There are potential reimbursement-related benefits to the designation (i.e., the ability to receive higher reimbursements than are received by incumbent devices); however, the implementation of these benefits has not been finalized by Congress and CMS and there is no guarantee that Breakthrough Device Designation will offer any benefit with respect to reimbursement.

Pre-Clinical Work and Early Feasibility Study

The Acclaim CI has undergone extensive benchtop and laboratory testing throughout the design and development process. Animal testing was done to demonstrate the reliability of the Acclaim CI's rechargeable battery and charging safety algorithm.

In the third quarter of 2022, we received an Investigational Device Designation ("IDE") approved by the FDA to undergo a small Early Feasibility Study ("*EFS*") at Mayo Clinic in Rochester, Minnesota. The principal investigator is Dr. Colin Driscoll, a respected veteran in the global cochlear implant industry. There were three patients enrolled, implanted, and activated in the fourth quarter of 2022.

The purpose of this early feasibility study was to demonstrate that the Acclaim CI is capable of operating as it was designed. In other words, there are no safety or efficacy endpoints. The study is essentially designed to elicit patient and professional feedback regarding their experience using the device and inform any necessary design changes prior to beginning the pivotal clinical study.

We believe that the initial results of the EFS were primarily promising. All EFS subjects have achieved hearing percepts through activation of the implant stimulator and achieve unique pitch percepts on each electrode, typical of all other cochlear implant recipients. The patients use their devices daily.

A few design shortcomings were identified and addressed. The primary concern was a signal to noise issue that limited programmability and performance. Mitigation and resolution strategies were put in place.

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10 Source: Holder JT, et al., *Current Profile of Adults Presenting for Preoperative Cochlear Implant Evaluation*; Trends in Hearing (2018).

Two of the three patients chose to wear a hearing aid on top of their Acclaim CI. This combination helped to mitigate the noise and provide patients with a signal to noise ratio that allows them to use and enjoy the performance of the device. It was an unanticipated discovery during the EFS that a hearing aid on top of the Acclaim CI could provide patients with additional improvement. We are intrigued by the possibility of offering a fully implanted cochlear implant that could also allow for the use of a hearing aid or other ear accessory (e.g., ear buds) because the Acclaim CI leverages the ear to pick up sound.

Timeline to Commercialization of Acclaim CI

In the United States, before we can market a new Class III medical device, which the Acclaim CI is, we must first receive FDA approval via the Premarket Approval ("PMA") approval process. We currently anticipate obtaining FDA approval in late 2027 or early 2028, although the process of obtaining FDA approval is uncertain, and we may not obtain approval on that timeline or at all.

A large component of our PMA will be a successful pivotal clinical study. We received approval for our IDE on October 31, 2024. However, FDA approved our IDE based on a staged clinical study that required approval from the FDA to move from the first stage to the second stage. We received approval to expand the study to the second and final stage on October 3, 2025.

The objective of this pivotal clinical study is to demonstrate the safety and efficacy of the Acclaim cochlear implant for the treatment of severe to profound sensorineural hearing loss and is designed as a prospective, multicenter, non-randomized, open label clinical trial to evaluate the safety and efficacy of the Acclaim CI. The pivotal clinical study protocol currently requires 56 total patients enrolled and followed for 12 months. We completed enrollment of all 56 patients on March 10, 2025.

The pivotal clinical study protocol has primary efficacy and safety endpoints, many secondary endpoints and few exploratory endpoints. The primary efficacy endpoint will compare speech perception (CNC words) from baseline to twelve-month follow-up and the safety endpoint will characterize incidence and frequency of adverse events. The total pivotal clinical study duration is estimated to be approximately two and a half years. There is no guarantee that we will meet any of the safety, efficacy, secondary, or exploratory endpoints or enroll all patients.

Once the pivotal study is completed, the data will be analyzed and sent to the FDA with the PMA submission. The FDA review may take 6-12 months depending on what comes up during the review and if the FDA review team recommends the device for a Panel Track review. There is no guarantee that PMA approval will be obtained.

If FDA approval is delayed, we will be unable to move forward with expansion of our corporate infrastructure, development of distribution capabilities, and implementation of product technical support and provider training, and the costs associated with delayed approval may limit the funds available for investment in these areas. Regulatory delays would also put us further behind our established competitors in the market and may allow additional competitors into the market with products that have competitive advantages over ours.

Moreover, if FDA approval is delayed beyond our current plan or if delay is based on safety or efficacy concerns that require product redesign, we will be required to raise significant additional capital to continue our operations. We may be unable to raise these additional funds on favorable terms or at all, especially if approval is delayed based on device performance or other issues with the Acclaim CI. Because the Acclaim CI is currently our only product candidate that we believe can be commercialized, we would be unable to continue operations if it were determined that we could not obtain FDA approval for the Acclaim CI.

Go-To-Market Strategy

Assuming PMA approval is received, our commercialization strategy will be quality over quantity to facilitate the Acclaim CI gaining a meaningful foothold in the marketplace without unnecessary complications stemming from attempting to grow too quickly.

The surgical professionals believed to be best suited to implant the Acclaim CI are otologists and neurotologists (i.e., sub-specialties of otolaryngologists). This community is relatively small compared to other specialties, with only a few hundred active professionals in the United States. We anticipate carefully selecting roughly 30 sites to be trained and ready to implant upon commercialization. These 30 sites are expected to be spread throughout the country and focus on quality of surgical care and capacity to serve a sufficient number of qualified patients. Following the initial

30 sites, we intend to add an additional 30 sites every year until there are roughly 150 sites actively implanting the Acclaim CI. However, this strategy will require significant investments in the development of our management team, corporate infrastructure, and manufacturing capabilities, as well as expansion of our sales, distribution, and training network. We do not anticipate offering the Acclaim CI at every cochlear implant center in the country.

The other key professional group is audiologists. Each surgical site will have its own audiology team familiar with cochlear implants. The audiology team is critical to the success of a surgical site's performance. We will invest resources for in-person training, and technical and product support as well as virtual training, and technical and product support for audiologists servicing patients with our products.

Outside of surgical sites, there is a subset of audiologists who traditionally work with patients currently using hearing aids. These audiologists will be instrumental in identifying and referring potential Acclaim CI patients to surgical sites. One of the largest barriers to more cochlear implant candidates becoming cochlear implant recipients is the lack of awareness and understanding by the audiologists of the technology and associated benefits available for their patients. We believe strong relationships can be built with both surgical teams and audiologists to ensure both are able to understand the options and benefits of the technology and differentiate themselves from the marketplace by offering and working with the Acclaim CI. However, we will be unable to commercialize until we are able to obtain FDA approval for the Acclaim CI.

Commercial Activities Outside of the United States

We anticipate pursuing the Conformité Européenne mark ("*CE Mark*") in the European Union shortly after FDA approval. The CE Mark will allow the Acclaim CI to be sold throughout the European Economic Area. We are currently focusing our resources on FDA approval and will address commercial activities outside of the United States when the FDA approval process is more advanced.

Eventually, we anticipate pursuing other markets based on the potential size of the markets and availability of reimbursement, such as Australia, Brazil, and parts of Asia, although no such approval is guaranteed, and approval may take longer and involve greater cost than we currently anticipate.

Product Evolution and Next Generation Products

The focus of research and development over the next several years will be to improve upon the existing product design of the Acclaim CI. Quality and reliability will be a primary focus of the team in the initial years of market release. We will also focus on the growing need for robust software and user interfaces for both the patient and the professional.

Esteem FI-AMEI — a potentially viable product with reimbursement

The Esteem FI-AMEI is a unique technology that could serve a niche segment of the hearing market. FDA-approved since 2010, the Esteem FI-AMEI suffered from a lack of reimbursement due to categorization as a hearing aid. We believe that this categorization is inaccurate as, unlike a hearing aid which is essentially an externally worn microphone and speaker simply making sounds louder, the Esteem FI-AMEI is fully implanted and replaces the function of the middle ear to directly stimulate the cochlear via the stapes. Although efforts to change that categorization have been unsuccessful to date, a bipartisan Congressional bill, titled the Hearing Device Coverage Clarification Act was introduced in both the House of Representatives and in the Senate. The bill seeks to clarify that fully implanted active middle ear hearing devices ("FI-AMEIs") are prosthetics and not subject to the current Medicare hearing aid coverage exclusion. If the bill is successful clarifying that FI-AMEIs are eligible for coverage and then a change does happen to reimbursement policy for fully implanted active middle ear implants, the Esteem FI-AMEI is an existing FDA approved product ready to capitalize on such a change.

Were the change in reimbursement policy to occur and we were to focus on marketing the Esteem FI-AMEI, it would benefit from upgrades to its power source and chip design. Such upgrades are not currently a priority of the organization as we view pursuing the commercialization of the Acclaim CI as the appropriate focus and best use of resources.

Existing Esteem FI-AMEI patients and professionals who work with those patients will continue to be supported. It is not only important for the market to know we support our patients for life, but it is the right thing to do for the patients.

New implantations of the Esteem FI-AMEI are not expected to be more than a few per year until, and if, the reimbursement policy changes. Absent a change in reimbursement policy, there only will be nominal revenue from replacement of sound processors for existing patients who need a new battery.

Intellectual Property

We rely on a combination of patent, copyright, trademark and trade secret laws and confidentiality and invention assignment agreements to protect our intellectual property rights. As of March 2, 2026, we had rights to 40 issued U.S. patents, which are estimated to expire between 2028 and 2043 assuming all required fees are paid, 9 pending U.S. patent applications, 48 issued foreign patents and 26 pending foreign and international patent applications. Our patents cover, among other things, aspects of our current Acclaim CI system and future product concepts. Some of the pending foreign and international patent applications preserve an opportunity to pursue patent rights in multiple countries.

Our pending patent applications may not result in issued patents, and we cannot assure you that any current or subsequently issued patents will protect our intellectual property rights or provide us with any competitive advantage. While there is no active litigation involving any of our patents or other intellectual property rights and we have not received any notices of patent infringement, we may be required to enforce or defend our intellectual property rights against third parties in the future. See "*Risk Factors — Risks Relating to our Intellectual Property*" for additional information regarding these and other risks related to our intellectual property portfolio and their potential effect on us.

Material Patents

As of March 2, 2026, our material patents, their jurisdiction, patent number, and expiration date are listed in the tables below:

Jurisdiction	Patent No.	Expiration Date	Title
U.S.	9782600	05/17/2033	Self-regulating transcutaneous energy transfer
U.S.	9497555	01/30/2035	Implantable middle ear transducer having improved frequency response
U.S.	10129660	10/27/2028	Implantable middle ear transducer having improved frequency response
U.S.	9036824	12/30/2033	Transducer impedance measurement for hearing aid
U.S.	9521493	05/03/2032	Transducer impedance measurement for hearing aid
U.S.	9682226	12/06/2033	Electronic lead connection and related devices
U.S.	10549090	10/20/2037	Communication system and methods for fully implantable modular cochlear implant system
U.S.	10646709	04/09/2038	Fully implantable modular cochlear implant system
U.S.	10569079	09/04/2037	Communication system and methods for fully implantable modular cochlear implant system
U.S.	10743812	03/25/2035	Implantable middle ear diagnostic transducer
U.S.	11260220	02/28/2040	Implantable cochlear system with integrated components and lead characterization
U.S.	11266831	06/13/2040	Implantable cochlear system with integrated components and lead characterization
U.S.	9525949	03/16/2034	Implantable middle ear transducer having diagnostic detection sensor
U.S.	11051116	10/11/2032	Implantable middle ear transducer having diagnostic detection sensor
U.S.	11471689	04/14/2041	Cochlear implant stimulation calibration
U.S.	11564046	07/17/2041	Programming of cochlear implant accessories

Jurisdiction	Patent No.	Expiration Date	Title
U.S.	9313590	03/13/2033	Hearing aid amplifier having feed forward bias control based on signal amplitude and frequency for reduced power consumption
U.S.	9635478	03/09/2034	Coulomb counter and battery management for hearing aid
U.S.	11672970	02/21/2040	Implantable cochlear system with integrated components and lead characterization
U.S.	11697019	12/02/2040	Combination hearing aid and cochlear implant system
U.S.	11711658	10/11/2032	Implantable middle ear transducer having diagnostic detection sensor
EP	3500337	08/17/2037	Implantable modular cochlear implant system with communication system and network
DE	3500337	08/17/2037	Implantable modular cochlear implant system with communication system and network
DK	3500337	08/17/2037	Implantable modular cochlear implant system with communication system and network
AT	3500337	08/17/2037	Implantable modular cochlear implant system with communication system and network
GB	3500337	08/17/2037	Implantable modular cochlear implant system with communication system and network
BE	3500337	08/17/2037	Implantable modular cochlear implant system with communication system and network
FR	3500337	08/17/2037	Implantable modular cochlear implant system with communication system and network
IT	3500337	08/17/2037	Implantable modular cochlear implant system with communication system and network
SE	3500337	08/17/2037	Implantable modular cochlear implant system with communication system and network
MX	421017	2/21/2040	Implantable cochlear system with integrated components and lead characterization
EP	3927420	2/21/2040	Implantable cochlear system with integrated components and lead characterization
UP	3927420	2/21/2040	Implantable cochlear system with integrated components and lead characterization
GB	3927420	2/21/2040	Implantable cochlear system with integrated components and lead characterization
U.S.	11633591	8/3/2041	Combination implant system with removable earplug sensor and implanted battery
U.S.	11806531	4/11/2041	Implantable cochlear system with inner ear sensor
U.S.	11839765	1/23/2042	Cochlear implant system with integrated signal analysis functionality
U.S.	11865339	6/22/2042	Cochlear implant system with electrode impedance diagnostics
EP	3858425	08/17/2037	Implantable Modular Cochlear Implant System with Communication System and Network
GB	3858425	08/17/2037	Implantable Modular Cochlear Implant System with Communication System and Network
UP	3858425	08/17/2037	Implantable Modular Cochlear Implant System with Communication System and Network
U.S.	12090318	02/21/2040	Implantable Cochlear System with Integrated Components and Lead Characterization
U.S.	12233256	10/09/2040	Implantable Cochlear System with Integrated Components and Lead Characterization

Jurisdiction	Patent No.	Expiration Date	Title
HK	HK40066136	02/21/2040	Implantable Cochlear System with Integrated Components and Lead Characterization
JP	7598401	02/21/2040	Implantable Cochlear System with Integrated Components and Lead Characterization
JP	7597846	02/21/2040	Implantable Cochlear System with Integrated Components and Lead Characterization
JP	7598327	02/21/2040	Implantable Cochlear System with Integrated Components and Lead Characterization
U.S.	12081061	02/07/2043	Recharge System For Implantable Battery
U.S.	12214195	12/02/2040	Implantable Cochlear System with Inner Ear Sensor
EP	4204071	08/27/2041	Programming Of Cochlear Implant Accessories
GB	4204071	08/27/2041	Programming Of Cochlear Implant Accessories
HK	HK40097814	08/27/2041	Programming Of Cochlear Implant Accessories
UP	4204071	08/27/2041	Programming Of Cochlear Implant Accessories
U.S.	12151102	12/02/2040	Combination Hearing Aid and Cochlear Implant System
EP	4255554	11/24/2041	Combination Hearing Aid and Cochlear Implant System
GB	4255554	11/24/2041	Combination Hearing Aid and Cochlear Implant System
UP	4255554	11/24/2041	Combination Hearing Aid and Cochlear Implant System
EP	4255555	11/24/2041	Cochlear Implant Stimulation Calibration
GB	4255555	11/24/2041	Cochlear Implant Stimulation Calibration
UP	4255555	11/24/2041	Cochlear Implant Stimulation Calibration
EP	4319866	04/01/2042	Cochlear Implant System with Electrode Impedance Diagnostics
GB	4319866	04/01/2042	Cochlear Implant System with Electrode Impedance Diagnostics
UP	4319866	04/01/2042	Cochlear Implant System with Electrode Impedance Diagnostics
U.S.	12390634	12/20/2040	Fully Implantable Modular Cochlear Implant System
U.S.	12318607	2/21/2040	Implantable Cochlear System with Integrated Components and Lead Characterization
AU	2022227534	2/21/2042	Recharge System for Implantable Battery
AU	2021390456	11/24/2041	Combination Hearing Aid and Cochlear Implant System
AU	2021391396	11/24/2041	Cochlear Implant Stimulation Calibration
U.S.	12318613	2/23/2041	Cochlear Implant System with Integrated Signal Analysis Functionality
AU	2022227537	2/21/2042	Combination Implant System with Removable Earplug Sensor and Implanted Battery
AU	2022227536	2/21/2042	Cochlear Implant System with Integrated Signal Analysis Functionality
AU	2020224666	2/21/2040	Implantable Cochlear System with Integrated Components and Lead Characterization
EP	4338791	2/21/2040	Implantable Cochlear System with Integrated Components and Lead Characterization
GB	4338791	2/21/2040	Implantable Cochlear System with Integrated Components and Lead Characterization
UP	4338791	2/21/2040	Implantable Cochlear System with Integrated Components and Lead Characterization
U.S.	12418758	8/12/2041	Programming of Cochlear Implant Accessories

Jurisdiction	Patent No.	Expiration Date	Title
AU	2021334336	8/27/2041	Programming of Cochlear Implant Accessories
U.S.	12485288	10/4/2041	Cochlear Implant Stimulation Calibration
HK	HK40101898	11/24/2041	Cochlear Implant Stimulation Calibration
AU	2022254630	4/1/2042	Cochlear Implant System with Electrode Impedance Diagnostics
U.S.	12465754	12/18/2041	Combination Implant System with Removable Earplug Sensor and Implanted Battery
AU	2022229818	3/3/2042	Cochlear Implant System with Improved Input Signal-to-Noise Ratio
HK	HK40102155	11/24/2041	Combination Hearing Aid and Cochlear Implant System
HK	HK40107235	4/1/2042	Cochlear Implant System with Electrode Impedance Diagnostics
U.S.	12544564	10/9/2043	Cochlear Implant System with Improved Input Signal-to-Noise Ratio

Trademarks

As of March 2, 2026, we had trademark registrations, covering "Acclaim", "Envoy", "Envoy Medical", "EnvoyCEM", "Esteem", "Invisible Hearing", and "MEDCEM." Our U.S. trademarks have registration dates between 2002 and 2021 and have upcoming renewal dates between 2027 and 2033. All of our trademarks are in current use, and we expect that they will remain in use for the foreseeable future. We also have pending trademark applications covering "Nature's Microphone", "Naturemic" and "America's Hearing Implant Company" with application dates in 2024 and 2025 and use in 2025.

We also rely, in part, upon unpatented trade secrets, know-how and continuing technological innovation, and may in the future rely upon licensing opportunities, to develop and maintain our competitive position. We protect our proprietary rights through a variety of methods, including confidentiality and assignment agreements with suppliers, employees, consultants and others who may have access to our proprietary information.

Manufacturing and Supply

We currently do all final manufacturing at our facility in White Bear Lake, Minnesota. We rely on a limited number of technicians and have some critical equipment that would be difficult to replace in a timely manner. In order to scale quickly, we will need to expand our manufacturing capacity and add additional shifts.

We rely on third-party suppliers to manufacture some of our critical sub-assemblies. Outsourcing sub-assemblies manufacturing reduces our need for additional capital investment. We select our suppliers carefully and require they adhere to all applicable regulations. We monitor our suppliers and always inspect all components received. Our quality assurance process monitors and maintains supplier performance through qualification and periodic supplier reviews and audits.

Certain components used in our products are supplied by single-source suppliers, but we believe that we are able to plan supply in a manner that would minimize the effect of losing any of our existing suppliers. Our suppliers manufacture the components they produce for us and test our components and devices to our specifications. We intend to maintain sufficient levels of inventory to enable us to continue our operations while we qualify additional potential suppliers in the event that one or more of our single-source suppliers were to encounter a delay in supply or end supply. Due to our current limited production numbers, we order components and sub-assemblies on a purchase order basis and do not have supply agreements with any of our suppliers.

Government Regulation

Our products and our operations are subject to extensive regulation by the FDA and other federal and state authorities in the U.S., as well as comparable authorities in the European Economic Area ("EEA") and other countries in which we may sell our products. In the U.S., our products are subject to regulation as medical devices under the Federal Food, Drug, and Cosmetic Act ("FDCA") as implemented and enforced by the FDA. The FDA regulates the development, design, non-clinical and clinical research, manufacturing, safety, efficacy, labeling, packaging, storage,

installation, servicing, recordkeeping, premarket clearance or approval, import, export, adverse event reporting, advertising, promotion, marketing and distribution, and import and export of medical devices to ensure that medical devices distributed domestically are safe and effective for their intended uses and otherwise meet the requirements of the FDCA.

In addition to U.S. regulations, we are subject to a variety of regulations in the EEA governing clinical trials and the commercial sales and distribution of our products. Even if we obtain the required FDA clearance or approval for a product in the United States, we will be required to obtain authorization before commencing clinical studies and to obtain marketing authorization or approval of our products under the comparable regulatory authorities of countries outside of the U.S. before we can commence clinical studies or commercialize our products in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA clearance or approval.

FDA Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device commercially distributed in the U.S. requires either FDA clearance of a 510(k) premarket notification or PMA. Under the FDCA, medical devices are classified into one of three classes, Class I, Class II, or Class III, depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of the FDA's Quality System Regulations ("QSR"), facility registration and product listing, reporting of adverse medical events, and truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Under the 510(k) process, the manufacturer must submit to the FDA a premarket notification demonstrating that the device is "substantially equivalent" to either a device that was legally marketed prior to May 28, 1976, the date upon which the Medical Device Amendments of 1976 were enacted, or another legally marketed device that was cleared through the 510(k) process.

Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a PMA.

Some pre-amendment devices are unclassified but are subject to the FDA's premarket notification and clearance process in order to be commercially distributed.

The Acclaim CI will be regulated as a Class III device and will require approval of a PMA prior to commercialization.

PMA Approval Pathway

Class III devices require PMA approval before they can be marketed although some pre-amendment Class III devices for which the FDA has not yet required a PMA are cleared through the 510(k) process. The PMA process is more demanding than the 510(k) premarket notification process. In a PMA process, the manufacturer must demonstrate that the device is safe and effective, and the PMA must be supported by extensive data, including data from preclinical studies and human clinical trials. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities and controls used for manufacturing, and proposed labeling. Following receipt of a PMA, the FDA determines whether the application is sufficiently complete to permit a substantive review. If the FDA accepts the application for review, it has 180 days under the FDCA to complete its review of a PMA, although in practice, the FDA's review often takes significantly longer, and can take up to several years. An advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will generally conduct a preapproval inspection of the applicant or its third-party manufacturers' or suppliers' manufacturing facility or facilities to ensure compliance with the QSR.

The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). The FDA may approve a PMA with post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution, and collection of long-term follow-up data from patients in the clinical study that supported the PMA or requirements to conduct additional clinical studies post-approval. The FDA may condition a PMA approval on some form of post-market surveillance when deemed necessary to protect the public health or to provide additional safety and efficacy data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to the FDA on the clinical status of those patients. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval.

Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which affect the safety or effectiveness of the device, require submission of a PMA supplement. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. Certain other changes to an approved device require the submission of a new PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness.

Clinical Trials

Clinical studies are almost always required to support a PMA and are sometimes required to support a 510(k) submission. All clinical investigations of investigational devices to determine safety and effectiveness must be conducted in accordance with the FDA's IDE regulations, which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk" to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical studies. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical study to proceed under a conditional approval. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

In addition, the study must be approved by, and conducted under the oversight of, an Institutional Review Board ("*IRB*") for each clinical site. The IRB is responsible for the initial and continuing review of the IDE, and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical studies may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical study after obtaining approval for the study by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and complying with labeling and record-keeping requirements.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, study monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping, and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol,

control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a study begins, we, the FDA or the IRB could suspend or terminate a clinical study at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Expedited Development and Review Programs

Following passage of the 21st Century Cures Act, the FDA implemented the Breakthrough Devices Program, which is a voluntary program offered to manufacturers of certain medical devices and device-led combination products, including the Acclaim CI, that may provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The goal of the program is to provide patients and health care providers with more timely access to qualifying devices by expediting their development, assessment and review, while preserving the statutory standards for FDA marketing authorization, although there is no guarantee that this designation will accelerate the timeline for approval or make it more likely that the Acclaim CI will be approved. The program is available to medical devices that meet certain eligibility criteria, including that the device provides more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions, and that the device meets one of the following criteria: (i) the device represents a breakthrough technology, (ii) no approved or cleared alternatives exist, (iii) the device offers significant advantages over existing approved or cleared alternatives, or (iv) the availability of the device is in the best interest of patients. Breakthrough Device designation provides certain benefits to device developers, including more interactive and timely communications with FDA staff, use of post-market data collection, when scientifically appropriate, to facilitate expedited and efficient development and review of the device, opportunities for efficient and flexible clinical study design, and prioritized review of premarket submissions. The Acclaim CI received Breakthrough Device designation in March 2019.

Post-market Regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling and marketing regulations, which require that promotion is truthful, not misleading, fairly balanced and provide adequate directions for use and that all claims are substantiated, and also prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling; FDA guidance on off-label dissemination of information and responding to unsolicited requests for information;
- the federal Physician Sunshine Act and various state and foreign laws on reporting remunerative relationships with health care customers;
- the federal Anti-Kickback Statute (and similar state laws) prohibiting, among other things, soliciting, receiving, offering or providing remuneration intended to induce the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as Medicare or Medicaid. A person or entity does not have to have actual knowledge of this statute or specific intent to violate it to have committed a violation;
- the federal False Claims Act (and similar state laws) prohibiting, among other things, knowingly presenting, or causing to be presented, claims for payment or approval to the federal government that are false or fraudulent, knowingly making a false statement material to an obligation to pay or transmit money or property to the federal government or knowingly concealing, or knowingly and improperly avoiding or decreasing, an obligation to pay or transmit money to the federal government. The government may assert that claim includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statute;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices, or approval of a supplement for certain modifications to PMA devices;

- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- complying with the new federal law and regulations requiring Unique Device Identifiers ("*UDI*") on devices and also requiring the submission of certain information about each device to the FDA's Global Unique Device Identification Database ("*GUDID*");
- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

We may be subject to similar foreign laws that may include applicable post-marketing requirements such as safety surveillance. Our manufacturing processes are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. As a manufacturer, our facilities, records and manufacturing processes are subject to periodic scheduled or unscheduled inspections by the FDA. Our failure to maintain compliance with the QSR or other applicable regulatory requirements could result in the shut-down of, or restrictions on, our manufacturing operations and the recall or seizure of our products.

The discovery of previously unknown problems with any of our products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- recalls, withdrawals, or administrative detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export or import approvals for our products; or
- criminal prosecution.

Foreign Regulation

In order for us to market our products in countries outside the U.S., we must obtain regulatory approvals or certifications and comply with extensive product and quality system regulations in other countries. These regulations, including the requirements for approvals, clearance or certifications and the time required for regulatory review, vary from country to country. Some countries have regulatory review processes that are substantially longer than U.S. processes. Failure to obtain regulatory approval or certification in a timely manner and meet all of the local requirements including language and specific safety standards in any foreign country in which we plan to market

our products could prevent us from marketing products in such countries or subject us to sanctions and fines. While we expect that will pursue the marketing our products outside of the U.S. in the future, we are only actively pursuing U.S. approval at this time.

Federal, State and Foreign Fraud and Abuse and Physician Payment Transparency Laws

In addition to FDA restrictions on marketing and promotion of drugs and devices, other federal, state, and foreign laws restrict our business practices. These laws include, without limitation, foreign, federal, and state anti-kickback and false claims laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value, including stock, stock options, and the compensation derived through ownership interests.

Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Conduct and business arrangements that do not fully satisfy one of these safe harbor provisions may result in increased scrutiny by government enforcement authorities. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the federal Anti-Kickback Statute has been violated. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The majority of states also have anti-kickback laws which establish similar prohibitions and in some cases may apply more broadly to items or services covered by any third-party payor, including commercial insurers and self-pay patients.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. The federal civil False Claims Act also applies to false submissions that cause the government to be paid less than the amount to which it is entitled, such as a rebate. Intent to deceive is not required to establish liability under the civil federal civil False Claims Act. Moreover, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. In addition, private parties may initiate "qui tam" whistleblower lawsuits against any person or entity under the federal civil False Claims Act in the name of the government and share in the proceeds of the lawsuit. The government may further prosecute conduct constituting a false claim under the federal criminal False Claims Act. The criminal False Claims Act prohibits the making or presenting of a claim to the government knowing such claim to be false, fictitious or fraudulent and, unlike the federal civil False Claims Act, requires proof of intent to submit a false claim.

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

The Health Insurance Portability and Accountability Act ("*HIPAA*") also created additional federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and

knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Many foreign countries have similar laws relating to healthcare fraud and abuse. Foreign laws and regulations may vary greatly from country to country. For example, the advertising and promotion of medical devices is subject to some general principles set forth in EU legislation. According to the EU Medical Devices Regulation, only devices that are CE marked may be marketed and advertised in the EU in accordance with their intended purpose. Directive 2006/114/EC concerning misleading and comparative advertising and Directive 2005/29/EC on unfair commercial practices, while not specific to the advertising of medical devices, also apply to the advertising thereof and contain general rules, for example, requiring that advertisements are evidenced, balanced and not misleading. Specific requirements are defined at a national level. EU member states' laws related to the advertising and promotion of medical devices, which vary between jurisdictions, may limit or restrict the advertising and promotion of products to the general public and may impose limitations on promotional activities with healthcare professionals. These laws, which vary between jurisdictions (thus making compliance more complex), may limit or restrict the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals. Many EU member states have adopted specific anti-gift statutes that further limit commercial practices for our products, in particular vis-à-vis healthcare professionals and organizations. Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to healthcare professionals or entities and many EU member states have adopted national "Sunshine Acts" which impose reporting and transparency requirements (often on an annual basis), similar to the requirements in the United States, on medical device manufacturers. Certain countries also mandate implementation of commercial compliance programs. Also, many U.S. states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs.

Additionally, there has been a recent trend of increased foreign, federal, and state regulation of payments and transfers of value provided to healthcare professionals or entities. In the U.S., the federal Physician Payments Sunshine Act imposes annual reporting requirements on certain drug, biologics, medical supplies and device manufacturers for which payment is available under Medicare, Medicaid or CHIP for payments and other transfers of value provided by them, directly or indirectly, to physicians, as defined by statute, certain other non-physician practitioners such as physician assistants and nurse practitioners, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Manufacturers must submit reports by the 90th day of each calendar year. Many EU member states have adopted national "Sunshine Acts" which impose similar reporting and transparency requirements (often on an annual basis) on certain drug, biologics and medical device manufacturers. Certain foreign countries and U.S. states also mandate implementation of commercial compliance programs, impose restrictions on device manufacturer marketing practices and require tracking and reporting of gifts, compensation, and other remuneration to healthcare professionals and entities.

Violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to device manufacturers may result in significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if the entity becomes subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of operations.

Data Privacy and Security Laws

Numerous state, federal and foreign laws, regulations, and standards govern the collection, use, access to, confidentiality and security of health-related and other personal information and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, including HIPAA, and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. For example, the General Data Protection Regulation (the "*GDPR*"), imposes strict requirements for processing the personal data of individuals within the EEA. Privacy and security laws, regulations, and other

obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Healthcare Reform

The U.S. and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our products. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our products.

The implementation of the Affordable Care Act ("*ACA*") in the U.S., for example, has changed healthcare financing and delivery by both governmental and private insurers substantially, and affected medical device manufacturers significantly. The ACA, among other things, provided incentives to programs that increase the federal government's comparative effectiveness research, and implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians, and other providers to improve the coordination, quality, and efficiency of certain healthcare services through bundled payment models. Additionally, the ACA expanded eligibility criteria for Medicaid programs and created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, among other things, included reductions to Medicare payments to providers, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect into 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, the Medicare Access and CHIP Reauthorization Act of 2015 enacted on April 16, 2015, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments began in 2019 that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations.

We expect additional state, federal, and foreign healthcare reform measures to be adopted in the future, any of which could limit the amounts that federal, state, and foreign governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

Anti-Bribery and Corruption Laws

Our U.S. operations are subject to the Foreign Corrupt Practices Act ("*FCPA*"). We are required to comply with the FCPA, which generally prohibits covered entities and their intermediaries from engaging in bribery or making other prohibited payments to foreign officials for the purpose of obtaining or retaining business or other benefits. In addition, the FCPA imposes accounting standards and requirements on publicly traded U.S. corporations and their foreign affiliates, which are intended to prevent the diversion of corporate funds to the payment of bribes and other improper payments, and to prevent the establishment of "off books" slush funds from which such improper payments

can be made. We also are subject to similar anticorruption legislation implemented in Europe under the Organization for Economic Co-operation and Development's Convention on Combating Bribery of Foreign Public Officials in International Business Transactions.

Segment Information

We manage our business within one reportable segment. Segment information is consistent with how management reviews our business, makes investing and resource allocation decisions, and assesses our operating performance.

Facilities

Our principal office is located at 4875 White Bear Parkway, White Bear Lake, Minnesota, where we lease approximately 13,500 square feet of office space. We lease this space under a lease that terminates on December 31, 2030. We believe that our existing facility is sufficient to meet our needs for the foreseeable future.

We also lease 1,100 square feet of office space in Ausbach, Germany pursuant to a lease that automatically renews each year for a successive one year period, unless we notify the landlord 6 months prior to the annual renewal. This lease renewed automatically on January 1, 2025 and again on January 1, 2026.

Employees and Human Capital

As of December 31, 2025, we had approximately 43 full time employees and 4 part time employees. A significant number of our employees have a technical background and hold advanced engineering or scientific degrees. We view our investment in human capital to be crucial to our success, and we are committed to ensuring an inclusive culture in which employees feel they are part of achieving a common goal.

Our work environment is highly collaborative and one that is based on trust and mutual respect. We believe that the relatively small size of our organization allows our employees to feel pride and ownership in their work and a sense of being part of fulfilling our mission more directly than with larger companies in our industry.

None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relationship with our employees to be good.

Legal Proceedings

From time to time, we may be involved in various claims and legal actions in the ordinary course of business. Except as described below, we are not currently involved in any material legal proceedings outside the ordinary course of our business.

On November 14, 2023, the Company, Whitney Haring-Smith (the former chief executive officer and a former director of the Company), Daniel Hirsch (the former chief financial officer of the Company), and Anzu SPAC GP I LLC were named as defendants in a complaint filed by Atlas Merchant Capital SPAC Fund I LP ("*Atlas*") in the Delaware Court of Chancery. Atlas alleges that it was not allowed to redeem its shares of the Anzu class A common stock and that Defendants acted to prevent Atlas's attempt to redeem its shares. Defendants assert that Atlas did not comply with the requirements for redeeming shares set forth in the Company's organizational documents. Atlas asserts damages in the amount of approximately $9.4 million, pre- and post-judgment interest, costs, and reasonable attorneys' fees. The Company has standard indemnification obligations to Dr. Haring-Smith and Mr. Hirsch. The Company believes that the lawsuit is meritless and has been defending this matter vigorously. The Company is unable to predict the outcome of this legal proceeding.

Available Information

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, and all amendments to those reports, filed with or furnished to the SEC, are available free of charge through the investor relations sections of the Company's website, *https://www.envoymedical.com/investors*, as soon as reasonably practicable after we have electronically filed such material with, or furnished it to, the SEC. In addition, the SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at *www.sec.gov*.

The information on our website is not, and shall not be deemed to be, part of this Report or incorporated into any other filings we make with the SEC, except as shall be expressly set forth by specific reference in any such filings.

ITEM 1A. Risk Factors

An investment in our securities involves substantial risks. In addition to other information in this Annual Report on Form 10-K, you should carefully consider the risks described in this Report, as well as other information and data set forth in this Report, before making an investment decision with respect to our securities. The occurrence of any of such risks could materially and adversely affect our business, prospects, financial condition and results of operations, which could cause you to lose all or a part of your investment in our securities. Some statements in this Report constitute forward-looking statements. See "*Cautionary Note Regarding Forward-Looking Statements*."

Risks Relating to Our Class A Common Stock

The market price of our Class A Common Stock has been and may continue to be extremely volatile, which could cause purchasers of our securities to incur substantial losses.

The market price and trading volume of our shares of Class A Common Stock has recently experienced, and may continue to experience, extreme volatility, which could cause purchasers of our Class A Common Stock to incur substantial losses. Since the closing of the Business Combination, our Class A Common Stock has traded as low as $0.36 and as high as $11.46. In addition, the volume of trading of our Class A Common Stock has been inconsistent.

We believe that the volatility and our current market prices reflect market and trading dynamics unrelated to our underlying business, or macro or industry fundamentals, and we do not know how long these dynamics will last. Under the circumstances, investors in our Class A Common Stock are subject to the risk of losing all or a substantial portion of their investment.

The market volatility and trading patterns we have experienced create several risks for investors, including the following:

- the market price of our Class A Common Stock has experienced and may continue to experience rapid and substantial increases or decreases unrelated to our operating performance or prospects, or macro or industry fundamentals, and substantial increases may be significantly inconsistent with the risks and uncertainties that we continue to face;
- factors in the public trading market for our Class A Common Stock may include the sentiment of retail investors, the direct access by retail investors to broadly available trading platforms, the amount and status of short interest in our securities, access to margin debt, trading in options and other derivatives on our Class A Common Stock and any related hedging and other trading factors;
- if the market price of our Class A Common Stock declines, you may be unable to resell your shares at or above the price at which you acquired them.

The trading price of our Class A Common Stock depends on many factors, including those described in this "*Risk Factors*" section, many of which are beyond our control and may not be related to our operating performance. Any of the factors listed below could have a material adverse effect on investment in our Class A Common Stock, and our Class A Common Stock may trade at prices significantly below the price paid for them. In such circumstances, the trading prices of our Class A Common Stock may not recover and may experience a further decline. Factors affecting the trading price of our Class A Common Stock may includes:

- changes in the market's expectations regarding our ability to obtain FDA approval for the Acclaim CI, and the time and capital required to reach an FDA decision;
- changes in the market's expectations about our operating results;
- the public's reaction to our press releases, our other public announcements and our filings with the SEC;
- speculation in the press or investment community;
- actual or anticipated developments in our business or our competitors' businesses or the competitive landscape generally;

- our failure to meet the expectation of securities analysts or investors in a particular period;
- changes in financial estimates and recommendations by securities analysts concerning us or the market in general;
- publications of research reports by securities analysts about us, our competitors, or the industry we operate in;
- changes in laws and regulations affecting our business;
- commencement of, or involvement in, litigation involving us;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- the volume of Class A Common Stock available for public sale;
- any major change in the Board or management;
- sales of substantial amounts of Class A Common Stock by directors, officers or significant stockholders or the perception that such sales could occur;
- general economic and political conditions such as recessions, interest rates, fuel prices, trade wars, pandemics, currency fluctuations and acts of war or terrorism; and
- other risk factors listed under this "*Risk Factors*" section.

Currently, our Class A Common Stock is listed on Nasdaq. However, limited liquidity in the market may limit the ability to sell shares of our Class A Common Stock at a favorable price.

Currently, our Class A Common Stock is listed on The Nasdaq Capital Market. However, trading in our Class A Common Stock has been variable, with periods of limited trading volume. If we do not maintain our increased trading volume, investors may not be able to re-sell their securities or may be required to take a lower price to liquidate their investment as sales reduce the trading price of our Class A Common Stock. We cannot predict the extent to which investor interest in us will lead allow us to maintain a consistent, active, and liquid trading market. The trading price of and demand for our Class A Common Stock will depend on a number of conditions, including the development of a market following, including by analysts and other investment professionals, the businesses, operations, results, and prospects of the Company, general market and economic conditions, governmental actions, regulatory considerations, legal proceedings, and developments or other factors. These and other factors may impair the development of a liquid market and the ability of investors to sell shares at an attractive price. These factors also could cause the market price and demand for the common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares and may otherwise negatively affect the price and liquidity of the common stock. Many of these factors and conditions are beyond the control of the Company or the stockholders.

The exercise of our outstanding Warrants would result in substantial increase in the number of shares eligible for future resale in the public market and result in dilution to our stockholders.

As of December 31, 2025, we had the following warrants to purchase our Class A Common stock: (i) 14,166,666 outstanding Public Warrants to purchase 14,166,666 shares of Class A Common Stock at an exercise price of $11.50 per share, (ii) 1,135,499 outstanding Shortfall Warrants to purchase 1,135,499 shares of Class A Common Stock at an exercise price of $1.50 per share, (iii) 3,500,000 outstanding GAT Warrants to purchase 3,500,000 shares of Class A Common Stock at exercise prices ranging from $1.24 per share to $3.04 per share, (iv) 5,725,206 outstanding September 2025 Warrants to purchase 5,725,206 shares of Class A Common Stock at an exercise price of $1.31 per share, (v) 9,022,572 outstanding October 2025 Warrants to purchase 9,022,572 shares of Class A Common Stock at an exercise price of $1.33 per share and (vi) 368,694 outstanding Placement Agent Warrants to purchase 368,694 shares of Class A Common Stock at exercises prices of $1.6375 and $1.6625 per share. In addition, in the February 2026 Offering we issued 120,000,000 Series A Warrants to purchase 120,000,000 shares of Class A Common Stock at an exercise price of $0.40 per share and 27,053,850 Pre-Funded Warrants to purchase 27,053,850 shares of Class A Common Stock at a price of $0.0001 per share. To the extent any of these warrants are exercised, the interest of the shares of Class A Common Stock outstanding prior to such warrant exercise will be diluted on a pro rata basis based on the number of additional shares of Class A Common Stock issued upon exercise. Although the Company will receive

additional capital upon exercise of these warrants (other than Pre-Funded Warrants for which the exercise price is nominal), we expect that the warrants would only be exercised when the exercise price is less than the current market value of our Class A Common Stock.

While we will pay dividends on shares of Series A Preferred Stock pursuant to the Certificate of Designation, we do not intend to pay dividends on shares of Class A Common Stock for the foreseeable future.

Except with respect to dividends on shares of Series A Preferred Stock pursuant to the terms of the Certificate of Designation, we currently intend to retain all available funds and any future earnings to fund the development and growth of our business. As a result, while we will pay dividends on shares of Series A Preferred Stock, we do not anticipate declaring or paying any cash dividends on shares of Class A Common Stock in the foreseeable future. Any decision to declare and pay dividends in the future will be made at the discretion of the Board of Directors of the Company and will depend on, among other things, the dividend rights of the Series A Preferred Stock pursuant to the Certificate of Designation, our business prospects, results of operations, financial condition, cash requirements and availability, certain restrictions related to our indebtedness, industry trends and other factors that the Board may deem relevant. Any such decision will also be subject to compliance with contractual restrictions and covenants in the agreements governing our current and future indebtedness. In addition, we may incur additional indebtedness, the terms of which may further restrict or prevent us from paying dividends on shares of Class A Common Stock. As a result, you may have to sell some or all of your shares of Class A Common Stock after price appreciation in order to generate cash flow from your investment, which you may not be able to do. Our inability or decision not to pay dividends, particularly when others in our industry have elected to do so, could also adversely affect the market price of shares of Class A Common Stock.

If analysts do not publish research about our business or if they publish inaccurate or unfavorable research, our stock price and trading volume could decline.

The trading market for our Class A Common Stock will depend in part on the research and reports that analysts publish about our business. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our Class A Common Stock or publish inaccurate or unfavorable research about our business, the price of our Class A Common Stock would likely decline. If few analysts cover us, demand for our Class A Common Stock could decrease and our Class A Common Stock price and trading volume may decline. Similar results may occur if one or more of these analysts stop covering us in the future or fail to publish reports on us regularly.

You may experience future dilution as a result of future equity offerings.

In order to raise additional capital, we may, in the future, offer additional shares of our Class A Common Stock or other securities convertible into or exchangeable for our Class A Common Stock at prices that may not be the same as the price per share paid by any investor. We may sell shares or other securities in any other offering at a price per share that is less than the price per share paid by any investor, and investors purchasing shares or other securities in the future could have rights superior to you. The price per share at which we sell additional shares of our Class A Common Stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by any investor.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our Class A Common Stock may continue to be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert management's attention from other business concerns, which could seriously harm our business.

We are and may become involved in legal proceedings, and no assurance can be provided as to the outcome of these matters.

From time to time, we are involved in various legal proceedings, lawsuits, and other claims relating to matters incidental to our business. For example, we are currently a defendant in a lawsuit in the Court of Chancery of the State of Delaware involving a stockholder's redemption request in connection with our special meeting of stockholders held on September 27, 2023. An unfavorable resolution of any litigation may have a material adverse effect on our business, results of operations and financial condition. Additionally, litigation may result in substantial costs and expenses and significantly divert the attention of management.

Our failure to meet Nasdaq's continued listing requirements could result in a delisting of our Class A Common Stock from Nasdaq.

If we fail to satisfy Nasdaq's continued listing requirements, such as the corporate governance requirements, the minimum market value of listed securities requirements, or closing bid price requirement, Nasdaq may take steps to delist our Class A Common Stock. We received a notice of delisting from Nasdaq on February 25, 2025 regarding the market value of listed securities standard and will be required to meet such standard to maintain our Nasdaq listing. On February 23, 2026, Nasdaq confirmed that we had regained compliance with the continued listing standards. However, we will need to continue to meet the Nasdaq listing standards, and we will have more limited ability to cure any non-compliance during the one year monitoring period following our regained compliance.

The Company received an additional staff determination notice from the Nasdaq Listing Qualifications Department, informing the Company that its Class A Common Stock had failed to comply with the $1.00 minimum bid price required for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2) for the 30 consecutive business days prior to the date of the Notice. The Company will have six months from the date of the determination letter to regain compliance with the minimum bid requirement.

If our Class A Common Stock was delisted from Nasdaq, such delisting would likely have a negative effect on the price of our Class A Common Stock and would impair a stockholder's ability to sell or purchase our Class A Common Stock when a stockholder wishes to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our Class A Common Stock to become listed again, stabilize the market price or improve the liquidity of our Class A Common Stock, prevent our Class A Common Stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements.

Risks Relating to Our Business and Operations

We are an early-stage company with a history of losses. We have not been profitable historically and may not be able to achieve profitability in the future.

We are a development-stage medical device company with a limited operating history. In recent years, we have focused almost exclusively on developing our lead product candidate, the Acclaim CI. We have funded our operations to date primarily through the issuance of our equity securities and convertible debt.

We have a limited operating history upon which you can evaluate our business and prospects. In addition, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the medical device industry. To date, we have not generated any revenue from the sale of the Acclaim CI. See the section entitled "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" for additional information. We have incurred losses in each year since our inception, including net losses of approximately $23.8 million and $20.8 million for the years ended December 31, 2025 and 2024, respectively. We had accumulated deficits of approximately $313.4 million and $284.7 million as of December 31, 2025 and 2024, respectively. Substantially all of our operating losses in such years resulted from costs incurred in connection with the development of the Acclaim CI and from general and administrative costs associated with our operations.

We will incur significant expenses related to clinical trials to obtain approval of the FDA to market the Acclaim CI. If we obtain FDA marketing approval for the Acclaim CI we will likely incur significant sales, marketing, and outsourced manufacturing expenses, as well as continued research and development expenses. Furthermore, now that the Business Combination has been completed, we expect to incur additional costs associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing a medical device, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

We expect to continue to incur significant losses until we receive the necessary regulatory approvals to commercialize the Acclaim CI in the United States, which we may not be successful in achieving. We anticipate that our expenses will increase substantially if and as we:

- continue the research and development of the Acclaim CI, including through clinical trials;

- seek additional regulatory and marketing approvals in jurisdictions outside the United States;
- establish a sales, marketing, and distribution infrastructure to commercialize our product candidate;
- rely on our third-party suppliers and manufacturers to obtain adequate supply of materials and components for our products;
- seek to identify, assess, acquire, license, and/or develop other product candidates and subsequent generations of our current product candidate;
- seek to maintain, protect, and expand our intellectual property portfolio;
- seek to identify, hire, and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product candidate development and planned future commercialization efforts; and
- experience any delays or encounter issues with respect to any of the above, including, but not limited to, failed studies, complex results, safety issues or other regulatory challenges that require longer follow-up of existing studies or additional supportive studies in order to pursue marketing approval.

The amount of any future operating losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings, strategic collaborations, or grants. Even if we obtain regulatory approvals to market the Acclaim CI or any future product candidates, our future revenue will depend upon the size of any markets in which our products and product candidates receive approval and our ability to achieve sufficient market acceptance, pricing and reimbursement from third-party payors for our products and product candidates. Further, the operating losses that we incur may fluctuate significantly from quarter-to-quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. Other unanticipated costs may also arise. If we continue to generate operating losses, there will be an adverse effect on our results of operations, financial condition, and the market price of our Class A Common Stock.

We have generated limited revenue from product sales and may never be profitable.

While we have historically obtained revenue from our legacy Esteem FI-AMEI product, such revenue has been limited, and we have not generated any revenue from sales of the Acclaim CI. Our ability to generate revenue and achieve profitability mainly depends on our ability to obtain FDA approval for the Acclaim CI and, if we obtain such approval, to successfully scale up production and market the device. We do not know when, or if, we will generate any such revenue. Our ability to generate future revenue from product sales will depend heavily on our success in many areas, including but not limited to:

- completing research and development of the Acclaim CI in a timely and successful manner;
- completing our pivotal clinical study in the United States successfully;
- obtaining FDA approval for the Acclaim CI;
- maintaining and enhancing a commercially viable, sustainable, scalable, reproducible and transferable manufacturing process for the Acclaim CI that is compliant with current good manufacturing practices, ("cGMP");
- establishing and maintaining supply and, if applicable, manufacturing relationships with third parties that can provide, in both amount and quality, adequate products to support development and the market demand for the Acclaim CI, if and when it is approved;
- identifying, assessing, acquiring and/or developing new product candidates;
- launching and commercializing any product candidates for which we obtain regulatory and marketing approval, either directly by establishing a sales force, marketing and distribution infrastructure, and/or with collaborators or distributors in the United States, Europe and other potential markets that we will target;

- accurately identifying demand for the Acclaim CI and any future product candidates;
- exposing and educating physicians and other medical professionals with respect to the use of our products;
- obtaining market acceptance of the Acclaim CI and any future product candidates from the medical community and third-party payors;
- ensuring our product candidates are approved for reimbursement from governmental agencies, health care providers and insurers in jurisdictions where they have been approved for marketing;
- addressing any competing technological and market developments that impact the Acclaim CI and any future product candidates or their prospective usage by medical professionals;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations under such arrangements;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, patent applications, trade secrets and know-how;
- avoiding and defending against third-party interference or infringement claims; and
- attracting, hiring and retaining qualified personnel.

We anticipate incurring significant incremental costs associated with commercializing the Acclaim CI. Our expenses could increase beyond expectations if we are required by the FDA, or other domestic or foreign regulatory agencies, to change our product design or manufacturing processes or to perform studies in addition to those that we currently anticipate. Even if we are successful in obtaining regulatory approvals to market the Acclaim CI, our revenue earned from such product candidate will be dependent in part upon the size of the markets in the territories for which we gain regulatory approval for such product candidate, the accepted price for such product candidate, our ability to obtain reimbursement for such product candidate at any price, and the expenses associated with manufacturing and marketing such product candidate for such markets. Therefore, we may not generate significant revenue from the sale of the Acclaim CI, even if we obtain FDA approval. Further, if we are not able to generate significant revenue from the sale of our approved products, we may be forced to curtail or cease our operations, in which case our investors may lose the full amount of their investment in us. Due to the numerous risks and uncertainties involved in product development, it is difficult to predict the timing or amount of increased expenses, or when, or if, we will be able to achieve or maintain profitability.

If the Acclaim CI contains design or manufacturing defects, our business and financial results could be harmed.

To date, we have completed initial patient implants of the Acclaim CI as part of our early feasibility study. As the Acclaim CI has no history of commercial operation, we have a limited frame of reference from which to evaluate its long-term performance. There can be no assurance that we will be able to detect and fix any defects in the Acclaim CI in time to maintain our FDA trial schedule. Once we have commenced with implantation in additional patients, we may discover latent defects in design, manufacture or construction that may cause our systems not to perform as expected or to cause side effects. The Acclaim CI also requires software to operate, which may need to be modified and updated over time.

There can be no assurance that we will be able to detect and fix any defects in the hardware or software of the Acclaim CI on the timescale necessary to maintain our clinical trial schedule, or at all. Further, such defects may not become apparent until our systems are implanted in patients and may cause adverse effects that cause harm to patients and require redesign of the Acclaim CI, which may result in great expense, harm to our reputation, and harm to our results of operations, financial condition, and the trading price of the Class A Common Stock.

We expect that we will need to raise substantial additional funding, which may not be available on acceptable terms, or at all. Failure to obtain funding on acceptable terms and on a timely basis may require us to curtail, delay or discontinue our product development efforts or other operations.

We will require substantial additional capital to commercialize the Acclaim CI. This additional capital may come from the exercise of Class A Warrants issued in the February 2026 Offering, for which we would receive an aggregate of $48 million in proceeds upon exercise. Provided, however, that there can be no guarantee that such

Series A Warrants will be exercised. In addition, our operating plans may change as a result of many factors that may currently be unknown to us, and we may need to seek additional funds sooner than planned. Our future funding requirements will depend on many factors, including but not limited to:

- the progress, results and costs of our planned studies and pivotal clinical trials;
- the cost, timing and outcomes of regulatory review of the Acclaim CI;
- the scope, progress, results and costs of product development, testing, manufacturing, preclinical development and, if applicable, clinical trials for any other product candidates that we may develop or otherwise obtain in the future;
- the costs of manufacturing the Acclaim CI, including costs related to engaging third-party manufacturers therefor;
- the cost of our future activities, including establishing sales, marketing and distribution capabilities for any product or product candidates in any particular geography where we receive marketing approval for such product candidates;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- the level of revenue, if any, received from commercial sales of any product candidates for which we receive marketing approval.

In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of holders of our securities and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the value of our securities to decline. The incurrence of indebtedness could result in increased fixed payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue our research and development program or the development or commercialization, if any, of the Acclaim CI or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially and adversely affect our business, financial condition, results of operations and value of our securities.

Raising additional capital would cause dilution to our existing stockholders and may adversely affect the rights of existing stockholders.

We may seek additional capital through a combination of private and public equity offerings, debt financings and collaborations, and strategic and licensing arrangements. To the extent that we raise additional capital through the issuance of equity or otherwise, including through additional preferred stock or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Future sales of our Class A Common Stock or of securities convertible into our Class A Common Stock, or the perception that such sales may occur, could cause immediate dilution and adversely affect the value of our Class A Common Stock.

Failure of a key information technology system, process or site could have an adverse effect on our business.

We rely extensively on information technology systems to conduct our business. These systems affect, among other things, ordering and managing materials from suppliers, summarizing and reporting results of operations, complying with regulatory, legal or tax requirements, data security and other processes necessary to manage our business. Our information technology systems and those of our third-party service providers, vendors, strategic partners and other contractors or consultants are vulnerable to damage or interruption from computer viruses and malware (e.g., ransomware), natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, malicious code, employee theft or misuse, human error, fraud,

denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased and evolved. As a result of the rise in remote work, we and our third-party service providers and partners may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Although we have implemented cybersecurity protections to safeguard our data, including our patient and subject data, we can provide no assurances that these protections will prevent all cybersecurity breaches. We primarily use common off-the-shelf software systems, such as Microsoft 365, which receive frequent security updates from the software providers. We also utilize a third-party vendor to maintain our IT system networks, and as a result of limited internal IT resources, we are only able to perform limited due diligence on our third-party IT vendors. We receive periodic security monitoring from our cybersecurity insurance provider.

However, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. Our third-party service providers and partners are also subject to these heightened risks. If our systems are damaged or cease to function properly due to any number of causes, ranging from catastrophic events to power outages to security breaches, and our business continuity plans do not effectively compensate on a timely basis, we may experience interruptions in our operations, which could have an adverse effect on our business.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur, it could lead to unauthorized access, disclosure and use of non-public information, including information from the patient information we create, receive, maintain or transmit, which are governed by HIPAA and other laws. Any such access, disclosure, or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and damage to our reputation, which would, in turn, materially and adversely affect our results of operations, financial condition, liquidity, and the value of our securities.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The global financial crisis caused extreme volatility and disruptions in the capital and credit markets. Factors such as geopolitical events, inflationary pressures, and the U.S. election cycles have contributed to this volatility. Recently, among other effects, volatile economic conditions have caused high levels of inflation, increases in interest rates by central banks with the intent of slowing inflation, and a reduction of available capital following increased interest rates. These global economic conditions could result in a variety of risks to our business, including difficulty in raising funding from capital markets and increased interest rates on loans used to finance our business. Such impacts would materially and adversely affect our financial condition, liquidity and the value of our securities.

Our primary exposures to inflationary pressures to date have been through increases in the market cost of employee compensation, third-party vendor pricing, and component procurement. In particular, since 2022, we have had to increase employee salaries and benefits to aid employee retention and to compete for new employees. If labor costs in our market continue to rise, we expect we will need to continue to increase our compensation levels. We have also seen an increase in pricing from third-party vendors such as advisors, attorneys, and consultants. The per part pricing of components has also increased, and, in many instances, without advanced warning. If we increase production of the Acclaim CI for clinical trials and, if the Acclaim CI obtains FDA approval, eventual commercialization, we will also have greater exposure to rising costs of components if inflation rates remain high. These increases in expenses could materially and adversely affect our financial condition, liquidity and the trading price of our securities.

Recent increases in interest rates may also affect our ability to finance the continued development of the Acclaim CI, the cost of FDA trials, and additional costs of commercializing the Acclaim CI. In recent years, we have financed our operations through convertible loans from a related party, which we believe to have been favorable to us at below market interest rates and we do not expect to be able to borrow at favorable rates in the future. Our inability to raise additional funds on favorable terms, or at all, would materially and adversely affect our results of operations, financial condition, liquidity, the trading price of our securities, and our growth prospects.

If we are able to proceed to FDA trials for the Acclaim CI and, if the Acclaim CI obtains FDA approval and eventual commercialization, we may be exposed to the risk of supply chain disruptions from events such as the wars and other armed conflicts, pandemics, and other global, national, regional, and local events that cannot yet be predicted. Supply constraints resulting from such events may also cause or exacerbate inflation. If such events prevent us from obtaining necessary components for production of Acclaim CI devices, or substantially raise the prices for such components, we may be delayed in the FDA trial process, or we may be unable to produce sufficient Acclaim CI devices to meet demand, which would materially and adversely affect our results of operations and financial condition.

We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and the value of our common stock.

As a privately held company, we were not required to evaluate our internal control over financial reporting in a manner that meets the standards of publicly traded companies required by Section 404(a) of the Sarbanes-Oxley Act. As a public company, we are required to provide management's attestation on internal control over financial reporting. If we are unable to establish or maintain appropriate internal control over financial reporting or implement these additional requirements in a timely manner or with adequate compliance, it could result in material misstatements in our consolidated financial statements, failure to meet our reporting obligations on a timely basis, increases in compliance costs, and subject us to adverse regulatory consequences, all of which may adversely affect investor confidence in us and the value of our Class A Common Stock.

In connection with the preparation and audit of our consolidated financial statements as of and for the years ended December 31, 2025 and 2024, material weaknesses were identified in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. The following material weaknesses were identified:

- We do not maintain a sufficient complement of personnel with accounting knowledge, experience and training to appropriately analyze, record and disclose certain accounting matters to provide reasonable assurance of preventing material misstatements.
- Our management does not implement a formal risk assessment that addresses risks relevant to financial reporting objectives, including cybersecurity and fraud risks.
- We have not designed, documented and maintained formal accounting policies, procedures and controls over significant accounts and disclosures to achieve complete, accurate and timely financial accounting, reporting and disclosures, including segregation of duties and adequate controls related to the preparation, posting, modification and review of journal entries.
- We have not designed and maintained effective controls around the interpretation and accounting treatment of the valuation of a material liability and the forward purchase agreement.
- We have not designed and maintained effective controls over certain information technology general controls for information systems that are relevant to the preparation of our consolidated financial statements, including ineffective controls around user access and segregation of duties.

The material weaknesses related to the insufficient complement of personnel and formal accounting policies, and the lack of procedures and controls resulted in adjustments to several accounts and disclosures. The information technology deficiencies did not result in a material misstatement to the consolidated financial statements; however, the

deficiencies, when aggregated, could result in potential misstatements that would not be prevented or detected. Each of these material weaknesses could result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected.

We have begun the process of conducting a formal risk assessment and implementation of a plan to remediate these material weaknesses. These remediation measures are ongoing and include the following steps:

- hiring additional accounting and financial reporting personnel with appropriate technical accounting knowledge and public company experience in financial reporting;
- designing, documenting, and implementing effective processes and controls over significant accounts and disclosure;
- designing, documenting, and implementing security management and change management controls over information technology systems, including adjusting user access levels and implementing external logging of activity and periodic review of such logs; and
- engaging an accounting advisory firm to assist with the documentation, evaluation, remediation and testing of our internal control over financial reporting based on the criteria established in "Internal Control — Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission.

While we are designing and implementing measures to remediate our existing material weaknesses, we cannot predict the success of such measures or the outcome of its assessment of these measures at this time. Our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business, personnel, information technology systems and applications, or other factors. If we fail to remediate our existing material weaknesses or identify new material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to conclude that our internal control over financial reporting is effective, it is possible that a material misstatement of our financial statements would not be prevented or detected on a timely basis, investors may lose confidence in the accuracy and completeness of our financial reports, and the value of our securities could be materially and adversely affected.

Our financial statements contain an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern, which could prevent us from obtaining new financing on reasonable terms or at all.

Our independent registered accounting firm has included an explanatory paragraph in its report expressing substantial doubt about our ability to continue as a going concern. This going concern opinion could materially limit our ability to raise additional funds through the issuance of equity or debt securities or otherwise. Future financial statements may include an explanatory paragraph with respect to our ability to continue as a going concern. Until we can generate significant recurring revenues, we expect to satisfy our future cash needs through debt or equity financing. We cannot be certain that additional funding will be available to us on acceptable terms, if at all. If funds are not available, we may be required to delay, reduce the scope of, or eliminate research or development plans for, or commercialization efforts with respect to our products. This may raise substantial doubts about our ability to continue as a going concern.

We are a development-stage company and are subject to all of the risks inherent in the establishment of a new product. We may not receive, or may be delayed in receiving, the necessary approval or clearance for the Acclaim CI.

Furthermore, even if our technology receives the necessary regulatory approvals and becomes commercially viable, our business models may not generate sufficient revenue necessary to support our business. If we are unable to address any issues mentioned above, or encounter other problems, expenses, difficulties, complications, and delays in connection with the establishment and expansion of our business, our entire business may fail, in which case you may lose part of, or your entire investment.

We have a history of net losses and negative cash flow from operations since our inception and we expect such losses and negative cash flows from operations to continue in the foreseeable future. We anticipate our losses will continue to increase from current levels because we expect to incur additional costs related to developing our business,

including research and development costs, manufacturing costs, employee-related costs, costs of complying with government regulations, intellectual property development and prosecution costs, marketing and promotion costs, capital expenditures, general and administrative expenses, and costs associated with operating as a public company.

Our ability to generate revenue from our operations and, ultimately, achieve profitability will depend on, among other factors, whether we can complete the development and commercialization of our product candidate, whether we can manufacture the Acclaim CI on a commercial scale in such amounts and at such costs as we anticipate, and whether we can achieve market acceptance of our products, services and business models. We may never generate any revenue or operate on a profitable basis. Even if we achieve profitability, we may not be able to sustain it. If we are unable to achieve sustainable profitability, our financial condition and the price of our securities will be materially and adversely affected.

Clinical failure can occur at any stage of clinical development. Our clinical experience to date does not necessarily predict future results and may not have revealed certain potential limitations of the technology or potential complications from the Acclaim CI and may require further clinical validation. Any product version we advance through clinical trials may not have favorable results in later clinical trials or receive regulatory approval.

Clinical failure can occur at any stage of clinical development. We received approval for our IDE on October 31, 2024. However, FDA approved our IDE based on a staged clinical study that will require approval from the FDA to move from the first stage to the second stage. As we have limited clinical experience, our ability to identify potential problems and/or inefficiencies concerning current and future versions of the Acclaim CI in advance of its use in general and expanded groups of patients may be limited, and we cannot assure you that actual clinical performances will be satisfactory to support proposed indications and regulatory approvals and clinical acceptance and adoption, or that its use will not result in unanticipated complications. If the results of our feasibility study are not satisfactory, our U.S. pivotal study could be delayed or may not occur. Furthermore, there can be no assurance that the implementation of our plan will be successful. In addition, the results of our clinical trials are subject to human analyses and interpretation of the data accumulated, which could be affected by various errors due to, among other factors, lack of sufficient clinical experience with the Acclaim CI, assumptions used in the statistical analysis of results, interpretation errors in the analysis of the clinical trials results, or uncertainty in the actual efficacy of the Acclaim CI in its current clinical stage. Therefore, the safety and efficacy of the Acclaim CI and the clinical results to date will require further independent professional validation and clinical study. If the Acclaim CI does not function as expected over time, we may not be able to develop the Acclaim CI at the rate or to the stage we desire, we could be subject to liability claims, our reputation may be harmed, the Acclaim CI may not achieve regulatory clearances, and the Acclaim CI may not be widely adopted by healthcare providers and patients. If the Acclaim CI is not widely adopted, our business, financial condition, and results of operations will be materially and adversely affected.

The successful commercialization of the Acclaim CI, if it receives FDA approval, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates could limit our ability to market those products and decrease our ability to generate revenue.

The availability of coverage and the adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors will be essential for most patients to be able to afford the Acclaim CI. Our ability to achieve coverage and acceptable levels of reimbursement for our products by third-party payors will affect our ability to successfully commercialize the Acclaim CI. Even if we obtain coverage for the Acclaim CI by a third-party payor, the resulting reimbursement payment rates may not be adequate. We can provide no assurance that coverage and reimbursement in the United States, the European Union, or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new products will be covered. Some third-party payors may require pre-approval of coverage for new or innovative devices before they will reimburse healthcare providers who use such therapies. Although we are confident that the Acclaim CI will be eligible for reimbursement, we cannot guarantee what third-party payors will decide with respect to the coverage and reimbursement for the Acclaim CI, if approved.

Obtaining and maintaining reimbursement status is time consuming, costly and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and medical devices. However, no uniform policy for coverage and reimbursement for such products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

Outside the United States, our international operations will generally be subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of our products. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates, if approved. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

If we are unable to obtain reimbursement coverage or adequate reimbursement levels, our results of operations, financial condition, the value of our securities, and our future prospects will be materially and adversely affected.

We operate in a very competitive business environment, and if we are unable to compete successfully against our existing or potential competitors, our business, financial condition and results of operations may be adversely affected.

The Acclaim CI will be subject to intense competition. The industry in which we operate is competitive, subject to change and sensitive to the introduction of new products, procedures or other market activities of industry participants. We will compete with large, diversified medical device companies, including Sonova, Demant, Cochlear, and others. We also compete with smaller companies similar to us.

At any time, these competitors and other potential market entrants may develop new products, procedures or treatment alternatives that could render our products obsolete or uncompetitive. In addition, one or more of such competitors may gain a market advantage by developing and patenting competitive products, procedures or treatment alternatives earlier than we can, obtaining regulatory clearances or approvals more rapidly than we can or selling competitive products at prices lower than ours. If medical research were to lead to the discovery of alternative therapies or technologies that better treat or cure hearing loss, our profitability could suffer through a reduction in sales or a loss in market share to a competitor. Many of our current and potential competitors have substantially greater sales and financial resources than we do. These competitors may also have more established distribution networks, a broader offering of products, entrenched relationships with physicians and distributors or greater experience in launching, marketing, distributing and selling products or treatment alternatives.

We also compete with our competitors to engage the services of independent sales agents, both those presently working with us and those with whom we hope to work as we expand. In addition, we compete with our competitors to acquire technologies and technology licenses complementary to our products or procedures or advantageous to our business. If we are unable to compete successfully against our existing or potential competitors, our business, financial condition and results of operations will be adversely affected, and we may not be able to grow at our expected rate, if at all.

We expect to derive most of our revenues from sales of the Acclaim CI. Our inability to successfully commercialize this product candidate or any subsequent decline in demand for this product candidate, could severely harm our ability to generate revenues.

We are currently dependent on the successful commercialization of the Acclaim CI to generate revenues. As a result, factors adversely affecting our ability to successfully commercialize, or the pricing of or demand for, this product could have a material adverse effect on our financial condition and results of operations. If we are unable to successfully commercialize or create market demand for the Acclaim CI, we will have limited ability to generate revenues.

Furthermore, we may be vulnerable to fluctuations in demand for the Acclaim CI, and a reduction in demand for the Acclaim CI would have a material adverse effect on our results of operations and financial condition. Such fluctuations in demand may be due to many factors, many of which are beyond our control, including, among others:

- market acceptance of a new product, including healthcare professionals' and patients' preferences;
- market acceptance of the clinical safety and performance of the Acclaim CI;
- development of similarly cost-effective products by our competitors;
- development delays of the Acclaim CI;
- adverse medical side effects suffered by patients using the Acclaim CI, whether actually resulting from the use of the Acclaim CI or not;
- changes in regulatory policies toward hearing loss technologies;
- changes in regulatory approval, clearance requirements and licensure for our product;
- third-party claims of intellectual property infringement;
- budget constraints and the availability of reimbursement or insurance coverage from third-party payors for the Acclaim CI;
- any developments affecting the long-term implantation and use of the Acclaim CI; and
- responses from certain of our competitors to the offering of the Acclaim CI.

If healthcare professionals do not recommend our product to their patients, the Acclaim CI may not achieve market acceptance and we may not become profitable.

If healthcare professionals, including physicians, do not recommend or prescribe our product to their patients, the Acclaim CI may not achieve market acceptance and we may not become profitable. In addition, physicians have historically been slow to change their medical diagnostic and treatment practices because of perceived liability risks arising from the use of new products. Delayed adoption of the Acclaim CI by healthcare professionals could lead to a delayed adoption by patients. Healthcare professionals may not recommend the Acclaim CI until certain conditions have been satisfied, including, among others:

- there is sufficient long-term clinical and health-economic evidence to convince them to alter their existing hearing loss treatments and recommendations;
- there are recommendations from prominent physicians, educators and/or associations indicating that the Acclaim CI is safe and effective;
- we obtain favorable data from clinical and health-economic studies for the Acclaim CI;
- reimbursement or insurance coverage from government and private third-party payors is available;
- healthcare professionals obtain required approvals and licensures for the handling, storage, dispensing and disposal of the Acclaim CI; and
- healthcare professionals become familiar with the advantages of the Acclaim CI in comparison to other hearing loss solutions.

We cannot predict when, if ever, healthcare professionals and patients will adopt the use of the Acclaim CI on a large scale. Even if favorable data is obtained from clinical studies for the regulatory approval of the Acclaim CI, there can be no assurance that prominent physicians would endorse it for use by their patients. If the Acclaim CI does not achieve an adequate level of acceptance by patients, healthcare professionals, and government and private third-party payors, we may not generate significant product revenues, we may not become profitable, in which case our results of operations, cash flows and the value of our securities will be materially and adversely affected.

We will be dependent upon contract manufacturing organizations and material suppliers, making us vulnerable to supply shortages and problems, increased costs and quality or compliance issues, any of which could harm our business.

Our production of Acclaim CI devices is currently limited to production of prototype devices and devices for our early feasibility study. As a result, our purchases of supplies and components are limited to date.

However, we expect that we will need to significantly increase our production rates to meet the supply of Acclaim CI devices needed for our clinical trials and, if the Acclaim CI obtains FDA approval, for eventual commercialization, which we are targeting to obtain in late 2027 or early 2028. We also expect that some of the critical materials and components used in manufacturing the Acclaim CI may be sourced from single suppliers, which may expose us to greater risks as we increase production of Acclaim CI devices than if our supplier base were more diversified. For example, our suppliers may encounter problems during manufacturing for a variety of reasons, including, for example, failure to follow specific protocols and procedures, failure to comply with applicable legal and regulatory requirements, equipment malfunction and environmental factors, failure to properly conduct their own business affairs, and infringement of third-party intellectual property rights, any of which could delay or impede their ability to meet our increased requirements. An interruption in the supply of a key component could significantly delay our production of the Acclaim CI or increase our production costs.

When we increase production, our reliance on these third-party suppliers will also subject us to other risks that could harm our business, including:

- we are not, and will not in the near future be, a major customer of many of our suppliers, and these suppliers may therefore give other customers' needs higher priority than us;
- we may not be able to obtain an adequate supply of components in a timely manner, on commercially reasonable terms or at all;
- our suppliers, especially new suppliers, may make errors in manufacturing that could adversely affect the efficacy or safety of our products or cause delays in shipment;
- we may have difficulty locating and qualifying additional or alternative suppliers;
- switching components or suppliers may require product redesign and possibly resubmission to the FDA or other similar foreign regulatory agencies, which could impede or delay our commercial activities;
- one or more of our suppliers may be unwilling or unable to supply components for our products in a timely manner, on commercially reasonable terms or at all;
- the occurrence of a fire, natural disaster or other catastrophe impacting one or more of our suppliers may affect their ability to deliver products to us in a timely manner or at all; and
- our suppliers may encounter financial or other business hardships unrelated to our demand, which could inhibit their ability to fulfill our orders and meet our requirements.

We may not be able to quickly establish additional or alternative suppliers if necessary, in part because we may need to undertake additional activities to establish such suppliers as required by the regulatory approval process. Any interruption or delay in obtaining products from our third-party suppliers, or our inability to obtain products from qualified alternate sources at acceptable prices in a timely manner, could materially impair our ability to meet the demand of our customers and cause them to switch to competing products. Given our reliance on a limited number of suppliers, we may be susceptible to supply shortages while looking for alternate suppliers, which could materially and adversely affect our business, financial condition, results of operations and the trading price of our securities.

Our business plan relies on certain assumptions about the market for our product; however, the size and expected growth of our addressable market has not been established with precision and may be smaller than we estimate, and even if the addressable market is as large as we have estimated, we may not be able to capture market share.

Our estimates of the addressable market for the Acclaim CI are based on a number of internal and third-party estimates and assumptions. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and our estimates may not be correct. As a result, the projected demand for our products could materially differ from actual demand if our assumptions regarding these trends and acceptance of our products by the medical community prove to be incorrect or do not materialize, or if non-surgical treatments gain more widespread acceptance. In addition, even if the Acclaim CI gains acceptance, technological or medical advances could provide alternatives to address hearing loss that are less invasive or offer other benefits over Acclaim CI. As a result, our estimates of the addressable market for our current or future products and procedures may prove to be incorrect. If the addressable market is not as large as we believe, our business, financial condition and results of operations and business prospects would be materially and adversely affected.

We will depend on third parties to manage our pre-clinical studies and clinical trials, perform related data collection and analysis, and to enroll patients for our clinical trials, and, as a result, we may face costs and delays that are beyond our control.

We rely upon third-party vendors, including Contract Research Organization ("CROs"), to monitor and manage data for our ongoing preclinical studies and will rely on them to manage our clinical trials. We also rely on CROs for execution of our preclinical studies and will rely on them for execution of our clinical trials. Although we control only certain aspects of their activities, we are and will be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the vendors and CROs does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with good clinical practice ("GCP"), cGMP, the Helsinki Declaration, the International Conference on Harmonization Guideline for Good Clinical Practice, applicable European Commission Directives on Clinical Trials, laws and regulations applicable to clinical trials conducted in other territories, and good laboratory practices, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the EEA, and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these regulations through periodic inspections of study sponsors, principal investigators, study sites and other contractors. If we or any of our CROs or vendors fail to comply with applicable regulations, including GCP and cGMP regulations, the clinical data generated in our clinical studies may be deemed unreliable and the FDA, European Medicines Agency ("EMA"), or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with third-party CROs or vendors terminate, we may not be able to enter into arrangements with alternative CROs or vendors or do so on commercially reasonable terms. In addition, our CROs are not our employees, and, except for remedies available to us under our agreements with such CROs, we cannot control whether they devote sufficient time and resources to our ongoing clinical programs. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Our CROs may also generate higher costs than anticipated, which could adversely affect our results of operations and the commercial prospects for our product candidate, increase our costs and delay our ability to generate revenue.

Replacing or finding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, we may encounter similar challenges or delays in the future, which could have a material adverse effect on our business, financial condition and prospects.

We have been and in the future may become a defendant in one or more stockholder derivative, class-action, and other litigation, and any such lawsuits may adversely affect our business, financial condition, results of operations and cash flows.

We and certain of our officers and directors have been and may in the future become defendants in one or more stockholder derivative actions or other class-action lawsuits. For example, a lawsuit was filed in November 2023 against Daniel Hirsch, Whitney Haring-Smith, the Sponsor and the Company, as successor to Anzu Special Acquisition Corp I, a Delaware corporation, which was renamed Envoy Medical, Inc., upon the closing of the Business Combination, alleging a claim for breach of Anzu's Amended and Restated Certificate of Incorporation against the Company, a claim for breach of fiduciary duty against Mr. Hirsch, Dr. Haring-Smith and the Sponsor and claims for unjust enrichment, fraudulent misrepresentation and tortious interference with economic relations against the defendants.

See the section entitled "*Business — Legal Proceedings*" for more information on these lawsuits.

These lawsuits can divert our management's attention and resources from our ordinary business operations, and we would likely incur significant expenses associated with their defense (including, without limitation, substantial attorneys' fees and other fees of professional advisors and potential obligations to indemnify current and former officers and directors who are or may become parties to such actions). In connection with these lawsuits, we may be required to pay material damages, consent to injunctions on future conduct and/or suffer other penalties, remedies or sanctions, or issue additional shares upon the exercise of certain warrants, which may cause additional dilution. In addition, any such future lawsuits could adversely impact our reputation and/or ability to launch and commercialize our products, thereby harming our ability to generate revenue. Accordingly, the ultimate resolution of these matters and any future matters could have a material adverse effect on our business, financial condition, results of operation and cash flow and, consequently, could negatively impact the trading price of our Class A Common Stock.

We are highly dependent on key members of our executive management team. Our inability to retain these individuals could impede our business plan and growth strategies, which could have a negative impact on our business and the value of your investment.

Our ability to implement our business plan depends on the continued services of key members of our senior management. In particular, and to a critical extent, we are dependent on the continued efforts and services of the members of our management team. If we lose the services of such key members of our management team, we would likely be forced to expend significant time and money in the pursuit of replacement individuals, which may result in a delay in the implementation of our business plan and plan of operations. We may not be able to find satisfactory replacements on terms that would not be unduly expensive or burdensome to us. We do not currently carry a key-man life insurance policy that would assist us in recouping our costs in the event of the death or disability of our management team. The loss of members of our management team, or our inability to attract or retain other qualified individuals, could have a material adverse effect on our business, results of operations and financial condition.

Certain of our directors and/or officers may have interests that are different from holders of our Class A Common Stock.

Certain of our directors and officers may have different interests than other holders of Class A Common Stock.

As of December 31, 2025, Glen A. Taylor, a former member of the Board, holds approximately 37.8% of the currently outstanding shares of Class A Common Stock and approximately 24.2% of the outstanding shares of our Series A Preferred Stock. As a result of these holdings, Mr. Taylor has the ability to exert significant influence over certain matters submitted to a vote of our shareholders. Brent. Lucas, a member of the Board and the Chief Executive Officer, has interest in continued employment with the Company that is different from other holders of Class A Common Stock.

For additional information regarding related party transactions and potential conflicts of interest, see "*Certain Relationships and Related Party Transactions.*"

Risks Relating to Our Intellectual Property

If we are unable to obtain significant patent protection for our products, or if our patents and other intellectual property rights do not adequately protect our products, we may be unable to gain significant market share and be unable to operate our business profitably.

We rely on patents, trade secrets, copyrights, know-how, trademarks, license agreements and contractual provisions to establish our intellectual property rights and protect our products. These legal means, however, afford only limited protection and may not completely protect our rights.

As of March 2, 2026, our exclusively-owned patent portfolio included 40 issued patents in the United States and 48 issued patents in other countries. We cannot assure you that our intellectual property position will not be challenged or that all patents for which we have applied will be granted. The validity and breadth of claims in patents involve complex legal and factual questions and, therefore, may be highly uncertain. Uncertainties and risks that we face include the following:

- our pending or future patent applications may not result in the issuance of patents;
- the scope of any existing or future patent protection may not exclude competitors or provide competitive advantages to us;
- our patents may not be held valid or enforceable if subsequently challenged;
- other parties may claim that our products and designs infringe the proprietary rights of others and even if we are successful in defending our patents and proprietary rights, the cost of such litigation may adversely affect our business; and
- other parties may develop similar products, duplicate our products, or design around our patents.

The patent prosecution process is expensive and time-consuming, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner, or in all jurisdictions. We may choose not to seek patent protection for certain innovations and may choose not to pursue patent protection in certain jurisdictions, and under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope. It is also possible that we will fail to identify patentable aspects of our developments before it is too late to obtain patent protection.

In addition, the laws of foreign jurisdictions may not protect our rights to the same extent as the laws of the United States. For example, most countries outside of the United States do not allow patents for methods of treating the human body. This may preclude us from obtaining method patents outside of the United States having similar scope to those we have obtained or may obtain in the future in the United States. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office (the "*USPTO*") or patent offices in foreign jurisdictions, or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology and compete directly with us, without payment to us.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical products and techniques, or limit the duration of the patent protection of our technology.

While we are aware of several third-party patents of interest, we do not believe that any of our products infringe any valid claims of patents or other proprietary rights held by others. However, there can be no assurances that we do not infringe any patents or other proprietary rights held by third parties. If our products were found to infringe any proprietary right of another party, we could be required to pay significant damages or license fees to such party and/or cease production, marketing and distribution of those products.

We also rely on trade secrets and other unpatented proprietary technology. There can be no assurances that we can meaningfully protect our rights in our unpatented proprietary technology or that others will not independently develop substantially equivalent proprietary products or processes or otherwise gain access to our proprietary technology. We seek to protect our trade secrets and proprietary know-how, in part, with confidentiality agreements with employees and consultants that include customary intellectual property assignment obligations. Litigation may also be necessary to defend infringement claims of third parties or to enforce patent rights we hold or to protect trade secrets or techniques we own. There can be no assurances, however, that the agreements will not be breached, adequate remedies for any breach would be available or competitors will not discover our trade secrets or independently develop comparable intellectual property. If we are unable to successfully protect our intellectual property, our business, financial condition, and results of operations will be materially and adversely affected.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees, renewal fees, annuity fees and various other government fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent and/or applications and any patent rights we may obtain in the future. While an unintentional lapse of a patent or patent application can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products, we may not be able to stop a competitor from marketing products that are the same as or similar to our products, which would have a material adverse effect on our business.

We may become a party to lawsuits or administrative proceedings involving patents or other intellectual property. If we were to lose any future intellectual property lawsuits, a court could require us to pay significant damages and/or prevent us from selling our products.

We may become a party to lawsuits or administrative proceedings involving patents or other intellectual property, including interference proceedings, post grant review and *inter partes* review before the USPTO or the equivalent foreign patent authority. A legal proceeding, regardless of the outcome, could drain our financial resources and divert the time and effort of our management. Protracted litigation to defend or prosecute our intellectual property rights could result in our customers or potential customers deferring or limiting their purchase or use of the affected products until resolution of the litigation.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue selling, developing and marketing our products and techniques. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the value of our securities to decline.

Because competition in our industry is intense, competitors may infringe or otherwise violate our issued patents, patents of our licensors or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming, and could distract our technical and management personnel from their normal responsibilities. Any claims we assert against perceived

infringers could provoke these parties to assert counterclaims or file administrative actions against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding or administrative action could put one or more of our patents at risk of being invalidated or interpreted narrowly. Our competitors may assert invalidity on various grounds, including lack of novelty, obviousness or that we were not the first applicant to file a patent application related to our product. We may elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes before litigation, and any such license agreements may require us to pay royalties and other fees that could be significant. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure.

Our competitors, many of which have made substantial investments in patent portfolios, trade secrets, trademarks and competing technologies, may have applied for or obtained, or may in the future apply for or obtain, patents or trademarks that may prevent, limit or otherwise interfere with our ability to make, use, sell and/or export our products or to use our technologies or product names. Moreover, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," purchase patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or "invitations to license," or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. The defense of these matters can be time consuming, costly to defend in litigation, divert management's attention and resources, damage our reputation and brand and cause us to incur significant expenses or make substantial payments. Negative results in litigation regarding our intellectual property, or the requirement to make substantial expenditures in litigation (regardless of whether we ultimately prevail) would have material adverse effect on our liquidity, business, financial condition, results of operations, and the value of our securities.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our competitive position may be harmed.

We rely on our trademarks, trade names and brand names to distinguish our products from the products of our competitors and have registered or applied to register many of these trademarks. There can be no assurance that our trademark applications will be approved. Third parties may also oppose our trademark applications or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. Further, there can be no assurance that competitors will not infringe our trademarks or that we will have adequate resources to enforce our trademarks. We also license third parties to use our trademarks. In an effort to preserve our trademark rights, we enter into license agreements with these third parties, which govern the use of our trademarks and require our licensees to abide by quality control standards with respect to the goods and services that they provide under our trademarks. Although we make efforts to monitor the use of our trademarks by our licensees, there can be no assurance that these efforts will be sufficient to ensure that our licensees abide by the terms of their licenses. In the event that our licensees fail to do so, our trademark rights could be diluted. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

Patent terms may not be sufficient to effectively protect our products and business for an adequate period of time.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective non-provisional filing date. Although various extensions may be available, the term of a patent, and the protection it affords, is limited. Even if patents covering our technologies and their uses are obtained, once the patent has expired, we may be open to competition. In addition, although upon issuance in the United States a patent's term can be extended based on certain delays caused by the USPTO, this extension can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. Given the amount of time required for the development, testing and regulatory review of new products, patents protecting such products might expire before or shortly after such products are commercialized. If we do not have sufficient patent terms to protect our products, technologies and their uses, our business would be materially adversely affected.

We may be unable to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending their intellectual property rights in certain foreign jurisdictions. This could make it difficult for us to stop infringement of our foreign patents, if obtained, or the misappropriation of our other intellectual property rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against certain third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of our intellectual property. If we are unable to fully protect our intellectual property, our business will be materially and adversely affected.

We may be subject to claims that we or our employees have misappropriated the intellectual property of a third party, including trade secrets or know-how, or are in breach of non-competition or non-solicitation agreements with our competitors and third parties may claim an ownership interest in intellectual property we regard as our own.

Many of our employees and consultants were previously employed at or engaged by other medical device companies, including our competitors or potential competitors. Some of these employees, consultants and contractors may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these individuals have, inadvertently or otherwise, misappropriated the intellectual property or disclosed the alleged trade secrets or other proprietary information of these former employers, competitors or other third parties. Additionally, we may be subject to claims from third parties challenging our ownership interest in or inventorship of intellectual property we regard as our own, for example, based on claims that our agreements with employees or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations to assign inventions to another employer, to a former employer, or to another person or entity. Litigation may be necessary to defend against claims, and it may be necessary or we may desire to enter into a license to settle any such claim; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. If our defense to those claims fails, in addition to paying monetary damages or a settlement payment, a court could prohibit us from using technologies, features or other intellectual property that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers, competitors or third parties. An inability to incorporate technologies, features or other intellectual property that are important or essential to our products could have a material adverse effect on our business and competitive position, and may prevent us from selling our products. In addition, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which could materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

Risks Relating to Our Organization and Structure

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

Our Charter provides that, unless we consent in writing to the selection of an alternative forum, the (i) Court of Chancery of the State of Delaware (the "***Court of Chancery***") shall, to the fullest extent permitted by law, be the sole and exclusive forum for: (a) any derivative action or proceeding brought on behalf of us, (b) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, stockholders, officers or other employees to us or our stockholders, (c) any action asserting a claim against us, our directors, officers or employees arising pursuant to any provision of the DGCL, our Bylaws or our Charter (as either may be amended from time to time), and (d) any action asserting a claim against us, our directors, officers or employees governed by the internal affairs doctrine; and (ii) subject to the foregoing, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Notwithstanding the foregoing, such forum selection provisions shall not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts of the United States have exclusive jurisdiction. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, and may potentially increase costs for investors to bring such a claim, both of which may discourage such lawsuits against us and our directors, officers, and other employees. Alternatively, if a court were to find the choice of 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, results of operations, and financial condition.

Additionally, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. As noted above, the Charter provides that the federal district courts of the United States of America shall have jurisdiction over any action arising under the Securities Act. Accordingly, there is uncertainty as to whether a court would enforce such provision. Our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

As an "emerging growth company," we cannot be certain if the reduced disclosure requirements applicable to "emerging growth companies" will make the Class A Common Stock less attractive to investors.

As an "emerging growth company," we take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including not being required to obtain an assessment of the effectiveness of our internal control over financial reporting from our independent registered public accounting firm pursuant to Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards, which we have elected to do.

We cannot predict if investors will find the Class A Common Stock less attractive because we rely on these exemptions. If some investors find the Class A Common Stock less attractive as a result, there may be a less active market for the Class A Common Stock, the share price of Class A Common Stock may be more volatile and the price at which our securities trade could be less than if we did not use these exemptions.

The requirements of being a public company may strain our resources and divert management's attention.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations. Compliance with these rules and regulations increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and increase

demand on our systems and resources, particularly after we are no longer an "emerging growth company." The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could adversely affect our business and operating results. We may need to hire more employees in the future or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

ITEM 1B. Unresolved Staff Comments

None.

ITEM 1C. Cybersecurity

Risk Management and Strategy

We have certain processes for the identification, assessment, and mitigation of cybersecurity risks which are incorporated into our overall risk management processes in coordination with our information technology function, which we rely on a third-party vendor who is associated with a Related Party to provide. Such processes include physical, procedural, and technical safeguards and routine review of our policies and procedures to identify risks and improve our practices. We use technology-based tools to mitigate cybersecurity risks and to bolster our employee-based cybersecurity programs. We consider the cybersecurity practices of our third-party service providers, including through a general security assessment and contractual requirements, as appropriate, before engaging them in order to help protect us from any related vulnerabilities.

We do not believe that there are currently any known risks from cybersecurity threats that are reasonably likely to materially affect us or our business strategy, results of operations or financial condition. For more information about the cybersecurity risks we face, see the risk factor entitled "*Failure of a key information technology system, process or site could have an adverse effect on our business*" in the section titled *"Risk Factors"* in Part 1, Item 1A of this Annual Report.

Governance

Our third-party vendor, alongside our senior management leads the operational oversight of the company-wide cybersecurity strategy, policy, standards and processes. As a smaller-reporting Company we do not have an employee who has significant and demonstrated professional IT management experience and possesses the requisite education, skills and experience expected to perform such a duty. The audit committee of the board of directors intends to provide oversight of our cybersecurity risk as part of its periodic review of enterprise risk management. Additionally, the board of directors intends to review our enterprise risk management processes and will be notified by management between management updates regarding significant new cybersecurity threats or incidents.

ITEM 2. Properties

Our principal office is located at 4875 White Bear Parkway, White Bear Lake, Minnesota, where we lease approximately 13,500 square feet of office space. We lease this space under a lease that terminates on December 31, 2030. We believe that our existing facility is sufficient to meet our needs for the foreseeable future.

We also lease 1,100 square feet of office space in Ausbach, Germany pursuant to a lease that automatically renews each year for a successive one year period, unless we notify the landlord 6 months prior to the annual renewal. This lease renewed automatically on January 1, 2025 and again on January 1, 2026.

ITEM 3. Legal Proceedings

From time to time, we may be involved in various claims and legal actions in the ordinary course of business. Except as described below, we are not currently involved in any material legal proceedings outside the ordinary course of our business.

On November 14, 2023, the Company, Whitney Haring-Smith (the former chief executive officer and a former director of the Company), Daniel Hirsch (the former chief financial officer of the Company), and Anzu SPAC GP I LLC were named as defendants in a complaint filed by Atlas Merchant Capital SPAC Fund I LP ("*Atlas*") in the Delaware Court of Chancery. Atlas alleges that it was not allowed to redeem its shares of the Anzu class A common stock and that Defendants acted to prevent Atlas's attempt to redeem its shares. Defendants assert that Atlas did not comply with the requirements for redeeming shares set forth in the Company's organizational documents. Atlas asserts damages in the amount of approximately $9.4 million, pre- and post-judgment interest, costs, and reasonable attorneys' fees. The Company has standard indemnification obligations to Dr. Haring-Smith and Mr. Hirsch. The Company believes that the lawsuit is meritless and has been defending this matter vigorously. The Company is unable to predict the outcome of this legal proceeding.

ITEM 4. Mine Safety Disclosures

Not applicable.

PART II

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

Our Class A Common Stock and Public Warrants are listed on Nasdaq under the symbols "COCH" and "COCHW," respectively.

As of March 19, 2026, there were 272 holders of record of Class A Common Stock and one holder of record of Public Warrants. However, because many of the shares of Class A Common Stock and Public Warrants are held by brokers and other institutions on behalf of stockholders, we believe there are substantially more beneficial holders of Class A Common Stock and Public Warrants than record holders.

Dividends

Except with respect to dividends on shares of Series A Preferred Stock pursuant to the terms of the Certificate of Designation, we currently intend to retain all available funds and any future earnings to fund the development and growth of our business. As a result, while we will pay dividends on shares of Series A Preferred Stock, we do not anticipate declaring or paying any cash dividends on shares of Class A Common Stock in the foreseeable future. Any decision to declare and pay dividends in the future will be made at the discretion of the Board and will depend on, among other things, the dividend rights of the Series A Preferred Stock pursuant to the Certificate of Designation, our business prospects, results of operations, financial condition, cash requirements and availability, certain restrictions related to our indebtedness, industry trends and other factors that the Board may deem relevant. Any such decision will also be subject to compliance with contractual restrictions and covenants in the agreements governing our current and future indebtedness. In addition, we may incur additional indebtedness, the terms of which may further restrict or prevent us from paying dividends on shares of Class A Common Stock.

Securities Authorized for Issuance under Equity Compensation Plans

Information regarding the equity compensation plans of the Company is set forth in *Item 11. Executive Compensation*, which is incorporated by reference to our Definitive Proxy Statement.

Recent Sales of Unregistered Securities, Use of Proceeds from Registered Public Offering

During the year ended December 31, 2025, there were no unregistered sales of our securities that were not reported in a Current Report on Form 8-K or Quarterly Report on Form 10-Q.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

There were no repurchases of our equity securities during the three months ended December 31, 2025.

ITEM 6. [Reserved]

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

The following analysis of our financial condition and results of operations should be read in conjunction with the consolidated financial statements and the notes included elsewhere in this Report, and other filings with the SEC. Unless otherwise indicated or the context otherwise requires, references in this section to the "Company," "Envoy Medical," "we," "us," "our" and other similar terms refer (i) prior to the Closing Date, to Envoy Medical Corporation and (ii) after the Closing Date, to Envoy Medical, Inc. The following discussion contains forward-looking statements based upon Envoy Medical's current expectations that involve risks, uncertainties, and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under the section of this Report titled "Risk Factors" and/or elsewhere in this Report. Our historical results are not necessarily indicative of the results that may be expected for any period in the future.

All dollar amounts are expressed in thousands of United States dollars ("$"), unless otherwise indicated.

Overview

We are a hearing health company focused on providing innovative medical technologies across the hearing loss spectrum. Our technologies are designed to shift the paradigm within the hearing industry and bring both providers and patients the hearing devices they desire. We are dedicated to pushing beyond the status quo to provide patients with improved access, usability, independence, and quality of life. We believe leveraging the ear's natural anatomy, rather than the external or sub-dermal artificial microphone, is the ideal way for people to hear. In recent years, we have focused almost exclusively on developing the fully implanted Acclaim® cochlear implant (the "Acclaim CI"), our lead product candidate.

We believe that the Acclaim CI is a first-of-its-kind cochlear implant. Our fully implanted technology includes a sensor designed to leverage the natural anatomy of the ear instead of a microphone to capture sound. The Acclaim CI is designed to address sensorineural hearing loss that is not adequately addressed by hearing aids. As part of the clinical trial, the Acclaim CI is intended for adults with severe-to-profound sensorineural hearing loss who have been deemed adequate candidates by a qualified physician. The Acclaim CI received the Breakthrough Device Designation from the United States Food and Drug Administration (the "FDA") in 2019.

Our first product, the Esteem® Fully Implanted Active Middle Ear Implant ("Esteem FI-AMEI"), received FDA approval in 2010. The Esteem FI-AMEI is a fully implanted active middle ear hearing device and remains the only FDA approved fully implanted active hearing implant in the U.S. market. Unfortunately, the Esteem FI-AMEI failed to gain commercial traction, primarily due to a lack of reimbursement or insurance coverage from third-party payors.

Despite the commercial challenges, approximately 1,000 Esteem FI-AMEI devices were implanted. Some devices were implanted in the early 2000s during clinical trials, providing Envoy Medical with over two decades of experience with our implantable sensor technology. Throughout our experience, our sensor technology proved a viable alternative and robust option to external or implanted microphones.

In late 2015, we made the decision to shift our focus from the Esteem FI-AMEI to a new product that would leverage our sensor technology and incorporate it into a cochlear implant. As a result, we now have the Acclaim CI, a fully implanted cochlear implant. We believe that Acclaim CI gives us the opportunity to disrupt the existing cochlear implant market. The cochlear implant market is one that already has established market acceptance and reimbursement pathways. In the United States, before we can market a new Class III medical device, like the Acclaim CI, we must first receive FDA approval via the premarket application approval process.

The Investigational Device Exemption ("IDE") to begin a pivotal clinical study on the Acclaim CI was granted by the FDA in October of 2024. Seven investigational sites were selected prior to the end of 2024.

The IDE was approved as a "staged" clinical trial. The first stage allowed for enrollment of 10 study participants prior to the Company having to formally request FDA approval to expand enrollment to the full subject cohort of 56 patients. The Company collected and submitted preliminary clinical data after the three-month follow up visit that adequately characterized device effectiveness of the first 10 study participants to justify study expansion into the second and final stage. Envoy Medical's expansion request to the FDA was formally approved by the FDA on October 3, 2025. We completed enrollment of all 56 patients on March 10,2 2025.

Each implanted study participant will be followed through their 12-month visit. After all 56 patients have been through their 12-month visits, the data will be collected and analyzed in accordance with the clinical study protocol and statistical analysis plan. Upon finalization of the results, Envoy Medical intends to submit a Premarket Approval ("PMA") application to the FDA. The FDA will have 180 days to review the PMA application unless a panel review is requested. If a panel review is requested, it may add several months of additional review time to the PMA application. As a result, Envoy Medical currently anticipates obtaining the FDA's decision on our PMA application at some point within the second half of 2027 assuming that no panel review is requested. If a panel review is requested, the FDA's decision could extend to the first half of 2028.

The FDA approval process is uncertain and there can be no guarantees of whether the Acclaim CI will ever successfully receive FDA approval. In addition, we cannot predict the effects that changes to federal regulatory staffing, funding, and policies and procedures will have on the timeline and ultimate FDA approval decision. As a result, we cannot guarantee that we will receive FDA approval on a specific timeline, or at all.

We had a net loss of $23,756 and $20,795 for the years ended December 31, 2025 and 2024, respectively, and had an accumulated deficit of $313,396 and $284,734 as of December 31, 2025 and, 2024, respectively. We have funded our operations to date primarily through the issuance of equity securities and debt. We expect to continue to incur net losses for the foreseeable future, and expect our research and development expenses, sales and marketing expenses, general and administrative expenses, and capital expenditures will continue to increase. In particular, we expect our expenses to increase as we continue our development of the Acclaim CI and seek the necessary regulatory approvals for our product candidate, as well as hire additional personnel, pay fees to outside consultants, attorneys and accountants, and incur other increased costs associated with being a public company. In addition, if and when we seek and obtain regulatory approval to commercialize the Acclaim CI in the United States, we will also incur increased expenses in connection with commercialization and marketing of such product. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials, if any, and our expenditures on other research and development activities. We anticipate that our expenses will increase significantly in connection with our ongoing activities, if and as we:

- continue our research and development efforts for the Acclaim CI product candidate, including through clinical trials;
- seek additional regulatory and marketing approvals in jurisdictions outside the United States;
- establish a sales, marketing and distribution infrastructure to commercialize our product candidate;
- rely on our third-party suppliers and manufacturers to obtain adequate supply of materials and components for our products;
- seek to identify, assess, acquire, license, and/or develop other product candidates and subsequent generations of our current product candidate;
- seek to maintain, protect, and expand our intellectual property portfolio;
- seek to identify, hire, and retain additional skilled personnel;
- create additional infrastructure to support our operations as a public company and our product candidate development and planned future commercialization efforts; and
- experience any delays or encounter issues with respect to any of the above, including, but not limited to, failed studies, complex results, safety issues or other regulatory challenges that require longer follow-up of existing studies or additional supportive studies in order to pursue marketing approval.

We expect that our financial performance may fluctuate significantly from quarter-to-quarter and year-to-year due to the development status of our Acclaim CI product and our efforts to obtain regulatory approval and commercialize the Acclaim CI product.

The Acclaim CI has not yet been approved for sale. We do not expect to generate any product sales from the Acclaim CI unless and until we successfully complete development and obtain regulatory approval for our product candidate. If we obtain regulatory approval for the Acclaim CI, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. As a result, until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including collaborations, licenses or similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed or on favorable terms, if at all. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies, including our research and development activities. If we are unable to raise capital, we will need to delay, reduce, or terminate planned activities to reduce costs.

Recent Developments

Enrollment of Clinical Trial

On March 10, 2026, we completed enrollment of our clinical trial for the Acclaim CI. With the successful implantation of the 56th and final patient, we are the first cochlear implant company to achieve full enrollment of a U.S. clinical trial to evaluate a fully implanted cochlear implant seeking FDA approval.

With enrollment completed, the study will now progress through scheduled follow-up visits and data collection in accordance with the trial protocol. Once 12-month follow up data has been collected for all patients, the data will then be analyzed and submitted to the FDA as part of a PMA application seeking FDA approval. Subject to FDA review and approval, commercialization in the United States would follow.

Nasdaq Market Value of Listed Securities Requirement

On February 25, 2025, we received a deficiency notification letter (the "Notification Letter") from The Nasdaq Stock Market ("Nasdaq") stating that we were not in compliance with Nasdaq Listing Rule 5550(b)(2) (the "Rule") because the market value of the Company's listed securities did not meet the minimum of $35,000 (the "MVLS Requirement") for the period for 31 consecutive business days between January 7, 2025 and February 24, 2025. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we had a grace period of 180 calendar days to regain compliance with Nasdaq Listing Rule 5550(b)(2) and would return to compliance if the market value of our listed securities exceeds $35,000 for ten consecutive business days.

On August 26, 2025, we received a determination letter from Nasdaq notifying us that we had not regained compliance with the MVLS Requirement within the 180-day cure period. The determination letter informed the Company that it can request a hearing regarding Nasdaq's determination with a Hearings Panel (the "Panel") to discuss how we believe we will regain compliance and why the Company believes the Panel should grant an extension. The Company timely requested a hearing, which occurred on October 2, 2025.

On October 23, 2025, the Panel notified us that it has granted the Company's request for an exception to demonstrate compliance with the MVLS Requirement for continued listing through February 23, 2026.

On February 23, 2026, we received a letter confirming that the Company has evidenced compliance with Nasdaq Listing Rule 5550(b)(2) in compliance with the Panel's letter dated October 23, 2025.

In addition, pursuant to Nasdaq Listing Rule 5815(d)(4)(B), we are subject to a monitoring period of one year from February 12, 2026.

February 2026 Offering

On February 12, 2026, we completed a public offering (the "February 2026 Offering") of an aggregate of (i) 47,946,150 shares of our Class A common stock, par value $0.0001 per share ("Class A Common Stock"), (ii) 27,053,850 pre-funded warrants (the "Issued Pre-Funded Warrants") to purchase 27,053,850 shares of Class A Common Stock, (iii) 45,000,000 Series A-1 Warrants to purchase 45,000,000 shares of Class A Common Stock and/or pre-funded warrants (the "Series A-1 Warrants"), and (iv) 75,000,000 Series A-2 Warrants to purchase 75,000,000 shares of Class A Common Stock and/or Issued Pre-Funded Warrants (the "Series A-2 Warrants" and, together with the Series A-1 Warrants, the "Series A Warrants"). The Series A Warrants and Issued Pre-Funded Warrants are collectively referred to herein as the "February 2026 Offering Warrants," and the shares of Class A Common Stock issuable upon exercise of the February 2026 Offering Warrants are collectively referred to as the "February 2026 Offering Warrant Shares." For each share of Class A Common Stock (or Issued Pre-Funded Warrant in lieu thereof) purchased, the investors received accompanying Series A Warrants in the amount of six-tenths (0.6) of a Series A-1 Warrant and one Series A-2 Warrant. The purchase price for the February 2026 Offering was $0.40 per Share (or $0.3999 per Pre-Funded Warrant in lieu thereof) and accompanying Series A Warrants.

The Series A-1 Warrants have an exercise price of $0.40 per share, become exercisable beginning on the effective date of stockholder approval of the issuance of the shares upon exercise of the February 2026 Offering (the "Stockholder Approval Date") and will expire on the earlier of (i) the 24-month anniversary of the Stockholder Approval Date or (ii) 30 days following the date we publicly announce that we have submitted a PMA to the FDA for the Acclaim CI. The Series A-2 Warrants have an exercise price of $0.40 per share, will become exercisable beginning on the Stockholder Approval Date and will expire on the earlier of (i) the 60-month anniversary of the Stockholder Approval Date or (ii) 30 days following the date we publicly announce that it has received FDA approval for the Acclaim CI.

The aggregate gross proceeds to us from the February 2026 Offering were approximately $30,000. After deducting the placement agent's fees and other offering expenses we received approximately $27,730 of net proceeds. The potential additional gross proceeds to the Company from the Series A-1 Warrants and Series A-2 Warrants, if fully-exercised on a cash basis following the Stockholder Approval Date, will be approximately $18,000 and $30,000, respectively, or $48,000 in total. We intend to use the net proceeds of the February 2026 Offering for working capital and other general corporate purposes to fund its operations during the clinical trial for the Acclaim CI.

Macroeconomic Conditions

Our business and financial performance are impacted by macroeconomic conditions. Global macroeconomic challenges, such as the effects of ongoing wars and armed conflicts, supply chain constraints, tariffs and trade wars, market uncertainty, volatility in exchange rates, inflationary trends, interest rates, and evolving dynamics in the global trade environment have impacted our business, financial performance, and our ability to raise capital.

Furthermore, a recession or market correction resulting from macroeconomic factors could materially affect our business and the value of our Class A Common Stock. The occurrence of any such events may lead to reduced disposable income which could adversely affect the number of Esteem FI-AMEI implants and replacement components sold as a result of customer and patient reluctance to seek treatment due to financial considerations.

Adverse macroeconomic conditions, including pandemics or international tensions, could also result in significant disruption of global economic conditions and consumer trends, as well as a significant disruption in financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity.

Key Components of Our Results of Operations

Revenue

Currently, we derive substantially all our revenue from the sale of the Esteem FI-AMEI implants and replacement components to Esteem FI-AMEI implants. We enter arrangements with patients to provide them with the Esteem FI-AMEI device, personal programmer devices, sound processor/battery assembly ("Battery") replacements, and/or an optional Care Plan, each of which are outputs of our ordinary activities in exchange for consideration. Revenue from product sales is recognized upon transfer of control of the product to a customer, which occurs at a point in time, when we are notified the product has been implanted or used by the customer in a surgical procedure. New implantations of the Esteem FI-AMEI are not expected to be more than a few per year and may be as low as zero. Although we believe it to be unlikely, Esteem FI-AMEI implantations could potentially increase with favorable reimbursement policy and coverage changes. We will continue our efforts to pursue positive reimbursement changes for fully implanted active middle ear implants. There will be continued nominal revenue from replacement of sound processors for patients who need a new Battery.

Upon commercialization of our Acclaim CI product, we expect that Acclaim CI revenues will more than exceed our Esteem FI-AMEI revenue. We are targeting FDA approval on our PMA application for the Acclaim CI in the second half of 2027 or first half of 2028, depending on the FDA's review process and timeline.

Cost of Goods Sold

Cost of goods sold includes direct and indirect costs related to the manufacturing and distribution of the Esteem FI-AMEI, including materials, labor costs for personnel involved in the manufacturing process, distribution-related services, indirect overhead costs, and charges for excess and obsolete inventory reserves and inventory write-offs.

We expect cost of goods sold to increase or decrease in absolute dollars primarily as, and to the extent, our revenue grows or declines, respectively.

Operating Expenses

Research and Development Expenses

Research and development ("R&D") expenses consist of costs incurred for our research activities, primarily our discovery efforts and the development of the Acclaim CI product. We also incur R&D costs related to continuing to support, and improving upon where possible, our Esteem FI-AMEI product. We expense R&D costs as incurred, which include:

- salaries, employee benefits, and other related costs for our personnel engaged in R&D functions;
- service fees incurred under agreements with independent consultants, including their fees and related travel expenses engaged in R&D functions;
- costs of laboratory testing including supplies and acquiring, developing, and manufacturing study materials; and
- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors, service providers and our clinical sites.

Our R&D expenses are currently tracked on a project basis. The majority of our R&D expenses incurred during the years ended December 31, 2025 and 2024 were for the development of the Acclaim CI.

Our products require human clinical trials to obtain regulatory approval for commercial sales. We cannot determine with certainty the size, duration, or completion costs of future clinical trials, or if or when they may be completed. Furthermore, we do not know if the clinical trials will show positive or negative results, or what those results will mean for regulatory approval or commercialization efforts.

The duration, costs and timing of future clinical trials and development of our products will depend on a variety of factors, including:

- the scope, rate of progress, and expense of our ongoing, as well as any additional, clinical trials and other R&D activities;
- interest in or demand for both investigational site and subject enrollment;
- future clinical trial results;
- potential changes in government regulation;
- potential changes in the reimbursement landscape; and
- the timing and receipt of any regulatory approvals.

A change in the outcome of any of these variables with respect to the development of our Acclaim CI product could mean a significant change in the costs and timing associated with the development of that implant. If the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in the enrollment in any clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

R&D activities are central to our business model. We expect that our R&D expenses will continue to increase for the foreseeable future as we initiate clinical trials for the Acclaim CI product and prepare the product for possible commercialization, should it gain regulatory approval(s). If the Acclaim CI product enters later stages of clinical trials and ongoing development, the product will generally incur higher R&D expenses than those in earlier stages of research and development, primarily due to simultaneously running clinical trials while also iterating the product for commercialization and preparing for the needs of commercialization. We will need to determine when we believe the product is ready for commercial production and then certain expenses will no longer be classified as R&D. There are numerous factors associated with the successful commercialization of the Acclaim CI product or any products we

may develop in the future, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development program and plans.

Sales and Marketing Expenses

Sales and marketing expenses consist primarily of salaries, benefits, and other related costs for personnel in our sales and marketing functions. Sales and marketing expenses also include certain indirect costs associated with efforts to secure insurance reimbursement of our products. We expect our sales and marketing expenses to increase in the foreseeable future as we increase our sales and marketing personnel to support our continuing growth.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, benefits, and other related costs for personnel in our executive, operations, legal, human resources, finance, insurance premiums, and administrative functions. Administrative expenses also include professional fees for legal, patent, consulting, accounting, tax, and audit services, travel expenses and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities, technology, and other operating costs.

We expect our general and administrative expenses to continue to increase in the foreseeable future as we increase our administrative personnel to support our continuing growth, our costs of expanding our operations and operating as a public company. These increases will likely include the hiring of additional personnel and legal, regulatory, and other fees and services associated with maintaining compliance with Nasdaq and SEC requirements, director and officer insurance costs and investor relations costs associated with being a public company.

Change in Fair Value of Forward Purchase Agreement Put Option Liability

We recognized the forward purchase agreement put option liability at fair value at each reporting period. The liability was subject to re-measurement at each balance sheet date, and any change in fair value was recognized in our consolidated statements of operations and comprehensive loss. The forward purchase agreement put option liability has been derecognized as of March 31, 2024 due to the sale of the shares associated with the Forward Purchase Agreement during the first quarter of 2024.

Change in Fair Value of Forward Purchase Agreement Warrant Liability

We recognize the forward purchase agreement warrant liability at fair value at each reporting period. The liability is subject to re-measurement at each balance sheet date, and any change in fair value is recognized in our consolidated statements of operations and comprehensive loss during each reporting period.

Change in Fair Value of Forward Purchase Agreement Warrant Liability due to Extension

Any changes in fair value associated with extending the warrants that are part of the Forward Purchase Agreement (as defined in Note 10 of the accompanying consolidated financial statements included elsewhere in this Report) are recognized in our consolidated statements of operations and comprehensive loss during each reporting period.

Loss on Offering and Change in Fair Value of Private Warrant Liability

We recognize the private warrant liability at fair value at each reporting period. The liability is subject to re-measurement at each balance sheet date, and any change in fair value is recognized in our consolidated statements of operations and comprehensive loss during each reporting period. The loss on offering and change in fair value of the private warrant liability also includes direct offering expenses and the immediate loss recognized upon issuance of the warrants, as the fair value of the warrants exceeded the proceeds received.

Change in Fair Value of Publicly Traded Warrant Liability

We recognize the publicly traded warrant liability at fair value at each reporting period. The liability is subject to re-measurement at each balance sheet date, and any change in fair value is recognized in our consolidated statements of operations and comprehensive loss during each reporting period.

Interest Expense, Related Party

Interest expense, related party consists of accrued interest for the term loans held by a related party (the "Term Loans"), as well as amortization of the debt discount recorded as a result of the warrants issued with the Term Loans. Amortization of the debt discount is recorded over the respective terms of the Term Loans. On August 25, 2025, the Term Loans were extinguished resulting in the Company no longer recognizing interest expense on the Term Loans.

Other Expense, Net

Other expense for the year ended December 31, 2025 and 2024 consists of interest incurred on insurance financing loans as well as interest income and other expenses.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

	Year Ended December 31,		Change in	
(Dollars in thousands)	**2025**	**2024**	**$**	**%**
Net revenues	$ 241	$ 225	$ 16	7.1%
Costs and operating expenses:				
Cost of goods sold	874	742	132	17.8%
Research and development	12,486	10,179	2,307	22.7%
Sales and marketing	1,220	1,734	(514)	(29.6)%
General and administrative	7,931	6,826	1,105	16.2%
Total costs and operating expenses	22,511	19,481	3,030	15.6%
Operating loss	(22,270)	(19,256)	(3,014)	15.7%
Other income (expense):				
Change in fair value of forward purchase agreement put option liability	—	103	(103)	(100.0)%
Change in fair value of forward purchase agreement warrant liability	534	411	123	29.9%
Change in fair value of forward purchase agreement warrant liability due to extension	(24)	(881)	857	(97.3)%
Loss on offering and change in fair value of private warrant liability	(494)	—	(494)	—
Change in fair value of publicly traded warrant liability	111	(330)	441	(133.6)%
Interest expense, related party	(1,590)	(816)	(774)	94.9%
Other expense, net	(23)	(26)	3	(11.5)%
Total other income (expense), net	(1,486)	(1,539)	53	(3.4)%
Net loss	$ (23,756)	$ (20,795)	$ (2,961)	14.2%

Net Revenues

Net revenues increased $16 for the year ended December 31, 2025, compared to the year ended December 31, 2024. Revenues are not significant to the results of our operations.

Cost of Goods Sold

Cost of goods sold increased $132 for the year ended December 31, 2025, compared to the year ended December 31, 2024. The increase is primarily due to an increase in scrap and non-recurring expenses of $190 partially offset by lower fees for third-parties performing work related to our products of $77.

Research and Development Expenses

The following table summarizes the components of our R&D expenses for the year ended December 31, 2025 and 2024:

	Year Ended December 31,		Change in	
(Dollars in thousands)	**2025**	**2024**	**$**	**%**
R&D personnel costs	6,005	5,415	590	10.9%
R&D product costs	$ 2,959	$ 3,633	$ (674)	(18.6)%
R&D clinical trial	2,686	352	2,334	663.1%
Other R&D costs	836	779	57	7.3%
Total research and development costs	$ 12,486	$ 10,179	$ 2,307	22.7%

R&D expenses increased by $2,307 for the year ended December 31, 2025 compared to the year ended December 31, 2024 reflecting the transition from the development phase into the clinical trial phase. R&D clinical trial expenses increased as Envoy Medical's expansion request to the FDA was formally approved by the FDA on October 3, 2025. As a result, we implanted an incremental 20 patients with the Acclaim CI as part of the final stage of the clinical trial bringing the total to 30 patients implanted with the Acclaim CI for the clinical trial as of December 31, 2025. R&D personnel costs increased $590 due to existing personnel and added headcount needed to support the clinical trial. These increases were partially offset by a $674 decrease in R&D product costs, driven by lower utilization of professional services as the product advanced in its development lifecycle during the year ended December 31,2025 compared to the prior period.

Sales and Marketing Expenses

Sales and marketing expenses decreased $514 for the year ended December 31, 2025, compared to the year ended December 31, 2024. The decrease is primarily due to a reduction of legal fees associated with securing insurance reimbursement for the Esteem FI-AMEI product.

General and Administrative Expenses

General and administrative expenses increased $1,105 for the year ended December 31, 2025, compared to the year ended December 31, 2024 due to a $315 severance accrual for the former chief financial officer as well as $299 of increased costs for consultants for the year ended December 31, 2025. The increase in consultant costs is related to replacing the former chief financial officer and a contract to hire resource. The remaining increases relate to other miscellaneous items.

Change in Fair Value of Forward Purchase Agreement Put Option Liability

The change in the fair value of the forward purchase agreement put option liability was zero for the year ended December 31, 2025 compared to a gain of $103 for the year ended December 31, 2024. During the first quarter of 2024, the shares associated with the forward purchase agreement put option were sold.

Change in Fair Value of Forward Purchase Agreement Warrant Liability

The gain from the change in the fair value of the forward purchase agreement warrant liability was $534 for the year ended December 31, 2025 compared to a gain of $411 for the year ended December 31, 2024. The change is primarily due to fewer warrants outstanding as of December 31,2025 compared to the prior period as well as a decrease in stock price.

Change in Fair Value of Forward Purchase Agreement Warrant Liability Due to Extension

The loss from changes in the fair value of the forward purchase agreement warrant liability due to extension was $24 and $881 for the year ended December 31, 2025 and 2024, respectively, due to amending the forward purchase agreement in December 2025 and 2024 to extend the term of the warrants. There was a decreased loss for the year ended December 31, 2025 compared to the prior period due to there being fewer warrants outstanding and a lower stock price.

Loss on Offering and Change in Fair Value of Private Warrant Liability

The amount recorded in the loss on offering and the change in the fair value of the private warrant liability was $494 for the year ended December 31, 2025. The loss on offering and change in fair value of private warrant liability was driven by $768 of direct offering expenses associated with the September 2025 Offering and October 2025 Offering (as defined in Note 10 of the accompanying consolidated financial statements included elsewhere in this Report), $391 from the issuance of the September 2025 Placement Agent Warrants and October 2025 Placement Agent Warrants (as defined in Note 10 of the accompanying consolidated financial statements included elsewhere in this Report), and $2,728 of immediate losses as a result of recognizing the Investor Warrants (as defined in Note 10 of the accompanying consolidated financial statements included elsewhere in this Report) at fair value upon issuance. The losses were offset by $3,393 of gains related to fair value remeasurements driven primarily due to the decrease in stock price.

Change in Fair Value of Publicly Traded Warrant Liability

The gain from the change in the fair value of the publicly traded warrant liability was $111 for the year ended December 31, 2025 compared to a loss of $330 for the year ended December 31, 2024. The fluctuation is due to a decrease in the Company's closing price for those warrants during the 2025 period compared to an increase for the 2024 period.

Interest Expense, Related Party

Interest expense, related party increased $774 for the year ended December 31, 2025, compared to the year ended December 31, 2024. The increase is due to additional issuances of Term Loans during the year ended December 31, 2025. On August 25, 2025, the Term Loans were settled and accordingly, interest expense is no longer recognized since that date.

Other Expense, Net

Other expense decreased by $3 for the year ended December 31, 2025 compared to the year ended December 31, 2024, primarily due to a reduction in interest incurred on insurance financing loans.

Liquidity and Capital Resources

Since inception, we have incurred significant operating losses. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we advance the clinical development of our products and fund the process of clinical FDA trials. We have funded our operations to date primarily with proceeds from issuing equity securities, term loans, convertible notes and proceeds from the Business Combination. As of December 31, 2025 and December 31, 2024, we had $3,739 and $5,483 of cash, respectively.

We proactively manage our access to capital to support liquidity and continued growth. Our sources of capital include issuances of our Class A Common Stock, Series A preferred stock ("Preferred Stock"), warrants, convertible debt, term debt and other financing agreements such as the forward purchase agreement, and proceeds from the sales of the Esteem FI-AMEI implants and replacement components. See Note 1, "Nature of the Business and Basis of Presentation", of the accompanying consolidated financial statements included elsewhere in this Report.

We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. There can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable to us. Based on our cash position as of December 31, 2025, the approximately $27,730 of net cash proceeds from the February 2026 Offering (as defined in Note 18 of the accompanying consolidated financial statements included elsewhere in this Report), and assuming there is no additional funding through the exercise of any outstanding warrants, we expect to have sufficient funds for our operations into the second quarter of 2027. Proceeds from the exercise of any outstanding warrants or other sources, which we expect, will provide us with funding beyond this timeframe. We have based our estimates as to how long we expect we will be able to fund our operations on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect, in which case we would be required to obtain additional financing sooner than currently projected, which may not be available to us on acceptable terms, or at all. If we are

unable to raise sufficient financing when needed or events or circumstances occur such that we do not meet our strategic plans, we may be required to reduce certain discretionary spending, be unable to develop new or enhanced production methods, or be unable to fund capital expenditures, which could have a material adverse effect on our financial position, results of operations, cash flows, and ability to achieve our intended business objectives. These matters raise substantial doubt about our ability to continue as a going concern. To the extent that we raise additional capital through additional collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our Acclaim CI, future revenue streams, research programs or to grant licenses on terms that may not be favorable to us. If we do raise additional capital through public or private equity or convertible debt offerings, the ownership interest of our existing stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends.

Our future capital requirements and the adequacy of available funds will depend on many factors, including those set forth in the section of this Report titled "*Risk Factors — Risks Relating to Our Business and Operations*."

Cash Flows

The following table presents a summary of our cash flow for the periods indicated:

	Year Ended December 31,	
(Dollars in thousands)	**2025**	**2024**
Net cash (used in) provided by:		
Operating activities	$ (18,201)	$ (17,949)
Investing activities	(179)	(980)
Financing activities	16,633	20,198
Effect of exchange rate changes on cash	3	(5)
Net decrease (increase) in cash	$ (1,744)	$ 1,264

Cash Flows Used in Operating Activities

Net cash used in operating activities for the year ended December 31, 2025 was primarily used to fund a net loss of $23,756 and $1,471 of cash inflows from net changes in the levels of operating assets and liabilities, adjusted for non-cash expenses in an aggregate amount of $3,716.

The $1,839 of cash inflows from net changes in the levels of operating assets and liabilities was primarily driven by a $2,224 increase in accounts payable and accrued expenses and a $126 decrease in inventories, partially offset by $239 of cash payments on the operating lease liability (related party), and $161 reduction in the product warrant liability. Activity within other receivable and other liability largely offset one another, both of which are related to an uncertain tax position. These changes also included typical fluctuations resulting from the timing of cash receipts and disbursements within operating accounts. We will continue to evaluate our capital requirements for both short-term and long-term liquidity needs, which could be affected by various risks and uncertainties, including, but not limited to, the effects of the current inflationary environment, rising interest rates, and other risks detailed in the section of this Report titled "Risk Factors."

Net cash used in operating activities for the year ended December 31, 2024 was primarily used to fund a net loss of $20,795, adjusted for non-cash expenses in an aggregate amount of $3,484 and $638 of cash outflows from net changes in the levels of operating assets and liabilities. The cash outflows from net changes in the levels of operating assets and liabilities were primarily due to decreases of $567 from lower accrued expenses, product warrant liability, and operating lease liability (related party), as well as a $380 increase in inventories related to the purchase of parts for the Esteem FI-AMEI product. There was also a cash outflow of $604 from an increase in other receivable due to the recognition of an incoming income tax refund. This outflow was more than offset by an $891 increase in other liability related to the tax refund and corresponding recognition of an uncertain tax benefit.

These were partially offset by increases to other receivable and other liability related to the recognition of an incoming income tax refund and corresponding recognition of an uncertain tax benefit.

Cash Flows Used in Investing Activities

Net cash used in investing activities for the year ended December 31, 2025 was $179 and primarily related to production tooling and laboratory equipment.

Net cash used in investing activities for the year ended December 31, 2024 was $980 and consisted of purchases of property and equipment, specifically equipment used in the production of finished goods.

Cash Flows Provided by Financing Activities

Net cash provided by financing activities for the year ended December 31, 2025 was $16,633 and was primarily a result of proceeds from the issuance of Term Loans in the amount of $10,000, proceeds from the September 2025 Offering and October 2025 Offering in the amount of $6,500, proceeds from the ATM equity offering program in the amount of $414, and proceeds from the exercise of Shortfall Warrants in the amount of $3,111 (as defined in Note 10 of the accompanying consolidated financial statements included elsewhere in this Report), partially offset by dividends paid to preferred stockholders in the amount of $1,819, payments made on insurance financing loans of $827, offering costs of $768 from the September 2025 Offering and October 2025 Offering, and $100 of costs related to extinguishing the Term Loans.

Net cash provided by financing activities for the year ended December 31, 2024 was $20,198. This increase was primarily driven by the $20,000 proceeds from the 2024 Term Loans, the receipt of $1,683 from the sale of Class A Common Stock associated with the forward purchase agreement as well as proceeds from the exercise of Shortfall Warrants of $1,815, partially offset by dividends paid to holders of the Series A Preferred Stock of $2,447 and payments made on insurance financing loans of $916.

Contractual Obligations and Commitments

Our principal commitments consist of our operating leases for office space and a litigation matter arising from the Company's Business Combination. Our obligations for leases are described in Note 7, "Operating Leases", and information on our open litigation matter is included in Note 16, "Commitments and Contingencies" of the accompanying consolidated financial statements included elsewhere in this Report.

Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements as defined under the rules and regulations of the SEC.

Related Party Arrangements

Our related party arrangements consist of receiving term loan financings, leasing our headquarters office space, and contracting for IT services from a stockholder. For further information on the related party arrangements, refer to Note 7, "Operating Leases", Note 9, "Debt (Related Party)" and Note 15, "Related Party Transactions", of the accompanying consolidated financial statements included elsewhere in this Report.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of our operations is based on our consolidated financial statements and accompanying notes, which have been prepared in accordance with accounting principles generally accepted in the United States. Certain amounts included in or affecting the consolidated financial statements presented in this Form 10-K and related disclosure must be estimated, requiring management to make assumptions with respect to values or conditions which cannot be known with certainty at the time the consolidated financial statements are prepared. Management believes that the accounting policies set forth below comprise the most important "critical accounting policies" for the Company. A "critical accounting policy" is one which is both important to the portrayal of our financial condition and results of operations and that involves difficult, subjective, or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Management evaluates such policies on an ongoing basis, based upon historical results and experience, consultation with experts and other methods that management considers reasonable in the particular circumstances under which the judgments and estimates are made, as well as management's forecasts as to the manner in which such circumstances may change in the future.

Fair Value Measurements

We determine the fair value of financial assets and liabilities using the fair value hierarchy established in Accounting Standards Codification ("ASC") Topic 820, *Fair Value Measurement* ("ASC 820"). ASC 820 identifies fair value as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. The hierarchy describes three levels of inputs that may be used to measure fair value, as follows:

- **Level 1** — Observable inputs, such as quoted prices in active markets for identical assets and liabilities.
- **Level 2** — Observable inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities, quoted prices 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 assets or liabilities.
- **Level 3** — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Management uses valuation techniques in measuring the fair value of financial instruments, where active market quotes are not available.

The following table summarizes the activity for our Level 3 instruments measured at fair value on a recurring basis (in thousands):

	Forward Purchase Agreement Warrant Liability
Balance as of December 31, 2024	$ 472
Change in fair value	(534)
Effect of amendments (see Note 10)	86
Balance as of December 31, 2025	$ 24

The fair value of the forward purchase agreement warrant liability, which is a Level 3 fair value measurement, was estimated using a Monte Carlo simulation model. Key estimates and assumptions impacting the fair value measurement include (i) the Company's stock price, (ii) the initial exercise price, (iii) volatility, (iv) the remaining term and (v) the risk-free rate.

Research and Development Expenses

We will incur substantial expenses associated with prototyping, improvements, testing and clinical trials. Accounting for clinical trials relating to activities performed by external vendors requires us to exercise significant estimates regarding the timing and accounting for these expenses. We estimate costs of R&D activities conducted by service providers, which include the conduct of sponsored research and contract manufacturing activities. The diverse nature of services being provided for our clinical trials and other arrangements, the different compensation arrangements that exist for each type of service and the lack of timely information related to certain clinical activities complicates the estimation of accruals for services rendered by third parties in connection with clinical trials. We record the estimated costs of R&D activities based upon the estimated amount of services provided but not yet invoiced and include these costs in accrued expenses or prepaid expenses on the consolidated balance sheets and within R&D expense on the consolidated statements of operations and comprehensive loss. In estimating the duration of a clinical study, we evaluate the start-up, treatment and wrap-up periods, compensation arrangements and services rendered attributable to each clinical trial and fluctuations are regularly tested against payment plans and trial completion assumptions.

We estimate these costs based on factors such as estimates of the work completed and budget provided and in accordance with agreements established with our collaboration partners and third-party service providers. We make significant judgments and estimates in determining the accrued liabilities and prepaid expense balances in each reporting period. As actual costs become known, we adjust our accrued liabilities or prepaid expenses. We have not experienced any material differences between accrued costs and actual costs incurred since our inception.

Our expenses related to clinical trials will be based on estimates of patient enrollment and related expenses at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions that may be used to conduct and manage clinical trials on our behalf. We will accrue expenses related to clinical trials based on contracted amounts applied to the level of patient enrollment and activity. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we will modify our estimates of accrued expenses accordingly on a prospective basis.

Recently Issued/Adopted Accounting Pronouncements

A discussion of recently issued accounting pronouncements and recently adopted accounting pronouncements is included in Note 2, "Summary of Significant Accounting Policies" of the accompanying consolidated financial statements included elsewhere in this Report.

Emerging Growth Company

Section 102(b)(1) of the Jumpstart Our Business Startups Act ("JOBS Act") exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or no not have a class of securities registered under the Securities Exchange Act of 1934, as amended) 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 and private companies, we, as an emerging growth company, can adopt the new or revised standard at the time the private companies adopt the new or revised standard, until such time we are no longer considered to be an emerging growth company. At times, we may elect to early adopt a new or revised standard.

ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to a variety of market risks, including currency risk, credit and counterparty risk, and inflation risk, as set out below. We manage and monitor these exposures to ensure appropriate measures are implemented in a timely and effective manner.

Currency Risk

Foreign currency risk is the risk that the value of a financial instrument fluctuates because of the change in foreign exchange rates. We primarily operate in the United States and Germany with most of the transactions settled in the United States dollar. Our presentation and functional currency is the United States dollar. Certain bank balances, deposits and other payables are denominated in the Euro, which exposes us to foreign currency risk. However, any transactions that may be conducted in foreign currencies are not expected to have a material effect on our results of operations, financial position or cash flows.

Credit and Counterparty Risk

Financial instruments that potentially expose us to concentrations of credit risk consist primarily of cash and accounts receivable, net. Periodically, we maintain deposits in accredited financial institutions in excess of federally insured limits. We maintain cash with financial institutions that management believes to be of high credit quality. We have not experienced any losses on such accounts and do not believe we are exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

With respect to accounts receivable, we perform credit evaluations of our customers and do not require collateral. There have been no material losses on accounts receivable. There were no customers that accounted for 10% or more of sales for the years ended December 31, 2025 and 2024.

Inflation Risk

Inflationary factors, such as increases in our cost of goods sold and selling and operating expenses, may adversely affect our operating results. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, a high rate of inflation in the future may have an adverse effect on our ability to maintain and increase our gross margin and decrease our selling and marketing and operating expenses as a percentage of our revenue if the selling prices of our products do not increase as much as or more than these increased costs.

ITEM 8. Financial Statements and Supplementary Data

Index to Consolidated Financial Statements

Envoy Medical, Inc.

December 31, 2025 and 2024

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Envoy Medical, Inc.

Opinion on the financial statements

We have audited the accompanying consolidated balance sheets of Envoy Medical, Inc. (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, changes in mezzanine equity and stockholders' deficit, and cash flows for each of the two years in the period ended December 31, 2025, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated 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 its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has incurred cumulative losses from operations, has an accumulated deficit of $313.4 million as of December 31, 2025, and relies on external sources of liquidity to sustain operations. These conditions, along with other matters set forth in Note 2, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans regarding these matters are also described in Note 2 to the consolidated financial statements. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated 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/ GRANT THORNTON LLP

We have served as the Company's auditor since 2023.

Fort Lauderdale, Florida
March 23, 2026

ENVOY MEDICAL, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)

	December 31, 2025	December 31, 2024
Current assets:		
Cash	$ 3,739	$ 5,483
Accounts receivable, net	34	38
Other receivable	19	780
Inventories	1,546	1,708
Prepaid expenses and other current assets	941	887
Total current assets	6,279	8,896
Property and equipment, net	1,035	1,275
Operating lease right-of-use asset (related party)	886	879
Prepaid expenses and other assets	358	488
Total assets	$ 8,558	$ 11,538
Liabilities, mezzanine equity, and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 2,920	$ 1,652
Accrued expenses	7,639	3,713
Accrued interest (related party)	—	703
Other current liabilities	518	573
Forward purchase agreement warrant liability	24	472
Product warranty liability, current portion	287	282
Operating lease liability, current portion (related party)	174	143
Total current liabilities	11,562	7,538
Term loans payable (related party)	—	18,716
Product warranty liability, net of current portion	1,605	1,771
Operating lease liability, net of current portion (related party)	745	802
Private warrant liability	5,835	—
Publicly traded warrant liability	551	662
Other liability	27	891
Total liabilities	20,325	30,380
Commitments and contingencies (see Note 16)		
Mezzanine equity		
Warrants issued to placement agent (see Note 10)	391	—
Stockholders' deficit		
Series A Preferred Stock, $0.0001 par value; 100,000,000 shares authorized and 10,000,000 shares designated as of December 31, 2025 and December 31, 2024; 4,126,667 shares issued and outstanding as of December 31, 2025 and December 31, 2024	—	—
Class A Common Stock, $0.0001 par value; 400,000,000 shares authorized as of December 31, 2025 and December 31, 2024; 28,934,960 shares issued and outstanding as of December 31, 2025 and 21,326,609 shares issued and outstanding as of December 31, 2024	3	2
Additional paid-in capital	301,355	266,013
Accumulated deficit	(313,396)	(284,734)
Accumulated other comprehensive loss	(120)	(123)
Total stockholders' deficit	(12,158)	(18,842)
Total liabilities, mezzanine equity, and stockholders' deficit	$ 8,558	$ 11,538

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

	Year Ended December 31,	
	2025	**2024**
Net revenues	$ 241	$ 225
Costs and operating expenses:		
Cost of goods sold	874	742
Research and development	12,486	10,179
Sales and marketing	1,220	1,734
General and administrative	7,931	6,826
Total costs and operating expenses	22,511	19,481
Operating loss	(22,270)	(19,256)
Other income (expense):		
Change in fair value of forward purchase agreement put option liability	—	103
Change in fair value of forward purchase agreement warrant liability	534	411
Change in fair value of forward purchase agreement warrant liability due to extension	(24)	(881)
Loss on offering and change in fair value of private warrant liability	(494)	—
Change in fair value of publicly traded warrant liability	111	(330)
Interest expense, related party	(1,590)	(816)
Other expense, net	(23)	(26)
Total other income (expense), net	(1,486)	(1,539)
Net loss	(23,756)	(20,795)
Induced conversion of Series A Preferred Stock into Class A Common Stock	—	(1,162)
Deemed dividend on waiver of restriction on Class A Common Stock	—	(495)
Cumulative preferred dividends	(4,906)	(5,521)
Net loss attributable to common stockholders, basic and diluted	$ (28,662)	$ (27,973)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.23)	$ (1.49)
Weighted-average Class A Common Stock outstanding, basic and diluted	23,259,598	18,790,448
Other comprehensive income (loss):		
Foreign currency translation adjustment	3	(5)
Other comprehensive income (loss)	3	(5)
Comprehensive loss	$ (23,753)	$ (20,800)

ENVOY MEDICAL, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN MEZZANINE EQUITY AND STOCKHOLDERS' DEFICIT
(In thousands, except share amounts)

	Mezzanine Equity		Permanent Equity							
	Number of Warrants	Amount	Series A Preferred Stock Shares	Series A Preferred Stock Amount	Class A Common Stock Shares	Class A Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Deficit
Balance at December 31, 2023	—	$ —	**4,500,000**	**$ —**	**18,599,982**	**$ 2**	**$ 255,596**	**$ (257,256)**	**$ (118)**	**$ (1,776)**
Dividends on the Series A Preferred Stock	—	—	—	—	—	—	—	(5,521)	—	(5,521)
Issuance of Class A Common Stock through forward purchase agreement	—	—	—	—	—	—	1,683	—	—	1,683
Exercise of forward purchase agreement warrant	—	—	—	—	664,883	—	1,815	—	—	1,815
Extinguishment of excess warrant liability upon exercise of warrants associated with the forward purchase agreement	—	—	—	—	—	—	96	—	—	96
Modification of forward purchase agreement	—	—	—	—	—	—	(94)	—	—	(94)
Stock-based compensation	—	—	—	—	—	—	562	—	—	562
Issuance of warrants associated with Term Loans	—	—	—	—	—	—	1,397	—	—	1,397
Issuance of Class A Common Stock under employee stock purchase plan	—	—	—	—	32,758	—	63	—	—	63
Waiver of accrued dividends associated with Sponsor Support Agreement	—	—	—	—	—	—	3,733	—	—	3,733
Induced conversion of Series A Preferred Stock into Class A Common Stock	—	—	(373,333)	—	1,028,986	—	1,162	(1,162)	—	—
Waiver of restriction and vesting requirement of Class A Common Stock	—	—	—	—	1,000,000	—	—	—	—	—
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	(5)	(5)
Net loss	—	—	—	—	—	—	—	(20,795)	—	(20,795)
Balance at December 31, 2024	**—**	**$ —**	**4,126,667**	**$ —**	**21,326,609**	**$ 2**	**$ 266,013**	**$ (284,734)**	**$ (123)**	**$ (18,842)**
Dividends on the Series A Preferred Stock	—	—	—	—	—	—	—	(4,906)	—	(4,906)
Exercise of forward purchase agreement warrant	—	—	—	—	2,074,012	—	3,111	—	—	3,111
Modification of forward purchase agreement	—	—	—	—	—	—	(62)	—	—	(62)
Stock-based compensation	—	—	—	—	—	—	657	—	—	657
Issuance of warrants associated with Term Loans	—	—	—	—	—	—	1,570	—	—	1,570
Issuance of Class A Common Stock under employee stock purchase plan	—	—	—	—	208,001	—	184	—	—	184
Issuance of Class A Common Stock from at-the-market ("ATM") offering	—	—	—	—	300,742	—	414	—	—	414

ENVOY MEDICAL, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN MEZZANINE EQUITY AND STOCKHOLDERS' DEFICIT — (Continued)
(In thousands, except share amounts)

	Mezzanine Equity		Permanent Equity							
			Series A Preferred Stock		Class A Common Stock					
	Number of Warrants	Amount	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Deficit
Issuance of Class A Common Stock from registered direct offering	—	—	—	—	4,915,926	1	—	—	—	1
Issuance of Placement Agent Warrants	368,694	391	—	—	—	—	—	—	—	—
Issuance of Class A Common Stock for services	—	—	—	—	109,670	—	134	—	—	134
Modification of Term Loan Warrants	—	—	—	—	—	—	1,455	—	—	1,455
Extinguishment of Term Loans	—	—	—	—	—	—	27,879	—	—	27,879
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	3	3
Net loss	—	—	—	—	—	—	—	(23,756)	—	(23,756)
Balance at December 31, 2025	**368,694**	**$ 391**	**4,126,667**	**$ —**	**28,934,960**	**$ 3**	**$ 301,355**	**$ (313,396)**	**$ (120)**	**$ (12,158)**

ENVOY MEDICAL, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Dollars in thousands)

	Year Ended December 31,	
	2025	**2024**
Cash flows from operating activities		
Net loss	$ (23,756)	$ (20,795)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	302	173
Interest expense and amortization of debt discount on Term Loans (related party)	1,590	816
Stock-based compensation for services	88	—
Amortization of prepaid insurance	964	1,047
Stock-based compensation	657	562
Loss on offering and change in fair value of private warrant liability	494	—
Change in fair value of publicly traded warrant liability	(111)	330
Change in fair value of forward purchase agreement warrant liability	(534)	(411)
Change in fair value of forward purchase agreement put option liability	—	(103)
Change in fair value of forward purchase agreement warrant liability due to extension	24	881
Net change in operating lease right-of-use assets and liability (related party)	206	113
Change in inventory reserve	36	76
Changes in operating assets and liabilities:		
Accounts receivable, net	4	32
Other receivable	761	(604)
Inventories	126	(380)
Prepaid expenses and other current assets	(8)	9
Accounts payable	1,385	(19)
Operating lease liability (related party)	(239)	(145)
Accrued expenses	839	(241)
Product warranty liability	(161)	(181)
Other liability	(868)	891
Net cash used in operating activities	(18,201)	(17,949)
Cash flows from investing activities		
Purchases of property and equipment	(179)	(980)
Net cash used in investing activities	(179)	(980)
Cash flows from financing activities		
Payments on insurance financing loans	(827)	(916)
Proceeds from the issuance of Term Loans (related party)	10,000	20,000
Dividends paid to stockholders of Series A Preferred Stock	(1,819)	(2,447)
Payment made for extinguishment of Term Loans (related party)	(100)	—
Proceeds from the issuance of Class A Common Stock from ATM offering	414	—
Proceeds from issuance of Class A Common Stock under employee stock purchase plan	184	63
Proceeds from exercise of forward purchase agreement warrants	3,111	1,815

ENVOY MEDICAL, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS — (Continued)
(Dollars in thousands)

	Year Ended December 31,	
	2025	**2024**
Proceeds from the issuance of Class A Common Stock and Investor Warrants from registered direct offering	6,500	—
Offering costs from the issuance of Class A Common Stock and Investor Warrants from registered direct offering	(768)	
Deferred offering costs	(62)	—
Proceeds from the issuance of Class A Common Stock associated with forward purchase agreement, net of transaction costs	—	1,683
Net cash provided by financing activities	16,633	20,198
Effect of exchange rate changes on cash	3	(5)
Net (decrease) increase in cash	(1,744)	1,264
Cash, beginning of year	5,483	4,219
Cash, end of year	$ 3,739	$ 5,483
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 36	$ 41
Non-cash investing and financing activities:		
Accrued and unpaid dividends on Series A Preferred Stock	$ 3,087	$ 3,074
Financing of prepaid insurance	$ 772	$ 843
Issuance of Term Loan Warrants (related party)	$ 1,570	$ 1,397
Accrued interest capitalized into term loans payable (related party)	$ 800	$ —
Modification of forward purchase agreement warrant	$ 62	$ 94
Lease liabilities arising from obtaining right-of-use assets	$ 121	$ 528
Extinguishment of excess warrant liability upon exercise of forward purchase agreement warrant	$ —	$ 96
Waiver of accrued dividends associated with Sponsor Support Agreement	$ —	$ 3,733
Deemed dividend on waiver of restriction on Class A Common Stock	$ —	$ 495
Induced conversion of Series A Preferred Stock to Class A Common Stock	$ —	$ 1,162
Property and equipment purchased on account	$ —	$ 117
Modification of Term Loan Warrants (related party)	$ 1,455	$ —
Deemed capital contribution associated with the extinguishment of Term Loans (related party)	$ 27,883	$ —
Issuance of Placement Agent Warrants	$ 391	$ —

1. Nature of the Business and Basis of Presentation

Envoy Medical, Inc. ("Envoy Medical" or the "Company") is a hearing health company focused on providing innovative medical technologies across the hearing loss spectrum. Envoy Medical's technologies are designed to shift the paradigm within the hearing industry and bring both providers and patients the hearing devices they desire. The Company has two fully implanted hearing devices built around the Company's differentiated sensor technology, which is implanted in the middle ear. The design of the sensor allows both products to be fully implanted, use the ear to pick up sound, and not require the use of an external or subdermal microphone. The Company's first product, the Esteem® Fully Implanted Active Middle Ear Implant ("Esteem FI-AMEI"), is a fully implanted active middle ear hearing device. The Esteem FI-AMEI received approval from the United States Food and Drug Administration ("FDA") in 2010 and remains the only fully implanted heading device to successfully receive FDA approval.

The Company has shifted its focus to the Company's second product, the investigational fully implanted Acclaim® Cochlear Implant ("Acclaim CI"), which is believed to be the first fully implantable cochlear implant of its kind. The Acclaim CI is designed with no external components worn on or behind the ear, does not use an external or subdermal microphone and incorporates an implanted rechargeable battery designed to last several days between charges. The Acclaim CI received the Breakthrough Device Designation from the FDA in 2019. The Acclaim CI is designed to address sensorineural hearing loss that is not adequately addressed by hearing aids. As part of the clinical trial, the Acclaim CI is intended for adults with severe-to-profound sensorineural hearing loss who have been deemed adequate candidates by a qualified physician.

On September 29, 2023 (the "Closing Date"), a merger transaction between Envoy Medical Corporation, Anzu Special Acquisition Corp I ("Anzu") and Envoy Merger Sub, Inc., a directly, wholly owned subsidiary of Anzu ("Merger Sub") was completed (hereinafter, the "Merger" or "Business Combination") pursuant to the business combination agreement, dated as of April 17, 2023 (as amended, the "Business Combination Agreement"). In connection with the closing of the Merger (the "Closing"), Merger Sub merged with Envoy Medical Corporation, with Envoy Medical Corporation surviving the merger as a wholly owned subsidiary of Anzu. In connection with the Closing, Anzu changed its name to Envoy Medical, Inc. The Company's Class A common stock, par value $0.0001 per share ("Class A Common Stock"), and the Company's public warrants commenced trading on the Nasdaq Stock Market LLC ("Nasdaq") on October 2, 2023 under the symbols "COCH" and "COCHW," respectively.

On April 17, 2023, prior to entering into the Business Combination Agreement, Anzu and Envoy Medical Corporation entered into an agreement (as amended to date, the "Forward Purchase Agreement") with Meteora Special Opportunity Fund I, LP ("MSOF"), Meteora Capital Partners, LP ("MCP"), Meteora Select Trading Opportunities Master, LP ("MSTO") and Meteora Strategic Capital, LLC ("MSC" and, collectively with MSOF, MCP and MSTO, the "Sellers" or "Meteora parties") for an over-the-counter equity prepaid forward transaction.

Pursuant to the terms of the Forward Purchase Agreement, on the Closing Date, the Sellers purchased 425,606 shares of the Company's Class A Common Stock (the "Recycled Shares") directly from the redeeming stockholders of Anzu. Also, effective upon the Closing Date, the Company paid to the Sellers a prepayment amount of $4,451 required under the Forward Purchase Agreement directly from the trust account and transferred to the Sellers 8,512 shares of the Company's Class A Common Stock. During the year ended December 31, 2024, the Sellers sold the full amount of the Recycled Shares and, pursuant to the Forward Purchase Agreement, the Company received $4.00 per share sold, or $1,683.

In addition, pursuant to a subscription agreement dated April 17, 2023 (as amended to date, the "Subscription Agreement"), by and between Anzu and Anzu SPAC GP I LLC (the "Sponsor"), the Company issued, and certain affiliates of the Sponsor purchased, concurrently with the Closing, an aggregate of 1,000,000 shares of the Company's Series A preferred stock, par value $0.0001 per share ("Series A Preferred Stock") in a private placement (the "PIPE Transaction") at a price of $10.00 per share for an aggregate purchase price of $10,000.

The consolidated financial statements include the accounts of Envoy Medical, Inc. and its wholly-owned subsidiaries Envoy Medical Corporation and Envoy Medical GmbH (Ansbach) (GmbH), which operates a sales office in Germany. All intercompany accounts and transactions have been eliminated in consolidation.

1. Nature of the Business and Basis of Presentation (cont.)

Basis of Presentation

The consolidated financial statements are presented in U.S. dollars in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") for financial information and pursuant to the rules and regulations of the U.S. Securities and Exchange Commission.

2. Summary of Significant Accounting Policies

Liquidity and Going Concern

Since inception, the Company has historically incurred negative operating cash flows and losses from operations and has an accumulated deficit of $313,396 at December 31, 2025 as the Company advances the clinical development of its product and the funding process of clinical FDA trials. From February 2024 to June 2025, the Company received advances of $30,000 from term loans provided by a related party that have since been extinguished (see Note 9). In February 2024, the Company received net proceeds of $1,683 from the sale of 425,606 shares of Class A Common Stock held by the Meteora parties (see Note 1). On various dates in 2024, the Company received net proceeds of $1,815 from the exercise by the Meteora parties of Shortfall Warrants, as defined in Note 10, for 664,883 shares of Class A Common Stock (see Note 10). On various dates in 2025, the Company received net proceeds of $414 from an at-the-market "ATM" offering for 300,742 shares of Class A Common Stock (see Note 10) and $3,111 from the exercise by the Meteora parties of Shortfall Warrants for 2,074,012 shares of Class A Common Stock (see Note 10). On September 23, 2025, the Company completed a registered direct offering (the "September 2025 Offering") and received net proceeds of $2,187 for 1,908,402 shares of Class A Common Stock (see Note 10). On October 9, 2025, the Company completed a registered direct offering (the "October 2025 Offering") and received net proceeds of $3,545 for 3,007,524 shares of Class A Common Stock (see Note 10).

The Company had cash of $3,739 as of December 31, 2025. As discussed further in Note 18, the Company completed the February 2026 Offering (as defined in Note 18). The initial aggregate net proceeds of the February 2026 Offering were approximately $27,730, after deducting the placement agent's fees and other offering expenses. The Company intends to use the proceeds of the February 2026 Offering for working capital and other general corporate purposes to fund its ongoing operations during the clinical trial for the Acclaim CI.

Management believes that its existing cash balances combined with the initial proceeds of the February 2026 Offering and cash receipts from product sales will be sufficient to fund ongoing operations, including the Acclaim CI clinical trials, through at least one year from the date the consolidated financial statements are issued. However, there can be no assurance that the Company will be successful in achieving its strategic plans, that the Company's cash balances and future capital raises will be sufficient to support its ongoing operations, or that any additional financing will be available in a timely manner or on acceptable terms, if at all. If the Company is unable to raise sufficient financing when needed or events or circumstances occur such that the Company does not meet its strategic plans, the Company may be required to reduce certain of its discretionary spending. The Company may be unable to develop new or enhanced production methods, or be unable to fund capital expenditures, which could have a material adverse effect on the Company's financial position, results of operations, cash flows, and ability to achieve its intended business objectives. These matters raise substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements have been prepared assuming the Company will continue as a going concern and do not include adjustments to reflect the possible effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

Use of Estimates

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

(Dollars in thousands, except share and per share data)

2. Summary of Significant Accounting Policies (cont.)

in these consolidated financial statements include but are not limited to the useful lives of property and equipment, the net realizable value of inventory, product warranty liability, stock-based compensation expense, the fair value of the forward purchase agreement put option liability, the fair value of forward purchase agreement warrant liability, publicly traded warrant liability, private warrant liability, and the outcome of litigation. Estimates and assumptions are reviewed periodically and the effect of changes, if any, are reflected in the consolidated statements of operations and comprehensive loss.

Revisions

Classification of Prepaid Insurance

The Company corrected the presentation of the non-current prepaid insurance expense that was not classified as long-term assets in the previously issued audited consolidated financial statements as of and for the year ended December 31, 2024. The Company determined that the correction was not material to any prior annual or interim periods and therefore, amendments of previously filed reports are not required.

Classification of Accrued Interest (Related Party)

The Company corrected the presentation of the accrued interest (related party) that was not classified as a separate financial statement line item in the previously issued audited consolidated financial statements as of and for the year ended December 31, 2024. The Company determined that the correction was not material to any prior annual or interim periods and therefore, amendments of previously filed reports are not required.

The effect of the classification of prepaid insurance expense and accrued interest (related party) revisions on each of the impacted financial statement line items within the Company's audited consolidated balance sheet as of December 31, 2024 was as follows:

	December 31, 2024		
	As Previously Reported	Adjustments	As Revised
Prepaid expenses and other assets, current	$ 1,375	$ (488)	$ 887
Total current assets	9,384	(488)	8,896
Prepaid expenses and other assets	—	488	488
Accrued expenses	4,416	(703)	3,713
Accrued interest (related party)	—	703	703

Concentration of Credit Risk and Significant Customers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and accounts receivable, net. Periodically, the Company maintains deposits in accredited financial institutions in excess of federally insured limits. The Company maintains its cash with financial institutions that management believes to be of high credit quality. The Company has not experienced any losses on such accounts and does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

With respect to accounts receivable, the Company performs credit evaluations of its customers and does not require collateral. There have been no material losses on the Company's accounts receivable. There were no customers that accounted for 10.0% or more of sales for the years ended December 31, 2025 and 2024. There were no customers that accounted for 10.0% or more of the accounts receivable balance as of December 31, 2025 and 2024.

2. Summary of Significant Accounting Policies (cont.)

Cash

The Company maintains cash balances in bank accounts which, at times, may exceed federally insured limits.

Accounts Receivable, Net

Accounts receivable are recorded at the invoiced amount and do not bear interest. The Company grants credit to customers in the normal course of business, but generally does not require collateral or other security to support amounts due. Accounts receivable are presented net of an allowance for credit losses. Management performs ongoing credit evaluations of its customers based on financial information provided by the customer. Accounts receivable outstanding longer than the contractual payment terms are considered past due. The Company estimates its allowance for credit losses by considering numerous factors, including delinquency trends along with ongoing customer credit evaluations. The Company writes off accounts receivable when they become uncollectible. Payments subsequently received on such receivables are credited to the allowance for credit losses. The Company had no material bad debt expense for the years ended December 31, 2025 and 2024. The allowance for credit losses was not material as of December 31, 2025 and 2024.

Inventories

Inventories are stated at the lower of cost or net realizable value. Cost is determined using the first-in, first-out method. The Company records write-downs of inventories that are obsolete, past the manufacturer's recommended 'use by' date, or in excess of anticipated demand or net realizable value based on a consideration of marketability and product life cycle stage, historical net sales and demand forecasts which consider the assumptions about future demand and market conditions. Inventory on hand that is not expected to be sold or utilized is considered excess, and the Company recognizes the write-down in cost of goods sold at the time of such determination. The write-down is determined by the excess of cost over net realizable value. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable cost of completion, disposal and transportation. At the time of loss recognition, a new cost basis is established and subsequent changes in facts and circumstances would not result in an increase in the cost basis.

Property and Equipment, Net

Property and equipment are stated at cost, net of accumulated depreciation. Additions and improvements that extend the lives of the assets are capitalized, while expenditures for repairs and maintenance are expensed as incurred. When assets are retired or otherwise disposed of, their costs and related accumulated depreciation are removed from the accounts and resulting gains or losses are included in operating results. Depreciation is calculated using the straight-line method over the estimated useful life of the asset, which is three years for computer equipment, three to five years for production equipment, and five years for both lab equipment and office equipment.

Operating Leases

The Company determines if an agreement is a lease at inception. The Company elected not to recognize the right to use an underlying asset ("ROU asset") and lease liabilities for short-term leases, which are those that have a lease term of twelve months or less, and includes renewal options in the measurement of lease liabilities only when the option to purchase or renew a lease for the underlying asset is reasonably certain to be exercised. The Company has elected as an accounting policy to account for lease components and associated non-lease components as a single component.

The Company leases its headquarters office space under an operating lease with a related party and also leases office space in Germany under an operating lease (see Note 7). The determination of whether an arrangement is, or contains, a lease is performed at the inception of the arrangement and as necessary at modification. An operating lease is recorded on the consolidated balance sheets with the operating lease asset representing the right to use the ROU

2. Summary of Significant Accounting Policies (cont.)

asset for the lease term and the lease liability representing the obligation to make lease payments arising from the lease. The Company excludes variable lease payments when measuring the ROU asset and lease liability, except for those that depend on an index, a rate or are in-substance fixed payments.

ROU assets and lease liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. In addition, ROU assets include initial direct costs incurred by the lessee as well as any lease payments made at or before the commencement date and exclude lease incentives. The discount rate implicit within the Company's leases is generally not determinable; therefore, the Company determines the discount rate using its incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments.

Impairment of Long-Lived Assets

Long-lived assets held and used by the Company, including property and equipment and ROU assets, are reviewed for impairment whenever events or changes in business circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment loss is recognized when estimated future undiscounted cash flows related to the assets are less than its carrying value. The amount of the impairment loss to be recorded, if any, is calculated by the excess of the asset's carrying value over its fair value. The Company did not incur any impairment charges during the years ended December 31, 2025 and 2024.

Fair Value of Financial Instruments

The Company calculates the fair value of its assets and liabilities that qualify as financial instruments and includes this additional information in the notes to the consolidated financial statements when the fair value is different than the carrying value of these financial instruments. The estimated fair value of cash, accounts receivable, other receivable, prepaid expenses and other current assets, accounts payable, and accrued expenses approximate their carrying amounts due to the relatively short maturity of these instruments. The carrying value of the operating lease liability also approximates fair value since the instrument bears market rates of interest. The carrying value of the term loans payable also approximates fair value based upon current borrowing rates with similar maturities. None of these instruments are held for trading purposes.

Fair Value Measurement

The Company determines the fair value of financial assets and liabilities using the fair value hierarchy established in Accounting Standards Codification ("ASC") Topic 820, "*Fair Value Measurement"* ("ASC 820"). ASC 820 identifies fair value as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. The hierarchy describes three levels of inputs that may be used to measure fair value, as follows:

- **Level 1** — Observable inputs, such as quoted prices in active markets for identical assets and liabilities.
- **Level 2** — Observable inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities, quoted prices 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 assets or liabilities.
- **Level 3** — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

2. Summary of Significant Accounting Policies (cont.)

Derivative Financial Instruments

The Company does not use derivative instruments to hedge exposures to cash flow, market, or foreign-currency risks. The Company evaluates its financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives in accordance with ASC Topic 815, *Derivatives and Hedging* ("ASC 815"). For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value on the grant date and is then re-valued at each reporting date, with changes in the fair value reported in the other income (expense) section of the Company's consolidated statements of operations and comprehensive loss. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is evaluated at the end of each reporting period. Derivative liabilities are classified in the consolidated balance sheets as current or non-current based on whether or not net-cash settlement or conversion of the instrument could be required within 12 months of the balance sheet date.

The Company accounts for its publicly traded warrant liability in accordance with ASC 815-40. Accordingly, the Company recognized the warrant instruments as a liability at fair value and adjusts the instruments to fair value at each reporting period. The publicly traded warrant liability is subject to re-measurement at each balance sheet date until exercised, and any change in fair value is recognized in the change in fair value of publicly traded warrant liability line item in the Company's consolidated statements of operations and comprehensive loss.

The Company accounts for its Forward Purchase Agreement in accordance with ASC 815-40. Accordingly, the Company recognized the forward purchase agreement put option liability and the forward purchase agreement warrant liability at fair value at each reporting period. The forward purchase agreement put option liability and forward purchase agreement warrant liability is subject to re-measurement at each balance sheet date, and changes in fair value is recognized in the change in the forward purchase agreement put option liability and change in fair value of forward purchase agreement warrant liability line items, respectively, in the Company's consolidated statements of operations and comprehensive loss. The forward purchase agreement put option liability has been derecognized as of March 31, 2024 due to the sale of the shares associated with the Forward Purchase Agreement during the first quarter of 2024. Accordingly, the forward purchase agreement put option liability is no longer presented in the Company's consolidated balance sheets as of December 31, 2025 and 2024.

The forward purchase agreement warrant liability has been amended with changes in fair value related to extending the term of the warrants recognized in change in fair value of forward purchase agreement warrant liability due to extension in the consolidated statements of operations and comprehensive loss. Modifications to the forward purchase warrant agreement liability that amends the exercise price to induce exercise are treated as issuance costs and offset proceeds within the consolidated statements of changes of changes in mezzanine equity and stockholders' deficit.

SPAC Excise Tax Liability

The Company recognized an excise tax liability of $2,248 upon completion of the Company's Business Combination as an incremental cost to repurchase the Company's treasury shares, with an offsetting tax liability recognized. The SPAC excise tax liability is recorded in accrued expenses in the Company's consolidated balance sheets. As of December 31, 2025 and 2024, the amount of accrued excise tax was $1,928 and $2,248 in the in the Company's consolidated balance sheets, respectively.

Revenue Recognition

The Company recognizes revenue in accordance with ASC Topic 606, *Revenue from Contracts with Customers*, which provides a five-step model for recognizing revenue from contracts with customers as follows:

- identify the contract with a customer
- identify the performance obligations in the contract

2. Summary of Significant Accounting Policies (cont.)

- determine the transaction price
- allocate the transaction price to the performance obligations in the contract
- recognize revenue when or as performance obligations are satisfied.

Revenue is recognized as performance obligations under the terms of a contract are satisfied, which generally occurs as control of the promised products or services is transferred to customers. Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products or services to a customer ("transaction price"). To the extent the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price using either the expected value or most likely amount method. Variable consideration is included in the transaction price if, in the Company's judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of the Company's anticipated performance and all information that is reasonably available.

The Company primarily derives revenue from the sale of its hearing device products. Revenue from product sales is recognized upon transfer of control of the product to a customer, which occurs at a point in time, at the time the Company is notified the product has been implanted or used by the customer in a surgical procedure. The Company also sells prepaid Battery (see Note 8) replacement options. Revenue from extended warranty plans is recognized ratably over time and was immaterial for each of the years ended December 31, 2025 and 2024. Amounts received from a customer prior to fulfillment of the performance obligation are included as accrued expenses on the consolidated balance sheets and are immaterial as of December 31, 2025 and 2024. The Company has elected to account for shipping and handling activities performed as activities to fulfill the promise to transfer the products; and therefore these activities are not assessed as a separate performance obligation to its customers.

Revenue is measured as the amount of consideration the Company expects to receive, which is based on the invoiced price. The majority of the Company's contracts have a single performance obligation and are short-term in nature. The Company's contracts do not include variable consideration.

Payment terms differ by geography and customer, but payment is generally required within 30 days from the date of product utilization. The Company also offers extended payment plans on a limited basis. Amounts due to the Company under payment plans that extend beyond 12 months are immaterial as of December 31, 2025 and 2024, and therefore the Company did not adjust the promised amount of consideration for the effects of a significant financing component.

Cost of Goods Sold

Cost of goods sold is comprised of the costs of merchandise sold, as well as the related inbound freight costs and labor directly attributable to bringing certain goods to a salable condition. In categorizing costs, the Company captures applicable depreciation and costs to maintain and run revenue generating technology, equipment related costs and any personnel-related costs as cost of goods sold.

Product Warranty

The Company provides a limited warranty for its implantable components. At the time product revenue is recognized, the Company reserves for estimated future costs that may be incurred under its warranties based on historical experience. The limited warranty liability is recorded in accrued expenses in the consolidated balance sheets. As of December 31, 2025 and 2024, the amount of accrued limited warranty was immaterial and the Company's warranty payments were immaterial.

2. Summary of Significant Accounting Policies (cont.)

During 2013, the Company offered a lifetime warranty to clinical trial patients to cover batteries and surgery related costs. The Company estimates the costs that may be incurred under this lifetime warranty and records a liability in the amount of such costs at its present value. The lifetime warranty is recorded in product warranty liability in the consolidated balance sheets. As of December 31, 2025 and 2024, the aggregate product warranty liability was $1,892 and $2,053, respectively, of which $287 and $282, respectively, was classified as a current liability in the consolidated balance sheets.

Patents

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

Research and Development Costs

Expenditures for research and development activities are charged to operations as incurred. Research and development costs include salaries, employee benefits, software, laboratory testing expenses, and other costs.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax base and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those items are expected to be recovered or settled. The Company has recorded a full valuation allowance against the net deferred tax asset due to the uncertainty of realizing the related benefits.

The Company recognizes the financial statement benefit of a tax position only to the extent the position is more likely than not to be sustained upon audit based on the technical merits of the position. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the Company's consolidated financial statements is the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement with the relevant tax authority. The Company has elected to recognize interest and penalties related to uncertain tax positions in the provision for income taxes.

On July 4, 2025, the One Big Beautiful Bill Act was signed into law in the United States, introducing a wide array of tax reform measures. These include extensions and modifications to certain provisions originally enacted under the Tax Cuts and Jobs Act. Key changes include the immediate expensing of domestic research and development costs, the reinstatement of 100% bonus depreciation, and a new interest expense limitation based on earnings before interest, taxes, depreciation and amortization. These provisions did not have a material effect on the Company's financial statements for the year ended December 31, 2025.

Foreign Currency Translation

The Euro is the functional currency for the Company's foreign subsidiary in Germany. The assets and liabilities of the Company's foreign operations are translated into U.S. dollars at the end-of-the-period exchange rates, and the revenues and expenses are translated at weighted-average rates for the respective reporting period. Unrealized translation gains and losses are recorded as a translation adjustment, which is included in the Company's consolidated statements of changes in mezzanine equity and stockholders' deficit as well as a component of accumulated other comprehensive loss on the Company's consolidated statements of operations and comprehensive loss.

2. Summary of Significant Accounting Policies (cont.)

Net Loss per Share

The Company's Series A Preferred Stock certificate of designation entitles the holders to participate in dividends on an as converted basis when declared on Class A Common Stock. As a result, the Series A Preferred Stock meets the definition of a participating security, which requires the Company to apply the two-class method to compute both basic and diluted net loss per share attributable to common stockholders. The two-class method is an earnings allocation formula that treats participating securities as having rights to earnings that would otherwise have been available to common stockholders. The two-class method requires income available to holders of the Company's Class A Common Stock for the period to be allocated between common and participating securities based upon their respective rights to share in the earnings as if all income for the period had been distributed. In periods where there is a net loss, no allocation of undistributed net loss to the Series A Preferred Stock is performed as the holders of the Series A Preferred Stock are not contractually obligated to participate in the Company's losses. The Company reported net losses of $28,662 and $27,973 attributable to the stockholders of the Company's Class A Common Stock for the years ended December 31, 2025 and 2024, respectively.

Basic net loss per share of common stock is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of Class A Common Stock outstanding during the period. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares outstanding, plus the impact of potential common shares, if dilutive, resulting from the potential exercise of warrants or options, and the potential conversion of preferred stock or convertible notes, into Class A Common Stock, under the if-converted method. In periods where a net loss is recorded, no effect is given to potentially dilutive securities, because the effect would be anti-dilutive.

Stock-based Compensation

Stock-based compensation is measured at the grant date, based on the fair value of the award, and is recognized as an expense over the requisite service period. The fair value of stock-based payment awards granted through June 30, 2024 is estimated using the Black-Scholes option model with a volatility figure derived from using a determined peer group of other companies' stock prices since the trading history of the Company's stock was too short to provide accurate data. The fair value of stock-based payment awards granted subsequent to June 30, 2024 is estimated using the Black-Scholes option model with a volatility figure derived from using the trading history of the Company's Class A Common Stock and from a peer group. Given limited historical exercise data, the Company accounts for the expected term of all options in all periods in accordance with the "simplified" method, which is used for "plain-vanilla" options, as defined in ASC Topic 718, *Compensation — Stock Compensation* ("ASC 718"). The simplified method calculates the expected term as the average of the time-to-vesting and the contractual life of the options. The risk-free interest rate was determined from the implied yields of U.S. Treasury zero-coupon bonds with a remaining life consistent with the expected term of the options.

The Company has adopted the guidance from Accounting Standards Update ("ASU") 2016-09, *Compensation — Stock Compensation (Topic 718): Improvements to Employee Share-Based Compensation Accounting,* and has determined not to apply a forfeiture rate and has made the accounting election that forfeitures will be recognized when the actual forfeiture takes place and therefore no estimated forfeiture rate will be recorded.

Stock-based payment awards to service providers are accounted for as stock-based compensation under ASC 718. These awards are measured at fair value on the grant date, with compensation cost recognized over the requisite service period. Warrants that meet equity classification criteria but contain redemption features outside the Company's control are classified as mezzanine equity.

2. Summary of Significant Accounting Policies (cont.)

Segments

Operating segments are identified as components of an enterprise about which discrete financial information is available for evaluation by the chief operating decision-maker ("CODM") in deciding resource allocation and assessing performance. The Company has determined that its CODM is its Chief Executive Officer. The Company's CODM reviews financial information presented on a consolidated basis for the purposes of making decisions, allocating resources and evaluating performance. Consequently, the Company has determined it operates in one operating and reportable segment.

Recently Adopted Accounting Pronouncements

In August 2020, the FASB issued ASU 2020-06, *Debt-Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40)* ("ASU 2020-06") to simplify certain financial instruments. ASU 2020-06 eliminates the current models that require separation of beneficial conversion and cash conversion features from convertible instruments and simplifies the derivative scope exception guidance pertaining to equity classification of contracts in an entity's own equity. The new standard also introduces additional disclosures for convertible debt and freestanding instruments that are indexed to and settled in an entity's own equity. ASU 2020-06 amends the diluted earnings per share guidance, including the requirement to use the if-converted method for all convertible instruments. For smaller reporting companies, ASU 2020-06 is effective for fiscal years beginning after December 15, 2023 and should be applied on a full or modified retrospective basis. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The Company adopted ASU 2020-06 effective January 1, 2024. The adoption of ASU 2020-06 did not have a material impact on the Company's consolidated financial statements.

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* ("ASU 2023-07"), which will add required disclosures of significant expenses for each reportable segment, as well as certain other disclosures to help investors understand how the CODM evaluates segment expenses and operating results. The new standard will also allow disclosure of multiple measures of segment profitability if those measures are used to allocate resources and assess performance. The Company adopted ASU 2023-07 effective for the year ended December 31, 2024. See Note 14 for related disclosures.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures ("ASU 2023-09")*, which requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. The standard is intended to benefit investors by providing more detailed income tax disclosures that would be useful in making capital allocation decisions. The standard is effective for public companies for fiscal years beginning after December 15, 2024. The Company adopted ASU 2023-09 effective January 1, 2025. See Note 13 for related disclosures.

Accounting Pronouncements Not Yet Effective

In November 2024, the FASB issued ASU 2024-03, *Income Statement — Reporting Comprehensive Income — Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses ("ASU 2024-03")*, that requires public companies to disclose, in interim and reporting periods, additional information about certain expenses in the financial statements. For public business entities, it is effective for annual periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted and is effective on either a prospective basis or retrospective basis. The Company is currently evaluating the impact that ASU 2024-03 will have on the Company's disclosures within the consolidated financial statements.

(Dollars in thousands, except share and per share data)

2. Summary of Significant Accounting Policies (cont.)

In December 2025, the FASB issued ASU No. 2025-11, "T*opic 270 — Interim Reporting*" ("*ASU 2025-11*"). The amendments in ASU 2025-11 clarify interim reporting requirements by improving navigability of Topic 270 and more clearly specifying what disclosures are required in interim reporting periods. The amendments also establish a principle that requires disclosure of events since the end of the last annual reporting period that have materially impacted the entity. ASU 2025-11 is effective for interim reporting periods within annual reporting periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact that ASU 2025-11 will have on the Company's interim condensed consolidated financial statements.

3. Fair Value Measurements

The following tables provide information related to the Company's assets and liabilities measured at fair value on a recurring basis as of December 31, 2025 and 2024:

	December 31, 2025			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Forward purchase agreement warrant liability	$ —	$ —	$ 24	$ 24
Private warrant liability	—	5,835	—	5,835
Publicly traded warrant liability	551	—	—	551
	$ 551	$ 5,835	$ 24	$ 6,410

	December 31, 2024			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Forward purchase agreement warrant liability	$ —	$ —	$ 472	$ 472
Publicly traded warrant liability	662	—	—	662
	$ 662	$ —	$ 472	$ 1,134

The Company has classified the publicly traded warrant liability within Level 1 of the hierarchy as the warrant is separately listed and traded in an active market. The publicly traded warrant's listed price in an active market was used as the fair value.

The private warrant liability includes the September 2025 Investor Warrants and October 2025 Investor Warrants (both as defined in Note 10), with fair values of $2,255 and $3,580, respectively, as of December 31, 2025. These fair values were estimated based upon observable inputs such as the risk-free rate and the Company's volatility which are considered Level 2 inputs. The following table presents the quantitative information regarding the Level 2 fair value measurements of the private warrant liability as of December 31, 2025:

	December 31, 2025
Stock price	$ 0.66
Exercise price	$1.31 – $1.33
Expected volatility	147.0% – 149.0%
Expected term (in years)	1.9 – 2.0
Risk-free rate	3.50%

The fair value of the forward purchase agreement warrant liability is a Level 3 fair value measurement, and was estimated using a Monte Carlo simulation model. The use of significant unobservable inputs could result in those inputs being different at the reporting dates, which could result in a significantly higher or lower fair

(Dollars in thousands, except share and per share data)

3. Fair Value Measurements (cont.)

value measurement at the reporting dates. The following table presents the quantitative information regarding the Level 3 fair value measurements of the forward purchase agreement warrant liability as of December 31, 2025 and December 31, 2024:

	December 31, 2025	December 31, 2024
Stock price	$ 0.66	$ 1.43
Initial exercise price	$ 10.46	$ 10.46
Annual volatility	115.0%	130.0%
Remaining term (in years)	1.0	1.0
Risk-free rate	3.42%	4.08%

The following table summarizes the activity for the Company's Level 3 instruments measured at fair value on a recurring basis:

	Forward Purchase Agreement Warrant Liability
Balance as of December 31, 2024	$ 472
Change in fair value	(534)
Effect of amendments (see Note 10)	86
Balance as of December 31, 2025	$ 24

There were no transfers between Level 1 and Level 2, nor into and out of Level 3, during the periods presented.

4. Inventories

Inventories, consisted of the following:

	December 31, 2025	December 31, 2024
Raw materials	$ 1,262	$ 1,386
Work-in-progress	88	203
Finished goods	196	119
Inventories	**$ 1,546**	**$ 1,708**

5. Property and Equipment, Net

Property and equipment consisted of the following:

	December 31, 2025	December 31, 2024
Lab equipment	$ 3,113	$ 3,106
Production equipment	2,276	2,249
Computer equipment	654	648
Office equipment	101	102
Total	6,144	6,105
Less: Accumulated depreciation	(5,109)	(4,830)
Property and equipment, net	**$ 1,035**	**$ 1,275**

Depreciation expense was $302 and $173 for the years ended December 31, 2025 and 2024, respectively.

(Dollars in thousands, except share and per share data)

6. Accrued Expenses

Accrued expenses consisted of the following:

	December 31, 2025	December 31, 2024
Accrued excise tax	$ 1,928	$ 2,248
Dividends payable	3,778	691
Accrued payroll	328	204
Accrued clinical trial	1,271	43
Accrued other	334	527
Accrued expenses	**$ 7,639**	**$ 3,713**

7. Operating Leases

The Company leases its headquarters office space in Minnesota and leases office space in Germany. The headquarters office space lease is with a stockholder, which is considered a related party. During the year ended December 31, 2024, the Company and the landlord agreed to modify the lease to extend the lease term for three (3) additional years through December 31, 2030. Additionally, the Company requested and the landlord provided an additional 1,664 square feet of usable office space, for a total of 11,540 square feet of rentable space. Accordingly, base rent was increased to $6 per month and increases each year by approximately four percent. Also, tenant improvements completed by the landlord totaling $150 will be repaid in three $50 annual payments beginning July 1, 2027. As a result of the modification, the Company recognized an increase to the operating lease right-of use asset (related party) and operating lease liability (related party) of $500 which is reflected in the consolidated balance sheets during the year ended December 31, 2024. During the year ended December 31, 2025, the lease was further modified to increase the usable office space to a total of 13,447 square feet. The Company accounted for the modification as a separate contract and recognized the lease as part of the operating lease right-of use asset (related party) and operating lease liability (related party) of $121 which is reflected in the consolidated balance sheets during the year ended December 31, 2025.

The lease of the office space in Germany is not with a related party and is immaterial.

The components of leases and lease costs were as follows:

	December 31, 2025	December 31, 2024
Operating lease right-of-use asset (related party)	$ 886	$ 879
Operating lease liability, current portion (related party)	174	143
Operating lease liability, net of current portion (related party)	745	802
	$ 919	**$ 945**

	Year Ended December 31,	
	2025	2024
Operating lease cost	$ 206	$ 180
	$ 206	**$ 180**

Other supplemental information of lease amounts recognized in the consolidated financial statements is summarized as follows:

	Year Ended December 31,	
	2025	2024
Cash paid for amounts included in the measurement of lease liability	$ 239	$ 201

(Dollars in thousands, except share and per share data)

7. Operating Leases (cont.)

	December 31, 2025	December 31, 2024
Weighted-average remaining lease term – in years	5.0	6.0
Weighted-average discount rate	9.9%	9.9%

Future minimum lease payments associated with these leases were as follows as of December 31, 2025:

2026	$ 255
2027	254
2028	222
2029	229
2030	186
	1,146
Less: Imputed interest	(227)
	$ 919

8. Product Warranty Liability

Changes in warranty liability were as follows:

	Warranty Liability
Balance as of December 31, 2023	$ 2,234
Utilization	(181)
Balance as of December 31, 2024	2,053
Utilization	(161)
Balance as of December 31, 2025	**$ 1,892**

The assumptions utilized in developing the liability as of December 31, 2025 include an estimated cost per unit of $6, an average sound processor/battery assembly ("Battery") life of five years, inflationary increase of 3.9%, and an average patient life calculated based on probabilities outlined in the PRI-2012 mortality tables, published from the Society of Actuaries. Additionally, a discount rate of 5.6% was used in the calculation as of December 31, 2025.

The assumptions utilized in developing the liability as of December 31, 2024, include an estimated cost per unit of $6, an average Battery life of five years, inflationary increase of 3.8%, and an average patient life calculated based on probabilities outlined in the PRI-2012 mortality tables, published from the Society of Actuaries. Additionally, a discount rate of 5.2% was used in the calculation as of December 31, 2024.

9. Debt (Related Party)

February 2024 Term Loan

In February 2024, the Company issued a promissory note (the "February 2024 Term Loan") with a minimum principal amount of $5,000 and up to $10,000 to GAT Funding, LLC ("GAT"), an entity controlled by Glen A. Taylor, then a member of the Company's board of directors and a controlling stockholder of the Company. At closing, the Company drew $5,000 from the February 2024 Term Loan. Provided that no event of default had occurred and the Company submitted a request for funding certifying that the Company had less than $7,500 of net tangible assets, the Company had the ability to draw the remaining $5,000 in $2,500 tranches, as long as each request was made prior to February 1, 2025. In both May 2024 and July 2024, the Company requested and received

9. Debt (Related Party) (cont.)

additional advances of $2,500 under the February 2024 Term Loan. The outstanding balance on the February 2024 Term Loan, net of discount, was $10,369 at the time the debt was extinguished as discussed below, and $9,489 as of December 31, 2024.

The February 2024 Term Loan had a five-year term and an original maturity date of February 27, 2029. The principal amount drawn bore interest at a rate of 8.0% per annum and was to be paid quarterly in arrears after the second anniversary of the February 2024 Term Loan. Interest accrued and was not payable for the first two years of the term and was compounded and added to the principal balance of the February 2024 Term Loan both on the first and second anniversary of the February 2024 Term Loan. The Company could prepay the accrued interest and principal of the February 2024 Term Loan without penalty, with 10 days' notice.

August 2024 Term Loan

In August 2024, the Company issued an additional promissory note (the "August 2024 Term Loan") with a principal amount of up to $10,000 to GAT. At closing, the Company drew $5,000 from the August 2024 Term Loan. Provided that no event of default had occurred and the Company submitted a request for funding certifying that the Company had less than $7,500 of net tangible assets, the Company had the ability to draw the remaining $5,000 in $2,500 tranches, as long as each request is made prior to August 1, 2025. In December 2024, the Company requested and received an additional advance of $5,000 under the August 2024 Term Loan. The outstanding balance on the February 2024 Term Loan, net of discount, was $9,334 at the time the debt was extinguished as discussed below, and $9,226 as of December 31, 2024.

The August 2024 Term Loan had a five-year term and an original maturity date of August 27, 2029. The principal amount drawn bore interest at a rate of 8.0% per annum and was to be paid quarterly in arrears after the second anniversary of the August 2024 Term Loan. Interest accrued and was not payable for the first two years of the term and was compounded and added to the principal balance of the August 2024 Term Loan both on the first and second anniversary of the August 2024 Term Loan. The Company could prepay the accrued interest and principal of the August 2024 Term Loan without penalty, with 10 days' notice.

Under the February 2024 Term Loan and August 2024 Term Loan, the Company was required to issue warrants to purchase 250,000 shares of its Class A Common Stock for each $2,500 of principal funded as a commitment fee. The warrants have an exercise price equal to the closing price on the date of funding of the applicable tranche.

Warrants — February 2024 Term Loan and August 2024 Term Loan

At closing of the initial funding of the February 2024 Term Loan, the Company issued warrants to purchase 500,000 shares of Class A Common Stock at an exercise price of $1.24 per share. These warrants expire on February 27, 2026. Upon the second draw made in May 2024, the Company issued warrants to purchase 250,000 shares of Class A Common Stock at an exercise price of $3.04 per share. These warrants expire on May 28, 2026. Upon the third draw made in July 2024, the Company issued warrants to purchase 250,000 shares of Class A Common Stock at an exercise price of $2.25 per share. At the time of their initial issuance, these warrants had a contractual expiration date of July 23, 2026. The expiration dates of each of these warrants issued in connection with the February 2024 Term Loan have been amended as discussed below.

At closing of the initial funding of the August 2024 Term Loan, the Company issued warrants to purchase 500,000 shares of Class A Common Stock at an exercise price of $2.97 per share. These warrants expire on August 27, 2026. Upon the second draw made in December 2024, the Company issued warrants to purchase 500,000 shares of Class A Common Stock at an exercise price of $2.20 per share. At the time of their initial issuances, these warrants had a contractual expiration date of December 11, 2026. The expiration dates of each of these warrants issued in connection with the August 2024 Term Loan have been amended as discussed below.

9. Debt (Related Party) (cont.)

March 2025 Term Loan

In March 2025, the Company issued a promissory note (the "March 2025 Term Loan" and, collectively with the February 2024 Term Loan and August 2024 Term Loan, the "Term Loans") with a minimum principal amount of $5,000 and up to $10,000 to GAT. At closing, the Company drew $5,000 from the March 2025 Term Loan. Provided that no event of default had occurred and the Company submitted a request for funding certifying that the Company had less than $7,500 of net tangible assets, the Company had the ability to draw the remaining $5,000 in $2,500 tranches, as long as each request is made prior to March 2026. On June 26, 2025, the Company requested and received an additional advance of $5,000 under the March 2025 Term Loan. The balance outstanding on the March 2025 Term Loan was $8,523, net of discount, at the time the debt was extinguished as discussed below.

The March 2025 Term Loan had a five-year term and an original maturity date of March 6, 2030. The principal amount drawn bore interest at a rate of 8.0% per annum and was to be paid quarterly in arrears after the second anniversary of the March 2025 Term Loan. Interest accrued and was not payable for the first two years of the term and was compounded and added to the principal balance of the March 2025 Term Loan both on the first and second anniversary of the March 2025 Term Loan. The Company could prepay the accrued interest and principal of the March 2025 Term Loan without penalty, with 10 days' notice.

As a commitment fee, the Company was required to issue warrants to purchase 375,000 shares of its Class A Common Stock for each $2,500 of principal funded under the March 2025 Term Loan. The warrants have an exercise price equal to the closing price on the date of funding of the applicable tranche. At closing of the initial funding of the March 2025 Term Loan, the Company issued warrants to purchase 750,000 shares of Class A Common Stock at an exercise price of $1.35 per share. At the time of their initial issuance, these warrants had a contractual expiration date of March 11, 2027. The expiration date has been amended as discussed below.

Upon the second draw made in June 2025, the Company issued warrants to purchase 750,000 shares of Class A Common Stock at an exercise price of $1.48. At the time of their initial issuances, these warrants had a contractual expiration date of June 26, 2027. The expiration date has been amended as discussed below. The warrants issued in conjunction with the Term Loans are referred to as "Term Loan Warrants".

The Term Loans were accounted for as a conventional debt instrument and are accounted for in accordance with ASC 470, *Debt* ("ASC 470") and ASC 815.

As a result of the issuance of the warrants with the February 2024, May 2024 and July 2024 closings of the February 2024 Term Loan, which met the criteria for equity classification under applicable U.S. GAAP, the Company recorded the fair value of the warrants on the issuance date in the amount of $179, $197, and $210, respectively, as a debt discount and additional paid-in capital on the consolidated balance sheets. Subsequently, these debt discounts were being recorded to interest expense, related party over the term of the February 2024 Term Loan.

As a result of the issuance of the warrants with the August 2024 and December 2024 closings of the August 2024 Term Loan, which met the criteria for equity classification under applicable U.S. GAAP, the Company recorded the fair value of the warrants on the issuance date in the amount of $489 and $321, respectively, as a debt discount and additional paid-in capital on the consolidated balance sheet. Subsequently, these debt discounts were being recorded to interest expense, related party over the term of the August 2024 Term Loan.

As a result of the issuance of the warrants with the March 2025 and June 2025 closings of the March 2025 Term Loan, which met the criteria for equity classification under applicable U.S. GAAP, the Company recorded the fair value of the warrants on the issuance date in the amount of $688 and $882, respectively, as a debt discount and additional paid-in capital on the consolidated balance sheets. Subsequently, these debt discounts were recorded to interest expense, related party over the term of the March 2025 Term Loan.

(Dollars in thousands, except share and per share data)

9. Debt (Related Party) (cont.)

The Company uses the Black-Scholes option model to estimate the fair value of warrants issued in connection with the Term Loans. In applying the Black-Scholes option model, the Company used the following assumptions in the valuation of warrants issued during the years ended December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	2024
Risk-free rate	3.7% – 3.9%	3.8% – 4.9%
Expected dividend yield	0%	0%
Expected term (years)	2.0	2.0
Expected volatility	136.0% – 144.0%	42.0% – 49.0%
Stock price and warrant exercise price	$1.35 – $1.48	$1.24 – $3.04

The Company uses a present value calculation of future cash flows to estimate the fair value of the Term Loans at the date of issuance. The Company used the following inputs in the valuation of Term Loans issued during the years ended December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	2024
Principal	$ 10,000	$ 20,000
Coupon rate	8.0%	8.0%
Issuance date	3/11/2025 – 6/26/2025	3/4/2024 – 12/11/2024
Interest type	Fixed rate	Fixed rate
Payment frequency	Maturity	Maturity
Interest day count	Actual/365	Actual/365
Maturity	3/6/2030	2/27/2029 – 8/27/2029
Market rate[(1)]	11.7% – 16.4%	9.1% – 18.9%

(1) Discounted using the interpolated S&P CCC yield curve commensurate with the remaining term of the note.

During the years ended December 31, 2025 and 2024, the Company recognized $1,590 and $816, respectively, of interest expense in relation to the Term Loans. Included within this interest expense total, the Company recognized $282 and $113 of debt discount amortization during the years ended December 31, 2025 and 2024, respectively.

Debt Extinguishment and Warrant Extension

On August 25, 2025, the Company entered into a satisfaction of promissory notes agreement (the "Satisfaction Agreement") with GAT. Pursuant to the stated terms of the Satisfaction Agreement, GAT agreed to forgive all outstanding principal and accrued interest on the Term Loans in exchange for a $100 payment from the Company.

On September 4, 2025, the Company entered into a voting and warrant extension agreement (the "Voting and Extension Agreement") with Glen Taylor, GAT, and another affiliated entity. Pursuant to the Voting and Extension Agreement, the Company agreed to extend the expiration date of the Term Loan Warrants to December 31, 2028. Prior to the extension, the Term Loan Warrants had expiration dates ranging from February 27, 2026 to June 26, 2027. In addition, Glen Taylor, GAT, and another affiliated entity agreed to vote in favor of any proposal that is submitted by the Company for approval by its stockholders under Nasdaq Listing Rule 5635 relating to stockholder approval of certain issuances of securities, provided that the proposal is unanimously approved and recommended by the Board of Directors of the Company. The voting obligations are in effect through December 31, 2028 and are binding on any transferees of the Class A Common Stock that is currently held by Glen Taylor, GAT or the other affiliated entity. The Voting and Extension Agreement also granted registration rights to Glen Taylor, GAT, or the other affiliated entity upon request on or after March 31, 2026.

(Dollars in thousands, except share and per share data)

9. Debt (Related Party) (cont.)

The Satisfaction Agreement and the Voting and Extension Agreement were considered as a single transaction for accounting purposes given that they were negotiated in close proximity to each other.

The debt extinguishment constitutes a troubled debt restructuring under ASC 470 because the Company is experiencing financial difficulty and a concession has been granted by the holder. As the holder of the Term Loans is a related party, the Company recorded a gain on extinguishment of $27,879 as a capital contribution recorded within additional paid-in-capital during the year ended December 31, 2025, which represents the carrying value of the Term Loans and corresponding accrued interest at the time of extinguishment of $29,438 offset by the $100 of cash consideration paid to GAT, the incremental fair value of the warrants due to modification of $1,455, and the direct and incremental costs associated with the Satisfaction Agreement and the Voting and Extension Agreement of $4.

The Company uses the Black-Scholes option model to estimate the fair value of the Term Loan Warrants immediately prior to modification and immediately after in connection with the Voting and Extension Agreement. In applying the Black-Scholes option model, the Company used the following assumptions:

	Assumptions	
	Pre-Modification	Post-Modification
Risk-free rate	3.6% – 4.0%	3.6%
Expected dividend yield	0%	0%
Expected term (years)	0.48 – 1.81	3.32
Expected volatility	63.0% – 147.0%	113.0%
Exercise price	$1.24 – $3.05	$1.24 – $3.05
Stock Price	$ 1.35	$ 1.35

10. Common Stock

As of December 31, 2025 and 2024, the Company was authorized to issue 400,000,000 shares of Class A Common Stock. The voting, dividend and liquidation rights of the holders of the Company's Class A Common Stock are subject to and qualified by the rights, powers and preferences of the holders of the Series A Preferred Stock (see Note 11).

Contingent Sponsor Shares

Pursuant to the sponsor support and forfeiture agreement dated April 17, 2023 by and between Anzu, Envoy Medical Corporation and the Sponsor, as amended or modified from time to time (the "Sponsor Support Agreement"), and as of the date of issuance, 1,000,000 shares of Class A Common Stock held by the Sponsor shall be unvested and subject to the restrictions and forfeiture provisions set forth in the Sponsor Support Agreement (the "Contingent Sponsor Shares"). The Contingent Sponsor Shares shall vest upon the FDA's approval of the Acclaim CI (the "FDA Approval"). If a change of control of the Company shall occur following the Closing, then the conditions for vesting of any Contingent Sponsor Shares that remain unvested as of immediately prior to the consummation of the change of control shall be deemed to have been achieved and such Contingent Sponsor Shares shall immediately vest as of immediately prior to the consummation of such change of control.

On December 20, 2024 the Company and the Sponsor entered into an agreement to remove the vesting restriction on the Contingent Sponsor Shares, more fully described in Note 11 under "Sponsor Induced Conversion".

At-The-Market Offering

On January 17, 2025, the Company entered into an At The Market Offering Agreement (the "Sales Agreement") with Roth Capital Partners, LLC (the "Sales Agent") to conduct an ATM equity offering program. Pursuant to the Sales Agreement, the Sales Agent acts as the Company's agent with respect to an offering and sale, at any time and

(Dollars in thousands, except share and per share data)

10. Common Stock (cont.)

from time to time, of the Company's Class A Common Stock. The Company has authorized the sale, at its discretion, of Class A Common Stock in an aggregate offering amount up to $15,000 under the Sales Agreement. During the year ended December 31, 2025, the Company sold 300,742 shares of its Class A Common Stock pursuant to the ATM equity offering program. The Company received $414 of net proceeds from the ATM offering during the year ended December 31, 2025.

On September 22, 2025 the ATM equity offering program was suspended in connection with the September 2025 Offering as defined below.

Outstanding Warrants

The following table summarizes the Company's outstanding warrant activity for the years ended December 31, 2025 and 2024 (*in number of warrant shares*):

	Shortfall Warrants	Publicly Traded Warrants	Term Loan Warrants	September 2025 Offering Warrants	October 2025 Offering Warrants
December 31, 2023	3,874,394	14,166,666	—	—	—
Issued	—	—	2,000,000	—	—
Exercised	(664,883)	—	—	—	—
December 31, 2024	3,209,511	14,166,666	2,000,000	—	—
Issued	—	—	1,500,000	5,868,336	9,248,136
Exercised	(2,074,012)	—	—	—	—
December 31, 2025	1,135,499	14,166,666	3,500,000	5,868,336	9,248,136

Forward Purchase Agreement Warrant Liability

Pursuant to the terms of the Forward Purchase Agreement, the Company issued to the Meteora parties warrants to purchase 3,874,394 shares of Class A Common Stock (the "Shortfall Warrants"). As issued, the Shortfall Warrants had an exercise price determined based on the volume weighted average price of the Class A Common Stock, subject to a $4.00 price floor (the "Exercise Price Floor"), which Exercise Price Floor is adjustable for certain issuances of Class A Common Stock at a price below the then-current Exercise Price Floor. The Shortfall Warrants had an expiration date of June 30, 2024 upon issuance. The fair value of the Shortfall Warrants is presented in the forward purchase agreement warrant liability line on the consolidated balance sheets. The change in fair value of the Shortfall Warrants each period is recorded within the change in fair value of forward purchase agreement warrant liability line on the consolidated statements of operations and comprehensive loss.

On June 24, 2024, the Company and the Meteora parties entered into Amendment No. 1 to the Shortfall Warrants to extend the expiration of the Shortfall Warrants to December 31, 2024. Amendment No. 1 did not have a material effect on the Company's financial statements for the year ended December 31, 2024.

On July 29, 2024, the Company and the Meteora parties entered into an amendment to the Forward Purchase Agreement to change the Exercise Price Floor of certain Shortfall Warrants from $4.00 to $2.00 for 1,000,000 of the Shortfall Warrants, $3.00 for an additional 1,000,000 Shortfall Warrants, and with remainder of the Shortfall Warrants retaining the $4.00 Exercise Price Floor.

On December 19, 2024, the Company and the Meteora parties entered into Amendment No. 2 to the Shortfall Warrants to extend the expiration date of the Shortfall Warrants to December 31, 2025.

(Dollars in thousands, except share and per share data)

10. Common Stock (cont.)

On July 28, 2025, the Company and the Meteora parties entered into Amendment No. 3 to the Shortfall Warrants that changed the Exercise Price Floor to $1.50 for the Shortfall Warrants that remained outstanding. The exercise price of the Shortfall Warrants continues to be based on the volume weighted average price of the Class A Common Stock subject to the amended Exercise Price Floor.

On December 18, 2025, the Company and the Meteora parties entered into Amendment No. 4 to the Shortfall Warrants to extend the expiration date of the Shortfall Warrants to December 31, 2026.

Due to the modification of the warrants on the various dates as described above, the warrants were remeasured at fair value as of each modification date with the incremental changes recognized in the consolidated statement of operations and comprehensive loss to the extent the modification was related to an extension of term and in the consolidated statements of changes in mezzanine equity and stockholders' deficit to the extent the modification related to a amendment of the exercise price. The Company uses a Monte Carlo simulation model to estimate the fair value of the Shortfall Warrants. The following table presents the quantitative information regarding the fair value measurements of the forward purchase agreement warrant liability for each amendment:

	July 29, 2024		December 19, 2024		July 28, 2025		December 18, 2025	
	Pre-Modification	Post-Modification	Pre-Modification	Post-Modification	Pre-Modification	Post-Modification	Pre-Modification	Post-Modification
Stock price	$ 2.06	$ 2.06	$ 1.84	$ 1.84	$ 1.53	$ 1.53	$ 0.70	$ 0.70
Initial exercise price	$ 10.46	$ 10.46	$ 10.46	$ 10.46	$ 10.46	$ 10.46	$ 10.46	$ 10.46
Annual volatility	138.0%	138.0%	80.0%	133.0%	62.0%	62.0%	45.0%	113.0%
Remaining term (in years)	0.4	0.4	0.0	1.0	0.4	0.4	0.0	1.0
Risk-free rate	5.12%	5.12%	4.30%	4.19%	4.24%	4.24%	3.71%	3.43%

During the years ended December 31, 2025 and 2024, the Meteora parties exercised Shortfall Warrants to purchase 2,074,012 and 664,883 shares of Class A Common Stock, respectively. Proceeds of $3,111 and $1,815 were received during the year ended December 31, 2025 and 2024, respectively, from the exercise of the Shortfall Warrants. As of December 31, 2025, Shortfall Warrants to purchase 1,135,499 shares of Class A Common Stock remained outstanding.

Publicly Traded Warrants

The Company has 14,166,666 publicly traded warrants to purchase 14,166,666 shares of its Class A Common Stock ("Publicly Traded Warrants"). The Publicly Traded Warrants have an exercise price of $11.50 and expire on September 29, 2028.

Term Loan Warrants

During the years ended December 31, 2025 and 2024, the Company issued Term Loan Warrants to purchase 1,500,000 and 2,000,000 shares, respectively, of its Class A Common Stock to a related party (see Note 9). The Term Loan Warrants are all outstanding as of December 31, 2025 and were amended with the Voting and Extension Agreement (see Note 9).

September 2025 Offering

On September 22, 2025, the Company entered into purchase agreements with certain investors providing for the issuance and sale by the Company of 1,908,402 shares of Class A Common Stock. The Class A Common Stock was offered at a price of $1.31 per share for gross proceeds of $2,500. After deducting direct offering expenses the net cash proceeds to the Company were $2,187. The offering costs were recognized in the loss on offering and change in fair value of private warrant liability in the Company's consolidated statements of operations and comprehensive loss. As part of the September 2025 Offering, the Company issued warrants to investors to purchase 5,725,206 shares of

10. Common Stock (cont.)

Class A Common Stock with an exercise price of $1.31 (the "September 2025 Investor Warrants") per share with each of the investors acquiring three warrants for every share of Class A Common Stock purchased (the "September 2025 Offering"). The closing of the September 2025 Offering occurred on September 23, 2025.

The September 2025 Investor Warrants include certain provisions that could result in a change in the settlement amount based on variables that are not inputs to a "fixed-for-fixed" model, including certain provisions around a change in control transaction. As a result, the warrants do not meet the criteria for equity classification and are accounted for as liabilities in accordance with ASC 815.

The September 2025 Investor Warrants were initially recognized at fair value on the date of issuance using a Black-Scholes option model. The initial fair value of the September 2025 Investor Warrants was $3,193. Since the fair value of the September 2025 Investor Warrants amount exceeded the proceeds from the September 2025 Offering, an immediate loss of $693 was recognized in the loss on offering and change in fair value of private warrant liability in the Company's consolidated statements of operations and comprehensive loss resulting in the private warrant liability in the Company's consolidated balance sheets being recorded as gross proceeds.

The September 2025 Investor Warrants are remeasured at fair value each reporting date until exercised. Changes in the fair value of the September 2025 Investor Warrants are recognized in the loss on offering and change in fair value of private warrant liability on the Company's statements of operations and comprehensive loss.

Additional warrants were issued to the placement agent to purchase 143,130 shares of Class A Common Stock with an exercise price of $1.6375 per share (the "September 2025 Placement Agent Warrants" and collectively with the September 2025 Investor Warrants the "September 2025 Offering Warrants"). The September 2025 Placement Agent Warrants were issued at 125% of the exercise price of the September 2025 Investor Warrants, based on 7.5% of Class A Common Stock issued as part of the September 2025 Offering, and the placement agent will be compensated in the same manner for future offerings under the engagement agreement. The September 2025 Placement Agent Warrants are classified as contingently redeemable in accordance with ASC 718. These warrants qualify for equity classification, however, because the September 2025 Placement Agent Warrants could be settled in cash or other assets upon a contingent redemption that is not solely within the Company's control, the September 2025 Placement Agent Warrants have been classified as temporary equity and reported as warrants issued to placement agent in mezzanine equity on the consolidated balance sheets. Upon issuance, the September 2025 Placement Agent Warrants were recognized at fair value using a Black-Scholes option model and the Company recognized $130 of expense recorded in the loss on offering and change in fair value of private warrant liability on the consolidated statement of operations and comprehensive loss for the year ended December 31, 2025 as the service was completed upon closing of the September 2025 Offering. The contingent redemption event is not probable and the September 2025 Placement Agent Warrants are not currently redeemable. Accordingly, the September 2025 Placement Agent Warrants are presented at grant date fair value on the consolidated balance sheets.

The September 2025 Offering Warrants expire on November 26, 2027, which is two years following stockholder approval of the issuance of the Class A Common Stock underlying the September 2025 Offering Warrants.

The Company used the Black-Scholes option model to estimate the fair value of the September 2025 Investor Warrants and September 2025 Placement Agent Warrants on the dates they were issued. In applying the Black-Scholes option model, the Company used the following assumptions: expected term of 2.25 years, risk free rate of 3.5%, expected volatility of 141%, a stock price of $0.85 for the September 2025 Investor Warrants, and a stock price of $1.31 for the September 2025 Placement Agent Warrants.

October 2025 Offering

On October 7, 2025, the Company entered into purchase agreements with certain investors providing for the issuance and sale by the Company of 3,007,524 shares of Class A Common Stock. The Class A Common Stock was offered at a price of $1.33 per share for gross proceeds of $4,000. After deducting direct offering expenses the net

10. Common Stock (cont.)

cash proceeds to the Company were $3,545. The offering costs were recognized in the loss on offering and change in fair value of private warrant liability in the Company's consolidated statements of operations and comprehensive loss. As part of the October 2025 Offering, the Company issued warrants to investors to purchase 9,022,572 shares of Class A Common Stock with an exercise price of $1.33 (the "October 2025 Investor Warrants" and collectively with the September 2025 Investor Warrants the "Investor Warrants") per share with each of the investors acquiring three warrants for every share of Class A Common Stock purchased (the "October 2025 Offering"). The closing of the October 2025 Offering occurred on October 9, 2025.

The October 2025 Investor Warrants include certain provisions that could result in a change in the settlement amount based on variables that are not inputs to a "fixed-for-fixed" model, including certain provisions around a change in control transaction. As a result, the warrants do not meet the criteria for equity classification and are accounted for as liabilities in accordance with ASC 815.

The October 2025 Investor Warrants were initially recognized at fair value on the date of issuance using a Black-Scholes option model. The initial fair value of the October 2025 Investor Warrants was $6,035. Since the fair value of the October 2025 Investor Warrants amount exceeded the proceeds from the October 2025 Offering, an immediate loss of $2,035 was recognized in the loss on offering and change in fair value of private warrant liability in the Company's consolidated statements of operations and comprehensive loss resulting in the private warrant liability in the Company's consolidated balance sheets being recorded as gross proceeds.

The October 2025 Investor Warrants are remeasured at fair value each reporting date until exercised. Changes in the fair value of the October 2025 Investor Warrants are recognized in the loss on offering and change in fair value of private warrant liability on the Company's statements of operations and comprehensive loss.

Additional warrants were issued to the placement agent to purchase 225,564 shares of Class A Common Stock with an exercise price of $1.6625 per share (the "October 2025 Placement Agent Warrants" and collectively with the October 2025 Investor Warrants the "October 2025 Offering Warrants"). The Placement Agent Warrants were issued at 125% of the exercise price of the October 2025 Investor Warrants, based on 7.5% of Class A Common Stock issued as part of the October 2025 Offering, and the placement agent will be compensated in the same manner for future offerings under the engagement agreement. The October 2025 Placement Agent Warrants are classified as contingently redeemable in accordance with ASC 718. These warrants qualify for equity classification, however, because the October 2025 Placement Agent Warrants could be settled in cash or other assets upon a contingent redemption that is not solely within the Company's control, the October 2025 Placement Agent Warrants have been classified as temporary equity and reported as warrants issued to placement agent in mezzanine equity on the consolidated balance sheets. Upon issuance, the October 2025 Placement Agent Warrants were recognized at fair value using a Black-Scholes option model and the Company recognized $262 of expense recorded in the loss on offering and change in fair value of private warrant liability on the consolidated statement of operations and comprehensive loss for the year ended December 31, 2025 as the service was completed upon closing of the October 2025 Offering. The contingent redemption event is not probable and the October 2025 Placement Agent Warrants are not currently redeemable. Accordingly, the October 2025 Placement Agent Warrants are presented at grant date fair value on the consolidated balance sheets.

The October 2025 Offering Warrants expire on December 30, 2027, two years after the effectiveness of the registration statement registering the resale of the October 2025 Offering Warrants. Proceeds were allocated entirely to the October 2025 Investor Warrants as the fair value of the October Investor Warrants exceeded the amount of proceeds received.

The Company used the Black-Scholes option model to estimate the fair value of the October 2025 Investor Warrants and October 2025 Placement Agent Warrants on the dates they were issued. In applying the Black-Scholes option model, the Company used the following assumptions: expected term of 2.25 years, risk free rate of 3.6%, expected volatility of 150% for the Investor Warrants, expected volatility of 146% for the Placement Agent Warrants, a stock price of $0.95 for the Investor Warrants, and a stock price of $1.66 for the Placement Agent Warrants.

10. Common Stock (cont.)

Common Stock Issued for Services

On September 3, 2025, the Company issued 109,670 shares of its Class A Common Stock to a vendor in exchange for services. The Company is recognizing the corresponding $133 of expense over the six-month service period based on the fair value of the stock at the time of issuance.

11. Series A Preferred Stock

As of December 31, 2025 and 2024, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 100,000,000 shares of $0.0001 par value preferred stock, of which 10,000,000 shares have been designated as Series A Preferred Stock.

Pursuant to a convertible promissory note, dated April 17, 2023, between Envoy Medical Corporation and GAT (the "Envoy Bridge Note"), the Sponsor Support Agreement and the Subscription Agreement, the Company has outstanding an aggregate of 4,126,667 shares of Series A Preferred Stock as of December 31, 2025 and 2024 originally issued to the following investors:

- 1,000,000 shares of Series A Preferred Stock to GAT pursuant to the Envoy Bridge Note;
- 2,500,000 shares of Series A Preferred Stock to the Sponsor pursuant to the Sponsor Support Agreement; and
- 1,000,000 shares of Series A Preferred Stock to certain affiliates of the Sponsor in the PIPE Transaction pursuant to the Subscription Agreement.

As described subsequently in this note, on December 20, 2024, the Company entered into a Conversion and Waiver Agreement with the Sponsor whereby 373,333 shares of Series A Preferred Stock were converted into Class A Common Stock.

The holders of the Series A Preferred Stock have the following rights and preferences:

Voting Rights

The holders of the Series A Preferred Stock are not entitled to vote or receive notice of any meeting of stockholders, except in the case that the Company creates any equity or debt instrument that ranks senior or pari passu to the rights of the Series A Preferred Stock or in the case of any adverse change to the powers, preferences or special rights of the Series A Preferred Stock.

Conversion Rights

Each share of Series A Preferred Stock shall be convertible, at the option of the holder, at any time after the date of issuance into such number of shares of Class A Common Stock as determined by dividing the issuance price of the shares of Series A Preferred Stock of $10.00, by the conversion price, which was $11.50 per share as of December 31, 2025 and is adjustable for certain dilutive events.

Redemption

The holders of Series A Preferred Stock are not entitled to any redemption rights, other than those under their liquidation rights discussed below. The Company does not have the option to redeem the Series A Preferred Stock.

11. Series A Preferred Stock (cont.)

Dividend Rights

The holders of Series A Preferred Stock are entitled to a cumulative dividend which accrues at the rate of 12% of the original issuance price of $10.00 per share per annum ("Regular Dividend"). The Regular Dividend accrues on a daily basis from and including the issuance date of such shares, whether or not declared, and will be payable in cash on a quarterly basis. If the Company fails to pay the Regular Dividends on the dividend payment date, then an additional dividend on the amount of the unpaid portion shall automatically accrue at 12%. The Company did not pay Regular Dividends during the quarters ended September 30, 2025 or December 31, 2025.

The holders of Series A Preferred Stock are also entitled to dividends or distributions ("Participating Dividends") senior to Class A Common Stock of the Company when such dividends are declared. There were no Participating Dividends declared as of December 31, 2025.

Specifically pursuant to the 2,500,000 shares of Series A Preferred Stock issued subject to the Sponsor Support Agreement, any dividends arising will accrue and not require timely payment at any time when the Company has less than $10,000 of net tangible assets. The Company has not met the $10,000 net tangible asset requirement and has deferred payment on the dividends related to the 2,500,000 shares of Series A Preferred Stock held by the Sponsor. As of December 31, 2025 and 2024, the Company had accrued $2,628 and $78, respectively, in unpaid dividends as a result of the Sponsor Support Agreement.

With respect to the holders of the Series A Preferred Stock other than the Series A Preferred Stock subject to the Sponsor Support Agreement held by the Sponsor, the Company had accrued $1,134 and $613 as of December 31, 2025 and 2024, respectively, in unpaid Regular Dividends.

As of December 31, 2025, an additional dividend of $16 has been accrued for the unpaid Regular Dividends owed to the holders of the Series A Preferred Stock not subject to the Sponsor Support Agreement related to an additional dividend on the amount of the unpaid Regular Dividends as described above.

Liquidation Preference

In the event of any liquidation, deemed liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, the holders of the Series A Preferred Stock are entitled to receive, prior and in preference to any distribution of any of the assets or surplus funds of the Company to the holders of any security of the Company that ranks junior to the Series A Preferred Stock, including, but not limited to, the Class A Common Stock, an amount per share of Series A Preferred Stock equal to the greater of i) $10.00 plus any unpaid cash dividends and ii) the amount the holder would have received, if such holder, immediately prior to such involuntary liquidation, dissolution or winding up of Company, had converted such shares of Series A Preferred Stock into Class A Common Stock.

Sponsor Induced Conversion

On December 20, 2024 (the "Effective Date"), the Company entered into a Conversion and Waiver Agreement (the "Conversion Agreement") with the Sponsor.

As of the Effective Date of the Conversion Agreement, the Sponsor was the holder of 2,500,000 shares of the Company's Series A Preferred Stock and the Contingent Sponsor Shares. The Contingent Sponsor Shares were unvested and subject to certain restrictions and risk of forfeiture under the Sponsor Support Agreement until certain milestones were achieved.

Pursuant to the terms of the Conversion Agreement, the Sponsor and the Company agreed that, upon the Effective Date of the Conversion Agreement: (i) the Sponsor waived the Company's obligation to pay the $3,733 of dividends accrued on the Series A Preferred Stock as of the Effective Date; (ii) the Company waived the restriction and vesting requirement for the Contingent Sponsor Shares, making these shares unrestricted and freely tradable; (iii) the Company agreed to make a voluntary, temporary reduction in the conversion price, pursuant to the terms of the

(Dollars in thousands, except share and per share data)

11. Series A Preferred Stock (cont.)

Certificate of Designation, of all of the outstanding shares of Series A Preferred Stock effective December 20, 2024 through January 20, 2025 from $11.50 per share of Class A Common Stock issuable upon conversion of a share of Series A Preferred Stock to $3.63 per share (the "Conversion Price Reduction"), with the conversion ratio determined by dividing the $10.00 original issue price of the Series A Preferred Stock by such Conversion Price; and (iv) the Sponsor agreed to convert 373,333 shares of Series A Preferred Stock into 1,028,986 shares of Class A Common Stock at the temporary Conversion Price.

As the Company was legally released from its obligation to pay certain accrued dividends to the Sponsor, the Company derecognized the accrued dividends in the amount of $3,733 as a result of the Conversion Agreement. The Company determined that the release of the accrued dividends represents paid-in-kind consideration in the form of a stock dividend, as the Sponsor agreed to receive Class A Common Stock at a reduced conversion price under the Conversion Agreement in exchange for waiving the Company's obligation to pay the accrued dividends.

Additionally, the Company determined that the conversion of the Series A Preferred Stock into Class A Common Stock was an induced conversion as the reduced conversion price was only offered for a limited time and included the issuance of all equity securities issuable pursuant to the conversion privileges included in the terms of the Series A Preferred Stock for each share of Series A Preferred Stock that was converted to Class A Common Stock.

12. Stock-Based Compensation

On April 17, 2023, the Company's board of directors adopted an equity incentive plan, and the plan was approved by the stockholders on September 27, 2023 (the "2023 Equity Incentive Plan"). An aggregate of 4,000,000 shares of Class A Common Stock are reserved and may be issued under the 2023 Equity Incentive Plan, provided that until such time as certain milestones are achieved the aggregate number of shares of Class A Common Stock that may be issued pursuant to the 2023 Equity Incentive Plan will be 2,500,000 shares. On May 28, 2025, stockholders approved the removal of the milestone requirement resulting in an aggregate of 4,000,000 shares of Class A Common Stock that may be issued under the 2023 Equity Incentive Plan.

As of December 31, 2025 there were options to acquire 2,260,934 shares of Class A Common Stock outstanding under the 2023 Equity Incentive Plan. The Company initially values options at fair value on the grant date. For awards with periodic vesting, the Company recognizes the related expense on a straight-line basis over the requisite service period for the entire award, which generally vest based on continued service over four years and expire ten years from the date of grant, subject to periodic adjustments to ensure that the cumulative amount of expense recognized through the end of any reporting period is at least equal to the portion of the grant date value of the award that has vested through that date. Certain stock options granted in 2023 and 2024 under the 2023 Equity Incentive Plan have a certain percentage that are exercisable at any time following the date of grant and then vest based on continuous service over three years and expire ten years from the date of grant. Certain stock options granted in 2025 under the 2023 Equity Incentive Plan vest on May 1, 2026.

The Company uses the Black-Scholes option model to estimate the fair value of stock options. In applying the Black-Scholes option model, the Company used the following assumptions in the valuation of options granted in 2025 and 2024:

	2025	2024
Expected volatility	76.0% – 86.3%	66.0% – 75.3%
Expected dividend yield	—	—
Expected life (years)	5.2 – 6.1	6.1 – 6.3
Risk-free rate	3.7% – 4.4%	3.9% – 4.4%

(Dollars in thousands, except share and per share data)

12. Stock-Based Compensation (cont.)

The following table summarizes the Company's stock option activity for the year ended December 31, 2025:

	Options	Weighted-average Exercise Price per Option	Weighted-average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2024	2,214,769	$ 2.38		
Granted	348,280	$ 1.11		
Forfeited	(302,115)	$ 2.41		
Outstanding at December 31, 2025	2,260,934	$ 2.18	8.2	$ —
Exercisable and vested at December 31, 2025	1,447,542	$ 2.38	7.9	$ —

The aggregate intrinsic value of stock options vested during the years ended December 31, 2025 and 2024 is zero because the fair value of the underlying Class A Common Stock was less than the exercise price for all options as of each date.

The stock-based compensation expense related to option grants was $620 and $562 for the years ended December 31, 2025 and 2024, respectively.

The weighted-average grant-date fair value of options granted during the year ended December 31, 2025 and 2024 was $0.78 and $2.41, respectively. The aggregate grant-date fair value of options that vested during the year ended December 31, 2025 and 2024 was $2.04 and $1.64, respectively.

As of December 31, 2025, stock-based compensation related to unvested option awards of $1,124 remains unamortized, which is expected to be recognized over a weighted-average period of 1.97 years.

Employee Stock Purchase Plan

In September 2023, the Company established an employee stock purchase plan under which eligible employees may direct the Company to withhold up to 15% of their gross pay to purchase shares of Class A Common Stock at a price equal to 85% of the lower of the offering date stock price or exercise date stock price. During the years ended December 31, 2025 and 2024, there were 208,001 and 32,758 shares of Class A Common Stock purchased respectively, representing $184 and $63, respectively in contributions made by employees, under the employee stock purchase plan. The stock-based compensation expense associated with the employee stock purchase plan was $37 for the year ended December 31, 2025.

Total stock-based compensation expense associated with stock options and the employee stock purchase plan was classified as follows on the consolidated statements of operations and comprehensive loss for the years ended December 31, 2025 and 2024:

	2025	2024
Research and development expense	$ 303	$ 165
Sales and marketing expense	19	11
General and administrative expense	335	386
Total stock-based compensation expenses	**$ 657**	**$ 562**

(Dollars in thousands, except share and per share data)

13. Income Taxes

The domestic and foreign components of total income (loss) before provision for (benefit from) income taxes are as follows:

	Year Ended December 31,	
	2025	2024
United States	$ (23,534)	$ (20,579)
Foreign	(222)	(216)
Total	**$ (23,756)**	**$ (20,795)**

The components of the benefit from income taxes consist of the following:

	Year Ended December 31,	
	2025	2024
Deferred:		
Federal deferred expense (benefit)	$ (1,889)	$ 3,684
State deferred expense (benefit)	(794)	(1,099)
Foreign deferred expense	67	—
Deferred tax asset valuation allowance	2,616	(2,585)
Total benefit from income taxes	**$ —**	**$ —**

The Company's effective tax rate differs from the federal statutory rate primarily due to the tax expense impact of nondeductible equity compensation and other permanent differences, tax credits, state taxes, and the valuation allowance.

The Company adopted ASC 2023-09 during the year ended December 31, 2025 prospectively. A reconciliation setting forth the differences between the effective tax rates and the U.S. federal statutory tax rate is as follows:

	Year Ended December 31, 2025	
	Amount	Rate
US federal statutory tax rate	$ (4,989)	21.0%
State and local income taxes, net of federal income tax effect	—	—%
Foreign tax effects:		
Germany	47	(0.2)%
Tax credits	155	(0.7)%
Changes in valuation allowances	(800)	3.4%
Nontaxable or nondeductible items:		
Cancellation of debt income	6,704	(28.2)%
Stock-based compensation	(164)	0.7%
Other	3	0.0%
Changes in unrecognized tax benefits	(1,028)	4.3%
Other adjustments	72	(0.3)%
Effective income tax rate	**—**	**—%**

(Dollars in thousands, except share and per share data)

13. Income Taxes (cont.)

A reconciliation setting forth the differences between the effective tax rates and the U.S. federal statutory tax rate, applying ASC 740 prior to the adoption of ASU 2023-09, is as follows:

	Year Ended December 31, 2024
Tax benefit at statutory rate	21.0%
State income tax, net of federal benefit	0.2%
Permanent items	(0.6)%
Federal business credits	(0.8)%
Valuation allowance	(14.9)%
Other	(4.9)%
Effective income tax rate	**—%**

The Company has not recorded deferred income taxes on certain outside basis differences related to its investment in its German subsidiary because such earnings are considered to be indefinitely reinvested. These earnings are expected to be used to support the subsidiary's working capital requirements, capital expenditures, and strategic growth initiatives in Europe.

Determination of the amount of unrecognized deferred tax liability associated with these outside basis differences is not practicable due to the complexities associated with estimating the timing of future distributions, potential foreign tax credits, and other tax attributes that would affect the calculation.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, as well as net operating loss carryforwards and research and development credit carryforwards. Income tax paid and refunds were both zero for federal, state, and foreign jurisdictions for the year December 31, 2025.

The components of deferred tax assets and liabilities consisted of the following:

	Year Ended December 31, 2025	
	2025	2024
Deferred tax assets:		
Net Operating Loss Carryforwards	$ 42,303	$ 43,283
Startup/organization costs	3,217	3,130
Tax credits	1,704	1,828
Capitalized research and development	2,061	3,720
Other	1,686	1,251
Total deferred tax assets	50,971	53,212
Valuation allowance	(50,163)	(52,779)
Net total deferred tax assets	808	433
Deferred tax liabilities:		
Derivative instruments	(532)	(194)
Other	(276)	(239)
Total deferred tax liabilities	(808)	(433)
Net deferred tax assets	**$ —**	**$ —**

(Dollars in thousands, except share and per share data)

13. Income Taxes (cont.)

The reconciliation of tax contingencies is as follows:

	Year Ended December 31,	
	2025	2024
Gross tax contingencies – beginning of year	$ 1,480	$ 516
Gross decreases for current year	(1,028)	—
Gross increases for current year	—	964
Gross tax contingencies – end of year	**$ 452**	**$ 1,480**

The change in valuation allowance was $2,616 and $2,551 for the years ended December 31, 2025 and 2024, respectively.

Management evaluates the realizability of its deferred tax assets by considering all available positive and negative evidence. As of December 31, 2025 the Company concluded that it is more-likely-than-not that its deferred tax assets will not be realized and has therefore recorded a full valuation allowance. In reaching this conclusion, management placed significant weight on negative evidence, including the Company's history of operating losses and the expectation of continued losses in the near term. Although the Company considered positive evidence, such evidence was not sufficient to overcome the objectively verifiable negative evidence.

As of December 31, 2025, the Company had federal tax net operating loss carryforwards of $190,278 which will be available to offset earnings during the carryforward period. Additionally, as of December 31, 2025, the Company had state net operating loss carryforwards of $32,182. If not used, these carryforwards, including federal tax carryforwards generated prior to December 31, 2017, expire in 2026 continuing through 2035. As a result of the Tax Cuts and Jobs Act, the federal tax net operating loss carryforwards generated in the years ended December 31, 2018 through 2024 do not expire. In addition, significant changes in ownership of the Company as defined in Section 382 of the Internal Revenue Code could put limitations on the availability of the net operating loss carryforwards. Currently, no analysis has been performed to determine the applicability of the limitations if any that may have occurred to date.

As of December 31, 2025, the Company had federal research and development credits carryforwards of $1,442. Additionally, the Company had state research and development credits carryforwards of $818 as of December 31, 2025. Both the federal and state research and development credits carryforwards will be available to offset earnings during the carryforward period. If not used, these credits expire in 2026 through 2035.

The impact of an uncertain tax position taken or expected to be taken on an income tax return must be recognized in the consolidated financial statements at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized in the consolidated financial statements unless it is more likely than not of being sustained.

During the year ended December 31, 2024, the Company received a notice from the Internal Revenue Service ("IRS") indicating that an additional refund of $997 was to be remitted to the Company. This refund was considered to be the result of estimated tax payments made by Anzu as reported on its short period tax return filed for the period January 1, 2023 to September 29, 2023, prior to the Business Combination. The Company received the refund during the first quarter of 2025. As of December 31, 2025, the matter related to the notice has been resolved and the Company repaid the previously received refund. Accordingly, no uncertain tax position liability remains in accordance with this matter.

The Company has reduced its deferred tax asset for research and development credit by $31 and $33 for uncertain tax positions as of December 31, 2025 and 2024, respectively. If not used, these credits expire in 2026 through 2032.

13. Income Taxes (cont.)

For U.S. federal income tax purposes, the Company is required to recognize cancellation of debt income ("CODI") when the adjusted issue price of debt exceeds the amount paid to settle such debt. During the year ended December 31, 2025, the Company extinguished certain outstanding indebtedness for cash consideration of $100 (see Note 9). As a result, the Company recognized $32,012 of CODI for U.S. tax purposes, representing the excess of the adjusted issue price of the extinguished debt, on a gross basis, over the cash paid.

For tax years beginning after December 31, 2024, One Big Beautiful Bill Act ("OBBA") enacted a new rule under Section 174A allowing companies to immediately expense any domestic research and developmental ("R&D") expenditures. For domestic R&D, companies may either immediately expense or elect to capitalize and amortize over at least 60 months under Section 174A.

For domestic R&D expenditures that were previously capitalized in tax years 2022-2024 under the Tax Cuts and Jobs Act ("TCJA"), companies may elect to recover the remaining unamortized balance by either expensing (1) fully in the first year beginning after December 31, 2024 or (2) ratably over two years beginning after December 31, 2024.

The Company has elected to immediately expense any domestic research and developmental ("R&D") expenditures and will amortize the previously capitalized costs ratably over the years ended December 31, 2025 and December 31, 2026. The law changes related to OBBBA did not materially impact the Company's ETR or cash tax position for the year ended December 31, 2025.

The Company currently files income tax returns in Arizona, California, Maryland, Michigan, Minnesota, Texas, and Vermont. Due to the previous losses incurred, the Company is subject to income tax examination by tax authorities since inception. The Company has not been, nor is it currently, under examination by any tax authorities. The Company has not recorded deferred U.S. Income taxes or foreign withholding taxes on the undistributed earnings of its German subsidiary, as such earnings are considered indefinitely reinvested to support foreign operations. The operations and undistritbuted earnings of the Company's German subsidiary are not material to the consolidated financial statements.

14. Segment Reporting

Operating segments are identified as components of an enterprise about which discrete financial information is available for evaluation by the CODM in deciding resource allocation and assessing performance. The Company has determined that its CODM is its Chief Executive Officer.

The Company has one reportable segment: hearing. The hearing segment derives revenue from the sale of the Esteem FI-AMEI implants and replacement components to Esteem FI-AMEI implants. The Company enters into arrangements with patients to provide them with the Esteem FI-AMEI device, personal programmer devices, sound processor replacements, and Battery replacements.

The Company derives revenue primarily in the United States and manages the business activities on a consolidated basis.

The accounting policies of the hearing segment are the same as those described in the summary of significant accounting policies. The CODM assesses performance for the hearing segment and decides how to allocate resources based on net loss that also is reported on the consolidated statements of operations and comprehensive loss. The measure of segment assets is reported on the consolidated balance sheets as total assets.

The CODM uses net loss to evaluate the results generated from segment assets (return on assets) in deciding whether to make investments into the hearing segment or into other parts of the entity, such as for entering into significant contracts, hiring of key management or executive personnel, making significant capital investment decisions, or changing Company-wide strategy.

(Dollars in thousands, except share and per share data)

14. Segment Reporting (cont.)

Net loss is used to monitor budget versus actual results and assist the CODM in understanding the Company's cash flows and liquidity position, which is critical as a development state entity. This allows the CODM to make the appropriate spending decisions for the Company.

The following table summarizes the significant expense categories regularly reviewed by the CODM for the years ended December 31, 2025 and 2024.

	Year Ended December 31,	
	2025	2024
Net revenues	$ 241	$ 225
Costs and operating expenses:		
Cost of goods sold	874	742
Research and development	12,486	10,179
Sales and marketing	1,220	1,734
General and administrative	7,931	6,826
Total costs and operating expenses	22,511	19,481
Operating loss	(22,270)	(19,256)
Other income (expense):		
Other segment items[(1)]	127	(697)
Interest expense, related party	(1,590)	(816)
Other income (expense), net	(23)	(26)
Total other income (expense), net	(1,486)	(1,539)
Net loss	$ (23,756)	$ (20,795)

(1) Other segment items include the change in fair value of forward purchase agreement put option liability, change in fair value of forward purchase agreement warrant liability, change in fair value of forward purchase agreement warrant liability due to extension, loss on offering and change in fair value of private warrant liability, and change in fair value of publicly traded warrant liability.

15. Related Party Transactions

The Company had various transactions with a member of the Company's board of directors and a controlling stockholder of the Company, which is considered a related party.

- The Company leases its headquarters office space in Minnesota from the stockholder. The lease is considered a common control leasing arrangement. See Note 7 for additional information related to this lease including the operating lease cost for the years ended December 31, 2025 and 2024 and the lease liability due to the stockholder as of December 31, 2025 and 2024.
- The Company received Term Loans from GAT during 2024 and 2025 that were extinguished on August 25, 2025 (see Note 9).
- The Company has a shared services arrangement with a company that is indirectly owned by the stockholder, for certain support services used in the course of business. In relation to the shared services arrangement, the Company's expenses are not material.

(Dollars in thousands, except share and per share data)

16. Commitment and Contingencies

Legal Proceedings

The Company is party to various litigation matters arising from time to time in the ordinary course of business.

On November 14, 2023, the Company, Whitney Haring-Smith (the former chief executive officer and a former director of the Company), Daniel Hirsch (the former chief financial officer of the Company), and Anzu SPAC GP I LLC were named as defendants in a complaint filed by Atlas Merchant Capital SPAC Fund I LP ("Atlas") in the Delaware Court of Chancery. Atlas alleges that it was not allowed to redeem its shares of Anzu class A common stock and that the defendants acted to prevent Atlas's attempt to redeem its shares. The defendants assert that Atlas did not comply with the requirements for redeeming shares set forth in the Company's organizational documents. Atlas asserts damages in the amount of approximately $9,400, pre- and post-judgment interest, costs, and reasonable attorneys' fees. The Company has standard indemnification obligations to Dr. Haring-Smith and Mr. Hirsch. The Company believes that the lawsuit is meritless and has been defending this matter vigorously. On March 3, 2025, the court partially granted a motion to dismiss which dismissed and reduced some of the Counts and allegations in the amended complaint, which narrowed the theories and facts at issue in this litigation. The Company is unable to predict the outcome of this legal proceeding.

The Company has business liability insurance to cover litigation costs exceeding $50. As of December 31, 2025 and 2024, the Company has not recorded accruals for potential losses related to any existing or pending litigation claims as the Company's management determined that there are no matters where a potential loss is probable and reasonably estimable.

Interest Related to an Uncertain Tax Position

The Company resolved the uncertain tax position discussed in Note 13. The Company timely remitted the related tax to the IRS, the IRS later refunded those amounts to the Company and has asserted that interest is due retroactive to the original payment date. The Company believes that, because the IRS had possession and use of the funds for a portion of the relevant period and was not the result of a substantive tax underpayment by the Company, any interest computation should be limited to the period, if any, during which the Company had use of the refunded amounts. While the Company does not believe it is probable that interest will ultimately be owed, it is reasonably possible that the IRS could prevail. If so, the Company could be required to pay up to approximately $150 of interest related to this matter. As of December 31, 2025, the Company has not accrued for interest related to interest from the uncertain tax position.

17. Net Loss per Share

The following table sets forth the computation of basic and diluted loss per share:

	Year Ended December 31,	
	2025	2024
Numerator:		
Net loss	$ (23,756)	$ (20,795)
Less: Induced conversion of Series A Preferred Stock into Class A Common Stock	—	(1,162)
Less: Deemed dividend on waiver of restriction on Class A Common Stock	—	(495)
Less: Cumulative preferred dividends	(4,906)	(5,521)
Net loss attributable to common stockholders, basic and diluted	$ (28,662)	(27,973)
Denominator:		
Weighted-average Class A Common Stock outstanding, basic and diluted	23,259,598	18,790,448
Net loss per share attributable to common stockholders, basic and diluted	$ (1.23)	$ (1.49)

(Dollars in thousands, except share and per share data)

17. Net Loss per Share (cont.)

The Company's potentially dilutive securities below, presented based on amounts outstanding at each period end, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of shares of Class A Common Stock outstanding used to calculate both basic and diluted net loss per share attributable to stockholders of Class A Common Stock for these periods is the same.

	Year Ended December 31,	
	2025	2024
Stock options	2,260,934	2,214,769
Series A Preferred Stock (as converted to Class A Common Stock)	3,588,406	3,588,406
Publicly traded warrants	14,166,666	14,166,666
Shortfall Warrants	1,135,499	3,209,511
Term Loan Warrants	3,500,000	2,000,000
September 2025 Offering Warrants	5,868,336	—
October 2025 Offering Warrants	9,248,136	—

18. Subsequent Events

The Company has evaluated all events occurring through the date on which these consolidated financial statements were issued, and during which time, nothing has occurred outside the normal course of business operations that would require disclosure, except for the following:

February 2026 Offering

On February 12, 2026, the Company completed a public offering (the "February 2026 Offering") of an aggregate of (i) 47,946,150 shares of Class A Common Stock, (ii) 27,053,850 pre-funded warrants (the "Issued Pre-Funded Warrants") to purchase 27,053,850 shares of Class A Common Stock, (iii) 45,000,000 Series A-1 Warrants to purchase 45,000,000 shares of Class A Common Stock and/or pre-funded warrants (the "Series A-1 Warrants"), and (iv) 75,000,000 Series A-2 Warrants to purchase 75,000,000 shares of Class A Common Stock and/or pre-funded warrants (the "Series A-2 Warrants" and, together with the Series A-1 Warrants, the "Series A Warrants"). The Series A Warrants and Issued Pre-Funded Warrants are collectively referred to herein as the "February 2026 Offering Warrants," and the shares of Class A Common Stock issuable upon exercise of the February 2026 Offering Warrants are collectively referred to as the "February 2026 Offering Warrant Shares." For each share of Class A Common Stock (or Issued Pre-Funded Warrant in lieu thereof) purchased, the investors received accompanying Series A Warrants in the amount of six-tenths (0.6) of a Series A-1 Warrant and one Series A-2 Warrant. The purchase price for the February 2026 Offering was $0.40 per Share (or $0.3999 per Issued Pre-Funded Warrant in lieu thereof) and accompanying Series A Warrants.

The Series A-1 Warrants have an exercise price of $0.40 per share, become exercisable beginning on the effective date of stockholder approval of the issuance of the shares upon exercise of the February 2026 Offering Warrants (the "Stockholder Approval Date") and will expire on the earlier of (i) the 24-month anniversary of the Stockholder Approval Date or (ii) 30 days following the date the Company publicly announces that it has submitted a Premarket Approval Application ("PMA") to the FDA for the Acclaim CI. The Series A-2 Warrants have an exercise price of $0.40 per share, will become exercisable beginning on the Stockholder Approval Date and will expire on the earlier of (i) the 60-month anniversary of the Stockholder Approval Date or (ii) 30 days following the date the Company publicly announces that it has received FDA approval for the Acclaim CI.

The aggregate gross proceeds to the Company from the February 2026 Offering were approximately $30,000. After deducting the placement agent's fees and other offering expenses the Company received approximately $27,730 of net proceeds. The potential additional gross proceeds to the Company from the Series A-1 Warrants and Series A-2 Warrants, if fully-exercised on a cash basis following the Stockholder Approval Date, will be approximately $18,000 and $30,000, respectively, or $48,000 in total. The Company intends to use the net proceeds of the February 2026 Offering for working capital and other general corporate purposes to fund its operations during the Acclaim CI clinical study.

ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

ITEM 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are designed to ensure that information required to be disclosed by us in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2025, as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on the evaluation of our disclosure controls and procedures as of December 31, 2025, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were not effective due to the existence of the material weaknesses in the Company's internal control over financial reporting described below.

Notwithstanding the conclusion by our Chief Executive Officer and Chief Financial Officer that our disclosure controls and procedures as of December 31, 2025 were not effective, and notwithstanding the material weaknesses in our internal control over financial reporting described below, management believes that the consolidated financial statements and related financial information included in this Annual Report on Form 10-K fairly present in all material respects our financial condition, results of operations and cash flows as of the dates presented, and for the periods ended on such dates, in conformity with GAAP.

Management's Report on Internal Controls Over Financial Reporting

As required by SEC rules and regulations implementing Section 404 of the Sarbanes-Oxley Act, our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in accordance with GAAP. Our internal control over financial reporting includes those policies and procedures that:

(1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company,

(2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors, and

(3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect errors or misstatements in our financial statements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree or compliance with the policies or procedures may deteriorate. Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2025. In making these assessments, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control — Integrated Framework (2013). Based on our assessments and those criteria, management determined that our internal control over financial reporting was ineffective as of December 31, 2025 and that there were control deficiencies that constituted material weaknesses as described below. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

This Report does not include an attestation report of our independent registered public accounting firm due to our status as an emerging growth company under the JOBS Act.

Material Weaknesses in Internal Control Over Financial Reporting

Management concluded the following material weaknesses existed as of December 31, 2025:

- The Company has limited personnel with accounting knowledge, experience and training to appropriately analyze, record and disclose certain accounting matters to provide reasonable assurance of preventing material misstatements.
- The Company's management has yet to fully implement a formal risk assessment that addresses risks relevant to financial reporting objectives, including cybersecurity and fraud risks.
- The Company has yet to fully design, document and maintain formal accounting policies, procedures and controls over significant accounts and disclosures to achieve complete, accurate and timely financial accounting, reporting and disclosures, including segregation of duties and adequate controls related to the preparation, posting, modification and review of journal entries, and the accounting treatment of complex transactions, including fair value measurements under U.S. GAAP.
- The Company has yet to fully design and maintain effective controls over certain information technology general controls for information systems that are relevant to the preparation of its consolidated financial statements, including ineffective controls around user access and segregation of duties.

Considering this, the Company performed additional procedures and analyses as deemed necessary to ensure that its financial statements were prepared in accordance with U.S. GAAP.

The Company has begun the process of conducting a formal risk assessment and implementation of a plan to remediate these material weaknesses. These remediation measures are ongoing and include the following steps:

- hiring additional accounting and financial reporting personnel with appropriate technical accounting knowledge and public company experience in financial reporting;
- designing, documenting and implementing effective processes and controls over significant accounts and disclosure;
- designing, documenting, and implementing security management and change management controls over information technology systems, including adjusting user access levels and implementing external logging on activity and periodic review of such logs; and
- engaging an accounting advisory firm to assist with the documentation, evaluation, remediation and testing of the Company's internal control over financial reporting based on the criteria established in "Internal Control — Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Changes in Internal Control Over Financial Reporting

There was no change in the Company's internal control over financial reporting that occurred during the fiscal quarter ended December 31, 2025 that has materially affected, or is reasonably likely to materially affect, its internal control over financial reporting.

ITEM 9B. Other Information

None of our directors or executive officers adopted or terminated a Rule 10b5-1 trading arrangement or adopted or terminated a non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K) during the three months ended December 31, 2025.

ITEM 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

ITEM 10. Directors, Executive Officers and Corporate Governance

Management

The following table sets forth information concerning our current directors and executive officers, including their ages as of March 20, 2026. There are no family relationships among any of our directors or executive officers.

Name	Age	Title
Brent T. Lucas	44	Chief Executive Officer and Director
Robert Potashnick	46	Interim Chief Financial Officer
Charles R. Brynelsen	69	Chairman
Michael Crowe	62	Director
Mona Patel	58	Director
Janis Smith-Gomez	58	Director
Susan J. Kantor	70	Director

Executive Officers

Brent T. Lucas. Brent T. Lucas has served as our Chief Executive Officer and a member of the Board since the closing of the Business Combination in September 2023. At the time of the Business Combination Mr. Lucas was the Chief Executive Officer (since 2015) and Board member of Envoy Medical Corporation (since 2016). Mr. Lucas brings 19 years of experience in active implantables in the hearing health industry. He has served in various roles with Envoy Medical Corporation and gained a tremendous amount of specialized experience and extensive industry-specific knowledge, working his way up from an intern to CEO. Mr. Lucas is currently one of the longest-tenured CEOs in the hearing industry. Mr. Lucas received his bachelor's degree from the University of St. Thomas and Juris Doctor degree from the Mitchell Hamline School of Law.

The Board believes Mr. Lucas is qualified to serve as a member of the Board given his specialized experience and knowledge in the hearing and medical device industries as the Company's Chief Executive Officer.

Robert Potashnick. Robert Potashnick has provided consulting services through Oasis Business Consulting LLC since October 2024. Previously, Mr. Potashnick served as the Chief Financial Officer of Flutterbee Education Group from January 2024 to October 2024 and FOXO Technologies Inc. (NYSE American: FOXO) from January 2021 to September 2023. From 2017 to 2020, Mr. Potashnick served in capital planning and business development finance roles at UnitedHealth Group (NYSE American: UNH). Before that, from 2010 to 2017, Mr. Potashnick worked as a certified public accountant at PricewaterhouseCoopers LLP. Mr. Potashnick holds a Bachelor of Arts degree in Economics from Northwestern University, a Master's Degree in Accountancy from the University of Illinois, and an MBA (Finance/Strategy) from DePaul University.

Non-Executive Directors

Charles R. Brynelsen. Charles R. Brynelsen has served as the Chairman of our Board since the closing of the Business Combination. Mr. Brynelsen has extensive experience in the medical device industry, including most recently serving as Senior Vice President and President of Abbott Vascular from 2017 to 2021. Since 2015 he has also been a Venture Partner of SpringRock Ventures, an investment firm that focuses on digital health, devices, services, oral health, SAAS, consumerization/ecommerce of healthcare, IT, wellness, HIPAA and other innovative companies improving general health. Mr. Brynelsen has also served on private companies' boards of directors, including Alebra Technologies since 2010 and Neuspera Medical from 2022 to 2023. Mr. Brynelsen previously served as Senior Vice President and President of Medtronic Early Technologies from 2015 to 2016, as the Global President of Covidien Early Technologies from 2013 to 2015, and as the Chief Executive Officer of IntraPace from 2005 to 2012. Earlier in his career, Mr. Brynelsen held various commercial, corporate, international, and general management leadership roles across Medtronic from 1981 to 2005.

The Board believes Mr. Brynelsen is qualified to serve as a member of the Board due to his extensive experience in the management of a multinational public company in the medical device industry, including significant product development, clinical/regulatory, manufacturing, business development and strategic planning experience. He also provides valuable insights into operating in highly regulated global healthcare markets.

Michael Crowe. Michael Crowe has decades of experience in the medical device industry with a focus on operations. Since March 2023, Mr. Crowe has served as Senior Vice President Operations for Bioventus LLC. Previously, he served as Vice President Operations for Abbott Vascular from January 2015 to March 2023. Mr. Crowe earlier served in similar roles for Caris Life Sciences, Covidien Devices, Johnson & Johnson, Iomega Corporation, and SKF USA, Inc. Mr. Crowe earned a bachelor's degree in engineering from the University of Louisville and an MBA from Duke University.

The Board believes Mr. Crowe is qualified to serve as a member of the Board due to his wide-ranging experience in the management and operations of multinational public companies in the medical device industry, including significant experience overseeing distribution, supply chain and sourcing, facilities, engineering, customer service, reimbursement services, and product launch, which the Board believes will be vital to the Company's next stages of development.

Mona Patel. Mona Patel has served as a member of our Board since the closing of the Business Combination. Ms. Patel has over 30 years of experience with medical devices in marketing, market development, clinical education and mergers and acquisitions. Most recently, Ms. Patel was the Vice President of Marketing and Clinical Education at Boston Scientific in their neuromodulation division, where she helped build the start-up into a market leader with approximately $1 billion in sales. While at Boston Scientific, she introduced the first rechargeable spinal cord stimulator into the market, helped convert the market from non-rechargeable to rechargeable stimulators, and launched the first rechargeable deep brain stimulator for Parkinson's disease. Prior to joining Boston Scientific, Ms. Patel worked in various positions at Guidant in marketing and business development, through which she acquired and licensed a portfolio of technologies that became the Guidant Cardiac and Vascular surgery division, including the acquisition of two med-tech start-ups. As a marketing leader, she drove the adoption of a new procedure, endoscopic vessel harvesting, to become the gold standard for cardiac surgery. She began her career as an engineer for Abbott Labs. Ms. Patel earned a BSE in Mechanical Engineering from the University of Michigan and an M.B.A. from the University of Pennsylvania, Wharton School of Business.

The Board believes Ms. Patel is qualified to serve on the Board due to her extensive background in the medical devices field and expertise in marketing and business development.

Janis Smith-Gomez. Janis Smith-Gomez has served as a member of our Board since the closing of the Business Combination. Ms. Smith-Gomez has more than 30 years of experience in marketing and innovation, positioning global brands for growth and competitive advantage, contributing to her strong business acumen and stakeholder insights focus. From 2006 to 2022, Ms. Smith-Gomez held a variety of leadership positions at Johnson& Johnson across medical devices and consumer health, where she focused on building brands, launch excellence and innovative marketing strategies for revenue and market share growth. In her most recent role at Johnson & Johnson as the Vice President of Global Brand Experience, she led the brand identity efforts to evolve the $27 billion medical devices business into a leading patient-centered, customer-focused, digitally powered med-tech innovator. As the Vice President of U.S. Marketing for Ethicon LLC, a subsidiary of Johnson & Johnson, from 2014−2018, Ms. Smith-Gomez returned the business to growth and strengthened customer engagement. Prior to working at Johnson& Johnson, Ms. Smith-Gomez held the roles of Vice President of Marketing at Mars, Incorporated, Senior Director at Kraft Foods, and Director of Marketing at PepsiCo, Inc. Ms. Smith-Gomez started her career in consulting with Booz, Allen & Hamilton and completed a summer internship with Procter & Gamble. Ms. Smith-Gomez is currently Chair of the Board and an independent director for The Honey Pot Company, LLC, a subsidiary of Compass Diversified and a member of the board of trustees of several non-profit organizations, including the New York Academy of Medicine, Black Public Media, and the Vanderbilt University Parents and Family Association. She also previously served as a trustee for Kent Place School and Citymeals on Wheels. Ms. Smith-Gomez received her bachelor's degree in Professional Option: Business and her M.B.A. from the University of Chicago.

The Board believes Ms. Smith-Gomez is qualified to serve on the board due to her extensive experience in the medical devices industry, her strategic planning expertise and her successful career as a senior executive, commercial leader and marketing strategist driving brand relevance and sustainable financial and operational performance.

Susan J. Kantor. Susan J. Kantor has served as a member of our Board since March 2021. Ms. Kantor has experience leading international finance, tax, treasury, risk, compliance and technology enablement for global services organizations. She was an Advisory Partner for PwC from 2011 to 2016, a Partner and CFO & Treasurer of PRTM Management Consultants from 1997 to 2011, and was previously a CFO/senior financial executive at corporate strategy and operations consulting firms Monitor Group and BCG, as well as Parexel International, a clinical research organization. She began her career in the audit practices at EY and PWC, where she provided audit services for over 12 years to privately held and publicly held companies across the industrial, life sciences and retail and consumer sectors. During her time at PRTM, she completed several successful M&A transactions in the U.S. and abroad, including the sale PRTM's global business to PwC in 2011. Ms. Kantor previously served on the board of Teknor Apex Company, a privately-held material science company and on the board and as Audit Committee Chair of Guest Services Inc., a privately held hospitality company and on the board and Audit Committee of Lionbridge Technologies, Inc. a publicly-traded company. She received her bachelor's degree from Grove City College in Accounting and Business Administration and her CPA in Massachusetts.

The Board believes Ms. Kantor is qualified to serve on the Board due to her extensive background and expertise in global financial and tax matters. Ms. Kantor qualifies as a "financial expert" and has served as the Chair of the Audit Committee since March 2021.

Other Key Executives

Tom Hoegh. Tom Hoegh has served as our Director of Engineering since the closing of the Business Combination. Mr. Hoegh has over 25 years of experience in the medical device industry, primarily in the development and on-market support of active implantable devices such as neuromodulation systems for spinal, sacral, deep brain, and hypoglossal nerve stimulation. Mr. Hoegh's previous experiences consist of leading engineering teams at Nuvectra, ICU/Smiths Medical, Medtronic, and Apnex Medical. Mr. Hoegh received a dual Bachelor of Science degree in Mechanical Engineering and Chemistry from Valparaiso University and a Master of Science degree in Technology Management from the University of St. Thomas.

Karin Simonson. Karin Simonson has served as our Vice President, General Counsel & Corporate Secretary since December, 2023. From April, 2023 to December, 2023, Ms. Simonson was General Counsel for Monarch Healthcare Management. She has over 20 years of diverse in-house counsel experience supporting clinical, regulatory, sales, marketing, compliance, data privacy, research and development, HR, IT, contracts and commercial operations with increasing responsibilities at both small and large companies including, Coloplast, Medtronic, American Medical Systems and Carlson Hotels Worldwide. She began her legal career over 25 years ago in commercial litigation, but over the last 15+ years has focused on the medical device industry. Ms. Simonson is currently and has been a board member of the Association of Corporate Counsel (ACC) — Minnesota Chapter for the last 10 years and has been an ACC member since 2007. Ms. Simonson has a BS, magna cum laude, from the University of Minnesota-Twin Cities and a JD, magna cum laude, from Mitchell Hamline School of Law. She is also a volunteer attorney with Children's Law Center of Minnesota.

Involvement in Certain Legal Proceedings

To our knowledge, there have been no events under any bankruptcy act, no criminal proceedings and no federal or state judicial or administrative orders, judgments or decrees or findings, no violations of any federal or state securities law, and no violations of any federal commodities law material to the evaluation of the ability and integrity of any director (existing or proposed) or executive officer (existing or proposed) of the Company during the past 10 years.

Corporate Governance

Code of Ethics

The Board has adopted a Code of Ethics, which is applicable to our employees, directors and officers, including our principal executive officer, principal financial officer, principal accounting officer or controller and other persons performing similar functions. The Code of Ethics covers topics including conflicts of interest, confidentiality of information, full and fair disclosure, reporting of violations and compliance with laws and regulations. Our Code of

Ethics is available, free of charge, on the investor relations page of our website, *https://www.envoymedical.com/investors.* This website address is intended to be an inactive, textual reference only; none of the material on this website is part of this Report.

If the Company amends or grants a waiver of one or more of the provisions of the Code of Ethics, it intends to satisfy the requirements under Item 5.05 of Item 8-K regarding the disclosure of amendments to or waivers from provisions of the Code of Ethics that apply to the Company's principal executive officer, principal financial officer and principal accounting officer by posting the required information on the investor relations page of the Company's website at *https://www.envoymedical.com/investors.*

ITEM 11. Executive Compensation

The information required by this Item 11 will be contained in the Definitive Proxy Statement under the captions "*Corporate Governance*," "*Executive Compensation*" and "*Director Compensation*" and is incorporated herein by reference.

ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this Item 12 will be contained in the Definitive Proxy Statement under the captions "*Security Ownership of Certain Beneficial Owners, Executive Management and Directors*" and "*Executive Compensation — Equity Compensation Plan Information*" and is incorporated herein by reference.

ITEM 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item 13 will be contained in the Definitive Proxy Statement under the captions and "*Corporate Governance*" and "*Certain Relationships and Related Transactions*" and is incorporated herein by reference.

ITEM 14. Principal Accounting Fees and Service

The information required by this Item 14 will be contained in the Definitive Proxy Statement under the caption "*Proposal No. 2 — Ratification of Appointment of Independent Registered Public Accounting Firm*" and is incorporated herein by reference.

PART IV

ITEM 15. Exhibits and Financial Statement Schedules

The following is a list of documents filed as a part of this Report:

(1) Financial Statements

The consolidated financial statements of the Company, together with the independent registered public accounting firm's report thereon, are included herein and are incorporated by reference. See *Item 8. Financial Statements and Supplementary Data*, filed herewith, for a list of financial statements.

(2) Financial Statement Schedules

All schedules for which provision is made in Regulation S-X are either not required to be included herein under the related instructions, are inapplicable or the related information is included in the footnotes to the applicable financial statement and, therefore, have been omitted.

(3) Exhibits

The exhibits required to be filed by Item 601 of Regulation S-K are listed in the accompanying Exhibit Index, which is incorporated by reference.

ITEM 16. Form 10-K Summary

None.

EXHIBIT INDEX

Exhibit Number	Description	Incorporated by Reference			
		Schedule/ Form	File No.	Exhibit	Filing Date
3.1	Second Amended and Restated Certificate of Incorporation of the Company.	8-K	001-40133	3.1	October 5, 2023
3.2	Amended and Restated Bylaws of the Company.	8-K	001-40133	3.2	October 5, 2023
3.3	Certificate of Designation of Series A Preferred Stock of the Company.	8-K	001-40133	3.3	October 5, 2023
4.1	Warrant Agreement, dated March 1, 2021, between Anzu Special Acquisition Corp I and Equiniti Trust Company, LLC (formerly known as American Stock Transfer & Trust Company, LLC), as Warrant Agent.	8-K	001-40133	10.1	March 4, 2021
4.2	Form of Shortfall Warrant.	S-1/A	333-276590	4.2	February 15, 2024
4.3	Description of Securities.	10-K	001-40133	4.3	April 1, 2024
4.4	Form of GAT Warrant.	10-K	001-40133	4.4	March 31, 2025
4.5	Form of September Private Placement Warrant	8-K	001-40133	4.1	September 23, 2025
4.6	Form of September Placement Agent Warrant	8-K	001-40133	4.2	September 23, 2025
4.7	Form of October Private Placement Warrant	8-K	001-40133	4.1	October 9, 2025
4.8	Form of October Placement Agent Warrant	8-K	001-40133	4.2	October 9, 2025
4.9	Form of Pre-Funded Warrant	S-1/A	333-292260	4.9	February 6, 2026
4.10	Form of Series A-1 Warrant	S-1/A	333-292260	4.10	February 6, 2026
4.11	Form of Series A-2 Warrant	S-1/A	333-292260	4.11	February 6, 2026
4.12	Form of Placement Agent Warrant to be issued in this offering	S-1/A	333-292260	4.12	February 6, 2026
10.1	Amendment to Letter Agreement, dated September 29, 2023, by and among Anzu Special Acquisition Corp I, Anzu SPAC GP I LLC and Anzu's officers and directors.	8-K	001-40133	10.2	October 5, 2023
10.2(+)	Amended and Restated Registration Rights Agreement, dated September 29, 2023, by and among Anzu Special Acquisition Corp I, Anzu SPAC GP I LLC and certain stockholders.	8-K	001-40133	10.3	October 5, 2023
10.3(*)	Envoy Medical, Inc. Equity Incentive Plan.	8-K	001-40133	10.22	October 5, 2023
10.4(*)	Envoy Medical, Inc. Employee Stock Purchase Plan.	8-K	001-40133	10.23	October 5, 2023
10.5(*)	Form of Envoy Medical, Inc. Indemnification Agreement.	8-K	001-40133	10.21	October 5, 2023
10.6	Forward Purchase Agreement, dated as of April 17, 2023.	8-K	001-40133	10.4	April 18, 2023
10.7(+)	Amendment No. 1 to Forward Purchase Agreement, dated as of May 25, 2023.	S-4/A	333-271920	10.27	June 30, 2023
10.8	Amendment No. 2 to Forward Purchase Agreement, dated as of September 28, 2023.	8-K	001-40133	10.24	October 5, 2023
10.9(*)	Employment Agreement, dated October 16, 2023, between Envoy Medical Corporation and Brent T. Lucas.	8-K	001-40133	10.1	October 20, 2023

Exhibit Number	Description	Incorporated by Reference			
		Schedule/ Form	File No.	Exhibit	Filing Date
10.10(*)	Employment Agreement, dated August 15, 2023, between Envoy Medical Corporation and David R. Wells.	10-Q	001-40133	10.10	November 17, 2023
10.11(*)	Letter Agreement, dated February 14, 2024, between Envoy Medical Corporation and Charles R. Brynelsen.	10-K	001-40133	10.11	April 1, 2024
10.12(*)	Letter Agreement, dated February 14, 2024, between Envoy Medical Corporation and Susan Kantor.	10-K	001-40133	10.12	April 1, 2024
10.13(*)	Letter Agreement, dated February 14, 2024, between Envoy Medical Corporation and Mona Patel.	10-K	001-40133	10.13	April 1, 2024
10.14(*)	Letter Agreement, dated February 14, 2024, between Envoy Medical Corporation and Janis Smith-Gomez.	10-K	001-40133	10.14	April 1, 2024
10.15(*)	Form of Option Award Agreement.	10-K	001-40133	10.15	April 1, 2024
10.16	Promissory Note, dated February 27, 2024, between Envoy Medical, Inc. and GAT Funding, LLC	10-Q	001-40133	10.1	May 15, 2024
10.17	Amendment to Forward Stock Purchase Agreement, dated July 29, 2024, between Envoy Medical, Inc. and the Meteroa FPA Parties.	8-K	001-40133	10.1	August 1, 2024
10.18	Promissory Note, dated August 27, 2024, between Envoy Medical, Inc. and GAT Funding, LLC.	10-Q	001-40133	10.1	November 14, 2024
10.19	Conversion and Waiver Agreement, dated December 20, 2024, by and between Envoy Medical, Inc. and Anzu SPAC GP I LLC.	8-K	001-40133	10.1	December 20, 2024
10.20	Amendment No. 1 to Common Stock Purchase Warrant, issued by Envoy Medical, Inc. to the Meteora Parties.	8-K	001-40133	10.1	June 25, 2024
10.21	Amendment No. 2 to Common Stock Purchase Warrant, issued by Envoy Medical, Inc. to the Meteora Parties.	8-K	001-40133	10.1	December 23, 2024
10.22	At The Market Offering Agreement dated as of January 17, 2025, between Envoy Medical, Inc and Roth Capital Partners, LLC	8-K	001-40133	10.1	January 17, 2025
10.23	Building Lease dated as of May 20, 2016, between Envoy Medical Corporation and Taylor Corporation, as amended.	10-K	001-40133	10.23	March 31, 2025
10.24	Services Agreement dated as of January 1, 2022, between Envoy Medical Corporation and Taylor Technology Services, Inc.	10-K	001-40133	10.24	March 31, 2025
10.25	Promissory Note, dated March 6, 2025, between Envoy Medical, Inc. and GAT Funding, LLC.	10-Q	001-40133	10.2	May 1, 2025
10.26	Amended and Restated Envoy Medical, Inc. 2023 Equity Incentive Plan	8-K	001-40133	10.1	June 3, 2025

Exhibit Number	Description	Incorporated by Reference			
		Schedule/ Form	File No.	Exhibit	Filing Date
10.27	Consulting Agreement by and between the Company and Oasis Business Consulting, LLC, dated effective June 23, 2025.	8-K	001-40133	10.1	June 25, 2025
10.28	Satisfaction of Promissory Notes by and between the Company and GAT Funding, LLC, dated effective August 25, 2025.	8-K	001-40133	10.1	August 26, 2025
10.29	Amendment No. 3 to Common Stock Purchase Warrant, issued by Envoy Medical, Inc. to the Meteora Parties, dated July 29, 2025.	8-K	001-40133	10.1	July 29, 2025
10.30	Warrant Extension and Voting Agreement, by and among the Company, GAT Funding, LLC, Taylor Sports Group, Inc., and Glen A. Taylor, dated September 4, 2025.	8-K	001-40133	10.1	September 9, 2025
10.31	Form of September 2025 Purchase Agreement	8-K	001-40133	10.1	September 23, 2025
10.32	Amendment No. 4 to Common Stock Purchase Warrant, issued by Envoy Medical, Inc. to the Meteora Parties, dated December 18, 2025.	8-K	001-40133	10.1	December 29, 2025
10.33	Form of October 2025 Purchase Agreement	8-K	001-40133	10.1	October 9, 2025
10.34	Engagement Letter, dated September 17, 2025, by and between Envoy Medical, Inc. and H.C. Wainwright & Co., LLC, as amended on December 17, 2025 and February 9, 2026.	S-1/A	333-292260	10.34	February 10, 2026
10.35	Amendment, dated February 11, 2026, to Engagement Letter, dated September 17, 2025, by and between Envoy Medical, Inc. and H.C. Wainwright & Co., LLC.	8-K	001-40133	10.3	February 13, 2026
10.36	Form of February 2026 Purchase Agreement	S-1/A	333-292260	10.33	February 6, 2026
19.1	Envoy Medical, Inc. Policy on Inside Information and Insider Trading.	10-K	001-40133	19.1	April 1, 2024
21.1	List of Subsidiaries.	10-K	001-40133	21.1	March 31, 2025
23.1(#)	Consent of Grant Thornton LLP.				
24.1(#)	Power of Attorney (included on signature page to this Registration Statement).				
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 Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2(#)	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
97.1	Clawback Policy				
101.INS(#)	Inline XBRL Instance Document.				

Exhibit Number	Description	Incorporated by Reference			
		Schedule/ Form	File No.	Exhibit	Filing Date
101.SCH(#)	Inline XBRL Taxonomy Extension Schema Document.				
101.CAL(#)	Inline XBRL Taxonomy Extension Calculation Linkbase Document.				
101.DEF(#)	Inline XBRL Taxonomy Extension Definition Linkbase Document.				
101.LAB(#)	Inline XBRL Taxonomy Extension Label Linkbase Document.				
101.PRE(#)	Inline XBRL Taxonomy Extension Presentation Linkbase Document.				
104(#)	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).				

(*) Indicates a management contract or compensatory plan.

(#) Filed herewith.

(+) Certain schedules and exhibits to this Exhibit have been omitted pursuant to Item 601(a)(5) or Item 601(b)(10)(iv), as applicable, of Regulation S-K. The registrant agrees to furnish supplemental copies of all omitted exhibits and schedules to the Securities and Exchange Commission upon its request.

SIGNATURES

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

March 23, 2026

ENVOY MEDICAL, INC.

/s/ Brent T. Lucas
Name: Brent T. Lucas
Title: Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Brent T. Lucas and Robert M. Potashnick and each or any one of them, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the United States Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons in the capacities and on the date indicated.

Signature	Title	Date
/s/ Brent T. Lucas Brent T. Lucas	Chief Executive Officer and Director (Principal Executive Officer)	March 23, 2026
/s/ Robert M. Potashnick Robert M. Potashnick	Interim Chief Financial Officer (Principal Financial and Accounting Officer)	March 23, 2026
/s/ Charles R. Brynelsen Charles R. Brynelsen	Director	March 23, 2026
/s/ Michael Crowe Michael Crowe	Director	March 23, 2026
/s/ Mona Patel Mona Patel	Director	March 23, 2026
/s/ Janis Smith-Gomez Janis Smith-Gomez	Director	March 23, 2026
/s/ Susan J. Kantor Susan J. Kantor	Director	March 23, 2026